Effective Health Care Program

Comparative Effectiveness Review
Number 90

Pressure Ulcer Treatment Strategies: Comparative Effectiveness

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This report is based on research conducted by the Oregon Evidence-based Practice Center (EPC) under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. 290-2007-10057-I). The findings and conclusions in this document are those of the authors, who are responsible for its contents; the findings and conclusions do not necessarily represent the views of AHRQ. Therefore, no statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of systematic reviews to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. These reviews provide comprehensive, science-based information on common, costly medical conditions, and new health care technologies and strategies.

Systematic reviews are the building blocks underlying evidence-based practice; they focus attention on the strength and limits of evidence from research studies about the effectiveness and safety of a clinical intervention. In the context of developing recommendations for practice, systematic reviews can help clarify whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about AHRQ EPC systematic reviews, see www.effectivehealthcare.ahrq.gov/reference/purpose.cfm.

AHRQ expects that these systematic reviews will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. Transparency and stakeholder input are essential to the Effective Health Care Program. Please visit the Web site (www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an e-mail list to learn about new program products and opportunities for input.

We welcome comments on this systematic review. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to epc@ahrq.hhs.gov.

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Pressure Ulcer Treatment Strategies: Comparative Effectiveness

Structured Abstract

Objectives. Pressure ulcers affect up to 3 million Americans and are a major source of morbidity, mortality, and health care cost. This review summarizes evidence comparing the effectiveness and safety of pressure ulcer treatment strategies.

Data sources. Articles published between January 1, 1985, and October 17, 2012, were identified from searches of MEDLINE® (Ovid), Embase (Elsevier), CINAHL (EBSCOhost), EBM Reviews (Ovid), Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, and Health Technology Assessment. Additional studies were identified by searching reference lists from included studies and systematic reviews of pressure ulcer treatments. Gray literature, including unpublished data, abstracts, dissertations, and individual product packets from manufacturers, was also reviewed.

Review methods. The literature, quality of included studies, and extracted data were dual-reviewed using predefined criteria. Results were summarized in evidence tables. Summary results were derived primarily from qualitative analysis and synthesis.

Results. We reviewed 7,274 titles and abstracts and 1,836 full-length articles. We included 174 studies (trials and observational studies) addressing the effectiveness and/or harms of different treatments for pressure ulcers. These studies examined a wide range of interventions, but sample sizes often were small. We found moderate-strength evidence that some interventions were associated with wound improvement, including the use of air-fluidized beds (compared with other support surfaces), protein-containing nutritional supplements (compared with placebos or other routine measures of nutritional support), radiant heat dressings (compared with other dressings), and electrical stimulation (compared with a sham treatment). Several other interventions had limited evidence of effectiveness (strength of evidence rated as low). Only a minority of studies examined complete wound healing as an outcome. In general, the evidence about the harms of any of these treatments was limited.

Limitations. Most studies were of poor quality and had followup periods inadequate to assess complete wound healing. Studies often measured healing outcomes using heterogeneous methods, making it difficult to compare results across studies.

Conclusions. There was limited evidence to draw firm conclusions about the best approaches for treating pressure ulcers, a finding consistent with other recent reviews on this topic. Future research with larger sample sizes, more rigorous adherence to methodological standards for clinical trials, longer followup periods, and more standardized and clinically meaningful outcome measures is needed to inform clinical practice and policy.

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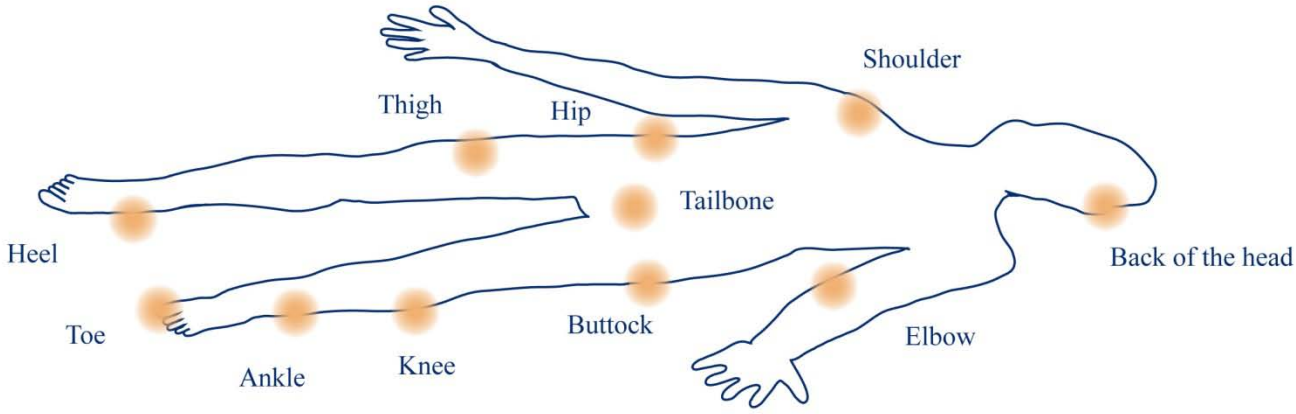
Executive Summary

Background

Uninterrupted pressure exerted on the skin, soft tissue, muscle, and bone can lead to the development of localized ischemia, tissue inflammation, shearing, anoxia, and necrosis. Pressure ulcers affect up to three million adults in the United States. Areas of the body prone to the development of pressure ulcers are depicted in Figure A. Estimates of the incidence of pressure ulcers vary according to the setting, with ranges of 0.4 to 38.0 percent in acute care hospitals, 2.2 to 23.9 percent in long-term nursing facilities, and 0 to 17 percent in home care settings.[1,2] The prevalence of pressure ulcers in acute and long-term care settings was 9.2 to 11.1 percent between 1989 and 1995 and 14.7 to 15.5 percent between 1999 and 2005.[3]

Figure A. Common pressure ulcer sites

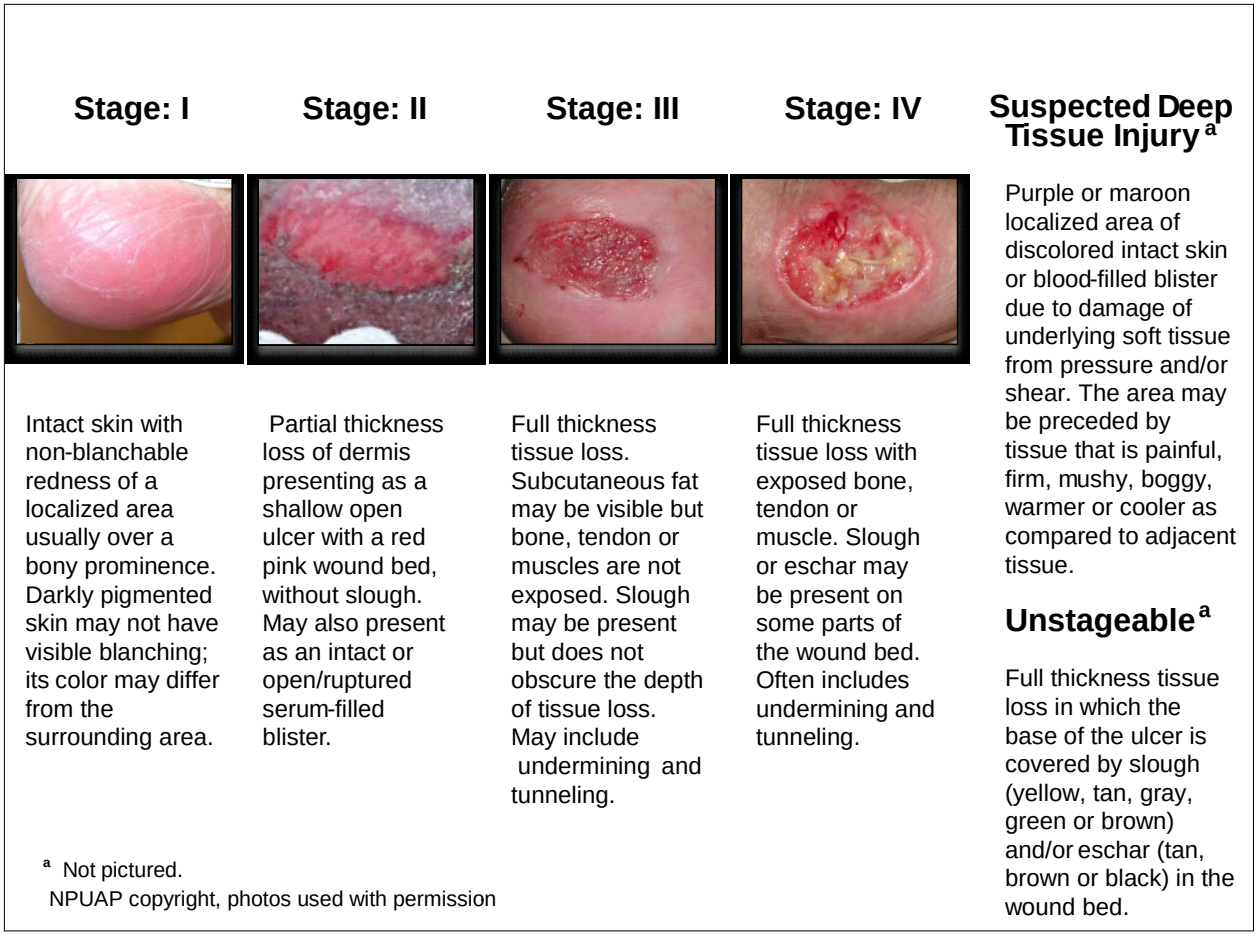


Pressure ulcer healing rates—which depend on comorbidities, clinical interventions, and ulcer severity—vary considerably. Ulcer severity is assessed using a variety of different staging or grading systems, but the National Pressure Ulcer Advisory Panel (NPUAP) staging system is the most commonly used (Figure B). Comorbidities predisposing toward pressure ulcer development and affecting ulcer healing include those affecting patient mobility (e.g., spinal cord injury), wound environments (e.g., incontinence), and wound healing (e.g., diabetes and vascular disease). Delayed healing can add to the length of hospitalization and impede return to full functioning.[2] Data on the costs of treatment vary, but some estimates range between $37,800 and $70,000 per ulcer, with total annual costs for pressure ulcers in the United States as high as $11 billion.[1,4] Prevalence of pressure ulcers is used as an indicator of quality for long-term care facilities, and progression of pressure ulcers in hospitalized patients is often considered an avoidable complication representing failure of inpatient management.

Given the negative impact pressure ulcers have on health status and patient quality of life, as well as health care costs, treatments are needed that promote healing, shorten healing time, and minimize the risk of complications. Pressure ulcer treatment involves a variety of different approaches, including interventions to treat the conditions that give rise to pressure ulcers (support surfaces and nutritional support); interventions to protect and promote healing of the ulcer (wound dressings, topical applications, and various adjunctive therapies, including vacuum-assisted closure, ultrasound therapy, electrical stimulation, and hyperbaric oxygen therapy); and surgical repair of the ulcer.[1,4] Most ulcers are treated using a combination of these approaches. Standards of care for pressure ulcer treatment are typically guided by clinical

practice guidelines, such as those developed by NPUAP, but also are informed by patient-related factors such as comorbidities and nutritional status,[5] local practice patterns, and the stage and features of the wound. Current guidelines primarily reflect expert opinions. An examination of the comparative effectiveness and harms of different therapies and approaches to treating pressure ulcers is important to guide clinical practice.

Figure B. National Pressure Ulcer Advisory Panel pressure ulcer stages/categories



[a] Not pictured.

Scope and Key Questions

The following Key Questions are the focus of our report.

Key Question 1. In adults with pressure ulcers, what is the comparative effectiveness of treatment strategies for improved health outcomes, including but not limited to: complete wound healing, healing time, reduced wound surface area, pain, and prevention of serious complications of infection?

Key Question 1a. Does the comparative effectiveness of treatment strategies differ according to features of the pressure ulcers, such as anatomic site or severity at baseline?

Key Question 1b. Does the comparative effectiveness of treatment strategies differ according to patient characteristics, including but not limited to: age, race/ethnicity, body weight, specific medical comorbidities, and known risk factors for pressure ulcers, such as functional ability, nutritional status, or incontinence?

Key Question 1c. Does the comparative effectiveness of treatment strategies differ according to patient care settings, such as home, nursing facility, or hospital, or according to features of patient care settings, including but not limited to nurse/patient staffing ratio, staff education and training in wound care, the use of wound care teams, and home caregiver support and training?

Key Question 2. What are the harms of treatments for pressure ulcers?

Key Question 2a. Do the harms of treatment strategies differ according to features of the pressure ulcers, such as anatomic site or severity at baseline?

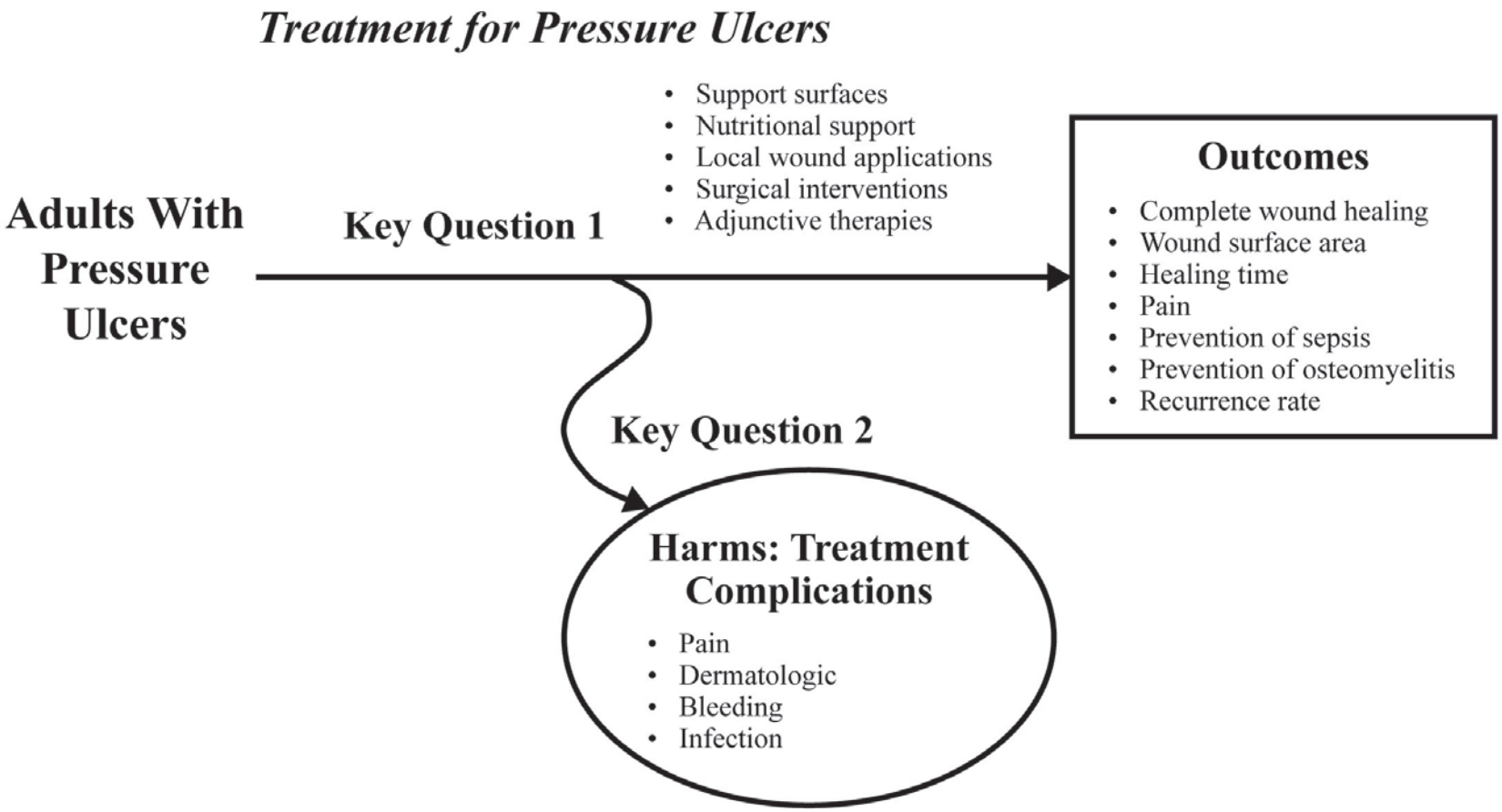
Key Question 2b. Do the harms of treatment strategies differ according to patient characteristics, including age, race/ethnicity, body weight, specific medical comorbidities, and known risk factors for pressure ulcers, such as functional ability, nutritional status, or incontinence?

Key Question 2c. Do the harms of treatment strategies differ according to patient care settings, such as home, nursing facility, or hospital, or according to features of patient care settings, including but not limited to nurse/patient staffing ratio, staff education and training in wound care, the use of wound care teams, and home caregiver support and training?

Analytic Framework

The analytic framework (Figure C) depicts the Key Questions and the population, interventions, outcomes, and harms considered in the review.

Figure C. Analytic framework: pressure ulcer treatment strategies



Population and Conditions of Interest

The population studied was adults ages 18 and older with a pressure ulcer. Patients with pressure ulcers usually also have limited or impaired mobility and suffer from other chronic illnesses. Pressure ulcers are most common in the elderly or people with spinal cord injuries or other conditions that restrict mobility. Patients with nonpressure-related ulcers, including but not limited to venous ulcers and diabetic foot ulcers, were excluded because treatment considerations for these patients may differ significantly from those for pressure ulcers. A systematic review of treatment for chronic venous ulcers, sponsored by the Agency for Healthcare Research and Quality (AHRQ), is in progress. We excluded children because this topic was originally nominated and scoped for adults.[a] Key Informants agreed with the broadly defined proposed population of interest, but they also noted that "adults with pressure ulcers" is a heterogeneous group and that variability in the comparative effectiveness of pressure ulcer treatments may be related to a large number of patient characteristics. In addition to age, sex, race/ethnicity, socioeconomic status, and diverse specific medical comorbidities (e.g., diabetes, end-stage renal disease, dementia), many Key Informants suggested that we include specific known risk factors for pressure ulcers (e.g., nutritional status, incontinence, peripheral vascular disease, mobility limitations, and functional ability).

Interventions and Comparators

Various treatment strategies for pressure ulcers were reviewed, including but not limited to therapies that address the underlying contributing factors (e.g., support surfaces and nutritional supplements), therapies that address local wound care (e.g., wound dressings, topical therapies, and biological agents), surgical repair, and adjunctive therapies (e.g., electrical stimulation). The comparative effectiveness and harms of other interventions (e.g., repositioning, wound debridement, and wound cleansing) were considered but not reviewed, based on input from the Technical Expert Panel (TEP) that these modalities either were considered standard care or lacked comparative studies.

Combined treatment modalities (cointerventions), such as comparison of two treatments in combination compared with a single treatment, were also evaluated.

Comparators included placebo or active control, usual care, and other interventions. In some cases, particularly in older studies, newer interventions were compared with older ones that might no longer be considered standard care in the field. However, in many care settings these applications (e.g., gauze dressings, standard hospital beds) are still used, and we therefore included studies using those types of comparators because of their continued relevance in some treatment settings.

Outcomes

The most commonly examined outcomes were measures of wound improvement. Some studies examined complete wound healing as the primary outcome, although many studies evaluated wound size reduction. Based on input from the TEP, we considered complete wound healing to be the principal health outcome of interest. However, we also considered other

[a]Although treatment approaches for children with pressure ulcers may be similar to those for adults, other factors may influence the effectiveness differently in this population, including setting, caregiver attention, healing potential, and comorbidities.

indicators of "wound improvement" in synthesizing evidence. Notably, many studies reported findings in terms of wound size reduction rather than complete wound healing. We considered wound size reduction to be an important outcome for two reasons. First, it represents a necessary intermediate step toward the principal outcome of complete wound healing: that is, complete wound healing can be considered 100-percent wound size reduction. Second, the likelihood of complete wound healing is lower for larger or higher stage ulcers, and therapies deployed for more advanced ulcers may not be expected to achieve complete wound healing over the course of several weeks, which was the duration of most of the studies in our review. Thus, in summarizing the evidence about a given treatment, we considered wound size reduction to be part of the continuum of wound healing. Some studies used composite outcome measures commonly employed to monitor pressure ulcer status. The Pressure Ulcer Scale for Healing (PUSH) tool combines wound surface area, amount of wound exudate, and tissue appearance.[6] The Pressure Sore Status Tool (PSST) considers multiple ulcer characteristics, including dimensions, exudate, and tissue appearance.[7] Other studies reported outcomes in terms of wound healing rate. We included these outcomes, when reported in studies, as indicators of "wound improvement" but prioritized findings for complete wound healing, as noted above, based on input from the TEP. Other outcomes included pain and avoidance of serious complications of infection. For harms of treatment, we evaluated pain, dermatologic complications, bleeding, infection, and other adverse outcomes as reported in included studies.

Timing

We did not apply minimum followup duration for studies.

Setting

Settings were patient care settings, including home, nursing facility, or hospital.

Methods

The methods for this Comparative Effectiveness Review (CER) follow the methods suggested in the AHRQ "Methods Guide for Effectiveness and Comparative Effectiveness Reviews"[8] and the standards suggested by the Institute of Medicine for conducting systematic reviews.[9]

Topic Refinement and Review Protocol

The Key Questions for this CER were developed with input from Key Informants, representing clinicians, wound care researchers, and patient advocates. The Key Informants helped refine Key Questions, identify important methodological and clinical issues, and define parameters for the review of evidence. The revised Key Questions were then posted to the AHRQ public Web site for a 4-week comment period. AHRQ and the Evidence-based Practice Center (EPC) agreed on the final Key Questions after reviewing public comments and receiving additional input from a TEP convened for this report. TEP members were selected to provide high-level content and methodological expertise throughout the development of the review, and the TEP consisted of a multidisciplinary group of clinicians, researchers, and patient advocates with expertise in pressure ulcer treatment and research. TEP members disclosed all financial or other conflicts of interest prior to participation. The AHRQ Task Order Officer and the authors reviewed the disclosures and determined that the panel members had no conflicts of interest that

precluded participation. The protocol for the CER was reviewed by the TEP and is available from the AHRQ Web site: (www.effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?productid=838&pageaction=displayproduct).

Search Strategy

The primary literature search was conducted through June 2012 in MEDLINE® (Ovid), Embase (Elsevier), CINAHL (EBSCOhost), EBM Reviews (Ovid), Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, and Health Technology Assessment. (See Appendix A of the full report for details.) The most relevant evidence about modalities and procedures currently used for treating pressure ulcers is found in studies conducted within the last 25 years. For this reason we set the search start date at 1985. This decision was affirmed by the Key Informants and TEP. Gray literature was identified by soliciting stakeholders, TEP recommendations, and searching relevant Web sites, including clinical trial registries (ClinicalTrials.gov, Current Controlled Trials, ClinicalStudyResults.org, and the World Health Organization International Clinical Trials Registry Platform), regulatory documents (Drugs@FDA and Devices@FDA), conference proceedings and dissertations (Conference Papers Index [ProQuest CSA]), Scopus (Elsevier), Dissertations & Theses (ProQuest UMI), and individual product Web sites. An additional focused search strategy on hyperbaric oxygen for the treatment of pressure ulcers was conducted at the recommendation of the TEP due to the paucity of evidence for this treatment obtained from the original search. Scientific information packets (SIPs) were requested from identified drug and device manufacturers, and a notice inviting submission of relevant scientific information was published in the "Federal Register" in an effort to identify any relevant unpublished literature that may contribute to the body of evidence. All interested parties had the opportunity to submit data for this review using the AHRQ Effective Health Care publicly accessible online SIP portal (effectivehealthcare.ahrq.gov/index.cfm/submit-scientific-information-packets/). Reviewers evaluated the SIPs received for data relevant to our review.

Additional studies were identified by reviewing the reference lists of published clinical trials, systematic reviews, and review articles.

Inclusion and Exclusion Criteria

The criteria for inclusion and exclusion of studies were based on the Key Questions and the populations, interventions, comparators, outcomes, timing, and setting (PICOTS) approach. We used the following inclusion criteria. (See Appendix B of the full report for details.)

Populations: Studies were limited to subject populations of adults ages 18 years and older being treated for existing pressure ulcers. Subgroups were defined by age, sex, race/ethnicity, socioeconomic status, and diverse specific medical comorbidities (e.g., diabetes, end-stage renal disease, and dementia), as well as patients with specific known risk factors for pressure ulcers (e.g., nutritional status, incontinence, peripheral vascular disease, mobility limitations, and functional ability). Studies conducted in populations including children, adolescents, and patients with nonpressure-related ulcers (including but not limited to venous ulcers and diabetic foot ulcers) were excluded because treatment considerations for these patients may differ significantly from those for adults with pressure ulcers.

Interventions: For efficacy and effectiveness assessments, all studies of interventions for treatment of pressure ulcers meeting the requirements of the PICOTS and Key Questions were included. Treatments for pressure ulcers included but were not limited to support surfaces,

nutritional supplementation, wound dressings, topical therapies, biological agents, and surgical repair. Adjunctive therapies included electrical stimulation, electromagnetic therapy, ultrasound, negative pressure wound therapy, light therapy, laser therapy, hydrotherapy, and hyperbaric oxygen therapy.

Comparators: Comparators included usual care, placebo or sham treatment, no treatment, and different treatment interventions. Studies that did not have a comparator were not considered in our evaluation of comparative effectiveness. They were included for the assessment of harms if they reported on harms of treatments for which data on comparative effectiveness were available in other studies.

Outcomes: Studies reporting clinical outcomes of complete wound healing, wound size (surface area, volume, depth) reduction, pain, prevention of sepsis, prevention of osteomyelitis, recurrence rate, and harms of treatment (including but not limited to pain, dermatologic complications, bleeding, and infection) were included. Studies of nonpressure-related ulcers were not included. We excluded studies that evaluated only nonclinical outcomes, including ease of use, comfort, or nursing time required to administer the intervention.

Timing: No minimum followup time was required. We limited our search to publications and investigations conducted from 1985 to June 2012.

Setting: We included studies conducted in patient-care settings such as home, nursing facility, or hospital. We excluded studies in hospice settings if complete wound healing was not an outcome measured.

Study Design: We included randomized trials, cohort studies, and case-control studies pertinent to all Key Questions. If such studies were not available, we included cross-sectional studies and intervention series studies. Systematic reviews were used as background information or to ensure completeness of the literature search. Case studies of only one patient were not included.

For studies of surgical interventions, we initially planned to include controlled trials, observational studies with at least two comparison groups, and noncomparative intervention series only if they were multicenter series with a population of 100 patients or more. An initial scan of the literature, however, revealed that studies of surgical interventions revealed primarily small series of specific surgical techniques performed at single centers. Because surgical outcomes are heavily influenced by individual surgeons, local practice patterns, and other contextual factors, the TEP raised concern that data from these small ($n < 50$) single-site studies would have limited generalizability and that they would not provide a sound basis for making indirect comparisons across studies. We therefore excluded small ($n < 50$) single-site studies reporting the results of specific surgical techniques for pressure ulcer management but expanded our inclusion criteria to include single-center intervention series reporting a large series ($n \geq 50$) of patients undergoing surgery for pressure ulcer. We included studies of any size that provided direct head-to-head comparisons of different surgical techniques.

Non–English-language studies were included in the abstract triage, but translation for full-text review was not feasible. In an effort to identify any relevant unpublished literature that may contribute to the body of evidence, gray literature, including unpublished data, abstracts, dissertations, and SIPs, were reviewed to determine if they added additional and meaningful data beyond the literature included in this review and should also be included.

Study Selection

To calibrate reviewer agreement and consistency in study selection, kappa values were calculated to estimate inter-reviewer reliability. After reconciling disagreements between reviewers, this process was repeated with additional sets of studies until a kappa value of greater than 0.50 for each pair of reviewers was reached. The remaining references were evaluated at the title and abstract level for inclusion, using the pre-established inclusion/exclusion criteria to determine eligibility for inclusion in the evidence synthesis. Excluded titles were reviewed again by a senior investigator/clinician for accuracy. All citations included by one or both of the reviewers were retrieved for full-text review.

Full-text articles were independently reviewed by two team members and included when consensus occurred between the reviewers. If consensus was not reached by the two initial reviewers, a senior investigator reviewed the article and adjudicated the decision on inclusion or exclusion.

Data Extraction

Data from included studies were extracted into evidence tables and entered into electronic databases using Microsoft Excel® and DistillerSR systematic review software. The data extracted into evidence tables included study design; year, setting, duration, and study inclusion and exclusion criteria; population and clinical characteristics, including sex, age, ethnicity, comorbidities, functional ability, and ulcer stage; intervention characteristics; results for each outcome of interest; and withdrawals due to adverse events. Outcomes of interest for effectiveness were wound improvement, as determined by complete wound healing, healing rate or time, or reduction in wound size (surface area, volume, depth); reduction in pain; prevention of serious complications of infection such as sepsis or osteomyelitis; and ulcer recurrence rates. Outcomes of interest for harms were pain; dermatologic reactions; bleeding; and complications, including but not limited to infection and need for surgical intervention. Data on settings included patient-care settings such as long-term care or nursing facility, hospital, and community. If available, we also extracted the number of patients randomized relative to the number of patients enrolled, how similar those patients were to the target population, and the funding source. Noncomparative observational studies were included if they evaluated harms of treatments for which comparative effectiveness evidence was available in other studies. These noncomparative observational studies were used for Key Question 2 (evaluation of harms) and were rated for study quality but were not formally extracted into evidence tables due to the paucity of data they contained. We recorded intention-to-treat results when available. All summary measure data were collected as available and presented in the individual studies, including but not limited to percentage of complete wound healing, relative risk and risk ratios, confidence intervals, and significance values. A second team member verified all study data extraction for accuracy and completeness.

One challenge in extracting data from pressure ulcer studies is that various systems have been used to assess the severity of pressure ulcers. Most use a four-stage categorization, with higher numbers indicating higher severity.[10] In 2007 NPUAP redefined their four-stage classification system that defines the pressure ulcer based on depth and tissue involvement (Figure B). Stage I is defined as superficial erythema, stage II as partial thickness ulceration, stage III as full thickness ulceration, and stage IV as full thickness with involvement of muscle and bone. A corresponding four-stage classification system was adopted by the European

Pressure Ulcer Advisory Panel (EPUAP). Given that the stages are based on depth and tissue involvement, when an ulcer has overlying purulent material or eschar prohibiting the ability to determine the depth or extent of tissue involvement, it is classified as unstageable, or stage X. Discolored localized areas of intact skin that may indicate pressure-related injury to subcutaneous tissue are categorized as suspected deep tissue injuries. The most commonly used systems to classify pressure ulcers prior to adapting the NPUAP system are reviewed in Appendix C of the full report and aligned with the current corresponding NPUAP stage.

In order to allow comparability across studies, we extracted the stage or grade reported but used the corresponding NPUAP stage in summary tables and text when possible.

Quality Assessment of Individual Studies

In this report, risk of bias is denoted as quality, with the following summary categories:

- Good quality is defined as a low risk of bias.
- Fair quality is defined as a moderate risk of bias.
- Poor quality is defined as a high risk of bias.

Using predefined criteria to assess the quality of controlled trials and observational studies at the individual study level, we adapted criteria from methods proposed by Downs and Black[11,12] (observational studies) and methods developed by the U.S. Preventive Services Task Force.[12,13]

We rated the quality of each controlled trial based on the methods described in the published reports about randomization and allocation concealment; the similarity of compared groups at baseline; maintenance of comparable groups; adequate reporting of dropouts, attrition, crossover, adherence, and contamination; loss to followup; the use of intention-to-treat analysis; and ascertainment of outcomes.[12] Individual studies were rated as "good," "fair," or "poor."

Studies rated "good" have the least risk of bias, and results are considered valid. Good-quality studies include clear descriptions of the population, setting, interventions, and comparison groups; a valid method for allocation of patients to treatment; low dropout rates and clear reporting of dropouts; appropriate means for preventing bias; and appropriate measurement of outcomes.

Studies rated "fair" do not meet all the criteria for a rating of good quality, but no flaw is likely to cause major bias. The study may be missing information, making it difficult to assess limitations and potential problems. The fair-quality category is broad, and studies with this rating vary in their strengths and weaknesses: the results of some fair-quality studies are *likely* to be valid, while others are only *probably* valid.

Studies rated "poor" have significant flaws that imply biases of various types that may invalidate the results. They have a serious or "fatal" flaw in design, analysis, or reporting; large amounts of missing information; discrepancies in reporting; or serious problems in the delivery of the intervention. The results of these studies are at least as likely to reflect flaws in the study design as they are to reflect the true differences between the interventions that were compared. We did not exclude studies rated poor quality a priori, but poor-quality studies were considered to be less valid than higher quality studies when synthesizing the evidence, particularly when discrepancies between studies were present.

Data Synthesis

Due to the heterogeneity of outcomes reported and the limited number and quality of studies for specific treatment comparisons, quantitative analysis was not appropriate for most bodies of literature included in this review. For most comparisons, we synthesized data qualitatively.

We evaluated the appropriateness of meta-analysis based on clinical and methodological diversity of studies and statistical heterogeneity. We conducted meta-analysis in selected instances (when the number, quality, and homogeneity of studies permitted) for comparisons examining the outcome of complete wound healing. We chose to limit meta-analysis to the outcome of complete wound healing because of (a) wide variability in the measurement of other outcomes, including wound size reduction, and (b) indication from the TEP that complete wound healing was the principal health outcome of interest. When meta-analysis was conducted, we used relative risk as the effect measure. We assessed the presence of statistical heterogeneity among the studies using standard χ^2 tests and the magnitude of heterogeneity using the I^2 statistic.[14] We used random-effects models to account for variation among studies[15] and fixed-effects Mantel-Haenszel models when variation among studies was estimated to be zero. Sensitivity analysis was conducted to assess the impact of quality on combined estimates, and metaregression was conducted to assess the association of effect measure with study duration. However, exploration of heterogeneity was typically limited by the small number of studies for each treatment category. All quantitative analyses were performed using Stata 11.0® (StataCorp, College Station, Texas, 2009).

Strength of the Body of Evidence

Within each Key Question, we graded the strength of evidence for effectiveness and for harms by intervention/comparator pair, and for harms by intervention, using an approach adapted from the AHRQ "Methods Guide for Effectiveness and Comparative Effectiveness Reviews."[8] Our approach considers four major categories to rate the strength of evidence:

- Quality of studies (good, fair, or poor)
- Consistency (low, moderate, or high)
- Directness (direct or indirect)
- Precision (low, moderate, or high).

As with our ratings of individual study quality, we used the term "quality" in lieu of "risk of bias" in rating the overall strength of evidence of a given finding. Good quality is defined as low risk of bias, fair quality is defined as moderate risk of bias, and poor quality is defined as high risk of bias. Our ratings for consistency and precision were trichotomous (low, moderate, high) rather than dichotomous (consistent vs. inconsistent, precise vs. imprecise) to allow for a more graded assessment of those domains.

We did not incorporate the domain of "dose-response association" into our strength-of-evidence ratings because few, if any, studies in our review included varying levels of exposure. We also did not include the domain "plausible confounding that would decrease observed effect" because this domain is relevant primarily for observational studies and nearly all of our findings were based on the results of clinical trials. We considered "strength of association" in rating strength of evidence but did not assign explicit scores for strength of association in the strength-of-evidence ratings due to variability in strength of association for the different measures of wound improvement used across studies.

We were not able to assess publication bias using a quantitative approach for most treatments because, in many instances, we were not able to perform a formal pooled analysis due to the heterogeneity of interventions, comparators, or outcomes, or due to the poor quality of studies. We evaluated the possibility of publication bias by qualitatively examining the directionality of study findings by sample size for a given intervention and by looking for unpublished studies through the gray literature search.

The strength of evidence was assigned an overall grade of high, moderate, low, or insufficient according to a four-level scale:

- High—High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect.
- Moderate—Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.
- Low—Low confidence that the evidence reflects the true effect. Further research is likely to change the confidence in the estimate of effect and is likely to change the estimate.
- Insufficient—Evidence either is unavailable or does not permit a conclusion.

Applicability

Applicability is "the extent to which the effects observed in published studies are likely to reflect the expected results when a specific intervention is applied to the population of interest under 'real-world' conditions."[16] We developed our review to provide evidence that might be useful to clinicians, policymakers, patients, and other decisionmakers interested in pressure ulcer treatment. Applicability depends on context, and there is no generally accepted universal rating system for it. We described features of the included studies that are relevant to applicability in terms of the PICOTS elements. These elements are the features embedded in the Key Questions that inform clinical decisionmaking and the degree to which the evidence is likely to pertain to the subpopulations. For example, it is important to determine whether techniques described in studies are representative of current practice. We extracted from studies included in our review key information that might affect applicability of findings, including characteristics of ulcers (e.g., stage), populations (e.g., spinal-cord–injured patients), study duration, cointerventions, comparators, and care setting. We based our approach to applicability on the guidance described by Atkins and colleagues.[12,16]

Peer Review

Experts in prevention and management of pressure ulcers, geriatric medicine, wound care research, and epidemiology, as well as individuals representing important stakeholder groups, were invited to provide external peer review of this CER. The AHRQ Task Order Officer and a designated EPC associate editor also provided comments and editorial review. To obtain public comment, the draft report was posted on the AHRQ Web site for 4 weeks. A disposition-of-comments report detailing the changes made to address the public and peer review comments will be made available 3 months after the Agency posts the final CER on the AHRQ Web site.

Results

Searches of databases, reviews of reference lists of published studies, and reviews of gray literature resulted in 7,274 potentially relevant articles. After dual review of abstracts and titles,

1,836 articles were selected for full-text review. Gray literature was assessed but did not meet the inclusion criteria for this report or provide data that were not already available in the peer-reviewed literature. One hundred seventy-four studies (with results published in 182 full-text articles) were included in this review. These studies examined a wide range of interventions, but sample sizes often were small. We found moderate-strength evidence that some interventions improved healing of pressure ulcers, but no interventions were found to be effective with a high strength of evidence. Several other interventions had limited evidence of effectiveness (strength of evidence rated as low). A minority of studies examined complete wound healing as an outcome. In general, the evidence about the harms of any of these treatments was limited.

Overall Effectiveness of Pressure Ulcer Treatment

Pressure ulcer treatment encompasses numerous intervention strategies: alleviating the conditions contributing to ulcer development (support surfaces, repositioning, nutritional support); protecting the wound from contamination, creating a clean wound environment, and promoting tissue healing (local wound applications, debridement, wound cleansing, various adjunctive therapies); and surgically repairing the wound. We evaluated evidence addressing the comparative effectiveness and harms in treatment categories for which significant uncertainty exists about the best therapeutic options. Results for each Key Question are presented within the following specific treatment categories: support surfaces, nutrition, local wound applications (including wound dressings, topical therapies, and biological agents), surgical interventions, and adjunctive therapies. Although we evaluated multiple outcomes, only measures of wound improvement (complete wound healing, wound size reduction, healing rate) were consistently reported. Other outcomes, including pain, were reported sporadically. Ulcer recurrence was used as an outcome in some studies of surgery and is reported in the sections of this report covering those studies. Prevention of serious infectious complications was not reported as an outcome in any included study. There was no body of literature from which it was possible to synthesize evidence for the impact of a given intervention on outcomes other than wound improvement. In reporting results of wound improvement, when a body of literature allowed conclusions about a particular measure of wound improvement (e.g., complete wound healing), we report those findings. In many cases, however, the use of different measures of wound improvement allowed us to report only on the overall effect of an intervention on wound improvement, which included complete wound healing, wound size reduction, and healing rates.

The overall findings of this review and a summary of the strength of the evidence for the key findings are presented in Table A.

Table A. Summary of evidence: impact of pressure ulcer treatment strategies on wound improvement and harms

Key Question and Treatment Strategy	Strength of Evidence	Conclusion
Key Question 1. In adults with pressure ulcers, what is the comparative effectiveness of treatment strategies for improved health outcomes, including but not limited to: complete wound healing, healing time, reduced wound surface area, pain, and prevention of serious complications of infection?		
Support		
Air-fluidized beds	Moderate	Air-fluidized beds produced better healing in terms of reduction in ulcer size compared with other surfaces (5 studies conducted in the late 1980s and 1990s).
Alternating pressure beds	Moderate	Complete wound healing and reduction in ulcer size were similar across different brands and types of alternating pressure beds (4 studies).
Alternating pressure beds compared with other surfaces	Low	Wound improvement was similar for alternating pressure beds when compared with air, fluid, or standard beds (4 studies).
Alternating pressure chair cushions	Insufficient	Evidence about alternating pressure chair cushions did not permit conclusions due to differences in the patient populations studied (2 studies).
Low-air-loss beds	Low	Wound improvement was similar for low-air-loss beds compared with foam surfaces (4 studies) and for low-air-loss beds compared with low-air-loss bed overlays (1 study).
Nutrition		
Protein-containing nutritional supplements	Moderate	When used in addition to other measures for treating pressure ulcers, protein-containing nutritional supplementation resulted in wound improvement (12 studies).
Vitamin C	Low	Vitamin C used as a single nutritional supplement did not result in wound improvement (1 study).
Zinc	Insufficient	The evidence did not allow conclusions as to whether zinc supplementation improves pressure ulcer healing (1 study).
Local Wound Applications		
Hydrocolloid dressings compared with conventional care	Low	Wound improvement was superior with hydrocolloid compared with gauze dressings (10 studies).
Hydrocolloid compared with foam	Moderate	Wound improvement was equivalent with hydrocolloid and foam dressings (8 studies).
Comparisons of different wound dressings	Insufficient	Evidence regarding the comparative effectiveness of hydrogel (compared with standard care or other dressing types; 7 studies), transparent film (4 studies), silicone (2 studies), and alginate dressings (1 study) was inconclusive due to limitations in the number, size, and quality of studies.
Radiant heat compared with other dressings (healing rate)	Moderate	Radiant heat dressings produced more rapid wound healing rates than other dressings for stage III and IV ulcers (4 studies).
Radiant heat compared with other dressings (complete wound healing)	Moderate	Radiant heat dressings were similar to other dressings in terms of complete wound healing of stage III and IV ulcers (4 studies).
Debriding enzymes compared with dressings or other topical therapies	Insufficient	Evidence about the effectiveness of collagenase and other debriding enzymes was inconclusive due to differences in the enzymes studied and outcomes measured (5 studies).

Table A. Summary of evidence: impact of pressure ulcer treatment strategies on wound improvement and harms (continued)

Key Question and Treatment Strategy	Strength of Evidence	Conclusion
Key Question 1. In adults with pressure ulcers, what is the comparative effectiveness of treatment strategies for improved health outcomes, including but not limited to: complete wound healing, healing time, reduced wound surface area, pain, and prevention of serious complications of infection? (continued)		
Local Wound Applications (continued)		
Dextranomer paste compared with wound dressings	Low	Dextranomer paste was inferior to wound dressings (alginate, hydrogel) in promoting wound area reduction (2 studies).
Topical collagen compared with hydrocolloid dressings or standard care	Low	Wound improvement was similar with topical collagen applications compared with hydrocolloid dressings or standard care (3 studies).
Topical phenytoin	Insufficient	Three studies of the effectiveness of topical phenytoin used different comparators and produced inconsistent results.
Maggot therapy	Insufficient	Evidence about the effectiveness of maggot therapy was inconclusive due to poor study quality (3 studies).
Platelet-derived growth factor	Low	Platelet-derived growth factor was superior to placebo in producing wound improvement in stage III and IV pressure ulcers (4 studies).
Biological agents other than platelet-derived growth factor (fibroblast, nerve, and macrophage suspension)	Insufficient	Evidence about the effectiveness of other biological agents used for the treatment of pressure ulcers was inconclusive due to limitations in the number, size, and quality of studies (7 studies of various biological agents).
Surgery		
Surgical techniques	Insufficient	Evidence was inconclusive as to whether one approach to closure of stage III to IV pressure ulcers was superior to others due to poor-quality studies and heterogeneity in patient populations and surgical procedures (4 studies).
Adjunctive		
Electrical stimulation	Moderate	Electrical stimulation was beneficial in accelerating the rate of healing of stage II, III, and IV pressure ulcers (9 studies).
Electromagnetic therapy	Low	Wound improvement of stage II, III, or IV pressure ulcers was similar with electromagnetic therapy compared with sham treatment (4 studies).
Therapeutic ultrasound	Low	Wound improvement was similar with ultrasound compared with standard care or sham treatment (3 studies).
Negative pressure wound therapy	Low	Wound improvement was similar with negative pressure wound therapy compared with standard care (3 studies).
Hydrotherapy	Insufficient	Evidence on the effectiveness of hydrotherapy was insufficient based on 2 randomized trials evaluating different treatment modalities (1 of whirlpool therapy and 1 of pulsatile lavage).
Light therapy (complete wound healing)	Low	Light therapy was similar to sham light therapy in producing complete wound healing based on 2 randomized trials.
Light therapy (wound surface area reduction)	Low	Light therapy reduced wound surface area over time compared with standard care or sham light therapy (5 studies).
Laser therapy	Low	Wound improvement was similar with laser therapy compared with sham treatment or standard care (4 studies).

Table A. Summary of evidence: impact of pressure ulcer treatment strategies on wound improvement and harms (continued)

Key Question and Treatment Strategy	Strength of Evidence	Conclusion
Key Question 1a. Does the comparative effectiveness of treatment strategies differ according to features of the pressure ulcers, such as anatomic site or severity at baseline?		
Support		
Support, all strategies	Insufficient	Only 4 studies reported results by ulcer stage or location, and the interventions, characteristics, and results varied and did not permit conclusions.
Nutrition		
Nutrition, all strategies	Insufficient	Only 3 of the 16 studies analyzed results by ulcer characteristics, and the impact on the conclusion was inconsistent.
Local Wound Applications		
Local wound applications, all strategies	Insufficient	Few studies conducted subgroup analyses by ulcer characteristics (7 studies). Indirect comparisons of results across studies were limited due to heterogeneity of studies.
Surgery		
Sacral compared with ischial pressure ulcers	Low	Sacral pressure ulcers had lower recurrence rates after surgery than ischial pressure ulcers (4 studies).
Adjunctive		
Adjunctive, all strategies	Insufficient	Evidence did not permit determination as to whether the effectiveness of adjunctive therapies varied based on pressure ulcer characteristics due to heterogeneity of studies (6 studies).
Key Question 1b. Does the comparative effectiveness of treatment strategies differ according to patient characteristics, including but not limited to: age, race/ethnicity, body weight, specific medical comorbidities, and known risk factors for pressure ulcers, such as functional ability, nutritional status, or incontinence?		
Support		
Support, all strategies	Insufficient	No studies were identified that allowed conclusions about the impact of patient characteristics on the effectiveness of different support surfaces in pressure ulcer wound improvement. Indirect comparisons of results across studies were limited due to heterogeneity of studies.
Nutrition		
Nutrition, all strategies	Insufficient	Evidence did not permit determination as to whether patient characteristics, including baseline nutritional status, modified the effect of nutritional support on pressure ulcer healing due to a limited number of studies reporting outcomes by baseline nutritional status (2 studies).
Local Wound Applications		
Local wound applications, all strategies	Insufficient	Studies generally did not report outcomes by patient characteristics, including incontinence and mobility (1 study). Indirect comparisons of results across studies were limited due to heterogeneity of studies.

Table A. Summary of evidence: impact of pressure ulcer treatment strategies on wound improvement and harms (continued)

Key Question and Treatment Strategy	Strength of Evidence	Conclusion
Key Question 1b. Does the comparative effectiveness of treatment strategies differ according to patient characteristics, including but not limited to: age, race/ethnicity, body weight, specific medical comorbidities, and known risk factors for pressure ulcers, such as functional ability, nutritional status, or incontinence? (continued)		
Surgery		
Surgical flap closure	Low	Spinal cord–injured patients had higher rates of recurrent pressure ulcer after surgical flap closure than other patients with pressure ulcers (1 study).
Adjunctive		
Electrical stimulation	Low	The effectiveness of electrical stimulation was similar in spinal-cord–injured patients compared with others (4 studies).
Electromagnetic therapy Therapeutic ultrasound Negative pressure wound therapy Light therapy Laser therapy	Insufficient	Evidence did not permit determination as to whether the effectiveness of electromagnetic therapy compared with sham electromagnetic therapy (2 studies), ultrasound therapy compared with sham ultrasound therapy, negative pressure wound therapy, light therapy, or laser therapy varied based on patient characteristics due to heterogeneity of studies and lack of reporting of specific patient characteristics.
Key Question 1c. Does the comparative effectiveness of treatment strategies differ according to patient care settings, such as home, nursing facility, or hospital, or according to features of patient care settings, including but not limited to nurse/patient staffing ratio, staff education and training in wound care, the use of wound care teams, and home caregiver support and training?		
Support		
Support, all strategies	Insufficient	Only 1 study provided data on results by setting and none provided information on setting characteristics. Indirect comparisons of results across studies were limited due to heterogeneity of studies.
Nutrition		
Nutrition, all strategies	Insufficient	No studies reported results by patient care settings. Indirect comparisons of results across studies were limited due to heterogeneity of studies.
Local Wound Applications		
Local wound applications, all strategies	Insufficient	No studies reported results by patient care settings. Indirect comparisons of results across studies were limited due to heterogeneity of studies.
Surgery		
Surgery, all strategies	Insufficient	No studies reported results by patient care settings. Indirect comparisons of results across studies were limited due to heterogeneity of studies.
Adjunctive		
Electrical stimulation	Low	Electrical stimulation produced similar results in a hospital compared with a rehabilitation center (9 studies).
Electromagnetic therapy Therapeutic ultrasound Negative pressure wound therapy Light therapy Laser therapy	Insufficient	Due to a lack of studies comparing different settings, evidence did not permit determination as to whether the effectiveness of electromagnetic therapy compared with sham electromagnetic therapy (2 studies), ultrasound therapy compared with sham ultrasound therapy, negative pressure wound therapy, light therapy, or laser therapy varied based on features of the patient care settings.

Table A. Summary of evidence: impact of pressure ulcer treatment strategies on wound improvement and harms (continued)

Key Question and Treatment Strategy	Strength of Evidence	Conclusion
Key Question 2. What are the harms of treatments for pressure ulcers?		
Harms: Support		
Support, all strategies	Insufficient	Few of the identified studies (7 out of 24) explicitly addressed harms attributable to support surfaces. In those where harms were mentioned, most reported no significant differences in harms across the different support surfaces. However, as the harms studied were different and were associated with different support surfaces, we were unable to summarize across studies.
Harms: Nutrition		
Nutrition, all strategies	Insufficient	Harms or adverse events were reported in about half of the studies (8 of 16), but the studies reported different harms, did not describe the harm, or did not specify if it was related to treatment.
Harms: Local Wound Applications		
Dressings and topical therapies	Moderate	Harms reported with dressings and topical therapies for pressure ulcers most commonly included skin irritation and inflammation and tissue damage and maceration. Variability in study populations, interventions, adverse event measurement, and reporting precluded an estimate of adverse event rates for dressings and topical therapies (30 studies).
Dressings and topical therapies	Insufficient	Evidence was inconclusive as to whether specific dressing types or topical therapies were associated with fewer harms than others due to poor study quality and differential reporting of harms across studies (7 studies).
Biological agents	Insufficient	Few harms were reported with biological agents, but evidence did not permit determination of the incidence of harms due to lack of precision across studies (5 studies).
Harms: Surgery		
Recurrence or flap failure	Low	Reoperation due to recurrence or flap failure ranged from 12 to 24 percent (2 studies).
Harms: Adjunctive		
Electrical stimulation	Low	The most common adverse effect of electrical stimulation was local skin irritation (3 studies).
Electromagnetic therapy Therapeutic ultrasound Negative pressure wound therapy	Insufficient	Due to a lack of reporting, evidence did not permit conclusions about the harms of electromagnetic therapy (1 study), ultrasound (3 studies), or negative pressure wound therapy (2 studies).
Light therapy	Low	Light therapy caused no significant adverse events based on 4 randomized studies (4 studies).
Laser therapy	Low	Short-term use of laser therapy caused no significant adverse events based on 3 randomized studies (4 studies in all).

Table A. Summary of evidence: impact of pressure ulcer treatment strategies on wound improvement and harms (continued)

Key Question and Treatment Strategy	Strength of Evidence	Conclusion
Key Question 2a. Do the harms of treatment strategies differ according to features of the pressure ulcers, such as anatomic site or severity at baseline?		
Harms: Support		
Support, all strategies	Insufficient	None of the identified studies reported if differences in harms of support surfaces varied based on features of the pressure ulcers. Indirect comparisons of harms across studies were limited due to heterogeneity of studies.
Harms: Nutrition		
Nutrition, all strategies	Insufficient	No studies reported harms by ulcer characteristics. Indirect comparisons of harms across studies were limited due to heterogeneity of studies.
Harms: Local Wound Applications		
Local wound applications, all strategies	Insufficient	No studies reported harms by ulcer characteristics. Indirect comparisons of harms across studies were limited due to heterogeneity of studies.
Harms: Surgery		
Surgery, all strategies	Low	Wound dehiscence was more common if bone was removed at time of surgical procedure (1 study).
Ischial ulcer surgery	Low	Complication rates after surgery were higher for ischial ulcers than for sacral or trochanteric ulcers (2 studies).
Harms: Adjunctive		
Adjunctive, all strategies	Insufficient	Due to a lack of reporting, there was inconclusive evidence to determine if differences in harms of any adjunctive therapies varied based on features of the pressure ulcers (3 studies of electrical stimulation).
Key Question 2b. Do the harms of treatment strategies differ according to patient characteristics, including age, race/ethnicity, body weight, specific medical comorbidities, and known risk factors for pressure ulcers, such as functional ability, nutritional status, or incontinence?		
Harms: Support		
Support, all strategies	Insufficient	None of the identified studies reported if differences in harms of support surfaces varied based on patient characteristics. Indirect comparisons of harms across studies were limited due to heterogeneity of studies.
Harms: Nutrition		
Nutrition, all strategies	Insufficient	No studies reported harms by patient characteristics. Indirect comparisons of harms across studies were limited due to heterogeneity of studies.
Harms: Local Wound Applications		
Local wound applications, all strategies	Insufficient	No studies reported harms by patient characteristics. Indirect comparisons of harms across studies were limited due to heterogeneity of studies.
Harms: Surgery		
Surgery, all strategies	Insufficient	No studies reported harms by patient characteristics. Indirect comparisons of harms across studies were limited due to a lack of studies and reporting.
Harms: Adjunctive		
Electrical stimulation	Low	Frail elderly patients experienced more adverse events with electrical stimulation compared with a younger population (3 studies).

Table A. Summary of evidence: impact of pressure ulcer treatment strategies on wound improvement and harms (continued)

Key Question and Treatment Strategy	Strength of Evidence	Conclusion
Key Question 2c. Do the harms of treatment strategies differ according to patient care settings, such as home, nursing facility, or hospital, or according to features of patient care settings, including but not limited to nurse/patient staffing ratio, staff education and training in wound care, the use of wound care teams, and home caregiver support and training?		
Harms: Support		
Support, all strategies	Insufficient	None of the identified studies reported if differences in harms of support surfaces varied by patient care setting. Indirect comparisons of harms across studies were limited due to heterogeneity of studies.
Harms: Nutrition		
Nutrition, all strategies	Insufficient	No studies reported harms by patient care setting. Indirect comparisons of harms across studies were limited due to heterogeneity of studies.
Harms: Local Wound Applications		
Local wound applications, all strategies	Insufficient	No studies reported harms by patient care setting. Indirect comparisons of harms across studies were limited due to heterogeneity of studies.
Harms: Surgery		
Surgery, all strategies	Insufficient	No studies reported harms by patient care setting. Indirect comparisons of harms across studies were limited due to heterogeneity of studies and surgical procedures.
Harms: Adjunctive		
Adjunctive, all strategies	Insufficient	No studies reported harms by patient care setting. Indirect comparisons of harms across studies were limited due to heterogeneity of studies and a lack of studies comparing different settings.

Key Findings and Strength of Evidence

We identified evidence addressing a variety of different support surfaces, including air-fluidized (AF) beds, alternating pressure (AP) beds and chair cushions, and low-air-loss (LAL) beds. Other types of support surfaces were evaluated only in small single studies. We found evidence of moderate strength that reductions in wound size were better with AF beds from studies that compared AF beds with other support surfaces, including standard hospital beds. Studies found no difference in wound improvement when different types of AP mattresses were compared (moderate strength of evidence). Evidence about the effectiveness of AP seat cushions was insufficient, as only two studies with very different populations were identified. There was low-strength evidence that AP beds or LAL beds led to similar wound improvement when compared with other surfaces, usually standard mattresses. The reported harms of different support surface options were minimal, although harms were infrequently and inconsistently reported in support surface studies.

Studies of nutritional support evaluated protein-containing nutritional supplementation and specific nutrient supplementation with vitamins or minerals, such as ascorbic acid (vitamin C) or zinc. Studies provided moderate strength of evidence that protein supplementation resulted in wound improvement. There was low strength of evidence indicating similar results with vitamin C compared with placebo. Evidence about zinc supplementation was insufficient to draw

conclusions. There was insufficient evidence to adequately describe the harms of nutritional supplementation in this patient population.

A wide variety of modern wound dressings have been compared with each other or with standard care, usually with gauze dressings. We found low-strength evidence that hydrocolloid dressings were superior to gauze and moderate-strength evidence that hydrocolloid and foam (hydrocellular or polyurethane) dressings produced similar wound improvement. Evidence about the comparative effectiveness of other dressings—hydrogels, transparent films, silicone, and alginates—was insufficient to draw conclusions. We found moderate-strength evidence from four studies that radiant heat dressings accelerated the rate of healing of stage III and IV ulcers compared with other dressings, but we did not find evidence of a benefit of radiant heat dressings in terms of complete wound healing.

The most commonly evaluated topical therapies were debriding enzymes (primarily collagenase), phenytoin solution, dextranomer paste, and collagen applications. There was low-strength evidence that dextranomer was less effective than wound dressings. Evidence about enzymes and phenytoin was inconsistent and insufficient to draw conclusions. Collagen applications did not produce wound improvement compared with standard care based on low-strength evidence.

The most commonly evaluated biological agent was platelet-derived growth factor (PDGF), for which there was low-strength evidence of benefit compared with placebo in promoting wound improvement in severe (stage III or IV) ulcers. There was insufficient evidence about the effectiveness of other biological agents.

There was moderate-strength evidence that the most common harms of wound dressings and topical agents were dermatologic complications, including irritation, inflammation, and maceration. However, variability across studies precluded an estimate of adverse events for specific dressings or topical therapies, and evidence was insufficient to determine whether certain types of dressings or topical therapies were more likely to cause these complications than others. Few harms were reported with biological agents, but the evidence about the harms of these agents was insufficient to reach conclusions about adverse event rates. Evidence was insufficient to make conclusions about the effectiveness or harms of local wound applications across different ulcer characteristics, patient characteristics, or settings.

Surgical interventions for pressure ulcers identified in studies meeting our inclusion criteria were primarily surgical flaps, most commonly myocutaneous and fasciocutaneous flaps. Studies of surgical interventions were nearly all observational, and most were conducted in single centers. There was insufficient evidence that one approach to closure of stage III to IV pressure ulcers was superior to others due to heterogeneity in patient populations and surgical procedures. There was low strength of evidence that sacral ulcers had a lower rate of ulcer recurrence when compared with ischial ulcers, that a higher rate of recurrent ulcers occurred among patients with spinal cord injury compared with others, that a greater wound dehiscence rate occurred with surgeries in which bone was removed as part of the operation, and that more adverse events occurred with surgery for ischial compared with sacral or trochanteric ulcers. Surgical flap failures requiring reoperation ranged from 12 percent to 24 percent.

Adjunctive therapies identified in our review included electrical stimulation, electromagnetic therapy, ultrasound, negative pressure wound therapy, hydrotherapy, light therapy, and laser therapy. Evidence about other adjunctive therapies—including vibration, shock wave, and hyperbaric oxygen—was limited to small single studies. There was moderate-strength evidence that electrical stimulation improved healing rates, but there was insufficient evidence about the

effect of electrical stimulation on complete wound healing due to heterogeneous findings across studies. Low-strength evidence indicated that the most common adverse effect of electrical stimulation was local skin irritation and that harms were more common in frail elderly compared with younger populations. There was also low-strength evidence indicating that electromagnetic therapy, therapeutic ultrasound, and negative pressure wound therapy were similar to sham treatment or standard care in wound improvement outcomes; there was insufficient evidence to evaluate the harms of those adjunctive therapies due to a lack of reporting of harms. Light therapy provided benefit in terms of wound area reduction, but not in terms of complete wound healing, and it was not associated with significant adverse events based on low-strength evidence. There was low-strength evidence that laser therapy was not associated with significant adverse events, but also that it did not provide wound improvement over sham or standard treatment. There was insufficient evidence to draw conclusions about hydrotherapy due to the paucity of studies.

Discussion

Findings in Relationship to What Is Already Known

Treatments for pressure ulcers have been described and evaluated with varying degrees of rigor in the past (e.g., Lyder, 2003[4]). A recent systematic review by Reddy and colleagues, published in December 2008, evaluated 103 randomized trials published during or prior to August 2008.[10] The review included studies evaluating support surfaces, nutritional supplements, wound dressings, biological agents, and adjunctive therapies. Our review included evaluations of those treatment categories and additionally evaluated surgical interventions. We included observational studies of pressure ulcer treatments, included assessments of treatment harms, and expanded the search to include studies published through June 2012. We assessed treatment harms in studies published through June 2012. Our review also included observational studies in addition to clinical trials in an effort to more comprehensively review the relevant literature.

The findings of the prior systematic review were qualitatively similar to ours, with a few exceptions. In the support surface category, Reddy and colleagues reported that AP surfaces and LAL beds were not superior to standard nonpowered surfaces, which is similar to our findings.[10] They did not, however, report specifically on AF beds, as only one of the five studies of AF beds we included in our review was retrieved in their literature search. Our finding that there was moderate-strength evidence that AF beds were more effective than other surfaces in achieving wound area reduction is based on the findings from these additional studies. Additional systematic reviews on the use of support surfaces have been published by the Cochrane Collaboration. A recent report[17] updated earlier versions[18-20] and separated treatment from prevention. This review summarized 18 trials. (Observational studies were not included.) This review, like ours, found some evidence that AF beds led to reductions in pressure ulcer size and no significant effect of LAL beds on healing. Unlike our review, the Cochrane review reported some benefit from the use of sheepskins, but this was based on a study that was excluded from our review because it was published in 1964. Finally, the authors of this review found, as we did, that the evidence base was weak, with studies that were small, had serious methodological limitations, and often did not report key elements such as variance data, p-values, and the characteristics of the surfaces used as the comparators.

Reddy and colleagues reported that, overall, nutritional supplements did not provide benefit in terms of ulcer healing, but that protein supplementation may have produced wound

improvement.[10] Our findings were similar. We found moderate-strength evidence that protein supplementation resulted in wound size reduction, but studies did not provide evidence of an effect on complete wound healing. The Cochrane Collaboration published a 2008 systematic review on nutritional interventions to treat and prevent pressure ulcers. The authors were unable to draw conclusions about the effectiveness of nutritional interventions in the treatment of pressure ulcers due to the small number and poor quality of the available studies.[21]

We found limited evidence to support the use of certain dressings and topical therapies over others in terms of wound improvement. Our findings were similar to the conclusions drawn by Reddy and colleagues.[10] Our finding that hydrocolloid dressings are likely to be superior to gauze in promoting wound improvement was similar to the conclusion in two other systematic reviews.[22,23] A review by Chaby and colleagues[22] found equivalence between hydrocolloid and foam dressings in promoting wound improvement, a finding supported by our meta-analysis of eight studies comparing those dressing types. Both Reddy and colleagues and Chaby and colleagues highlighted a study demonstrating the superiority of alginate dressings to dextranomer paste.[10,22] We also found dextranomer paste to be inferior to dressing but considered the evidence for this to be low strength. We found moderate-strength evidence that radiant heat dressings accelerated the rate of wound area reduction, but we did not find evidence of a benefit of radiant heat dressings in terms of complete wound healing. Like Reddy and colleagues, we found a potential benefit, based on low-strength evidence, for platelet-derived growth factor in promoting wound improvement in stage III and IV ulcers.[10]

We found evidence to evaluate the comparative effectiveness of eight adjunctive therapies used in the treatment of pressure ulcers. Of these, none demonstrated consistent effectiveness in complete wound healing. Electrical stimulation, electromagnetic therapy, and light therapy showed a tendency for wound improvement, while other adjunctive therapies showed no evidence of effectiveness. Our findings are consistent with the findings of two prior systematic reviews of electrical stimulation for pressure ulcers,[10,24] two systematic reviews of therapeutic ultrasound,[10,25] one prior systematic review of negative pressure wound therapy,[10] and two systematic reviews of laser therapy.[10,26] Our findings of no significant difference in wound improvement with electromagnetic therapy (EMT) are consistent with those of a prior Cochrane review.[27] Although a trend toward improvement in rate of healing with EMT has been observed, consistent with prior systematic reviews,[10,28] we found that the clinical significance of this trend remains unknown.

Applicability

The applicability of our findings to real-world clinical settings is supported by several features of the body of literature we reviewed. First, the populations studied included a broad representation of patients with pressure ulcers—elderly patients, general populations of patients with limited mobility, and patients with spinal cord injury—cared for in a wide variety of settings, including hospitals, nursing homes, wound care clinics, and at home. Second, the interventions represented most of the therapeutic modalities commonly used in clinical settings. Comparators were also commonly used therapies and often included standard care as defined by local practice patterns. In some studies this included use of comparators that may not be considered best practices, such as standard hospital beds and plain gauze dressings. However, as these treatment strategies remain in use in many settings, both in the United States and other countries, we retained these studies in our review.

Other features of the studies we identified, however, limited the applicability of our findings. First, the outcome in many studies was wound size (area, volume, or depth) reduction as opposed to complete wound healing. Although wound size reduction is a reasonable measure of therapeutic effect, in clinical practice the goal of therapy is almost always complete wound healing, making wound size reduction a surrogate outcome with less clinical significance than complete wound healing. A principal reason for findings of wound size reduction without complete wound healing was the short duration of most trials. Complete healing takes time. Interventions lasting only a few weeks (as was the case for most of the trials included in our review) are less likely to achieve complete wound healing than interventions carried out for periods long enough for complete healing to occur (as would be the case in clinical practice). A second reason that applicability is limited is that the treatment of pressure ulcers in clinical practice often involves multiple concurrent therapies, such as support surfaces, nutritional supplementation, biological or topical therapies, and adjunctive interventions. No studies compared one combination of concurrent or sequential therapies with another, and no conclusions can be drawn regarding the effectiveness of one compared with another.A second issue affecting applicability is that treatment of pressure ulcers is typically multimodal and often involves the sequential use of different therapies. In practice, the relevant question is often not "Which therapy works best?" but rather "Which combination of therapies works best?" and "When is a specific treatment indicated?" Most comparative studies of pressure ulcer treatments examined head-to-head comparisons of single treatment modalities. Although contextual data and cointerventions were sometimes reported, integrating those data to answer questions about treatment combinations and timing was difficult.

Studies of surgery are additionally limited by the fact that most were observational and conducted in one or, at most, a few centers. Since surgical technique and quality are often operator and/or site dependent, and because outcomes are influenced by local practices, staffing, and other features of the environment, it is difficult to generalize the findings of studies of surgery included in this review.

Implications for Clinical and Policy Decisionmaking

The limitations in applicability discussed above, as well as the limitations of the evidence base discussed below, make it difficult to draw firm conclusions with implications for clinical and policy decisionmaking. Notably, we generated no findings that were supported by high-strength evidence and only a few findings supported by moderate-strength evidence. Most findings were based on low-strength evidence, and for many issues there was insufficient evidence to draw any conclusions.

The finding that AF beds promote wound improvement compared with other surfaces might warrant consideration of this technology. However, it is important to point out that while the five studies of these beds had consistent findings, they are somewhat dated and most compared AF beds with standard beds rather than with other specialized options. Decisions about investments in support surfaces would benefit from head-to-head trials of current technologies that measure effectiveness in terms of complete wound healing, not only reduction in wound size.

Nutritional supplementation may provide benefit in terms of wound improvement, although the effects of nutritional supplementation were not dramatic and it was not clear from the studies in our review whether nutritional supplementation was beneficial to all patients or only those with evidence of nutritional deficiencies. Because nutritional support is commonly prescribed for ill or debilitated patients with evidence of malnutrition, it is not clear whether nutritional support

affects ulcer healing and whether patients without evidence of malnutrition might benefit from nutritional supplementation.

Decisions about dressings and topical applications are often guided by matching the primary functions of different dressings (e.g., absorbent and hydrating) with the primary considerations for treatment of individual ulcers (e.g., dryness, contamination risk, and exudate). Given the wide array of options, comparative effectiveness and harms data have great potential to guide individualized decisionmaking. We found limited evidence, however, to provide such guidance. Overall, we did not find substantial evidence to support certain local wound applications over others. There was evidence to suggest that radiant heat improved the pace of wound healing, but not complete wound healing. Some biological agents showed promise for the treatment of severe ulcers, but the evidence was not substantial. In light of the cost of these agents, more and better evidence is likely needed before they are widely adopted.

Surgery is typically reserved for refractory ulcers unlikely to heal with conservative management. Evidence about surgery is limited to mainly single-center observational studies. However, we found some evidence to inform decisions and expectations about which ulcers

will fare best with surgical intervention and which surgeries are likely to produce the lowest complication rates. The influence of those findings on clinical decisionmaking should be tempered by the low quality of the studies that produced the findings and the potentially limited generalizability of the findings across sites and surgeons.

Adjunctive therapies include therapies that are variably used in the treatment of pressure ulcers. Our review revealed moderate-strength evidence that electrical stimulation accelerated healing but did not otherwise produce findings that would support greater use of adjunctive therapies for the goal of wound healing.

Limitations of the Comparative Effectiveness Review Process

The most important potential limitation of our review is that important studies whose findings might influence clinical and policy decisionmaking may not have been identified. We conducted a comprehensive, broadly inclusive search that produced 7,274 study titles and abstracts. Although we excluded studies published before 1985, we do not believe that important studies of therapies used in current practice were missed. The general consistency of our findings with those of other systematic reviews, which included studies published prior to 1985, provides some assurance that our review was not biased by our timeframe selection. Although we did not include foreign-language studies, we identified these studies and, based on review of their abstracts, found that none would have altered our conclusions. Our review focused on clinical outcomes of pressure ulcer treatments, particularly wound improvement. Other outcomes, such as ease of use and nursing/staff time, might also influence treatment decisions but were beyond the scope of our review. Finally, we excluded studies of the treatment of nonpressure ulcers. To the extent that evidence for interventions studied in other types of wounds, including venous ulcers, is applicable to the treatment of pressure ulcers, our review may have underestimated the quantity and quality of the body of evidence for these interventions.

There may have been biased reporting of results in the literature such that only selected studies were published and retrievable, and that published studies may have been affected by conflicts of interest. Reporting bias and conflicts of interest are concerns with any systematic review. We were not able to conduct quantitative analyses to evaluate the possibility of reporting bias for most of our findings because the heterogeneity across studies in our review, and in many cases the lack of key information needed to perform quantitative syntheses, generally precluded

meaningful comparison of effect sizes. Mitigating against the likelihood of reporting bias in our review, however, is the fact that the majority of studies in our review were small (most fewer than 100 patients, many fewer than 50), and most reported no significant effect of the intervention. Reporting bias typically results in selective publication of larger studies and/or those with positive findings, and studies biased by conflicts of interest would also be more likely to report positive findings. We also conducted gray literature searches to look for unpublished data and did not find evidence of unreported studies.

We took several measures to guard against the influence of bias in our identification and evaluation of studies. Abstracts were reviewed by at least two team members, including a clinician/senior investigator. Studies were extracted based on prespecified data elements, extraction done by one team member was checked by another, and quality rating of studies was performed by two team members, with disagreements adjudicated by consensus. Rating of elements of strength of evidence was discussed and calibrated among team members.

Limitations of the Evidence Base

The main limitation of the evidence base in our review was poor study quality. Most trials did not specify randomization method, did not conceal allocation, and did not mask outcomes assessment. Most studies were small, and many were underpowered to detect significant differences. Studies were also highly variable in terms of patient populations; ulcer characteristics (e.g., anatomic site, duration, and stage); interventions (even within a given intervention category such as different types of foam dressings); and comparators (especially in implementation of standard, or usual, care), limiting our ability to combine or compare results across studies.

Another major limitation of the evidence base relates to the most common outcome measure: wound size reduction. Comparing changes in the size of pressure ulcers poses several measurement issues. For example, reduction in the size of larger and smaller pressure ulcers is hard to compare. Healing could involve "bridges" that split a large ulcer into two. In addition, measurement in person or from tracings or photographs can be difficult, especially when measurement and photographic techniques are not standardized across studies.

Finally, a major limitation of studies in our review was the duration of interventions and followup periods, typically a few weeks. Many pressure ulcers, especially more severe ulcers, may take months, or even years, to heal. Many of the studies in our review were implemented over a period that did not necessarily allow for complete ulcer healing, and therefore detection of significant differences in ulcer healing across groups. However, one strength in this body of literature was that most studies used intention-to-treat analyses.

Research Gaps

The major gaps in research identified by our review relate to the limitations of the evidence base, as described above. Future studies with larger sample sizes, more rigorous adherence to methodological standards for clinical trials or observational studies, longer followup periods, standardization of comparators, and more standardized and clinically meaningful outcome measures (including more patient-centered outcomes, such as quality of life and pain) are needed to inform clinical practice and policy. Inclusion of information about cointerventions and the timing of studied interventions in relation to other interventions would improve the applicability of study findings. Similarly, stratification of findings by patient characteristics (e.g., comorbidities, ulcer stage) would help determine the applicability of different interventions for

specific patients and situations. It is particularly important for future studies to report findings according to ulcer stage, as the rate of healing, conditions necessary to promote healing, and therefore treatment choices may differ for partial- and full-thickness ulcers. Decisions about defining other aspects of patient populations, interventions, comparators, outcomes, study timing and duration, and study settings should be guided by clinical practice, expertise, and factors most relevant to decisionmakers, including patients, clinicians, and policymakers.

For several interventions, there was insufficient evidence to reach conclusions due to small sample sizes or mixed results across studies. These interventions included AP beds compared with other surfaces, topical debriding enzymes, phenytoin, and growth factors. Future studies should clarify the comparative effectiveness of these interventions and identify possible reasons for disparate results. For other interventions, findings indicated a possible benefit, but the strength of evidence was low due to study quality, duration, sample size, and measured outcomes (wound size reduction rather than complete wound healing). These interventions included platelet-derived growth factor and light therapy. Future studies are needed to confirm or refute the effectiveness of these interventions.

As mentioned, further study is warranted comparing AF beds with more modern support surfaces and evaluating comparative effectiveness in terms of complete wound healing. Similarly, in light of findings suggesting a benefit for radiant heat dressings and electrical stimulation in terms of wound healing rate, further study should compare these technologies with other treatments, with sufficient followup to evaluate complete wound healing. There was limited evidence to support the use of nutritional supplements as a component of pressure ulcer care, but few studies examined whether supplementation might have a differential effect for patients with and without baseline nutritional deficiencies. Future studies should address this issue.

Hyperbaric oxygen therapy is one clinical area that our TEP identified as high priority but for which we found limited evidence. Although studies and systematic reviews have evaluated this treatment in chronic wounds generally, its utility among patients with pressure ulcers specifically has undergone limited evaluation.

Conclusions

Choices of treatments for pressure ulcers are often guided by product availability, local practice patterns, and individualized decisionmaking based on specific patients and the features of a given pressure ulcer. Our review did not generate many findings to guide those choices based on evidence.

We found limited evidence to draw firm conclusions about the best approaches for treating pressure ulcers. This finding is consistent with that of a prior systematic review addressing most of the same treatment categories included in our review.[10] We found evidence from five studies indicating greater wound improvement with AF beds over other support surfaces, from four studies indicating a benefit of radiant heat dressings over other dressings, and from nine studies indicating a benefit of electrical stimulation. However, the benefit observed in all cases was wound size reduction or better healing rates rather than completely healed wounds, and evidence for the benefit of support surfaces in promoting wound improvement was based primarily on comparisons of AF beds with hospital beds that may not be considered the standard of care in the field. The balance of costs and potential harms of those technologies against the benefits observed is unclear.

Studies generally did not provide evidence to support the use of one type of commonly used wound dressing over another. There was evidence that hydrocolloid and foam dressings performed similarly, but evidence for other dressing types—hydrogels, alginates, transparent films, and silicone dressings—compared with each other or with standard gauze dressings was limited. Similarly, there was low-strength or insufficient evidence to judge the balance of effectiveness and harms for nutritional supplementation, topical therapies, biological agents, surgical interventions, and adjunctive therapies other than electrical stimulation.

Advancing pressure ulcer care will require more rigorous study to solidify the evidence base for this widely used set of treatments.

References

1. Bergstrom N, Bennett MA, Carlson CE, et al. Pressure Ulcer Treatment Clinical Practice Guideline. Quick Reference Guide for Clinicians No. 15. Rockville, MD: U.S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research AHCPR Pub. No. 95-0653. Dec. 1994.
2. Graves N, Birrell F, Whitby M. Effect of pressure ulcers on length of hospital stay. Infect Control Hosp Epidemiol. 2005;26(3):293-7. PMID: 15796283.
3. Vangilder C, Macfarlane GD, Meyer S. Results of nine international pressure ulcer prevalence surveys: 1989 to 2005. Ostomy Wound Manage. 2008;54(2):40-54. PMID: 18382042.
4. Lyder CH. Pressure ulcer prevention and management. JAMA. 2003 Jan 8;289(2):223-6. PMID: 12517234.
5. National Pressure Ulcer Advisory Panel. Pressure Ulcer Prevention and Treatment: Clinical Practice Guideline. National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel; 2009.
6. Thomas DR, Rodeheaver GT, Bartolucci AA, et al. Pressure ulcer scale for healing: derivation and validation of the PUSH tool. The PUSH Task Force. Adv Wound Care. 1997;10(5):96-101. PMID: 9362591.
7. Bates-Jensen BM, Vredevoe DL, Brecht ML. Validity and reliability of the Pressure Sore Status Tool. Decubitus. 1992 Nov;5(6):20-8. PMID: 1489512.
8. Agency for Healthcare Research and Quality. Methods Guide for Effectiveness and Comparative Effectiveness Reviews. www.effectivehealthcare.ahrq.gov.
9. Institute of Medicine. Finding What Works in Health Care: Standards for Systematic Reviews. Washington, DC: The National Academy of Sciences; 2011.
10. Reddy M, Gill SS, Kalkar SR, et al. Treatment of pressure ulcers: a systematic review. JAMA. 2008 Dec 10;300(22):2647-62. PMID: 19066385.
11. Downs SH, Black N. The feasibility of creating a checklist for the assessment of the methodological quality both of randomised and non-randomised studies of health care interventions. J Epidemiol Community Health. 1998;52(6):377-84. PMID: 9764259.
12. Harris RP, Helfand M, Woolf SH, et al. Current methods of the US Preventive Services Task Force: a review of the process. Am J Prev Med. 2001;20(3 Suppl):21-35. PMID: 11306229.
13. U.S. Preventive Services Task Force Procedure Manual. Section 4: Evidence Report Development. AHRQ Publication No. 08-05118-EF. July 2008. www.uspreventiveservicestaskforce.org/uspstf08/methods/procmanual.htm.
14. Higgins JP, Thompson SG. Quantifying heterogeneity in a meta-analysis. Stat Med. 2002 Jun 15;21(11):1539-58. PMID: 12111919.
15. DerSimonian R, Laird N. Meta-analysis in clinical trials. Control Clin Trials. 1986 Sep;7(3):177-88.
16. Atkins D, Chang S, Gartlehner G, et al. Assessing applicability when comparing medical interventions: Agency for Healthcare Research and Quality and the Effective Health Care Program. J Clin Epidemiol. 2011;64(11):1198-207. PMID: 21463926.
17. McInnes E, Jammali-Blasi A, Bell-Syer SE, et al. Support surfaces for pressure ulcer prevention. Cochrane Database of Systematic Reviews. 2011(4):CD001735. PMID: 21491384.
18. Cullum N, Deeks JJ, Fletcher AW, et al. Effectiveness bulletin. Preventing and treating pressure sores. Qual Health Care. 1995;4(4):289-97. PMID: 10156400.
19. Cullum N, Deeks J, Sheldon TA, et al. Beds, mattresses and cushions for pressure sore prevention and treatment. J Tissue Viability. 1999 Oct;9(4):138. PMID: 10808844.

20. Cullum N, Nelson EA, Flemming K, et al. Systematic reviews of wound care management: (5) beds; (6) compression; (7) laser therapy, therapeutic ultrasound, electrotherapy and electromagnetic therapy. Health Technol Assess. 2001;5(9):1-221. PMID: 11368833.

21. Langer G, Schloemer G, Knerr A, et al. Nutritional interventions for preventing and treating pressure ulcers. Cochrane Database of Systematic Reviews. 2003(4):CD003216. PMID: 14583961.

22. Chaby G, Senet P, Vaneau M, et al. Dressings for acute and chronic wounds: a systematic review. Arch Dermatol. 2007 Oct;143(10):1297-304.

23. Heyneman A, Beele H, Vanderwee K, et al. A systematic review of the use of hydrocolloids in the treatment of pressure ulcers. J Clin Nurs. 2008 May;17(9):1164-73.

24. Gardner SE, Frantz RA, Schmidt FL. Effect of electrical stimulation on chronic wound healing: a meta-analysis. Wound Repair Regen. 1999 Nov-Dec;7(6):495-503. PMID: 10633009.

25. Sari AA, Flemming K, Cullum NA, et al. Therapeutic ultrasound for pressure ulcers. Cochrane Database of Systematic Reviews. 2009(4).

26. Lucas C, Stanborough RW, Freeman CL, et al. Efficacy of low-level laser therapy on wound healing in human subjects: a systematic review. Lasers Med Sci. 2000;15(2):84-93.

27. Aziz Z, Flemming K, Cullum NA, et al. Electromagnetic therapy for treating pressure ulcers. Cochrane Database of Systematic Reviews. 2010(11):CD002930. PMID: 21069672.

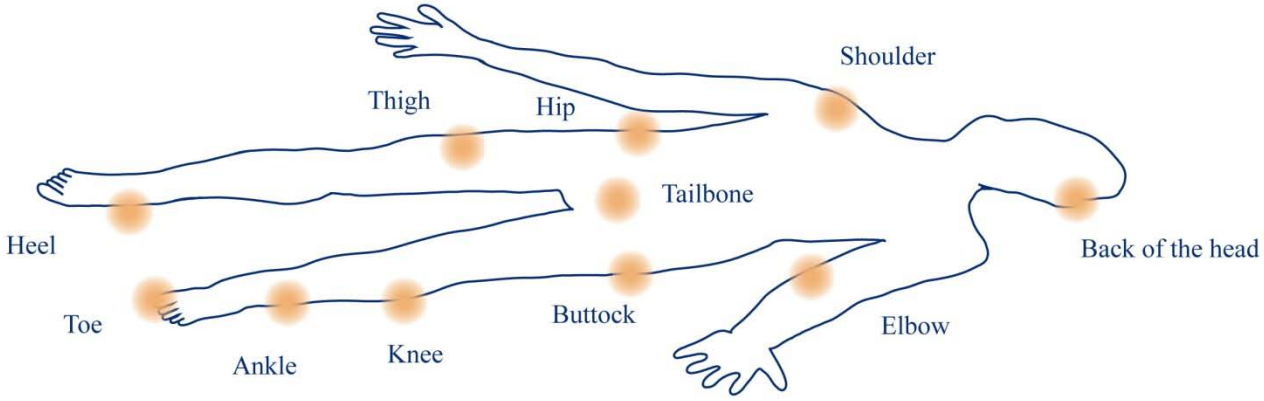
28. McGaughey H, Dhamija S, Oliver L, et al. Pulsed electromagnetic energy in management of chronic wounds: a systematic review. Phys Ther Rev. 2009;14(2):132-46.

Introduction

Background

Uninterrupted pressure exerted on the skin, soft tissue, muscle, and bone can lead to the development of localized ischemia, tissue inflammation, shearing, anoxia, and necrosis. Pressure ulcers affect up to three million adults in the United States. Areas of the body prone to the development of pressure ulcers are depicted in Figure 1. Estimates of the incidence of pressure ulcers vary according to the setting, with ranges of 0.4 to 38.0 percent in acute-care hospitals, 2.2 to 23.9 percent in long-term nursing facilities, and 0 to 17 percent in home care.[1,2] A review of international pressure ulcer prevalence surveys found an overall prevalence in acute and long-term care settings of 9.2 to 11.1 percent between 1989 and 1995 and a prevalence of 14.7 to 15.5 percent between 1999 and 2005.[3]

Figure 1. Common pressure ulcer sites



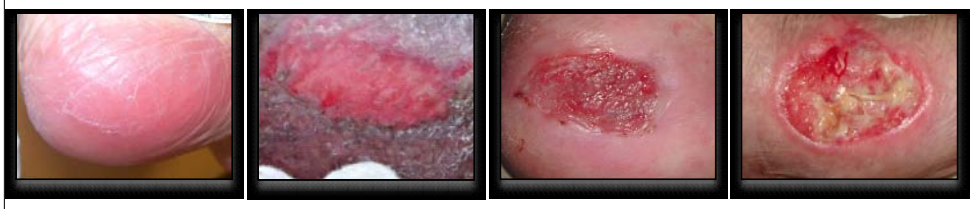
Oregon EPC

Pressure ulcer healing rates – which are dependent on comorbidities, clinical interventions, and severity of the ulcer – vary considerably. Ulcer severity is assessed using a variety of different staging or grading systems; the United States National Pressure Ulcer Advisory Panel (NPUAP) staging system is the most commonly used (Figure 2). Comorbidities predisposing toward pressure ulcer development and affecting ulcer healing include those affecting patient mobility (e.g., spinal cord injury), wound environments (e.g., incontinence), and wound healing (e.g., diabetes, vascular disease). Delayed healing can add to the length of hospitalization and impede return to full functioning.[2] Data on the costs of treatment for a pressure ulcer vary, but some estimates range between $37,800 and $70,000 per ulcer, with total annual costs for pressure ulcers in the United States as high as $11 billion.[1,4] Pressure ulcers are used as an indicator of quality for long-term care facilities, and progression of pressure ulcers in hospitalized patients is often considered an avoidable complication representing failure of inpatient management.

Given the negative impact pressure ulcers have on health status and patient quality of life, as well as health care costs, treatments are needed that promote healing, shorten healing time, minimize the risk of complications, and increase the likelihood of complete healing. Pressure ulcer treatment involves a variety of different approaches, including interventions to treat the conditions that give rise to pressure ulcers (support surfaces and nutritional support), interventions to protect and promote healing of the ulcer itself (wound dressings, topical applications, and various adjunctive therapies including vacuum-assisted closure, ultrasound

therapy, electrical stimulation, and hyperbaric oxygen therapy), and surgical repair of the ulcer.[1,4] Most ulcers are treated using a combination of these approaches. Standards of care for pressure ulcer treatment are typically guided by clinical practice guidelines, such as those developed by the NPUAP, but also vary by patient-related factors such as comorbidities and nutritional status,[5] local practice patterns, and the stage and features of the wound. Current guidelines primarily reflect expert opinions. An examination of the comparative effectiveness and harms of the wide variety of different therapies and approaches to treating pressure ulcers is important to guide clinical practice.

Figure 2. National Pressure Ulcer Advisory Panel pressure ulcer stages



Stage: I

Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area.

Stage: II

Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum-filled blister.

Stage: III

Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscles are not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling.

Stage: IV

Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often includes undermining and tunneling.

Suspected Deep Tissue Injury [a]

Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue.

Unstageable [a]

Full thickness tissue loss in which the base of the ulcer is covered by slough (yellow, tan, gray, green or brown) and/or eschar (tan, brown or black) in the wound bed.

[a] Not pictured.
NPUAP copyright, photos used with permission

Scope and Key Questions

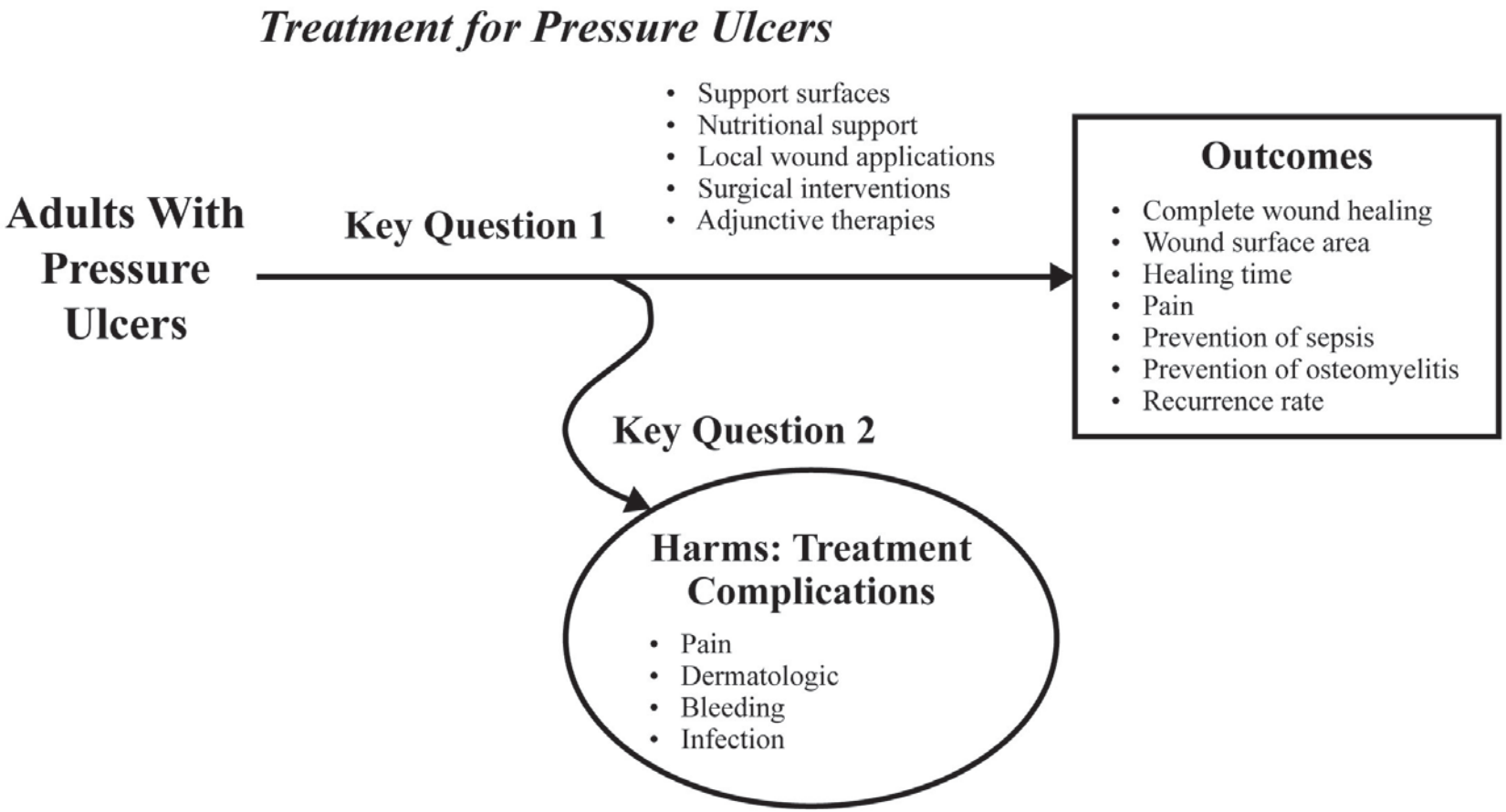
This topic was selected for review based on two separate nominations that also included questions related to risk assessment and prevention of pressure ulcers. This report addresses the comparative effectiveness of various pressure ulcer treatment approaches while the topic of prevention, including secondary prevention of recurrent pressure ulcers, is addressed in a companion report. Both reports are intended to serve as the foundation for the development of updated guidelines on pressure ulcer prevention and treatment.

The key questions were developed with input from Key Informants, including clinicians, wound care researchers, and patient advocates. The analytic framework and key questions used

to guide this report are shown below (Figure 3). The analytic framework shows the target populations, interventions, outcomes, and harms that we evaluated.

The general categories of treatment included in this report are support surfaces, nutritional supplements, local wound applications (including wound dressings, topical therapies, and biological agents), surgical procedures, and various adjunctive therapies. Other facets of pressure ulcer care (e.g., repositioning, nonsurgical wound debridement, and wound cleansing) were not considered areas where comparative effectiveness evidence was likely to be found or to significantly influence clinical care. We evaluated the evidence on comparisons within the general categories (for example, comparisons between two types of dressings). We also sought direct evidence on comparisons across the general categories (for example, dressings vs. support surfaces). This review also included an assessment of adverse effects or harms associated with pressure ulcer treatment, such as dermatologic complications, bleeding, pain, or infection. Finally, we included an assessment of future research needs on this important clinical topic.

Figure 3. Analytic framework: Pressure ulcer treatment strategies



Key Question 1. In adults with pressure ulcers, what is the comparative effectiveness of treatment strategies for improved health outcomes including but not limited to: complete wound healing, healing time, reduced wound surface area, pain, and prevention of serious complications of infection?

Key Question 1a. Does the comparative effectiveness of treatment strategies differ according to features of the pressure ulcers, such as anatomic site or severity at baseline?

Key Question 1b. Does the comparative effectiveness of treatment strategies differ according to patient characteristics, including, but not limited to: age, race/ethnicity, body weight. specific medical comorbidities, and known risk factors for pressure ulcers, such as functional ability, nutritional status, or incontinence?

Key Question 1c. Does the comparative effectiveness of treatment strategies differ according to patient care settings such as home, nursing facility, or hospital, or according to features of patient care settings, including, but not limited to, nurse/patient staffing ratio, staff education and training in wound care, the use of wound care teams, and home caregiver support and training?

Key Question 2. What are the harms of treatments for pressure ulcers?

Key Question 2a. Do the harms of treatment strategies differ according to features of the pressure ulcers, such as anatomic site or severity at baseline?

Key Question 2b. Do the harms of treatment strategies differ according to patient characteristics, including: age, race/ethnicity, body weight, specific medical comorbidities, and known risk factors for pressure ulcers, such as functional ability, nutritional status, or incontinence?

Key Question 2c. Do the harms of treatment strategies differ according to patient care settings such as home, nursing facility, or hospital, or according to features of patient care settings, including, but not limited to, nurse/patient staffing ratio, staff education and training in wound care, the use of wound care teams, and home caregiver support and training?

Population and Conditions of Interest

The population studied was adults ages 18 and older with a pressure ulcer. Patients with pressure ulcers usually also have limited or impaired mobility and suffer from other chronic illnesses. Pressure ulcers are most common in the elderly or people with spinal cord injuries or other conditions that restrict mobility. Patients with nonpressure-related ulcers, including, but not limited to, venous ulcers and diabetic foot ulcers, were excluded because treatment considerations for these patients may differ significantly from those for pressure ulcers. A systematic review of treatment for chronic venous ulcers, sponsored by the Agency for Healthcare Research and Quality (AHRQ), is in progress. We excluded children because this topic was originally nominated and scoped for adults.[a] Key Informants agreed with the broadly defined proposed population of interest as "adults with pressure ulcers." They endorsed the proposed list of included patient characteristics that should be considered, but they also noted that "adults with pressure ulcers" are a heterogeneous group and that variability in the comparative effectiveness of pressure ulcer treatments may be related to a large number of patient characteristics. In addition to age, sex,

[a]Although treatment approaches for children with pressure ulcers may be similar to those for adults, other factors may influence the effectiveness differently in this population, including setting, caregiver attention, healing potential, and comorbidities.

race/ethnicity, socioeconomic status, and diverse specific medical comorbidities (e.g., diabetes, end-stage renal disease, and dementia), many informants suggested that we include specific known risk factors for pressure ulcers (e.g., nutritional status, incontinence, peripheral vascular disease, mobility limitations, and functional ability). See Appendix B for detailed inclusion and exclusion criteria.

Interventions and Comparators

Various treatment strategies for pressure ulcers were addressed, including, but not limited to, therapies that address the underlying contributing factors (e.g., support surfaces and nutritional supplements), therapies that address local wound care (e.g., wound dressings, topical therapies, and biological agents), surgical repair, and adjunctive therapies (e.g., electrical stimulation). The comparative effectiveness and harms of other interventions (e.g., repositioning, wound debridement, and wound cleansing) were considered but not reviewed, based on input from the Technical Expert Panel (TEP) that these modalities were either considered standard care or lacked comparative studies.

Combined treatment modalities (cointerventions), such as comparison of two treatments in combination compared with a single treatment, were also evaluated.

Comparators included placebo or active control, usual care, or other interventions. In some cases, particularly in older studies, newer interventions were compared to older ones that might no longer be considered standard care in the field. However, in many care settings these applications (e.g., gauze dressings, standard hospital beds) are still used, and we therefore included studies using those types of comparators because of their continued relevance in some treatment settings.

Outcomes

The most commonly examined outcomes were various measures of wound improvement. Some studies examined complete wound healing as the primary outcome, though many studies evaluated wound size reduction. Based on input from the TEP, we considered complete wound healing to be the principal health outcome of interest. However, we also considered other indicators of "wound improvement" in synthesizing evidence. Notably, many studies reported findings in terms of wound size reduction rather than complete wound healing. We considered wound size reduction to be an important outcome for two reasons. First, it represents a necessary intermediate step towards the principal outcome of complete wound healing (i.e., complete wound healing can be considered 100 percent wound size reduction). Second, the likelihood of complete wound healing is lower for larger or higher-stage ulcers and therapies deployed for more advanced ulcers may not be expected to achieve complete wound healing over the course of several weeks, which was the duration of most of the studies in our review. Thus, in summarizing the evidence about a given treatment, we considered wound size reduction to be part of the continuum of the outcome of "wound healing," but we gave more weight to evidence of complete wound healing. Some studies used composite outcome measures commonly used to monitor pressure ulcer status. The Pressure Ulcer Scale for Healing (PUSH) tool combines wound surface area, amount of wound exudate, and tissue appearance.[6] The Pressure Sore Status Tool (PSST) considers multiple ulcer characteristics including dimensions, exudate, and tissue appearance.[7] Other studies reported outcomes in terms of wound healing rate. We included these outcomes, when reported in studies, as indicators of "wound improvement" but prioritized findings for complete wound healing, as noted above, based on feedback from the TEP. Other outcomes included wound healing rate and time, pain, and avoidance of serious complications of infection. For harms of treatment, we

evaluated pain, dermatologic complications, bleeding, infection, and other adverse outcomes as reported in identified studies.

Timing

We did not apply minimum followup duration for studies.

Setting

Settings included patient care settings, such as home, nursing facility, or hospital.

Methods

The methods for this comparative effectiveness review (CER) follow the methods suggested in the AHRQ "Methods Guide for Effectiveness and Comparative Effectiveness Reviews"[8] and the standards suggested by the Institute of Medicine for conducting systematic reviews.[9]

Topic Refinement and Review Protocol

The key questions for this CER were developed with input from Key Informants, representing clinicians, wound care researchers, and patient advocates, who helped refine key questions, identify important methodological and clinical issues, and define parameters for the review of evidence. The revised key questions were then posted to the Agency for Healthcare Research and Quality (AHRQ) public Web site for a four-week comment period. AHRQ and the Evidence-based Practice Center (EPC) agreed upon the final key questions after reviewing the public comments and receiving additional input from a Technical Expert Panel (TEP) convened for this report.

The protocol for the CER was reviewed by the TEP and is available from the AHRQ Web site: (www.effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?productid=838&pageaction=displayproduct).

A multidisciplinary group of clinicians, researchers, and patient advocates with expertise in pressure ulcer treatment and research was selected to serve on the TEP to provide high-level content and methodological expertise throughout the development of the review. Participants included leaders in the areas of pressure ulcer treatment and research, wound care and physical therapy, and plastic and reconstructive surgery, as well as patient safety advocates and United States National Pressure Ulcer Advisory Panel (NPUAP) members.

TEP members disclosed all financial or other conflicts of interest prior to participation. The AHRQ Task Order Officer and the authors reviewed the disclosures and determined the panel members had no conflicts of interest that precluded participation.

Search Strategy

For the primary literature we searched (through June 2012) MEDLINE (Ovid), Embase (Elsevier), CINAHL (EBSCOhost), EBM Reviews (Ovid), Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, and Health Technology Assessment (see Appendix A for details). The most relevant evidence about modalities and procedures currently used for treating pressure ulcers is found in studies conducted within the last 25 years. For this reason we have set the search start date at 1985. This decision was affirmed by the Key Informants and TEP. Gray literature was identified by soliciting stakeholders, TEP recommendations, and searching relevant Web sites, including clinical trial registries (ClinicalTrials.gov, Current Controlled Trials, ClinicalStudyResults.org, and the World Health Organization International Clinical Trials Registry Platform), regulatory documents (Drugs@FDA and Devices@FDA), conference proceedings and dissertations (Conference Papers Index [ProQuest CSA]), Scopus (Elsevier), Dissertations & Theses (ProQuest UMI), and individual product Web sites. An additional, focused MEDLINE search on hyperbaric oxygen for the treatment of pressure ulcers was conducted at the recommendation of the TEP due to the paucity of evidence on this subject obtained from the original search.

Scientific information packets (SIPs) were requested from identified drug and device manufacturers, and a notice inviting submission of relevant scientific information was published in the Federal Register. All interested parties had the opportunity to submit data for this review using

the AHRQ Effective Health Care publicly accessible online SIP portal (http://effectivehealthcare.ahrq.gov/index.cfm/submit-scientific-information-packets/). Reviewers evaluated the SIPs received for data relevant to our review.

Additional studies were identified by reviewing the reference lists of published clinical trials, systematic reviews, and review articles.

Inclusion and Exclusion Criteria

The criteria for inclusion and exclusion of studies were based on the key questions and the populations, interventions, comparators, outcomes, timing, and setting (PICOTS) approach. We used the following inclusion criteria (See Appendix B for details):

Populations: Studies were limited to of adults age 18 years and older being treated for existing pressure ulcers. Subgroups were defined by age, sex, race/ethnicity, socioeconomic status, and diverse specific medical comorbidities (e.g., diabetes, end-stage renal disease, and dementia), and patients with specific known risk factors for pressure ulcers (e.g., nutritional status, incontinence, peripheral vascular disease, mobility limitations, and functional ability). Studies conducted in populations including children, adolescents, and patients with nonpressure-related ulcers, including, but not limited to, venous ulcers and diabetic foot ulcers, were excluded because treatment considerations for these patients may differ significantly from those for adults with pressure ulcers.

Interventions: For efficacy and effectiveness assessments, all studies of interventions for treatment of pressure ulcers meeting the requirements of the PICOTS and key questions were included. Treatments for pressure ulcers included, but were not limited to, support surfaces, nutritional supplementation, wound dressings, topical therapies, biological agents, and surgical repair. Adjunctive therapies included electrical stimulation, electromagnetic therapy, ultrasound, negative pressure wound therapy, light therapy, laser therapy, hydrotherapy, and hyperbaric oxygen therapy.

Comparators: Comparators included usual care, placebo or sham treatment, no treatment, or different treatment interventions. Studies with no comparator were not considered in our evaluation of comparative effectiveness. They were included for the assessment of harms if they reported on harms of treatments for which data on comparative effectiveness were available in other studies.

Outcomes: Studies reporting clinical outcomes of complete wound healing, wound size (surface area, volume, depth) reduction, pain, prevention of sepsis, prevention of osteomyelitis, recurrence rate, and harms of treatment (including but not limited to pain, dermatologic complications, bleeding, and infection) were included. Studies of nonpressure-related ulcers were not included. We excluded studies that only evaluated nonclinical outcomes including ease of use, comfort, or nursing time required to administer the intervention.

Timing: No minimum followup time was required. We limited our search to publications and investigations conducted from 1985 to June 2012.

Setting: We included studies conducted in patient-care settings such as home, nursing facility, or hospitals. We excluded studies in hospice settings if complete wound healing was not an outcome measured.

Study design: We included randomized trials, cohort studies, and case-control studies pertinent to all key questions. If such studies were not available, we included cross-sectional studies and intervention series studies. Systematic reviews were used as background information

or to ensure completeness of the literature search. Case studies of only one patient were not included.

For studies of surgical interventions, we initially planned to include controlled trials, observational studies with at least two comparison groups, and noncomparative intervention series only if they were multicenter series with a population of 100 patients or more. An initial scan of the literature, however, revealed that studies of surgical interventions revealed primarily small series of specific surgical techniques performed at single centers. Because surgical outcomes are heavily influenced by individual surgeons, local practice patterns, and other contextual factors, the TEP raised concern that data from these small single-site studies ($n< 50$) would have limited generalizability and that they would not provide a sound basis for making indirect comparisons across studies. We therefore excluded small ($n<50$) single-site studies reporting the results of specific surgical techniques for pressure ulcer management, but expanded our inclusion criteria to include single-center intervention series reporting a large series ($n\geq 50$) of patients undergoing surgery for pressure ulcer. We included studies of any size that provided direct, head-to-head comparisons of different surgical techniques.

According to guidance from the European Pressure Ulcer Advisory Panel (EPUAP), and suggestions of literature from our Key Informants, the most relevant evidence about modalities and procedures for treating pressure ulcers used in clinical practice today comes from investigations conducted within the past 25 years. Therefore we limited the search to 1985 to present. Guidance from the TEP indicated that current literature (1985 to present) not only captures historically significant treatments and evidence, but also provides the most current information and treatments currently used in clinical practice. Non-English language studies were included in the abstract triage, but translation for full-text review was not feasible. Gray literature including unpublished data, abstracts, dissertations, and SIPs were reviewed to determine if they added additional and meaningful data beyond the literature included in this review and should also be included.

Study Selection

To calibrate reviewer agreement and consistency in study selection, each reviewer evaluated the same set of 200 citations for inclusion and kappa values were calculated to estimate inter-reviewer reliability. After discussing and reconciling disagreements between reviewers, the same four team members reviewed an additional 100 citations. This process was continued until a kappa value of greater than 0.50 for each pair of reviewers was reached. For the remaining references, each reviewer evaluated each title and abstract for inclusion and exclusion, using the pre-established inclusion/exclusion criteria to determine eligibility for inclusion in the evidence synthesis. To ensure accuracy, a senior investigator/clinician conducted secondary reviews of all excluded abstracts. All citations deemed appropriate for inclusion by one or both of the reviewers were retrieved for full-text review.

Full-text articles were independently reviewed by two team members. When the two team members did not agree on inclusion or exclusion of an article, they met to discuss and reach consensus, and then the article was either included or excluded accordingly.

If consensus was not reached by the two initial reviewers, a senior investigator reviewed the article and adjudicated the decision on inclusion or exclusion.

Appendix E contains a record of excluded studies with reasons for exclusion.

Data Extraction

Data from included studies were extracted into evidence tables and entered into electronic databases using Microsoft Excel® and DistillerSR systematic review software. The data extracted into evidence tables included: study design; year, setting, duration, and study inclusion and exclusion criteria; population and clinical characteristics, including sex, age, ethnicity, comorbidities, functional ability, and ulcer stage; intervention characteristics; results for each outcome of interest; and withdrawals due to adverse events. Outcomes of interest for effectiveness were wound improvement – as determined by complete wound healing, healing rate or time, or reduction in wound size (surface area, volume, depth) – reduction in pain, prevention of serious complications of infection such as sepsis or osteomyelitis, and ulcer recurrence rates. Outcomes of interest for harms were pain, dermatologic reactions, bleeding, and complications including, but not limited to, infection and need for surgical intervention. Data on settings included patient care settings such as long-term care or nursing facility, hospital, and community. If available, we also extracted the number of patients randomized relative to the number of patients enrolled, how similar those patients were to the target population, and the funding source. Noncomparative observational studies were included if they evaluated harms of treatments for which comparative effectiveness evidence was available in other studies. These noncomparative observational studies were used for Key Question 2 (evaluation of harms) and were rated for study quality but were not formally extracted into evidence tables, due to the paucity of data they contained. We recorded intention-to-treat results when available. All summary measure data were collected as available and presented in the individual studies, including, but not limited to, percentage of complete wound healing, relative risk and risk ratios, confidence intervals, and significance values. A second team member verified all study data extraction for accuracy and completeness.

One of the challenges in extracting data from pressure ulcer studies is that various systems have been used to assess the severity of pressure ulcers. Most use a four-stage categorization with higher numbers indicating higher severity.[10] In 2007 NPUAP redefined their four-stage classification system that defines the pressure ulcer based on depth and tissue involvement (Figure 2). Stage I is defined as superficial erythema, stage II as partial thickness ulceration, stage III as full thickness ulceration, and stage IV as full thickness with involvement of muscle and bone. A corresponding four-stage classification system was similarly adopted by EPUAP. Given that the stages are based on depth and tissue involvement, when an ulcer has overlying purulent material or eschar prohibiting the ability to determine the depth or extent of tissue involvement, the ulcer is classified as unstageable, or stage X. Discolored localized areas of intact skin that may indicate pressure-related injury to subcutaneous tissue are categorized as suspected deep tissue injuries. A description of the most commonly used systems to classify pressure ulcers prior to adapting the NPUAP system is reviewed in Appendix C and aligned with the current corresponding NPUAP stage.

In order to allow comparability across studies, we extracted the stage or grade reported, but used the corresponding NPUAP stage in summary tables and text when possible.

Quality Assessment of Individual Studies

In this report, risk of bias is denoted as quality, with the following summary categories:

- Good quality is defined as a low risk of bias.
- Fair quality is defined as a moderate risk of bias.
- Poor quality is defined as a high risk of bias.

We used predefined criteria to assess the quality of controlled trials and observational studies at the individual study level (Appendix F). We also adapted criteria from methods proposed by Downs and Black[11,12] (observational studies) and methods developed by the U.S. Preventive Services Task Force.[12,13]

We rated the quality of each controlled trial based on the methods described in published reports about randomization and allocation concealment; the similarity of compared groups at baseline; maintenance of comparable groups; adequate reporting of dropouts, attrition, crossover, adherence, and contamination; loss to followup; the use of intention-to-treat analysis; and ascertainment of outcomes.[12] Individual studies were rated as "good," "fair," or "poor" (see Appendix F). Studies rated "good" have the least risk of bias and results are considered valid. Good-quality studies include clear descriptions of the population, setting, interventions, and comparison groups; a valid method for allocation of patients to treatment; low dropout rates and clear reporting of dropouts; appropriate means for preventing bias; and appropriate measurement of outcomes.

Studies rated "fair" do not meet all the criteria for a rating of good quality, but no flaw is likely to cause major bias. The study may be missing information, making it difficult to assess limitations and potential problems. The "fair" quality category is broad, and studies with this rating vary in their strengths and weaknesses: the results of some fair-quality studies are *likely* to be valid, while others are only *probably* valid.

Studies rated "poor" have significant flaws that imply biases of various types that may invalidate the results. They have a serious or "fatal" flaw in design, analysis, or reporting; large amounts of missing information; discrepancies in reporting; or serious problems in the delivery of the intervention. The results of these studies are at least as likely to reflect flaws in the study design as they are to reflect the true differences between the interventions that were compared. We did not exclude studies rated poor quality a priori, but poor-quality studies were considered to be less valid than higher-quality studies when synthesizing the evidence, particularly when discrepancies between studies were present.

Data Synthesis

Due to the heterogeneity of outcomes reported, variation in the comparators to which interventions were compared, and the limited number and quality of studies for specific treatment comparisons, quantitative analysis was not appropriate for most bodies of literature included in this review. For most comparisons, we synthesized data qualitatively.

We evaluated the appropriateness of meta-analysis based on clinical and methodological diversity of studies and statistical heterogeneity. We conducted meta-analysis in selected instances (when the number, quality, and homogeneity of studies permitted) for comparisons examining the outcome of complete wound healing. We chose to limit meta-analysis to the outcome of complete wound healing because of (a) wide variability in the measurement of other outcomes including wound size reduction and (b) indication from the TEP that complete wound healing was the principal health outcome of interest. When meta-analysis was conducted, we used relative risk as the effect measure. We assessed the presence of statistical heterogeneity among the studies using standard χ^2 tests and the magnitude of heterogeneity using the I^2 statistic.[14] We used random effects models to account for variation among studies[15] and fixed effects Mantel-Haenszel models when variation among studies was estimated to be zero. Sensitivity analysis was conducted to assess the impact of quality on combined estimates and meta-regression was conducted to assess

the association of effect measure with study duration. However, exploration of heterogeneity was typically limited by the small number of studies for each treatment category. All quantitative analyses were performed using Stata 11.0® (StataCorp, College Station, Texas, 2009)

Strength of the Body of Evidence

Within each key question, we graded the strength of evidence for effectiveness and for harms by intervention/comparator pair, and for harms by intervention, using an approach adapted from the AHRQ "Methods Guide for Effectiveness and Comparative Effectiveness Reviews."[8] Our approach considers four major categories to rate the strength of evidence:

- Quality of studies (good, fair, or poor)
- Consistency (low, moderate, or high)
- Directness (direct or indirect)
- Precision (low, moderate, or high).

As with our ratings of individual study quality, we used the terms "quality" in lieu of "risk of bias" in rating the overall strength of evidence of a given finding. Good quality is defined as low risk of bias, fair quality is defined as moderate risk of bias, and poor quality is defined as high risk of bias. Our ratings for consistency and precision were trichotomous (low, moderate, high) rather than dichotomous (consistent vs. inconsistent, precise vs. imprecise), to allow for a more graded assessment of those domains. For the domain of "directness," we rated evidence from head-to-head comparisons as direct. We did not incorporate the distinction between ultimate outcomes (e.g., complete wound healing) and intermediate/surrogate outcomes (e.g., wound size reduction) into our ratings for directness. We did, however, give greater weight to studies demonstrating an effect on complete wound healing, as opposed to wound size reduction, based on input from the TEP that complete wound healing represents the most clinically important outcome of interest in pressure ulcer treatment.

We did not incorporate the domain of "dose-response association" into our strength of evidence ratings because few, if any, studies in our review included varying levels of exposure. We also did not include the domain of "plausible confounding that would decrease observed effect" because this domain is relevant primarily for observational studies and nearly all of our findings were based on the results of clinical trials. We did consider "strength of association" in rating strength of evidence, but did not assign explicit scores for strength of association in our strength of evidence ratings, due to variability in strength of association for the different measures of wound improvement used across studies.

We were not able to assess publication bias using a quantitative approach for most treatments because, in many instances, we were not able to perform a formal pooled analysis due to the heterogeneity of interventions, comparators, or outcomes, or due to the poor quality of studies. We did attempt to evaluate the possibility of publication bias by qualitatively examining the directionality of study findings by sample size for a given intervention and by looking for unpublished studies through our gray literature search.

The strength of evidence was assigned an overall grade of high, moderate, low, or insufficient according to a four-level scale:

- High—High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect.
- Moderate—Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.

- Low—Low confidence that the evidence reflects the true effect. Further research is likely to change the confidence in the estimate of effect and is likely to change the estimate.
- Insufficient— Evidence either is unavailable or does not permit a conclusion.

Applicability

Applicability is "the extent to which the effects observed in published studies are likely to reflect the expected results when a specific intervention is applied to the population of interest under 'real-world' conditions."[16] Applicability depends on the particular question and the needs of the user of the review. We developed our review to provide evidence that might be useful to clinicians, policymakers, patients, and other decisionmakers interested in pressure ulcer treatment. Because it depends on context, there is no generally accepted universal rating system for applicability. We described features of the included studies that are relevant to applicability in terms of the PICOTS elements. These elements are the features embedded in the key questions that inform clinical decisionmaking and the degree to which the evidence is likely to pertain to subpopulations. For example, it is important to determine whether techniques described in studies are representative of current practice. We extracted from studies included in our review key information that might affect applicability of findings, including characteristics of ulcers (e.g., stage), populations (e.g., spinal cord injured patients), study duration, cointerventions, comparators, and care setting. We based our approach to applicability on the guidance described by Atkins and colleagues.[12,16]

Peer Review

Experts in prevention and management of pressure ulcers, geriatric medicine, wound care research, and epidemiology, as well as individuals representing important stakeholder groups, were invited to provide external peer review of this CER.

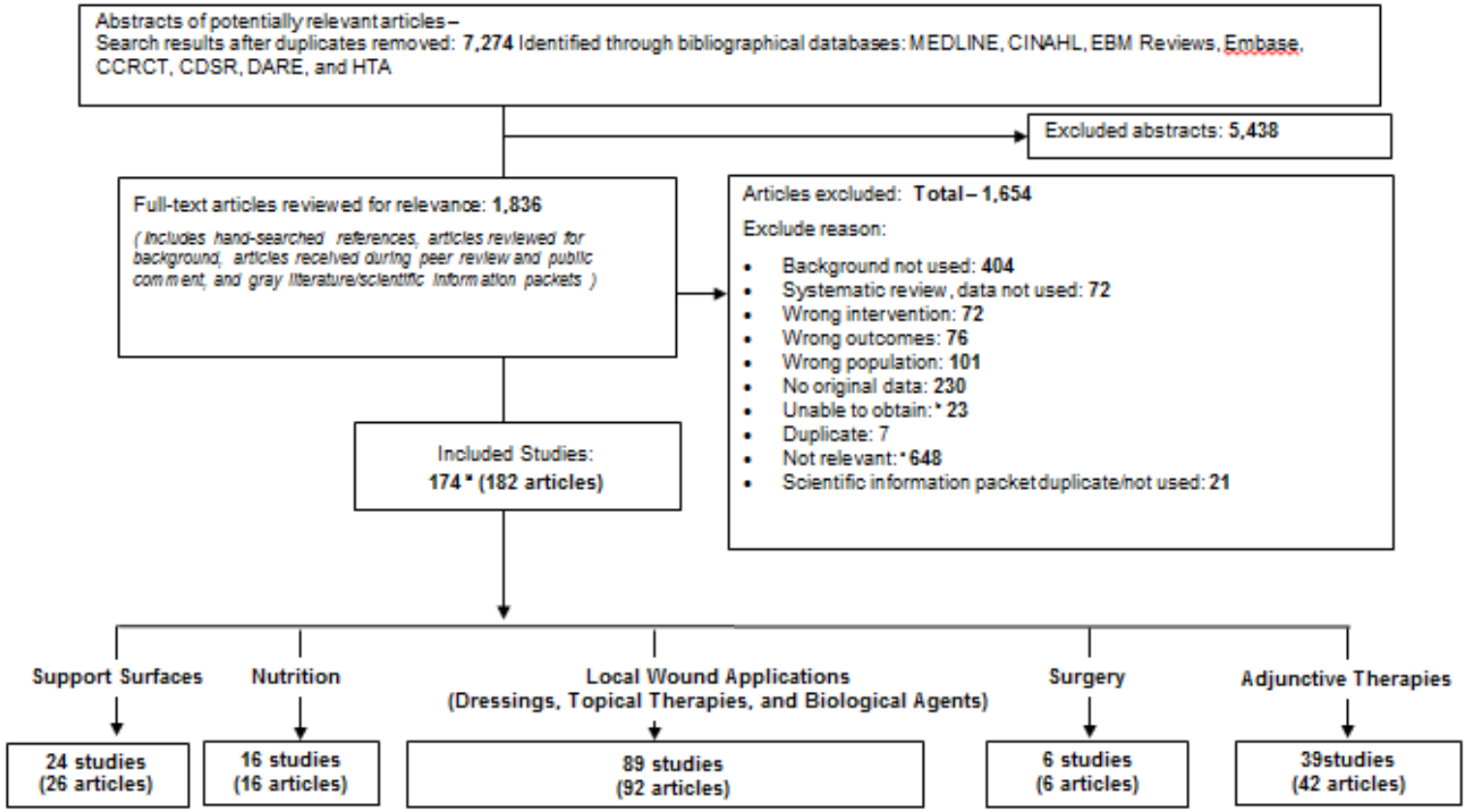
The AHRQ Task Order Officer and a designated EPC associate editor also provided comments and editorial review. To obtain public comment, the draft report was posted on the AHRQ Web site for 4 weeks. A disposition-of-comments report detailing the changes made to address the public and peer review comments will be made available 3 months after the Agency posts the final CER on the AHRQ Web site.

Results

Overview

The results of the search and study selection are summarized in the study flow diagram (Figure 4 and Table 1). Searches of databases, review of reference lists of published studies, and review of gray literature resulted in 7,274 potentially relevant articles. After dual review of abstracts and titles 1,836 studies were selected for full-text review. Gray literature was assessed, but did not meet the inclusion criteria for this report or provide data that was not already available in the peer reviewed literature. One hundred seventy-four studies (with results published in 182 full-text articles) were included in this review. These studies examined a wide range of interventions, but sample sizes often were small. We found moderate-strength evidence that some interventions improved healing of pressure ulcers, but no interventions were found to be effective with a high strength of evidence. Several other interventions had limited evidence of effectiveness (strength of evidence rated as low). A minority of studies examined complete wound healing as an outcome. In general, the evidence about the harms of any of these treatments was limited. See Appendix B for complete inclusion and exclusion criteria and Appendix G for strength of evidence assessments.

Figure 4. Study flow diagram: Comparative effectiveness of treatment for pressure ulcers



CCRCT = Cochrane Central Register of Controlled Trials; CDSR = Cochrane Database of Systematic Reviews; CINAHL = Cumulative Index to Nursing and Allied Health Literature; DARE = Database of Abstracts of Reviews of Effectiveness; EBM Reviews = Evidence-Based Medicine Reviews; Embase = Excerpta Medica Database; HTA = Health Technology Assessment; MEDLINE = Medical Literature Analysis and Retrieval System Online

[a]The code for "Unable to obtain" includes conference proceedings without full text publications (33), untranslatable foreign language texts (33), unobtainable full texts, excluded as abstracts (23), and articles that were not available (22). The full text code for "Not relevant" includes non-English language articles, animal studies, wrong study design, and other excluded articles for which existing codes did not apply.

Overall Effectiveness of Pressure Ulcer Treatment

Pressure ulcer treatment encompasses numerous intervention strategies: alleviating the conditions contributing to ulcer development (support surfaces, repositioning, and nutritional support); protecting the wound from contamination, creating a clean wound environment, and promoting tissue healing (local wound applications, debridement, wound cleansing, and various adjunctive therapies); and surgically repairing the wound. We evaluated evidence addressing the comparative effectiveness and harms in treatment categories where significant uncertainty exists about the best therapeutic options. Results for each key question are presented here, within these specific treatment categories: support surfaces, nutrition, local wound applications (including wound dressings, topical therapies and biological agents), surgical interventions, and adjunctive therapies. Although we evaluated multiple outcomes, only measures of wound improvement (complete wound healing, wound size reduction, healing time) were consistently reported. Other outcomes including pain were reported sporadically. Ulcer recurrence was used as an outcome in some studies of surgery and are reported in that section of this report. Prevention of serious infectious complications was not reported as an outcome in any included study. There was no body of literature for which it was possible to synthesize evidence for the impact of a given intervention on outcomes other than wound improvement. In reporting results of wound improvement, when a body of literature allowed conclusions about a particular measure of wound improvement (e.g., complete wound healing), we report those findings. In many cases, however, the use of different measures of wound improvement allowed us only to report on the overall effect of an intervention on wound improvement, which included complete wound healing, wound size reduction, and healing time. The overall findings of this review and a summary of the strength of the evidence for the key findings are presented in Table 31.

Table 1. Overview of included studies by treatment strategy

Treatment Strategy	Included Trials	Included Observational Studies
Support	21	3
Nutrition	11	5
Local wound applications	76	13
Surgery	1	5
Adjunctive	34	5

Results of Pressure Ulcer Treatment by Treatment Strategy

Effectiveness of *Support Surfaces*

Many factors contribute to both the development of pressure ulcers and the likelihood that pressure ulcers will heal once they develop. Of these, pressure, friction, or shear that limits blood flow and/or damages skin and underlying tissues are the most direct contributors to the development of pressure ulcers. Treatments that redistribute pressure, reduce friction, and prevent shear are used to promote healing and prevent further damage to the skin in the area of the ulcer.

Healing can be promoted by a variety of types of support surfaces. A support surface is defined as "a specialized device for pressure redistribution designed for management of tissue loads, micro-climate, and/or other therapeutic functions (i.e., any mattress, integrated bed system, mattress replacement, overlay, or seat cushion, or seat cushion overlay)."[17] While support surfaces are frequently used to prevent pressure ulcers for people at risk, they are also

used (though less frequently studied) as a component of pressure ulcer treatment. This section summarizes the studies that met the inclusion criteria for this review, including that they compare different support surfaces used in the treatment of existing pressure ulcers and evaluate the impact of these support surfaces on healing.

Description of Studies

We identified 24 studies of the use of various support surfaces that met our inclusion criteria (see Appendix D). These studies were reported in 26 articles published between 1987 and 2012. Two studies were reported in more than one publication.[18-21] Most of the studies were published in the 1990s (10 studies[22-31]) and early 2000s (six studies; eight articles[18-21,32-35]). Only five were published during or after 2005[36-40] and these were sometimes based on older data (e.g., Valente was published in 2012 but reports data from patients treated in July 2001 to June 2002). A limitation of the literature on support surfaces for pressure ulcer treatment is that there are few recent comparative studies.

Details extracted from each study are included in the evidence tables (see Appendix H, Table H-1). Of these, four were rated as good quality, 10 as fair, and 10 as poor. The assessments of the quality rating criteria used for each study are provided in Appendix H, Table H-2.

Of the 24 studies identified, 20 were randomized trials. The other four included one trial in which the method of assignment was not clearly stated,[24] two retrospective cohort studies,[40,41] and one small, prospective cohort study.[30] Fourteen of these studies were conducted in the United States,[26,27,29,32,34,38,41-46] seven in the United Kingdom,[18-21,23,25,33,35,36] and one each in Holland,[31] Japan,[24] and Belgium.[39]

The *populations* in the studies were predominately older hospital patients and long-term care residents. Mean ages were in the late 60s to 80s, with the exception of one study of people with spinal cord injuries living in the community. In this study the mean ages for the treatment and control groups were 42 and 45.[38] All subjects had at least one pressure ulcer, as this was the key inclusion criteria. The stage of the ulcers varied, with most studies including people with a range of severities (see details in Summary Table 31), though some studies were limited to patients with ulcers of a particular stage (e.g., Stage II[19,36] or Stage I[33]).

The *interventions and comparators* in studies of support surfaces included several different types of surfaces and brands. Support surfaces vary in terms of form factor (e.g., mattress, mattress overlays, seat cushions, and seat overlays), materials, action, and method of pressure redistribution or environment control. While definitions of key terms have been proposed,[17] currently there is no universally accepted classification of support surfaces into categories that are mutually exclusive. Some studies, reviews, and guidelines have classified support surfaces based on reimbursement policies[37,41] or the primary action such as constant low pressure (CLP), low-air-loss (LAL), alternating pressure (AP), or air-fluidized (AF). Other studies have created categories such as whether they require power or not for operation[10] or as "low tech" compared with "high tech."[47,48] There is significant overlap with nonpowered, CLP, and "low tech," while powered is often AP or AF and considered "high tech." However, this categorization does not allow for the possibility of a high-tech material or design that does not require power. Some studies compared a new design with AP as "standard care." For this reason, we organized our presentation of the studies into four groups (AF, AP, LAL, and "other") based on the surface that is considered to be the experimental intervention. The "other" category corresponds to surfaces that are not AF, AP, or LAL and were tested as new interventions.

The comparators in the studies varied and were not always well specified. Some studies compared two specific types and/or brands of surfaces, while others compared the study surface to "usual care" or normal hospital beds. These comparators were not always described in the articles. The comparator is specified in as much detail as is provided by the article authors in the evidence tables in the appendix as well as discussed in the detailed analyses as appropriate. Although it might not be considered best practice today to treat a patient with a pressure ulcer on a normal hospital bed, it is not unheard of for less severe pressure ulcers to be treated on a normal hospital bad. For this reason we retained studies that met the overall inclusion criteria for this review (e.g. published after 1985 and report the comparative impact on a measure of healing) even if they compared the support surface that was the subject of study to a surface that could be considered outdated or not currently the best recommended practice because these are still used in some circumstances.

The *outcomes* measured and reported in the identified studies reflect the goals of treatment, but were restrained by the *timing* of possible followup measurement, which ranged from 5 days[33] to 36 weeks.[45] The ultimate goal, and therefore *outcome,* of pressure ulcer treatment is complete healing of the wound. Eight of the identified studies reported how many patients in the study had pressure ulcers that healed,[23,25,29,31,33,36,40,42] two also reported the time to complete healing,[34,36] while one reported time to 30 percent healed.[38] Most pressure ulcers, particularly larger ulcers and those that involve many layers of tissue, often require months to heal[17] and some never heal completely in the patient's lifetime. Given these constraints, the majority of studies (16 of 24) included in this review[20,21,23-27,30,32,36,38,39,41-44,46] reported changes in the surface area or volume of either an index ulcer (usually the worst) or all pressure ulcers over a set period of time or until the patient was discharged or died. An additional outcome reported in seven studies was simply "improvement." Improvement was defined as healing or change in the stage of the ulcer determined through blinded assessment by experts.[18,19,24,35,39,43-45] Five studies also reported pain or patient comfort as an outcome[20,21,23,27,43,46] and two included hospital admissions and emergency department visits[41,45] as an outcome compared across patients treated on different surfaces.

The *setting* for these studies included hospitals, long-term care facilities (e.g., nursing facilities, post-acute care facilities, and home health care agencies), and the community. Eleven studies were conducted in acute care hospitals[18,19,26,27,30,33,35,36,39,43,44,46] and ten in long-term care facilities.[23,24,29,31,32,34,40-42,45] One study was of people living in the community[38] and two included both hospital patients and nursing facility residents.[20,21,25]

Key Points

Five studies conducted in the late 1980s and 1990s were identified that compared AF beds to other surfaces. All reported greater wound improvement on the AF beds in terms of reduction in ulcer size (strength of evidence: moderate).

Complete wound healing and reduction in ulcer size were similar across different brands of AP beds made by different manufacturers or types of AP surfaces (i.e., overlays and full beds). (four studies, strength of evidence: moderate).

The evidence about the effectiveness of AP beds was mixed, though most findings were of similar wound improvement for AP beds when compared to air, fluid or standard beds . (four studies, strength of evidence: low).

Two studies of AP chair cushions were conducted in two very different populations (younger people with spinal cord injury and older hospital patients or nursing home residents) and

produced different results, making it difficult to draw a generalizable conclusion about AP chair cushions (strength of evidence: insufficient).

Wound improvement was similar with LAL beds compared with foam surfaces (three of five studies) or with LAL beds compared with LAL overlays (strength of evidence: low).

While harms were reported in seven studies, each study included different harms for different surfaces (strength of evidence: insufficient).

There was insufficient evidence to draw conclusions about the impact of patient or setting characteristics on the effectiveness or harms of different support surfaces in ulcer healing because most studies did not provide relevant information.

Detailed Analysis

The identified studies are categorized by the experimental surface in both the summary of evidence in Table 31 and the narrative below.

Evidence About the Comparative Effectiveness of Support Surfaces (Key Question 1)

Air-Fluidized Beds

AF beds are made of small beads and air is forced through the beads to create a fluid-like surface that redistributes pressure. The five studies of AF beds (Table 2) were all conducted in the United States and included one large, fair-quality cohort study published in 2005 and four randomized trials published between 1987 and 1991. One trial was rated as good quality,[43] two as fair,[45,46] and one as poor.[44] The combined results of these studies provide limited evidence that AF beds have a positive effect in that they are more effective than alternatives in promoting the reduction in the size of pressure ulcers. The moderate strength of evidence rating is based in part on the fact that the results are consistent across all of these studies. However, as is detailed in the text and Table 2, the trials were conducted 10 or more years ago in the late 1980s and early 1990s and in three of the trials the AF bed was compared with standard beds or multiple surfaces that were not well defined.[44-46]

The one good-quality randomized trial compared 31 hospitalized patients on an AF bed who were repositioned every four hours with 34 patients on an AP bed with a foam overlay, which was conventional treatment for patients with pressure ulcers at the location of the study, who were repositioned every two hours.[43] Those on AF beds experienced a median decrease in the size of their pressure ulcers (-1.2 cm^2) that was significantly better than the median increase (+0.5 cm^2) in the size of pressure ulcers in patients on the AP beds. Blinded assessors rated 71 percent of patients on the AF beds as improved compared with 47 percent on the AP beds and 62 percent of patients on the AF mattress reported a decrease in pain compared to 36 percent on the AP beds despite the difference in repositioning that could have favored the AP bed.[43] A fair-quality study of hospital patients[46] compared 20 people on AF beds with 20 on standard hospital beds and reported that the mean ulcer area declined on the AF beds and increased for those on standard beds and that pain declined for all patients and did not differ by bed type. A third study (poor quality) of hospital patients compared 15 patients on AF beds with 20 patients that used several alternatives that were standard care and found wound surface area reductions were higher in the patients treated on the AF beds.[44]

The other two studies of AF beds were in long-term care settings and similarly report favorable results in terms of reduction in pressure ulcer size. One followed 97 home care patients

randomized to either an AF bed (n=47) or conventional treatment (n=50). The authors reported that more stage III and IV ulcers healed and were assessed as stage II after treatment on the AF beds (29 of 47, data for control group not provided) compared with patients on conventional surfaces and a higher proportion were rated as improved by blinded nurse raters.[45] A large, fair-quality retrospective cohort study (n=664) of residents with at least one pressure ulcer in their medical record examined healing rates across groups of patients on AF beds, low-tech surfaces, and high-tech surfaces other than AF beds. Comparisons were made for healing rates for the largest ulcer for each person as well as the change in each ulcer (multiples allowed per resident) during 7 to 10 day episodes. Stage III and IV ulcers healed more quickly for patients on the AF beds (3.1 cm^2 per week) compared with other high- (0.7) and low-tech surfaces (0.6). Residents on AF beds and residents on lower-tech surfaces (who overall were less severely ill) had fewer hospitalizations and emergency room visits than did residents who used the other higher-tech beds.[41]

Table 2. Support surfaces: Air-fluidized beds

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (range) Sex Population	Followup	Surfaces Compared	Outcome Measures and Treatment Effect	Benefit: Wound Improvement
Allman 1987[43] Trial Good N=72/65 Hospital	I, II, III, IV, and unstageable	67 years (NR) Female: 58% General	Median13 days (range 4 to 77 days)	A: AF bed (Clinitron Therapy) B:AP-air covered with foam (Lapidus Air Float)	Complete wound healing (mean): A: 65% B: 44% (p=0.10) Change in total surface area (median): A: -1.2 cm^2 B: +0.5 cm^2 (p=0.01) Regression results: Odds of improvement in A vs. B: 5.6 (95% CI, 1.0 to 27.5) Decrease in Pain A: 62% B: 36% (p=0.01) Harms: New skin breakdown (29% vs. 44%); epistaxis, (1 in A)	**~/+** **~ complete healing** **+ change is size**

Table 2. Support surfaces: Air-fluidized beds (continued)

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Surfaces Compared	Outcome Measures and Treatment Effect	Benefit: Wound Improvement
Jackson 1988[44] Trial Poor N=35/35 Hospital	II, III, IV	77 years (NR) Female: 64% General	Until discharge	A: AF mattress B: Several non-AF surfaces	Complete wound healing: NR Wound area reduction (% of patients): A: 60% B: 45% (p-value NR) No significant difference in changes of stage, granulation/ bleeding, necrosis. Harms: NR	+
Munro 1989[46] Trial Fair N=40/40 VA Hospital	II, III	67 years (48-88) Female: 0% General	15 days	A: AF bed (Clinitron Therapy) B: Standard hospital bed	Complete wound healing: NR Wound area reduction: Significant improvement in A vs. B (p=0.05). No difference between groups in pain scores (p=0.359). Harms: NR	+
Ochs 2005[41] Observational Fair N=664/664 Nursing facility	I, II, III, IV Eschar and unstaged	78 years (19-106) Female: 63% General	3 months	A: AF beds B: Low tech surfaces C: High tech except AF	Complete wound healing: NR Wound healing rate (mean for largest ulcer): A: 5.2 cm^2/week (p=0.0071 vs. B and C) B: 1.5 cm^2/week C: 1.8 cm^2/week Faster healing with A compared with B or C when assessed by stage. Harms: NR	+

Table 2. Support surfaces: Air-fluidized beds (continued)

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Surfaces Compared	Outcome Measures and Treatment Effect	Benefit: Wound Improvement
Strauss 1991[45] Trial Fair N=112/97 Home Care	III, IV	Age: 64 years (NR) Female: 49% General	36 weeks	A: AF bed (Clinitron Therapy) B: Conventional or standard therapy	Complete wound healing: NR More patients in A improved to stage II (62%) vs. B (% NR) (p-value NR) More patients in A classified as improved by independent assessment (NS; p-value NR) Harms: Dry skin in several patients; mild dehydration in 1 patient	+

AF = air-fluidized; AP = alternating pressure; NPUAP = National Pressure Ulcer Advisory Panel; NR = not reported; NS = not significant

[a]Pressure ulcer stage indicates NPUAP staging unless otherwise stated. Non-NPUAP staging was converted to the equivalent. NPUAP stage where possible.

++Complete wound healing.

+Reduction in wound size.

~No difference.

Alternating Pressure Beds and Chair Cushions

AP mattresses, overlays, and cushions have cells or sections that inflate and deflate to change the distribution of pressure. The sizes of the cells, patterns of inflation and deflation, and the length of the cycles can vary across brands. Ten studies—six conducted in the United Kingdom,[18-21,23,25,35,36] two in the United States,[39,40] and one each in Belgium[39] and Japan[24]—evaluated AP mattresses or chair cushions (Table 3).

Different Brands or Form Factors of Alternating Pressure Beds

Researchers found no significant differences in healing in the three studies that compared different AP beds, all involving a version of the Nimbus brand bed.[18-20,23,49] One additional study that compared AP beds with AP overlays[36] also found no significant difference in the number of ulcers that healed or the number of days they took to heal (four studies, moderate strength of evidence).

A fair-quality study of residents admitted to a geriatric hospital in Scotland found that, in 4 weeks, 10 of 16 patients on the Nimbus 1 AP bed healed compared with five of 14 who used the Pegasus brand AP bed, but this difference was not significant, there was no difference in patient-reported comfort and the study was stopped after 2 years due to difficulties recruiting patients and changes in the beds.[23] Other researchers comparing a later version of the same AP mattress

(Nimbus 3) with other brands of AP mattresses in a good-quality trial found no significant difference in change in size of the pressure ulcers in 12 hospital patients and 20 nursing facility residents. This study found that there were some differences in comfort, with the Nimbus 3 rated as more comfortable.[20,21] The third study (fair quality) found a trend toward improvement in heel ulcers on the Nimbus 3 beds compared with another brand (Pegasus C airwave), but there was no significant difference in healing for sacral ulcers.[18,19] A good-quality study that compared an AP mattress to an AP overlay reported no statistically significant differences in the number of ulcers healed or the median time to healing.[36]

Alternating Pressure Beds Compared With Other Surfaces

Four studies (two fair quality and two poor quality) evaluated AP surfaces by comparing them with other surfaces. Three studies included patients with pressure ulcers at all stages[24,35,39] and one excluded patients with pressure ulcers that advanced to stage III or IV.[40] The findings were conflicting, though most studies found no significant differences in at least one measure of healing (low strength of evidence).

Two studies followed hospital patients who were predominately elderly until discharge.[35,39] One fair-quality trial found no significant difference in ulcer progress for 83 patients treated on the AP mattress compared with 75 patients treated on a fluid mattress overlay.[35] The most recently published of the identified studies compared hospitalized patients on ventilators on AP beds with patients on air overlays and documented significant improvement (reduction in wound surface area) on the AP mattress, however the sample size was small (n=16).[39] A poor-quality trial involving long-term care hospital patients in Japan found no significant difference in change in pressure ulcer surface area in patients on a specific type of AP bed (lateral rolling bed which moves residents from left side to back to right side on a timed cycle) compared with a traditional hospital bed. However, the mean stage of the pressure ulcers for patients on the rolling bed declined while the mean stage increased on the standard hospital bed.[24] A poor-quality observational study published in 2012 reports on chart review data of patients admitted to long-term care beds between July 2001 and June 2002.

Physicians treated patients with pressure ulcers with either an AP overlay or a gel overlay. The study reported that a higher percentage of patients on the AP overlay experienced complete wound healing, but the difference was not statistically significant.[40]

Alternating Pressure Chair Cushions

AP is also used in chair cushions. Two studies compared AP cushions used in wheelchairs or day chairs with other types of cushions.[25,38] One fair-quality trial of AP cushions, conducted in the United States, randomized 44 wheelchair users with spinal cord injuries living in the community who had stage II or III pressure ulcers to either an AP wheelchair cushion or a standard foam cushion for 30 days. People using the AP cushion experienced significantly better rates of healing measured as reduction in wound area, days to 30 percent wound closure, and probability of wound closure within 30 days.[38]

The second study of AP cushions included 25 hospital or nursing residents who used an AP cushion or a dry floatation cushion in their wheelchair or day chair. Pressure ulcers healed for three of 14 patients on AP cushions and five of 11 on the dry floatation cushions; however, this difference was not significant.[25]

Table 3. Support surfaces: Alternating pressure beds and chair cushions

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Surfaces Compared	Outcome Measures and Treatment Effect	Benefit: Wound Improvement
Alternating Pressure Beds: Different Brands or Forms						
Devine 1995[23] Trial Fair N=41/30 Hospital	II, III, IV	83 years (69-98) Female: 59% General	4 weeks	A: AP bed (Nimbus 1) B: AP bed (Pegasus Airwave)	Complete wound healing: A: 63% B: 36% (NS; p-value NR) Wound area reduction (median): A: 0.089 cm^2/day B: 0.107 cm^2/day (p=0.92) No difference in patient reported comfort Harms: NR	~
Evans and Land 2000[20,21] Trial Good N=32/32 (12 hospital; 20 nursing facility)	II, III, IV	Hospital: 81 years (65-91) Female: 50% Nursing facility 85 years (71-99) years Female: 95% Elderly	Until healing, discharge, or death	A: AP bed (Nimbus 3) B: AP bed (other brands)	Complete Wound Healing: NR Wound area reduction (median): Hospital: A: 0.12 cm^2 B: 0.08 cm^2 (NS; p-value NR) Nursing facility: A: 0.11 cm^2 B: 0.05 cm^2 (NS; p-value NR) Median Comfort Rating: 1 (least) to 5 (most) Hospital A: 5 B: 4 p=0.006 Nursing facility A: 5 B: 4 p=0.002 Harms: NR	~

Table 3. Support surfaces: Alternating pressure beds and chair cushions (continued)

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Surfaces Compared	Outcome Measures and Treatment Effect	Benefit: Wound Improvement
Alternating Pressure Beds: Different Brands or Forms (continued)						
Nixon 2006[36] Trial Good N=1971/1540 (113 patients with pressure ulcers) Hospital	II (split into IIa partial thickness wound involving dermis only or IIb also epidermis)	75 years (55-100) Female: 64% General	30 days	A: AP bed B: AP bed overlay	Complete wound healing A: 20/59 (33.9%) B: 19/54 (35.2%) (NS) No difference between groups in time to healing (p=0.86) Harms: Mattress-related adverse events reported in 8 patients (2 overlay, 7 bed)	~
Russell 2000[18,19] Trial Fair N=183/112 Hospital	I, II	84 years (NR) Female: NR General	Until healing or discharge	A: AP bed (Nimbus 3) and Aura seat cushion B: AP bed (Pegasus C airwave) and ProActive seat cushion	Complete wound healing: NR Wound improvement: All ulcers A: 91% B: 93% (p=0.78) Sacral ulcers A: 45% B: 51% (p=0.45) Heel ulcers A: 33% B: 57% (p=0.025) Harms: NR	~
AP Beds vs. Other Surfaces						
Izutsu 1998[24] Trial Poor N=31/31 Long-term care	I, II, III, IV	78 years (NR) Female: 58% General	3 months	A: Lateral rolling bed B: Standard hospital bed	Complete wound healing: NR Wound area reduction: No significant difference (p-value NR) Wound grade change: A: -0.8 B: +0.2 (p<0.01) Harms: NR	~

Table 3. Support surfaces: Alternating pressure beds and chair cushions (continued)

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Surfaces Compared	Outcome Measures and Treatment Effect	Benefit: Wound Improvement
AP Beds vs. Other Surfaces (continued)						
Malbrain 2010[39] Trial Fair N=16/16 Hospital	I, II, III	64 years (NR) Female: 50% ICU	Until discharge	A: AP bed (Nimbus 3) B: Air overlay (ROHO)	Complete wound healing: NR Wound area reduction: A: -2.1 cm^2 B: 25.8 cm^2 (p=0.05) Wound grade change: A: 0 B: 0.8 (p=0.03) Harms: NR	+
Russell 2003[35] Trial Fair N=199/158 Hospital	I or higher	80 years (NR) Female: 54% General	Until discharge	A: AP bed (Nimbus 3) B: Fluid overlay (RIK)	Complete wound healing: NR Wound progress (Worst ulcer per patient improved): A: 76% B: 84% (p=0.053) (Overall ulcer progress): A: 72% B: 75% (p=0.67) Harms: NR	~
Valente, 2012[40] Observational Poor N=122/122 Long-term Care	Unclear (Stage II and IV excluded)	68 years (NR) Female: 65% General	2, 3 or 4 weeks	A. Alternating Pressure Overlay (FirstStep Power Air Overlay) B. Gel Overlay (KIKTM fluid mattress	Complete wound healing: PU on admission Treatment A: 27% Treatment B: 17% (p-value NR) PU developed during stay Treatment A: 22% Treatment B: 11% (p-value NR) Harms: None	~

Table 3. Support surfaces: Alternating pressure beds and chair cushions (continued)

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Surfaces Compared	Outcome Measures and Treatment Effect	Benefit: Wound Improvement
AP Cushions						
Clark 1998[25] Trial Fair N=33/25 Hospital and Nursing facility	II, III, IV	83 years (NR) Female: 72% Elderly	Until healing, discharge, or death	A: AP cushion (Pegasus) B: Static air-filled cushion (ROHO)	Complete wound healing: A: 21% B: 45% (p-value NR) Wound area reduction (superficial sores only): A: 0.13 cm^2 B: 0.27 cm (p-value NR) Harms: Malfunction of cushion (1 in each group)	~
Makhsous 2009[38] Trial Fair N=44/44 Community	Unclear (Stage II or III, staging system not cited or described)	43 years (18-79) Female: 7% Spinal cord injury	30 days	A: AP, cyclic pressure relief system B: Regular wheelchair cushions	Complete Wound Healing: NR Wound area reduction: A: 45% B: 10% (p=0.001) Time to 30% healing: A: 25 days B : >30 days (p=0.007) Probability of 30% closure within 30 days: A: 0.73 B: 0.36 (p=0.007) Harms: NR	+

AP = alternating pressure; EPUAP = European Pressure Ulcer Advisory Panel; ICU = Intensive-care unit; NPUAP = National Pressure Ulcer Advisory Panel; NR = not reported; NS = not significant; PU = Pressure ulcer

[a]Pressure ulcer stage indicates NPUAP staging unless otherwise stated. Non-NPUAP staging was converted to the equivalent NPUAP stage where possible.

++Complete wound healing.

+Reduction in wound size.

~No difference.

Low-Air-Loss Beds

Five studies evaluated LAL mattresses,[27,29,30,32,42] which use power to provide a flow of air that helps regulate heat and humidity and also may adjust pressure. All of these studies were conducted in the United States. Two trials and one observational cohort study followed hospitalized patients and two studied nursing facility residents. Four of the studies compared the LAL bed with a foam overlay[27,29,42] or foam mattress[30] and one compared an LAL bed with an LAL overlay (Table 4).[26]

None of the five studies found the LAL bed had a significant advantage over other surfaces for the study's primary outcome. Two of the studies in long-term care compared LAL beds with foam overlays and reported mixed findings for residents with stage III or IV pressure ulcers: One study found no significant difference in complete wound healing, but did report a significantly larger reduction in surface area on the LAL bed.[42] Similarly, the second study reported higher rates of wound healing and decrease in surface area, but no significant difference in complete healing.[29]

One poor-quality trial of LAL beds used with hospital patients compared the LAL mattress with foam overlays and found no significant difference in changes in wound surface area and no significant difference in comfort.[27] A second observational study followed patients for up to 4 weeks and found no difference between the LAL bed and foam bed in terms of progress to wound closure.[30] The study that compared an LAL bed with an LAL overlay for hospital patients also reported that there was no significant difference in changes in pressure ulcer surface area.[26]

Table 4. Support surfaces: Low-air-loss beds

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Surfaces Compared	Outcome Measures and Treatment Effect	Benefit: Wound Improvement
Caley 1994[26] Trial Poor N=93/55 Hospital	NR	76 years (42-98) Female: 60% General	1 month or until discharge; mean time in study 23.9 days	A: LAL bed (Monarch) B: LAL overlay	Wound surface area change (mean): A: 3.8 cm^2 B: 10.2 cm^2 (p=0.06) Healing progress over time: A: 0.22 B: 0.39 (p-0.10) Harms: NR	~
Day 1993[27] Trial Poor N=83/83 Hospital	II, III IV	Age: 76 years (32-102) Female: 58% General	Until discharge	A: LAL bed B: Foam overlay	Complete wound healing: No difference between groups (p>0.05) Change in wound surface area controlling for initial size: No difference between groups (p>0.05) No significant difference in comfort scores (n=39) Harms: NR	~

Table 4. Support surfaces: Low-air-loss beds (continued)

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Surfaces Compared	Outcome Measures and Treatment Effect	Benefit: Wound Improvement
Ferrell 1993[42] Trial Good N=84/84 Nursing facility	III, IV	85 years (NR) Female: 50% Elderly	Until healing, transfer, or, death	A: LAL bed (Kinair) B: Foam overlay	Complete wound healing: A: 60% B: 46% (p=0.19) Decrease in wound surface area: A: 9.0 mm^2 per day B: 2.5 mm^2 per day (p=0.0002) Harms: NR	**~ /+ ~ complete healing** **+ change is size**
Mulder 1994[29] Trial Poor N=49/39 Nursing facility	III, IV	Age: NR Female: NR General	Shorter of 12 weeks or ulcer completely healed	A: LAL bed (Therapulse) B: Foam overlay (GeoMatt)	Complete wound healing: A: 5/31 (16%) B: 3/18 (17%) (p-value NR) Change in ulcer area adjusted for initial stage: A more effective than B (p=0.042) Harms: No major adverse effects	**~ /+ ~ complete healing** **+ change is size**
Warner, 1992[30] Observational Poor N=20/20 Hospital	I, II, III	64 years (NR) Female 45% General	Up to 4 weeks	A: LAL bed (Mediscus) B: Foam mattress with loose-fitting cover (Comfortex)	Complete wound healing: NR Progress to wound closure: Treatment A: mean 0.16 cm (SD 0.13) Treatment B: mean 0.27 cm (SD 0.23) No statistically significant difference ANOVA (f [1, 18] =1.568, p>0.05) Harms: NR	~

LAL = low-air-loss; NPUAP = National Pressure Ulcer Advisory Panel; NR = not reported; NS = not significant; PU=pressure ulcer

[a]Pressure ulcer stage indicates NPUAP staging unless otherwise stated. Non-NPUAP staging was converted to the equivalent NPUAP stage where possible.

++Complete wound healing.

+Reduction in wound size.

~No difference.

Other Surfaces

Four studies compared a surface that was a new design to a surface that was the standard of care at the time or conducted a cost-effectiveness analysis.[31-34] These four studies involved 361 total subjects. Two studies were conducted in the United States,[32,34] one in Holland,[31] and one in the United Kingdom.[33] The experimental surfaces included a high-quality foam mattress, a profiling bed, an airbed with a foam overlay, and a total contact seat (see Table 5). Given these differences and the overall quality of the studies (one fair[31] and three poor quality[32-34]) the evidence could not be summarized across the studies. Each study is described below and in Table 5.

Three of the studies were in long-term care settings.[31,32,34] The one fair-quality study followed nursing facility residents randomized to either foam or water mattresses for 4 weeks.[31]In that time the number of residents who were completely healed was not significantly different on the two surfaces (45 percent on foam and 48.3 percent on water).[31] A randomized trial compared the use of a seat with customized shape and air bladders, a LAL bed, and a foam bed overlay in the treatment of nursing facility residents and found that ulcers healed most quickly in patients treated up to 4 hours a day in the seat as opposed to a LAL bed or bed with overlay.[34] The third study in long-term care treated the LAL bed as the standard of care and compared it with a less expensive air bed with foam overlay for 20 patients in a post-acute care center. The researchers reported that the wound surface area closures per week were similar or better on the air and foam bed (9 percent air/foam vs. 5 percent LAL, no statistical test or variance reported).[32]

A larger study of the incidence of pressure ulcers in hospital patients randomized patients to either a profiling bed (electronically controlled and designed to keep patients from slipping down in bed) or a conventional bed. The recruited subjects included a subset of 14 patients with stage I pressure ulcers on admission; four of the four on the profiling bed healed by discharge and two of 10 assigned to conventional beds healed (no statistical tests reported).[33]

Table 5. Support surfaces: Other surfaces

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Support Surfaces Compared	Outcome Measures and Treatment Effect	Benefit: Wound Improvement
Branom 2001[32] Trial Poor N=20/20 Long-term care hospital/ post-acute center	Unclear (Stage III or IV, staging system not cited)	74 years (36-100) Female: NR Bedridden	8 weeks	B: Air bed with foam overlay (PressureGuard CFT) B: LAL bed	Healing rate as % of wound closed per week: A: 9% B: 5% (p-value NR; summary data only presented) Harms: NR	+
Groen 1999[31] Trial Fair N=120/101 Nursing facility	II, III, IV (Grade III=superficial cutaneous or subcutaneous necrosis or Grade IV = deep subcutaneous necrosis. Grading system not cited)	83 years (NR) Female: NR General	4 weeks	A: High-quality foam replacement mattress (TheraRest) B: Water mattress (Secutex)	Complete wound healing: A: 45% B: 48.3% (NS; p-value NR) Harms: NR	~
Keogh 2001[33] Trial Poor N=100/70 (14 patients had pressure ulcers) Hospital	I (Grade 1 EPUAP Grade)	70 (40-90) years Female: 45% General	5 to 10 days	A: Profiling bed B: Conventional bed	Incidence of pressure ulcers was 0% in both groups Complete wound healing: A: 4/4 (100%) B: 2/10 (20%) (p-value NR) Harms: NR	++
Rosenthal 2003[34]Trial Poor N=207/203 Nursing home	III, IV (Stage III or IV, cites AHCPR Practice Guideline, 1984)	70 years (NR) Female: NR General	6 months or until healed	A: Generic total contact seat with adjustable air bladders (Sandia Labs) B: LAL bed (TheraPulse) C: Bed overlay-foam (Geo-Matt)	Median time to complete healing: A: 3.33 months B: 4.38 months C: 4.55 months (p<0.001 for A vs. B or C) No difference between B and C (p=0.58) Harms: 3 patients worsened on bed overlay and were withdrawn.	++

AHCPR=Agency for Health Care Policy and Research, EPUAP=European Pressure Ulcer Advisory Panel, LAL=low-air-loss, NPUAP=National Pressure Ulcer Advisory Panel, NR=not reported, NS=not significant, PU=pressure ulcer

[a]Pressure ulcer stage indicates NPUAP staging unless otherwise stated. Non-NPUAP staging was converted to the equivalent NPUAP stage where possible.

++Complete wound healing.

+Reduction in wound size.

~No difference.

Evidence About the Comparative Effectiveness of Support Surfaces by Subgroup Analysis (Key Question 1a, 1b, and 1c)

Most of the studies of support surfaces identified for this review did not include any subgroup analyses. Four studies presented some results by pressure ulcer characteristics,[18, 19, 27, 34,42] addressing Key Question 1a, however these subgroup analyses were not always presented as part of the original analysis plan.

While initial stage of the pressure ulcer or size at enrollment were incorporated into results by reporting changes or by including these as variables in regressions or ANOVA analyses, four of the 23 studies addressed whether the effect of the support surface varied across patients with differences in baseline pressure ulcer severity.

In a study of hospitalized patients that compared two brands of AP mattresses, results were compared for pressure ulcers staged (as defined by the study authors) as IIa (persistent erythema with intact epidermis) compared with IIb (persistent erythema with epidermal loss). There was no significant difference in healing on the two beds, whether the results were combined or separated by ulcer stages.[18,19]

Nursing home residents using an LAL bed and a foam overlay were divided by whether their pressure ulcers were superficial or deep. However, the results were the same for the two categories with residents on the LAL beds experiencing a larger decrease in wound surface area regardless of the initial depth of the pressure ulcer.[42]

A comparison of LAL beds with foam beds in hospitals presented the initial and end size of ulcers separately for stage II and stages III/IV, but the authors did not discuss differences in healing by pressure ulcer stage and no test of differences by stage was provided. The data presented suggests that the change was similar on the two types of beds for stage II pressure ulcers, but that there was greater improvement on the LAL bed for stage III/IV pressure ulcers.[27]

In the comparison of a generic total contact seat with a LAL bed and foam overlay, the results were divided by the location of pressure ulcer. Pressure ulcers on the trochanter and coccyx healed more quickly on the total contact seat, while there was no significant difference in the time to complete healing for pressure ulcers located on the ischial tuberosity.[34]

None of the identified studies examined the impact of support surfaces by other patient characteristics (Key Question 1b).

None of the studies in a single setting reported on any relationships between setting characteristics and pressure ulcer outcomes. Three studies included both hospital patients and nursing home residents, but only one reported the results separately by setting[20,21] and then only in one of two articles reporting the results of the trial.[21] In this study comparing a specific brand of AP bed (Nimbus 3) with any other AP beds, the results were examined together and separately for the 12 hospital patients and the 20 nursing home residents, and no significant differences were found in wound size when the results were examined by setting.

Support Surfaces: Harms (Key Question 2)

Few of the identified studies, 7 of 24, explicitly addressed harms that could be attributable to or related to support surfaces.[29,31,36,43-46] Harms were rarely mentioned in the study descriptions, discussions, or results of the articles about support surfaces. In these seven studies where harms were mentioned, four reported no significant differences in harms in the treatment and comparator groups. For this reason they are not reported in the tables above; however, they are described in the text that follows.

Four of the seven studies that mentioned harms were from the subgroup of five studies of AF beds. One study reported that a single patient on the AF bed had a severe episode of epistaxis requiring a transfusion that might have been caused by the drying action of the bed and four patients had trouble transferring in and out of the AF bed.[43] Another study reported no significant differences in bleeding, granulation, necrosis, or nursing time on the AF beds compared with a variety of surfaces.[44] In a study comparing AF beds with standard hospital beds, the author stated that they tested for dehydration, pulmonary congestion, confusion, and microsphere leakage. They found that none of the patients experienced these problems.[46] The study of AF bed use in home care reported safety issues including minor mechanical problems that were corrected within 24 hours (six leaks and seven beds overheated), several cases (number not reported) of dry skin, and one case of mild dehydration.[45]

One[29] of the three studies of LAL beds compared LAL beds with foam overlays and mentioned that no harms were identified, but did not specify what harms were considered. Pain was reported as a potential complicating factor in another study and was found not to differ across the support surfaces (foam and water beds) during the course of the trial.[31]

A large trial (n=1972; but n=113 in the treatment subgroup, the rest in prevention) of AP beds and AP overlays for both prevention and treatment reported nine mattress-related adverse events (four falls, three other slips, one suspected contact dermatitis, and one patient who caught his back on the bed rail) for the entire trial, but did not report whether these occurred in the prevention or treatment arm.[36]

Evidence About the Harms Related to Support Surfaces by Subgroups According to Pressure Ulcer Characteristics (Key Question 2a), Patient Characteristics (Key Question 2b), or Setting (Key Question 2c)

None of the identified studies examined harms by any subgroups.

Effectiveness of *Nutrition*

Studies of risk factors for the development of pressure ulcers have found that signs of poor nutrition, such as low levels of prealbumin, vitamin C, or zinc, are associated with an increased incidence of pressure ulcers.[50,51] Guidelines for pressure ulcer prevention developed by the European Pressure Ulcer Advisory Panel (EPUAP) and the United States National Pressure Ulcer Advisory Panel (NPUAP) include recommendations for providing high-protein, mixed nutritional supplementation to patients at risk for pressure ulcer development.[52] These approaches provide the rationale for using various types of dietary supplements as a treatment for patients who have developed a pressure ulcer. The most widely studied nutritional intervention is the use of dietary protein or single amino acids. Vitamin and zinc supplements have also been examined as either sole interventions or in combination with protein-based supplements. Nutritional interventions have always been studied along with other interventions such as specialized beds and dressings. The predominant clinical view is that nutritional supplementation is one part of multi-component regimens to treat pressure ulcers.

Description of Studies

We identified eleven randomized controlled trials of nutritional interventions for the treatment of pressure ulcers. Three were rated good quality,[53-55] two were rated fair quality,[56,57] and six were rated poor quality.[58-63] These trials were published between 1990 and 2012 and were conducted in the United States,[60,61,63,64] Australia,[55,59] Italy,[53,58] Japan,[62,65]and The

Netherlands.[54] Two trials were conducted in multiple European countries.[56,57] The studies generally were small, with sample sizes ranging from 16-160 (total n=527). Only one study had more than 100 participants.[56]

We also identified five observational studies. Of these three were rated fair[66,67,68,69] and two were rated poor.[70,71] These studies were conducted in the United States,[64-66,68,70] Japan,[64,65,69] and Australia.[67] The sample sizes of the observational studies ranged from 7 to 70 (total n=192). The observational studies were published between 1993 and 2010.

Details extracted from each study are included in the evidence tables (see Appendix H, Table H-3). The assessments of the quality rating criteria used for each study are provided in Appendix H, Table H-4.

The *populations* in the studies were predominantly older patients, some with mobility impairment. Although not all studies reported prior nutritional status, only one study was conducted among patients without reported baseline malnutrition.[57] Mean age of the patients ranged from 49 to 83 years. The two studies with the lowest mean ages both studied groups of patients with spinal cord injuries.[64,67] All subjects had at least one pressure ulcer and the majority of studies included patients with ulcers ranging in stage from II-IV. Two observational studies also included patients with stage I ulcers[61,69] (see details in Table 6). All studies included both male and female patients.

Six of the randomized trials used a protein-fortified formula that also included amino acids and micronutrients as the nutritional intervention.[53,57-59,62,63] One trial used a single amino acid (arginine),[55] one used a specialized amino acid compound,[56] and another used a collagen protein hydrolysate.[60] One trial used a variety of nutrition support measures[61] and one used only vitamin C.[54] Of the observational studies, five[64,66,67,69,71] studied the use of protein-containing dietary supplements. One observational study evaluated zinc supplementation[68] and two did not specify the type of nutritional supplement.[65,70]

The *comparators* used in four of the clinical trials were placebos similar in look and taste to the treatments.[54,56,57,60] Four other clinical trials performed head-to-head comparisons. Two trials compared different doses of a nutritional supplement,[55,63] and two trials compared a protein supplement to the same supplement plus arginine and vitamins.[58,59] Three studies used standard nutritional care as the comparator.[53,61,62] One observational study also performed a comparison between two different dosages of a protein supplement.[66] Three observational studies did not report comparators.[64,70,71]

The key *outcomes* measured were complete wound healing, healing time, and reduced wound surface area. The most commonly reported harms were gastrointestinal events and infection.

The *timing,* or duration of followup for all but two of the studies ranged from 3 to 12 weeks. One study evaluated patients for 12 months[67] and another study followed patients for 1 week.[61]

The *setting* for the studies included hospitals or long-term care facilities, and one study was conducted among people living in the community.[67] The studies were conducted in Australia, Europe, Japan, and the United States.

Key Points

- When used in addition to other measures for treating pressure ulcers, protein-containing nutritional supplementation resulted in wound improvement (strength of evidence: moderate).
- The optimal dosage and form of protein has not been defined in nine clinical trials of protein supplementation (strength of evidence: insufficient).

- Vitamin C used as a single nutritional supplement does not result in wound improvement (strength of evidence: low).
- The evidence is insufficient to determine whether zinc supplementation improves pressure ulcer healing.
- Harms or adverse events were reported in about half of the studies (8 of 19), but they reported different harms, did not describe the harm, or did not specify if it was related to treatment (strength of evidence: insufficient).

Detailed Analysis

We were unable to conduct meta-analyses of nutritional supplementation treatment comparisons due to the small number of studies, the variety of specific nutritional formulas studied, and the poor quality of some of the clinical trials.

Evidence About the Comparative Effectiveness of Nutritional Supplementation (Key Question 1)

Protein-Containing Nutritional Supplements

The most frequently studied nutritional supplements were formulas that included a mixture of protein, carbohydrates, lipids, and various micronutrients. Although there were some differences in the content of the nutritional supplements used in the clinical trials, these differences were generally small. To assess whether protein supplementation in any form appears to provide benefit for the healing of pressure ulcers, we evaluated clinical trials that compared protein supplementation to a placebo or usual care comparator. One good-quality trial and one fair-quality trial used a liquid formula known as Cubitan that contains protein, arginine, zinc, and vitamin C.[53,57] Both trials compared Cubitan supplementation to a placebo. In the good-quality trial,[53] patients in the intervention group were provided an additional 500 kilocalories of the formula each day. In the fair-quality trial,[57] patients in the intervention group were provided 750 more kilocalories of nutritional support than patients in the comparison group. The outcome measure in both studies was reduction in surface area of the pressure ulcer. Both studies found slightly greater reductions in ulcer size in the intervention groups by 8 to 12 weeks. Neither study examined complete healing of the pressure ulcers.

A fair-quality clinical trial examined the use of ornithine alpha-ketoglutarate (OKG) as a nutritional supplement.[56] OKG is an amino acid salt containing ornithine and glutarate in a 2:1 ratio; it has been advocated as a stimulant of wound healing. The dose of OKG used in this trial was 10 grams per day and all participants had healed ulcers. The primary outcome was reduction in surface area of the ulcer at 6 weeks. The participants were stratified by size of the ulcer at baseline. In the subgroup with ulcers of 8 cm^2 or less, the group given OKG had a greater reduction is ulcer size that the placebo group. There was no difference in ulcer size reduction in the subgroup having ulcers greater than 8 cm^2 in size.[56]

Four poor-quality clinical trials also examined protein-based nutritional support.[58,59,61,62] All of these trials were relatively small, with the largest trial enrolling 89 participants.[60] All studies used measures of pressure ulcer size as the outcome variable, with followup periods ranging from 15 days to 12 weeks. All studies found greater reductions in pressure ulcer size in the intervention groups. One study assessed complete healing by 12 weeks.[60] Complete healing occurred in 33 percent of the intervention group patients and in 14 percent of the control group

patients. (difference not statistically significant). In this trial the intervention group patients received on average 27 percent higher protein and calorie intake than the control group patients.

A fair-quality observational study[67] examined the use of arginine as a single amino acid for treating pressure ulcers. Participants receiving the intervention were treated with 9 g of arginine and 310 mg of vitamin C per day. The outcome measure was mean time to complete healing of the ulcer. The intervention patients had a mean time of 10.5 weeks while a historical control group had a mean time of 21.1 weeks. The only other study that examined arginine as a sole means of nutritional supplementation was a good-quality clinical trial that randomized patients to receive either 4.5 g or 9 g of arginine per day.[55] Only 23 patients were enrolled and the pressure ulcers were followed for 3 weeks. The two groups did not differ in the mean reduction of size of the ulcers.

One poor-quality clinical trial[61] examined generic nutritional support for patients with pressure ulcers. There was no difference in either ulcer size or ulcer stage, but followup in this study was only 7 days. Due to poor specification of the nutritional intervention and the limited duration of followup, this study provides little useful information.

A poor-quality clinical trial and a fair-quality observational study compared differing dosages of protein-containing nutritional supplements. The clinical trial randomized patients to receive either 16 or 25 percent of their calories as protein.[63] The ulcer healing rate was faster in the group receiving 25 percent protein. In the observational study, patients were allocated in a nonrandomized fashion to either of two commercial nutritional formulas.[66] One formula contained 14 percent protein and the other contained 24 percent protein. Reduction in ulcer area was greater in the group receiving the 24 percent protein formula. The analyses found that both protein intake and intake of total calories was associated with ulcer size reduction. While these studies do not define the optimal dosage of protein, both support the conclusion that protein supplementation enhances healing of pressure ulcers.

The studies of protein supplementation used a wide variety of formulations that included single amino acids (arginine), OKG, generic protein formulations, and formulas supplemented with vitamins. The studies uniformly showed small, positive benefits. In general, higher protein dosages appeared to provide better results. Although the nutritional formulas used in the studies are diverse, they have the common characteristic that they all include protein or amino acids. The most commonly studied outcome was size reduction rather than complete healing of ulcers. All of the studies also included other standard approaches (dressings and support surfaces) for pressure ulcer treatment, with protein supplementation being an adjunct to these other treatments.

Due to the consistency of findings across the studies, we concluded that the strength of evidence is moderate that protein supplementation improves healing of pressure ulcers (when used along with other standard treatments for pressure ulcers). Due to there being only a small number of head-to-head trials, the existing evidence base does not define whether any specific type of protein supplementation is superior to any others. All of the studies had relatively small sample sizes, and several were of poor quality.

Table 6. Nutrition therapy: Protein or amino acid supplementation

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Nutrition Interventions Compared	Outcome Measures and Treatment Effect	Benefit: Wound Improvement
Barnes 2007[70] Observational Poor N=28/28 Hospital	III, IV	NR (NR) Female: NR Chronically malnourished	≥30 days	A: Oral or enteral nutrition support to raise prealbumin levels B: No comparator	Complete wound healing: NR Wound healing rate: Significant improvement for patients with prealbumin levels > 9.0 mg/dL (0.82cc/day) vs. patients with prealbumin levels <9.0 mg/dL (0.02cc/day) (p<0.03) Harms: NR	+
Benati 2001[58] Trial Poor N=36/16 Hospital	NR	NR (72- 91 years) Female: 44% Severe cognitive Impairment	2 weeks	A: Normal hospital diet B: High protein supplement C: High protein enriched with arginine, zinc and antioxidants	Complete wound healing: NR Improvement in pressure sore status tool scores in arms B and C, with greatest improvement in arm C (p-value NR) Harms: NR	~
Breslow 1993[66] Observational Fair N=48/28 Nursing facility	III, IV	72 years (NR) Female: 57% Malnourished	8 weeks	A: Oral or enteral nutrition supplement, 14% protein B: Oral or enteral nutrition supplement, 24% protein	Complete wound healing: NR Wound area reduction, all ulcer stages (% improvement): A: 2.1 cm^2 (15%) B: 4.2 cm^2 (15%) (p<0.02) Stage IV ulcers: A: 3.2 cm^2 B: 7.6 cm^2 (p<0.05) Harms: None	+

Table 6. Nutrition therapy: Protein or amino acid supplementation (continued)

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Nutrition Interventions Compared	Outcome Measures and Treatment Effect	Benefit: Wound Improvement
Brewer 2010[67] Observational Fair N=35/35 Community	II, III, IV	51 years (NR) Female: 3% Spinal cord injury	10 months	A: Daily supplement of 9 mg of arginine (essential amino acid) B: Historical controls	Complete wound healing: A: 100% (n=30) B: 100% (n=26) Mean ulcer healing time: A: 11 weeks B: 21 weeks (p<0.05) Harms: NR	++
Cereda 2009[53] Trial Good N=30/28 Nursing facility	II, III, IV	82 years (NR) Female: 64% Population: Elderly	12 weeks	A: Oral nutrition supplement/ enteral nutrition supplement B: Standard hospital diet	Complete Wound Healing: Documented for only 1 patient in A Wound area reduction, week 12: A: 68% B: 41% (p<0.005) Harms: No hospitalizations to treat complications.	+
Chernoff, 1990[63] Trial Poor N=NR/12 Hospital	II, III, IV	72 years (NR) Female: 58% Elderly, tube feeding dependant	8 weeks	A: High protein (16% of calories) B: Very high protein (25% of calories)	Complete wound healing: A: 0% B: 67% (p-value NR) Reduction in ulcer size: A: 42% B: 73% (p-value NR) Harms: NR	+

Table 6. Nutrition therapy: Protein or amino acid supplementation (continued)

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Nutrition Interventions Compared	Outcome Measures and Treatment Effect	Benefit: Wound Improvement
Desneves 2005[59] Trial Poor N=16/16 Hospital	II, III, IV	73 years (37-92) Female: 38% Elderly	3 weeks	A: Standard hospital diet B: Standard hospital diet plus high-protein, high-energy supplement C: Standard hospital diet plus arginine supplement	PUSH score at 3 weeks (lower is better) : A: 7.0 B: 6.0 C: 2.6 (p<0.05) Estimated time to complete healing: A: 16 weeks B: 15 weeks C: 5 weeks (p-value NR) Harms: NR	+
Lee 2006[60] Trial Poor N=89/71 Nursing facility	II, III or IV	NR Female: NR Residents of long-term care facilities	8 weeks	A: Standard care plus concentrated, fortified, collagen protein hydrolysate supplement, 3 times per day B: Standard care plus placebo, 3 times per day	Reduction in PUSH tool scores: A: 5.56 (60%) B: 2.85 (48%) (p<0.05) Harms; (discontinuations): Hip fracture due to fall (2), changes in renal lab values (3), nausea or distention (4), death (2). No difference between groups in rate of events (p>0.05)	+
Leigh 2012[55] Australia Trial Good N=29/23 Nursing facility	II, III or IV	69 years (NR) Female: 39% Elderly	3 weeks	A:Standard hospital diet plus 4.5 g arginine B:Standard hospital diet plus 9g arginine	Complete wound healing: A: 0% B: 0% Reduction in PUSH tool scores: A: 8.9 to 5.0 (56%) B: 9.0 to 5.9 (66%) (p<0.01) Estimated time to complete healing: A: 9 weeks B. 8 weeks (p=0.99) Harms: None	~

Table 6. Nutrition therapy: Protein or amino acid supplementation (continued)

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Nutrition Interventions Compared	Outcome Measures and Treatment Effect	Benefit: Wound Improvement
Meaume 2009[56] Trial Fair N=165/160 Hospital	II or III	81 years (NR) Female: 57% Elderly	6 weeks	A: Ornithine alpha-ketoglutarate (amino acid salt, precursor of glutamine, arginine, polyamines), 10 g/day B: Placebo	Complete wound healing: A: 2% (n=2) B: 4% (n=3) Change in wound area (wounds with baseline area ≤ 8 cm^2) A: -2.3cm^2 B: -1.7 cm^2 (p=0.0006) Wounds with baseline area > 8 cm^2: no significant differences Closure rate A: -0.07 cm^2/day B: 0.4 cm^2/day (p=0.0007) Harms: 33 adverse events reported in 22 patients (15 OKG, 7 placebo). Higher incidence of gastrointestinal events in treatment group. No serious adverse events related to treatment.	+
Myers 1990[61] Trial Poor N=80/80 Hospital	I to IV	70 years (NR) Female: 43% General(NR)	7 days	A: Wound care B: Nutritional support C: Wound care and nutritional support D: Standard hospital care	Complete wound healing: NR Wound surface area, mean change in ulcer size (% improvement): A: 2.76 mm (70%) B: 2.6 mm (70%) C: 2.34 mm (65%) D: 2.7 mm (50%) (p-value NS)	~

Table 6. Nutrition therapy: Protein or amino acid supplementation (continued)

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Nutrition Interventions Compared	Outcome Measures and Treatment Effect	Benefit: Wound Improvement
Ohura 2011[62] Trial Poor N=60/50 Hospital	III, IV	81 years (58-95) Female: 68% Tube-fed patients	12 weeks	A: Increased caloric intake of Racol® enteral nutrition B: Standard caloric intake of Racol®	Complete Wound Healing A: 24% (n=7) B : 19% (n=4) (p-value NR) Wound Area Reduction (% improvement): A: 30cm^2 to 0.5cm^2 (83%) B: 40cm^2 to 7cm^2 (82%) Ulcer Depth Reduction: Significant improvement in A vs. B ($p<0.05$) Harms: None	+
van Anholt 2010[57] Trial Fair N=47/43 Health care centers, hospitals, Nursing facility	III, IV	75 years (NR) Female: 56% General	8 weeks	A: High energy enriched oral nutritional supplement B: Placebo	Complete wound healing: A: 27% (n=6) B: 24% (n=5) (NS; p-value NR) Wound area reduction (%improvement): A: 10.5cm^2 to 2cm^2 (81%) B: 11.5cm^2 to 3cm^2 (74%) (p=0.0006) Harms: Similar in both groups, including constipation, diarrhea, dyspepsia, nausea, and vomiting.	+

Table 6. Nutrition therapy: Protein or amino acid supplementation (continued)

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Nutrition Interventions Compared	Outcome Measures and Treatment Effect	Benefit: Wound Improvement
Yamamoto, 2009[69] Observational Fair N=40/40 Hospital	I, II	69 years (NR) Female: NR General	6 weeks	Retrospective assessment of total energy intake through normal feeding and nutritional supplementation	Complete wound healing: 53% (n=21) healed or improved Wound area reduction: 53% (n=21) healed or improved Nutrition status: Patients that healed or improved had higher total energy intake and protein intake along with increased serum albumin levels and stable hemoglobin levels than patients that did not improve Harms: NR	+

NPUAP = National Pressure Ulcer Advisory Panel; NR = not reported; NS = not significant; OKG = ornithine alpha-ketoglutarate; PUSH = Pressure Ulcer Scale for Healing

[a]Pressure ulcer stage indicates NPUAP staging unless otherwise stated. Non-NPUAP staging was converted to the equivalent NPUAP stage where possible.

++Complete wound healing.

+Some improvement.

~No difference.

Micronutrient-Containing Nutritional Supplements

Few other nutritional interventions for pressure ulcers have been studied. A good-quality clinical trial[54] has examined ascorbic acid (vitamin C), and a fair-quality observational study[68] has evaluated zinc supplementation. The clinical trial of vitamin C used a dose of 1000 mg per day for a population of nursing home patients in The Netherlands.[54] About two-thirds of patients in both groups were judged to have poor nutritional status. The outcome measure was complete healing of pressure ulcers. About half of the ulcers had healed by 12 weeks, with no significant difference in healing rate between the vitamin C and placebo groups. This single good-quality study suggests that vitamin C as a single agent is ineffective, but the confidence in this conclusion is low given the lack of other studies (see Table 7).

The study of zinc supplementation performed a retrospective analysis comparing patients who had been prescribed zinc sulfate 440 mg per day to patients who had not been prescribed this supplement.[68] After controlling for patient characteristics, there was no difference between the two groups in ulcer healing rates over 30 days. This study is limited by its small size and

retrospective design. We concluded that the evidence is insufficient to draw a conclusion about zinc as a single agent to enhance pressure ulcer healing.

Table 7. Nutrition therapy: Vitamin supplementation with vitamin C or zinc

Author Year Quality Study Type Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Age Sex Population	Duration/ Followup	Nutrition Interventions Compared	Outcome Measures and Treatment Effect	Benefit: Wound Improvement
Houston 2001[68] Observational Fair N=70/68 Nursing facility	II-IV	NR (NR) Female: NR Elderly	30 days	A: 440 mg/day zinc sulfate B: Similar care without zinc sulfate supplementation	Complete wound healing: NR Wound healing: greater improvement in volume in Stage III and IV, not Stage II ($p<0.05$) No difference in surface area or complete closure Harms (A vs. B): Infection requiring antibiotic: Odds ratio=7.8 ($p=0.0009$) Nausea/vomiting: Odds ratio=12.5 ($p=0.02$)	~
Ter Riet[54b] Trial Good N=88/67 Nursing facility/ hospital	II, III	NR (NR) Female: NR Residents of nursing facilities	12 weeks	A: Ascorbic acid supplementation, 500 mg twice daily B: Ascorbic acid, 10 mg twice daily	Complete wound healing: A: 40% (n=17) B: 55% (n=25) Mean wound surface area reduction per week: A: 13.9% B: 22.9% (NS) No difference between groups in wound survival curves (projected time to healing) Harms: None	~

NPUAP = National Pressure Ulcer Advisory Panel; NR = not reported; NS = not significant

[a]Pressure ulcer stage indicates NPUAP staging unless otherwise stated. Non-NPUAP staging was converted to the equivalent NPUAP stage where possible.

[b]A 1974 publication, Taylor also evaluated Vitamin C but did not meet the inclusion criteria because of our 1985 cutoff.

++Complete wound healing.

+Some improvement.

~No difference.

Evidence About the Comparative Effectiveness of Nutrition by Subgroup-Analysis (Key Question 1a, 1b, and 1c)

Because of the generally small sample sizes of the studies in this category, there was limited power to detect subgroup effects. All of the information about sub-groups comes from studies of protein-containing supplements. The clinical trial of vitamin C[54] found no subgroup effects for this intervention.

In the one study of OKG,[56] the study participants were stratified by size of the pressure ulcer at baseline (all participants had healed ulcers). The beneficial effect of OKG was found only in the subgroup with ulcer sizes of 8 cm^2 or smaller. While other studies included patients with varying sizes of pressure ulcers, none examined this factor in the data analyses.

There is some evidence that a patient's baseline nutritional status may affect whether protein-containing nutritional supplementation accelerates ulcer healing. A fair-quality observational study compared patients whose pressure ulcers improved to those whose ulcers did not improve.[64,65,69] Patients in the group that improved had a higher sustained daily calorie intake than those in the unimproved group. A poor-quality observational study stratified patients by baseline level of prealbumin in an open-label study of generic nutritional support.[70] Patients with a baseline prealbumin level of less than 8 mg/dL showed little healing of pressure ulcers. Because prealbumin reflects sustained calorie intake, these two studies suggest that adequate calorie intake is necessary for protein-containing supplements to be effective.

In general, the published clinical trials did not include severely malnourished patients. The clinical trials evaluating OKG,[56] Cubitan,[53,57] another product similar to Cubitan,[59] and a protein hydrolysate[60] included subjects whose body mass indexes were between 20 and 30. A poor-quality clinical trial of a protein supplement enrolled patients having a mean body mass index of 18.6[62] This study found a significantly higher rate of complete healing of pressure ulcers in the group given the nutritional supplement. Overall, there are too few studies that included participants with very poor baseline nutritional status. Thus, there is insufficient indirect evidence to determine whether baseline nutritional status affects the results of using protein-containing nutritional supplements.

All but one of the studies were conducted in inpatient or nursing home settings. The one study conducted among community-dwelling individuals[67] had findings similar to those of the other studies. There were no trends toward different results in nursing home settings than in acute-care hospital settings.

Nutritional Supplementation: Harms (Key Question 2)

Eight studies reported information about harms or adverse events. Six of these were studies of protein supplements and two were studies of nutrients. Harms were not always described, nor was it always clear whether they were attributed to treatment. The most commonly reported harms were gastrointestinal events and infection. Studies did not always specify whether the harms could be reasonably attributed to the treatment.

Five clinical trials provided information about harms related to the use of protein-containing supplements. In the study of OKG, diarrhea, vomiting, and nausea occurred in 12 percent of patients randomized to the active product and in 7 percent of patients randomized to the placebo.[56] In the study of a protein hydrolysate, adverse event rates were reported to be equal in the two study arms, but the actual rates were not reported.[60] A study including 50 patients reported study-related adverse events in five controls (16.7 percent) and eight intervention patients (27.6 percent), but these events were not described and the authors report that the

difference in the rate of the events is not significantly different for the two groups.[62] Another study of mixed nutritional supplementation reported that none of the 28 patients studied were hospitalized to treat complications of treatment and that the control group had slightly higher occurrence of infection (9 vs. 3 points, p=0.07) and greater number of days of antibiotic therapy (103 vs. 36, p<0.001).[53] In a study that followed 43 patients, 41 adverse events were reported in 16 patients in the treatment group and 35 events for 13 patients in the control. Most (88 percent) of the events were considered were mild or moderate. Four in the control group were related to treatment (two diarrhea, one nausea, and one vomiting) compared with nine in the intervention group (six diarrhea, one constipation, and dyspepsia, and one nausea). Overall, 41 percent of those receiving the supplement and 19 percent of those receiving placebo reported diarrhea, constipation, dyspepsia, or nausea. These differences between the groups were not significant.[57]

In the multicenter trial of amino acid supplementation, involving 160 patients, 33 mild to moderate adverse events were reported for 22 patients (15 in the intervention group and seven in placebo) that were considered related to study medication. Gastrointestinal events were more common in intervention patients, but more serious gastrointestinal events (diarrhea, vomiting and nausea) were evenly distributed with 68 percent of events in the intervention group and 67 percent in the placebo group, suggesting the difference is in mild events. There were 30 serious adverse events reported during the course of the study, but none were considered treatment related.[56] In a study comparing high and low protein supplementation among 28 patients, recurring mild diarrhea was reported in one patient receiving high protein (24 percent) in the tube feeding group and mild to severe diarrhea was reported in one patient each in the high and lower protein group receiving tube feeding, but no problems were reported for any patients receiving oral nutrition.[66] Another study of protein supplementation that included 71 patients reported reasons for study discontinuation by 11 patients (two hip fractures, three change in renal lab values; four nausea or distention, and two patients died) and added that there was no significant difference in events for the intervention and comparison group but did not discuss whether these reasons were related to the treatment.[60]

Nausea also is a side effect associated with zinc treatment. In the observational study of zinc supplementation, nausea or vomiting occurred in 20 percent of those receiving the zinc sulfate and 2 percent of those not receiving the product.[68]

Evidence About the Harms Related to Nutritional Supplementation by Subgroups According to Pressure Ulcer Characteristics (Key Question 2a), Patient Characteristics (Key Question 2b), or Setting (Key Question 2c)

No studies reported subgroup analyses to evaluate harms by ulcer, patient, or setting characteristics.

Effectiveness of *Local Wound Applications*

Wound dressings are a mainstay of pressure ulcer treatment. Dressings serve multiple functions, including padding and protection of the ulcer from pressure and friction, providing a moist wound environment and protection against drying, serving as a barrier in patients with incontinence or other sources of wound contamination, absorbing wound exudate, and promoting autolytic debridement of necrotic tissue and slough. Topical ointments and other therapies such as fibrinolytic enzymes and antimicrobial agents are also used in pressure ulcer management to provide moisture, promote tissue debridement, and eliminate or prevent infection. Finally,

biological agents, particularly cellular growth factors, are used to enhance pressure ulcer healing by promoting angiogenesis, epithelialization, and connective tissue deposition.

Different types of local wound applications have different primary functions and the choice of a particular therapy or combination of therapies is often guided by the features and severity of the ulcer. For many pressure ulcers, however, there is more than a single therapeutic need (e.g., exudate absorption, tissue debridement, moist environment), and the most appropriate choice of dressing or topical therapies is not always clear. The harms of different treatments also differ. Studies have therefore compared the effectiveness and harms of different local wound applications for pressure ulcers.

Description of Studies

We identified two systematic reviews that were used for background and 89 original studies, reported in 92 articles published between 1985 and 2012, examining the effectiveness and/or harms of local wound applications for pressure ulcers in a total of 7,115 patients. Seventy-six of the original studies were clinical trials. Of these, 11 were rated as good-quality studies, 20 as fair, and 45 as poor. Sample sizes in the trials ranged from 10 to 168 patients. There were 13 observational studies, including two cohort studies with concurrent intervention and control groups, one pre-post intervention study, and three studies describing outcomes of a single series of patients who all received the same intervention. One cohort study was rated as fair quality and the other observational studies were poor quality.

Details extracted from each study are included in the evidence tables (see Appendix H, Table H-5). The assessments of the quality rating criteria used for each study are provided in Appendix H, Table H-6.

The *populations* in most studies were elderly patients (mean age typically between 70 and 85) with 11 studies including patients with spinal cord injury who were typically younger (mean age between 30 and 50). There was a relatively even distribution of men and women across studies, except in the spinal cord injury populations, which were predominantly men. Patient race and ethnicity were infrequently reported. Most studies included NPUAP stage II and III ulcers, except for studies of biological agents, in which most patients had stage III and IV ulcers. Ulcer sites varied widely, but most commonly included the sacrum, trochanter, ischium, buttocks, and heel.

The *interventions* studied included a wide range of dressings, topical treatments, and biological agents.

- Dressings come in a variety of forms and serve various functions. Dressings within a given category vary in design and composition, but generally have several common features.
    - Hydrocolloid dressings were the most commonly studied. These are adhesive wafers that absorb wound fluid to form a gelatinous mass that conforms to the wound and creates a protective and moist wound environment.
    - Hydrogel dressings are moisture-producing and are commonly used to hydrate dry wounds.
    - Transparent films are clear, semipermeable membranes that provide a protective barrier that allows wound visualization and promote autolytic debridement.
    - Foam and polymeric membrane dressings provide wound padding and protection and absorb exudate.

    - Silicone dressings offer benefits similar to foam dressings, but are less adhesive and have the potential to reduce skin damage during dressing changes.
    - Alginates are seaweed-derived dressings that are typically used to absorb large amounts of exudate.
    - Radiant heat dressings are noncontact dressings attached to a heating element that provides warmth intended to promote wound healing by increasing capillary blood flow and resistance to infection.
    - Gauze dressings are fabrics used to protect wounds and provide a wet or dry wound environment and are often used in conjunction with topical solutions and ointments. Gauze dressings are often considered conventional care and used as the comparator in studies of other types of dressings.
- A wide variety of topical ointments and solutions have been used in the treatment of pressure ulcers. Common topical therapies include antimicrobials, enzymes promoting tissue debridement, polymeric pastes (e.g., dextranomer) that absorb wound exudate, and phenytoin, which is thought to promote wound healing through a variety of mechanisms.
- Biological agents include primarily cellular growth factors, most notably platelet-derived and fibroblast-derived growth factors.

Cointerventions were variably reported. In studies that did report them, cointerventions applied to intervention and comparator groups most often included debridement, saline cleansing, pressure-relieving surfaces, and repositioning.

The *comparators* in most studies of dressings and topical treatments were other dressings and/or topical treatments. Some studies used "usual" or "conventional" care as the comparison group, which typically included moist gauze dressings, but in some cases was not described. For most studies of biological agents, the comparison group received a placebo.

The *outcomes* reported in most studies included complete wound healing, time to complete healing, and/or reduction in wound surface area or volume. Few studies reported pain reduction or wound infection as an outcome, and no studies reported on infectious complications such as osteomyelitis or sepsis. Most studies did not report harms of treatment. Harms that were reported included dermatologic complications such as rash or skin maceration, hypergranulation, wound deterioration, and summative counts of overall adverse events. Some studies reported on costs of care, though the methods used to calculate costs were usually not well described. No studies reported on measures of utilization such as length of hospital or nursing home stay.

The *timing* of studies, in terms of median ulcer duration prior to intervention, was typically 3 weeks to 3 months, though some studies included ulcers with duration of 1 to 2 years. Most interventions lasted 3 to 12 weeks.

The *setting* for these studies included hospitals (n=37), long-term care facilities (n=23), wound care clinics (n=5), and patients' homes (n=9). Some studies were implemented in a variety of settings. Most studies were conducted in the United States or Europe, although several studies were conducted in other parts of the world.

Key Points

Dressings

- Wound improvement was superior with hydrocolloid compared to gauze dressings (10 studies, strength of evidence: low).

- Wound improvement were similar with hydrocolloid and foam dressings (pooled relative risk (RR) 1.12; 95% confidence interval (CI), 0.88 to 1.41; I^2=16.4%; p=0.301) (eight studies, strength of evidence: moderate).
- There was insufficient evidence regarding the comparative effectiveness of hydrogel, transparent film, silicone, and alginate dressings.
- Radiant heat dressings produced more rapid wound improvement than other dressings but were similar to other dressings in terms of complete wound healing (pooled RR 1.32, 95% CI, 0.88 to 1.98, I^2=0.0% p=0.985) (four studies, strength of evidence: moderate).

Topical Therapies

- Evidence about the effectiveness of collagenase and other debriding enzymes was inconclusive due to differences in the enzymes studied and in outcomes measured (five studies, strength of evidence: insufficient).
- Three studies of the effectiveness of topical phenytoin used different comparators and produced inconsistent results (strength of evidence: insufficient).
- Dextranomer paste was inferior to wound dressings (alginate, hydrogel) in promoting wound area reduction (two studies, strength of evidence: low).
- Wound improvement was similar with topical collagen applications compared with hydrocolloid dressings or standard care (three studies, strength of evidence: low).
- There was insufficient evidence about the effectiveness of maggot therapy, based on three poor-quality observational studies (strength of evidence: insufficient).

Biological Agents

- Platelet-derived growth factor was superior to placebo in producing wound improvement in stage III and IV pressure ulcers (three studies, strength of evidence: low).
- There was insufficient evidence about the effectiveness of other biological agents used for the treatment of pressure ulcers due to limitations in the number, size, and quality of studies.

Harms of Local Wound Applications

- Harms reported with dressings and topical therapies for pressure ulcers most commonly included skin irritation and inflammation and tissue damage and maceration (31 studies, strength of evidence: moderate). Variability in study populations, interventions, adverse event measurement, and reporting precluded an estimate of adverse event rates for dressings and topical therapies.
- There was insufficient evidence as to whether specific dressing types or topical therapies are associated with fewer harms than others due to poor study quality and differential reporting of harms across studies (seven studies).

Subgroups

- Few harms were reported with biological agents but evidence did not allow an estimate of the incidence of harms, due to lack of precision across studies. (strength of evidence: insufficient).

- There was insufficient evidence about differences in the effectiveness or harms of wound dressings, topical treatments, or biological agents according to ulcer, patient, or setting characteristics.

Detailed Analysis

Our analysis is grouped by key question and placed in subgroups based on comparisons within and across the general categories of wound dressings, topical therapies, biological agents, and conventional care (most commonly gauze dressings).

Evidence About the Comparative Effectiveness of Local Wound Applications (Key Question 1)

Wound Dressings Compared With Conventional Care

Studies comparing wound dressings with conventional care are described below and in Tables 8-11.

Hydrocolloid Dressings

Ten trials, one good quality,[72] two fair quality,[73,74] and seven poor quality,[75-81] including a total of 670 patients compared hydrocolloid with gauze dressings, typically saline gauze. Overall, wound improvement was better with hydrocolloid, though several studies found no statistically significant differences in outcomes between intervention and control groups. We attempted to meta-analyze results from the seven trials reporting complete wound healing as an outcome, but statistical heterogeneity precluded quantitative pooling of results. The single good-quality study reported better rates of complete wound healing with hydrocolloid compared with saline gauze (74 percent vs. 27 percent) over an 8-week timeframe among patients with stage I and II ulcers.[72] The two fair-quality studies included 105 patients and were conducted in hospitals[73] and a long-term care facility.[74] The former study, which included shallow ulcers, found significantly more complete wound healing after 6 weeks with hydrocolloid (see Table 8 below). The latter study, which included stage III ulcers, found no significant difference in complete healing or time to healing between hydrocolloid and saline gauze dressings. Results were similarly mixed in the poor-quality studies, with one[77] reporting significantly better wound improvement with hydrocolloid in patients with stage III and IV ulcers.

Table 8. Local wound applications: Wound dressings compared with conventional care – *hydrocolloid dressings*

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Wound Applications Compared	Outcomes Measured and Treatment Effect	Benefit: Wound Improvement
Alm 1989[73] Trial Fair N=50/50 Hospitals	NR	83 years (NR) Female: 75% Long-term ward patients	6 weeks	A: Hydrocolloid B: Saline gauze	Complete wound healing: (remaining ulcer area at 6 weeks) A: 0% B: 31% (p=0.016) Harms: None	++
Chang 1998[75] Trial Poor N=34/34 Hospital	II, III	58 years (20-85) Female: NR Neurological problems or cancer	8 weeks	A: Hydrocolloid (DuoDerm) B: Saline gauze	No significant difference in surface area change (A, 34% reduction; B, 9% increase; p=0.23) No harms observed in A. One wound infection in B.	~
Colwell 1993[76] Trial Poor N=94/70 Hospital	II, III	67 years (18-100) Female: 47% General	14 months	A: Hydrocolloid (DuoDerm) B: Saline gauze	Complete wound healing: A: 22% B: 2% (p-value NR) Wound area reduction: A: 0.73 cm reduction B: 0.67 cm increase (NS; p-value NR) Harms: NR	++

Table 8. Local wound applications: Wound dressings compared with conventional care – *hydrocolloid dressings* (continued)

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Wound Applications Compared	Outcomes Measured and Treatment Effect	Benefit: Wound Improvement
Gorse 1987[77] Trial Poor N=52/52 Hospital	III, IV	70 years (NR) Female: 0% > 70% nonambulatory	Days of followup: range: 5-40 days	A: Hydrocolloid (DuoDerm) B: Saline gauze + chloramine-T (Dakin's solution)	Complete wound healing: (reports "healed or healing") A: 87% B: 69% (p=0.026) Treatment days: A: 10.0 days B: 8.7 days (NS; p-value NR) Harms: No patients reported pain related to application and removal of A, but pain associated with B was a common complaint (data NR).	+
Hollisaz 2004[72] Trial Good N=83/83 Nursing facility or home	I, II	37 years (NR) Female: 0% Spinal cord injury	8 weeks	A: Hydrocolloid B: Saline gauze C: Simple dressing	Complete wound healing: A: 74% B: 27% (p<0.01) Harms: NR	++
Kim 1996[78] Trial Poor N=44/44 Rehabilitation department	I, II	49 years (NR) Female: 18% General	3 weeks	A: Hydrocolloid (DuoDerm) B: Wet-to-dry gauze dressing, iodine	Complete healing A: 80% B: 78% (NS; p-value NR) Lower overall treatment cost in A. Harms: NR	~
Mulder 1993[79] Trial Poor N=67/60 Inpatients and outpatients at 3 sites	II, III	59 years (23-86) Female: 15% General	8 weeks	A: Hydrogel (Clearsite) B: Hydrocolloid (DuoDerm) C: Wet-to-moist gauze	No significant differences in weekly wound size change (p=0.89) Harms: inflammation and excoriation in A (12%); minor irritation and skin sensitivity in B (14%).	~

Table 8. Local wound applications: Wound dressings compared with conventional care – *hydrocolloid dressings* (continued)

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Wound Applications Compared	Outcomes Measured and Treatment Effect	Benefit: Wound Improvement
Neill 1989[80] Trial Poor N=65/65 Tertiary care facility	III	NR Female: NR General	15 months	A: Hydrocolloid (Tegasorb) B: Saline gauze (WTD)	Complete wound healing: A: 50% B: 40% (NS; p-value NR) Wound size reduction (median): A: 46% B: 43% (NS; p-value NR) Harms (adverse reaction to dressing): A: 18% B: 2% (p<0.006)	+
Winter 1990[81] Trial Poor N=114/46 Inpatient and outpatient	NR "Ordinary vs. difficult" ulcers	Median 74 years (25-93) Female: 67% General	12 weeks	A: Hydrocolloid B: Paraffin gauze	Complete wound healing: A: 63% B:19% (p-value NR) Harms: NR	++
Xakellis1992[74] Trial Fair N=39/39 Nursing facility	III	81 years (NR) Female: 92% General	6 months	A: Hydrocolloid B: Saline gauze	Complete wound healing: A: 89% B: 86% (p-value NR) Healing time: (median time to healing) A: 9 days B: 11 days (p=0.12) Harms: NR	~

NPUAP = National Pressure Ulcer Advisory Panel; NR = not reported; NS = not significant

[a]Pressure ulcer stage indicates NPUAP staging unless otherwise stated. Non-NPUAP staging was converted to the equivalent NPUAP stage where possible.

++Complete wound healing.

+Some improvement in wound healing.

~No difference.

Hydrogel Dressings

Four poor-quality trials[79,82-84] compared hydrogel dressings with gauze. The poor quality and inconsistency of results across studies limited the ability to draw conclusions. Complete wound healing was significantly better with hydrogel than gauze with iodine (84 percent vs. 54 percent)

in one study of hospitalized patients with stage I, II, and III ulcers.[83] The other three studies reported no significant difference.

Table 9. Local wound applications: Wound dressings compared with conventional care – *hydrogel dressings*

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Wound Applications Compared	Outcomes Measured and Treatment Effect	Benefit: Wound Improvement
Kaya 2005[83] Trial Poor N=27/27 Hospital	I, II, III	19 years (16-56) Female: 84% Spinal cord injury	15 weeks	A: Hydrogel (Coloplast) B: Iodine gauze	Complete wound healing: A: 84% B: 54% (p=0.04) No difference between groups in healing rate (p=0.40) or healing time (p=0.06) Harms: NR	+
Matzen 1999[82] Trial Poor N=32/12 Clinic	III, IV	83 years (32-97) Female: 84% General	12 weeks	A: Hydrogel (Coloplast) B: Saline gauze	Complete healing: A: 29% B: 0% (p-value NR) Lower ulcer volume (p<0.02) and less need for repeat debridement in A (p<0.03). Harms: NR	~
Mulder 1993[79] Trial Poor N=67/60 Inpatients and outpatients at 3 sites	II, III	59 years (23-86) Female: 15% General	8 weeks	A: Hydrogel (Clearsite) B: Hydrocolloid (DuoDerm) C: Wet-to-moist gauze	No significant differences in weekly wound size change (p=0.89). Harms: inflammation and excoriation in A (12%); minor irritation and skin sensitivity in B (14%).	~

Table 9. Local wound applications: Wound dressings compared with conventional care – *hydrogel dressings* (continued)

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Wound Applications Compared	Outcomes Measured and Treatment Effect	Benefit: Wound Improvement
Parnell 2005[85] Observational Poor N=10/7 Nursing facility	II, III	Age: NR Female: NR Nursing facility residents	12 weeks	A: Post topical hydrogel with endopeptidase enzymes (Hydrovase) + gauze B: Before treatment	Complete wound healing: A: 50% B: 0% (p-value NR) Harms: Skin irritation and wound deterioration	++
Thomas 1998[84] Trial Poor N=41/30 Community	II, III, IV	77 years (35-97) Female: 54% General	10 weeks	A: Topical hydrogel dressing B: Saline gauze	Complete wound healing: A: 63% B: 64% (NS, p-value NR) Mean time to healing: A: 5.3 weeks B: 5.2 weeks (p=0.87) Harms: (worsening of ulcer) A: 6% B: 7%	~

NPUAP = National Pressure Ulcer Advisory Panel; NR = not reported; NS = not significant
[a]Pressure ulcer stage indicates NPUAP staging unless otherwise stated. Non-NPUAP staging was converted to the equivalent NPUAP stage where possible.
++Complete wound healing.
+Some improvement in wound healing.
~No difference.

Foam Dressings

Three poor-quality studies provided insufficient evidence about the effectiveness of foam vs. gauze dressings. One poor-quality study among patients with stage II ulcers found greater improvement in Pressure Ulcer Scale for Healing (PUSH) scores with a polymeric foam dressing compared with dry gauze with antibiotic ointment.[86] Two poor-quality trials comparing polyurethane foam dressings to gauze found no significant differences in time to healing[87] or complete wound healing.[88] Both studies reported lower overall costs with foam dressings, attributable to fewer dressing changes and consequently less personnel time.

Table 10. Local wound applications: Wound dressings compared with conventional care – *foam dressings*

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Wound Applications Compared	Outcomes Measured and Treatment Effect	Benefit: Wound Improvement
Kraft 1993[88] Trial Poor N=38/38 Hospital	II, III	56 years (28-78) Female: NR Geriatric and spinal cord injury	24 weeks	A: Polyurethane foam (Epi-Lock) B: Saline gauze	Complete wound healing: A: 42% B: 21% (p-value NR) Lower calculated cost in A. Harms: NR	++
Payne 2009[87] Trial Poor N=36/27 Inpatient, outpatient, long-term care	II	73 years (NR) Female: 39% General	4 weeks	A: Polyurethane foam B: Saline gauze	Median time to healing: 28 days in both groups). Lower overall cost in A. Harms: NR	~
Yastrub 2004[86] Trial Poor N=50/44 Nursing facility	II	NR (>65) Female: NR Elderly	4 weeks	A: Polymer membrane dressing B: Dry clean dressing (gauze + antibiotic ointment	Complete wound healing: NR Improvement in wound healing: A: 87% B: 65.2% Harms: NR	+

NPUAP = National Pressure Ulcer Advisory Panel; NR = not reported

[a]Pressure ulcer stage indicates NPUAP staging unless otherwise stated. Non-NPUAP staging was converted to the equivalent NPUAP stage where possible.

++Complete wound healing.

+Some improvement in wound healing.

~No difference.

Transparent Film Dressings

Three poor-quality trials provided inconsistent results about the effectiveness of transparent film dressings. In one 8 week trial,[89] more complete wound healing was found in a transparent moisture vapor permeable (MVP) dressing compared with saline gauze (64 percent vs. 0 percent). The benefits of the MVP dressing were observed only in less advanced ulcers (Shea grade II but not III). Two studies[90,91] found no significant differences between transparent film (Op-Site) dressings and gauze.

Table 11. Local wound applications: Wound dressings compared with conventional care – *transparent film dressings*

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Wound Applications Compared	Outcomes Measured and Treatment Effect	Benefit: Wound Improvement
Kurzuk-Howard 1985[90] Trial Poor N=43/43 Hospital	I-IV	77 years (36-94) Female: 70% General	20 days	A: Transparent film (Op-Site) B: Usual care (variable)	Complete wound healing: 14/43 overall (33%); no analysis between groups. No difference between groups on other measures. Harms NR	~
Oleske 1986[91] Trial Poor N=16/15 Hospital	I, II	69 years (52-93) Female: NR General	10 days	A: Transparent film (Op-Site) B: Saline gauze	Wound surface area reduction: A: 43% B: 3% (p-value NR) Harms NR	+
Sebern 1986[89] Sebern 1989 Trial Poor N=48/48 Community	III	74 years (NR) Female: NR Chronic illness, SCI, Neurological disorders	8 weeks	A: Transparent moisture vapor permeable dressing (MVP) B: Saline gauze	Complete wound healing (Grade II ulcers; N=34): A: 64% B: 0% (p<0.01) Wound area reduction (median improvement): A: 100% B: 52% (p<0.05) No differences between groups for Grade III ulcers (N=14) Harms: (wound deterioration or discontinued, Grade II ulcers) A: 14% B: 58% (p<0.01)	++

MVP = moisture vapor permeable; NPUAP = National Pressure Ulcer Advisory Panel; NR = not reported; SCI = spinal cord injury

[a]Pressure ulcer stage indicates NPUAP staging unless otherwise stated. Non-NPUAP staging was converted to the equivalent NPUAP stage where possible.

++Complete wound healing.

+Some improvement in wound healing.

~No difference.

Comparisons of Different Wound Dressings

Comparisons of different wound dressings are described below and in Table 12-16.

Hydrocolloid Compared With Hydrocolloid

One fair-quality trial[92] found more favorable reductions in wound area (32 percent vs. 17 percent) and pain with a triangular compared with oval hydrocolloid dressing in patients with stage II and III sacral ulcers.

Hydrocolloid Compared With Hydrogel

Three poor-quality trials compared hydrocolloid to hydrogel dressings and provided insufficient evidence to draw conclusions. One poor-quality trial[93] reported better complete wound healing (43 percent vs. 24 percent) over 2 months, with hydrogel compared with hydrocolloid dressings in stage I and II ulcers. Two other poor-quality trials[79,94] found no significant differences in outcomes comparing hydrocolloid and hydrogel dressings in stage II and III ulcers over 8 weeks.

Hydrocolloid Compared With Transparent Film

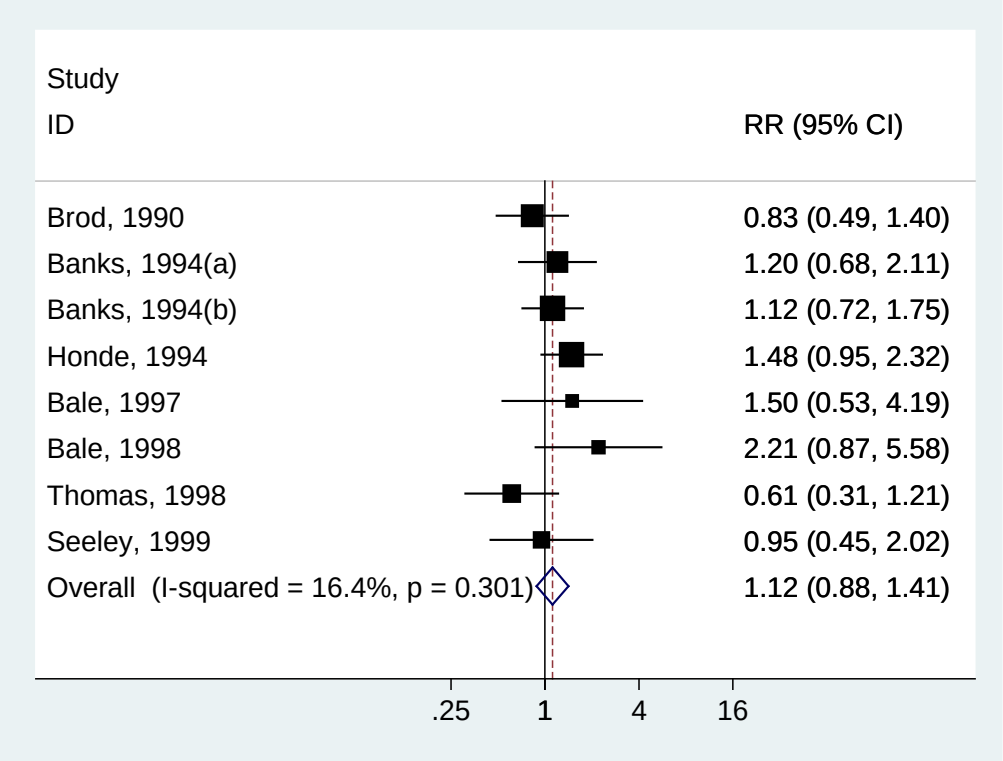
Only one trial, of fair quality,[95] compared hydrocolloid and transparent film dressings and found no significant difference in complete wound healing (60 percent in both groups over 8 weeks) among patients with stage II and III ulcers.

Hydrocolloid Compared With Foam

Three fair-quality[96-98] and five poor-quality[99-103] trials compared hydrocolloid dressings with a variety of different polymeric or hydrocellular foam dressings. Overall the evidence suggested similar complete wound healing with these two dressing types. One fair-quality study reported similar healing outcomes at 8 weeks, but slightly faster time to healing (32 vs. 38 days) with an amino acid copolymer dressing compared with hydrocolloid in patients with stage III and IV ulcers.[97] One poor-quality study reported better complete healing rates (59 percent vs. 27 percent) with a hydrocellular foam dressing compared with hydrocolloid.[102] All other studies reported similar healing outcomes for both dressing types.

We conducted a meta-analysis of the eight studies comparing hydrocolloid with foam dressings. Complete wound healing was similar with foam compared with hydrocolloid dressings (pooled RR 1.12, 95% CI, 0.88 to 1.41, I2=16.4%, p=0.301) (Figure 5). An analysis excluding the four poor-quality trials produced similar results (pooled RR 1.25, 95% CI, 0.94 to 1.65, I2=0.0%, p=0.675).[84,97-102,104]

Figure 5. Hydrocolloid dressings compared with foam dressings: Pooled results



Hydrocolloid Compared With Alginate

A single fair-quality trial[105] compared a strategy of using a calcium alginate dressing for 4 weeks followed by a hydrocolloid dressing for 4 weeks with using the hydrocolloid dressing for all 8 weeks. Complete wound healing was similar across groups but wound area reduction was greater with the alginate/hydrocolloid strategy (69 percent vs. 43 percent). See Table 12.

Table 12. Local wound applications: Comparisons of different wound dressings – *hydrocolloids vs. other dressings*

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage [a]	Mean Age (Range) Sex Population	Followup	Wound Applications Compared	Outcome Measures and Treatment Effect	Benefit: Wound Improvement
Hydrocolloid vs. Hydrocolloid						
Day 1995[92] Trial Fair N=103/96 Hospital (acute care)	II, III	75 years (NR) Female: 49% Elderly, poor health	10 days (mean)	A: Hydrocolloid triangle dressing B: Hydrocolloid oval	Complete wound healing: A: 36% B: 22% (p=0.17) Wound area reduction (width): A: 32% B: 17% (p=0.034) Wound area reduction (length): A: 28% B: 24% (NS; p-value NR) Reduction in pain: (baseline vs. final) A: 47% vs.18% B: 39% vs. 32% Pain higher at final assessment in B (p=0.04) Harms (wound deterioration): A: 4% B: 31% (p<0.05) (erythema, severe pain, increase in necrotic tissue, wound size, and depth): A: 4% B: 31%	**+** (triangle dressing superior)
Hydrocolloid vs. Hydrogel						
Darkovich 1990[93] Trial Poor N=90/90 Acute care and nursing facility	II Stage I, II (Enis & Sarmieti)	75 years (30-98) Female: 55% General	60 days	A: Hydrogel (BioFilm) B: Hydrocolloid	Complete wound healing: A: 43% B: 24% Healing time: (mean treatment days) A: 12 B: 11.3 Wound area reduction: A: 68% B: 40% Harms: (wound deterioration) A: 1.5% B: 10% (p-values NR)	**++**

Table 12. Local wound applications: Comparisons of different wound dressings – *hydrocolloids vs. other dressings* (continued)

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Wound Applications Compared	Outcome Measures and Treatment Effect	Benefit: Wound Improvement
Hydrocolloid vs. Hydrocolloid (continued)						
Motta 1999[94] Trial Poor N=10/10 Setting	II, III	60 years (NR) Female: 50% General	8 weeks	A: Hydrogel polymer (Flexigel) B: Hydrocolloid (DuoDerm)	Complete wound healing: 40% in both No differences in wound improvement or healing rate Fewer dressing used (with lower total cost) in A Harms: NR	~
Mulder 1993[79] Trial Poor N=67/60 Inpatients and outpatients at 3 sites	II, III	59 years (23-86) Female: 16% General	8 weeks	A: Hydrogel (Clearsite) B: Hydrocolloid (DuoDerm) C: Wet-to-moist gauze	No significant differences in weekly wound size change (p=0.89). Harms: inflammation and excoriation in A (12%); minor irritation and skin sensitivity in B (14%).	~
Hydrocolloid vs. Transparent Film						
Brown-Etris 2008[95] Trial Fair N=72/72 Wound care clinic, home, nursing facility	II, III	75 years (NR) Female: 56% General	8 weeks	A: Acrylic (Tegaderm) B: Hydrocolloid (DuoDerm)	No difference in complete wound healing (60% in both arms; p=0.96). Harms: None	~
Hydrocolloid vs. Foam						
Bale 1997[96] Trial Fair N=51/50 NR	II-III (Stirling)	74 years (NR) Female: 55% general	30 days	A: Polyurethane foam B: Hydrocolloid	Complete wound healing: A: 24% B: 16% (p-value NR) Harms: One case of rash in group A. No harms observed in group B.	~
Bale 1998[102] Trial Poor N=32/32 Community	II, III	76 years (NR) Female: 77% General	8 weeks	A: Hydrocolloid dressing B: Hydrocellular dressing	Complete wound healing: A: 59% B: 27% (p-value NR) Harms: NR	**++**

Table 12. Local wound applications: Comparisons of different wound dressings – *hydrocolloids vs. other dressings* (continued)

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Wound Applications Compared	Outcome Measures and Treatment Effect	Benefit: Wound Improvement
Hydrocolloid vs. Foam (continued)						
Banks 1994a[99] Trial Poor N=40/28 Community dwelling patients	II, III	72 years (40-100) Female: 48% General	6 weeks	A: Polyurethane membrane (Spyrosorb) B: Hydrocolloid (Granuflex)	No difference in complete wound healing A: 60% B: 50% (p-value NR) Harms (all in B): Overgranulation (10%), discomfort (10%), wound deterioration (10%)	~
Banks 1994b[100] Trial Poor N=29/29 Hospital	II, III	Median 74 (40-95) years Female: 60% Elderly	6 weeks	A: Semi-permeable polyurethane B: Hydrocolloid	Complete wound healing: A: 77% B: 70% (p-value NR) Harms: NR	~
Brod 1990[101] Trial Poor N= 43/38 Nursing facility	II, III	Median 86/82 years (NR) Female: NR Elderly	16 weeks	A: Poly-hema B: Hydrocolloid (DuoDerm)	Complete wound healing: A: 52% B: 62% (p=0.54) Wound healing time: (median) A: 32 days B: 42 days (p=0.54) Harms: NR	~
Honde 1994[97] Trial Fair N=168/129 Hospitals	III, IV	82 years (63-101) Female: 72% Elderly	8 weeks	A: Amino acid copolymer membrane (Inerpan) B: Hydrocolloid (Comfeel)	Complete wound healing A: 39% B: 26% (p=0.89) Median healing time (range) A: 32 (13-59) days B: 38 11-63) days (p=0.044) Harms: NR	+

Table 12. Local wound applications: Comparisons of different wound dressings – *hydrocolloids vs. other dressings* (continued)

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Wound Applications Compared	Outcome Measures and Treatment Effect	Benefit: Wound Improvement
Hydrocolloid vs. Foam (continued)						
Seeley 1999[98] Trial Fair N=40/39 Outpatient wound clinic	II, III	76 years (NR) Female: 54% General, diabetic and wound clinic patients	8 weeks	A: Hydrocellular dressing B: Hydrocolloid dressing	Complete wound healing: A: 40% B: 40% Wound area reduction: A: 50% B: 52% (p=0.31) Harms (Wound deterioration): A: 1% B: 0.5% (infection, rash or maceration): A: 0 .5% B: 1%	~
Thomas 1997[103] Trial Poor N=99[b] Community	II, III (Stirling)	77 years (overall), 79 years (pressure ulcers); ranges NR Female: 70% (overall), 69% (pressure ulcers)	15 days	A: Hydropolymer dressing B: Hydrocolloid dressing	Complete wound healing: A: 33% B: 20% Improved, not healed: B: 47% B: 58% Harms (adverse events including bleeding, excess granulation, and wound dehydration): A: n=10 B: n=7 (p-values NR)	~

Table 12. Local wound applications: Comparisons of different wound dressings – *hydrocolloids vs. other dressings* (continued)

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Wound Applications Compared	Outcome Measures and Treatment Effect	Benefit: Wound Improvement
Hydro-Colloid vs. Alginate						
Belmin 2002[105] Trial Fair N=110/77 Hospitals	III, IV	84 years (NR) Female: 71% Population: Elderly	8 weeks	A: Calcium alginate (UrgoSorb) x 4 weeks then hydrocolloid (Algoplaque) x 4 weeks B: Hydrocolloid (DuoDerm) x 8 weeks	Complete wound healing: A: 5% B:15% (p=0.162) Wound surface area reduction A: 69% B: 43% (p<0.0001) Harms (excessive granulation): A: 11% B: 9%	+ (alginate then HC superior to HC alone)

NA = not applicable; NPUAP = National Pressure Ulcer Advisory Panel; NR = not reported; NS = not significant
[a]Pressure ulcer stage indicates NPUAP staging unless otherwise noted. Non-NPUAP staging was converted to the equivalent NPUAP stage where possible.
[b]Pressure ulcers only. Including venous ulcers, n=99.
++Complete wound healing.
+Some improvement in wound healing.
~No difference.

Alginate Compared With Alginate

A single fair-quality trial comparing a silver hydroalginate to a calcium alginate dressing found more wound area reduction (32 percent vs. 14 percent) over 4 weeks and faster wound closure rates with the silver-based dressing (0.26 vs. 0.03 cm^2 per day), though the study included multiple wound types and the significance of differences for pressure ulcers alone was not reported.[106] Infection rates were similar with the two dressings (see Table 13).

Hydrogel Compared With Hydrogel

A single poor-quality trial comparing two types of amorphous hydrogel found no differences in the outcome of wound pain[104] (see Table 13).

Table 13. Local wound applications: Comparisons of different wound dressings – *within-category comparisons*

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Wound Applications Compared	Outcome Measures and Treatment Effect	Benefit: Wound Improvement
Alginate vs. Alginate						
Meaume 2005[106] Trial Fair N= 28/28 [b] Multicenter (Hospitals)	III, IV	77 years (NR) Female: 59% vs. 69% Population: general	4 weeks	A: Silver release hydroalginate dressing (Silvercel) B: Calcium alginate dressing (Algosteril)	Wound area reduction: A: 32% B:14% (p-value NR separately for pressure ulcers) Healing rate (cm2/day): A: 0.26 B: 0.03 (p-value NR separately for pressure ulcers) Harms: NR separately for pressure ulcers	**+** (silver alginate superior)
Hydrogel vs. Hydrogel						
Bale 1998[104] Trial Poor N=50/42 Hospital and community settings	II-IV	78 years (20-99) Female: 62% Population: general	4 weeks	A: Amorphous hydrogel (Sterigel) B: Amorphous hydrogel (Intrasite)	No differences between groups in improvement in wound pain (p=0.55) Harms: Maceration in 38% (group A) vs. 53% (group B) (p-value NR)	~

NPUAP = National Pressure Ulcer Advisory Panel; NR = not reported; NS = not significant
[a]Pressure ulcer stage indicates NPUAP staging unless otherwise noted. Non-NPUAP staging was converted to the equivalent NPUAP stage where possible.
[b]Pressure ulcers only. Including venous ulcers, n=199.
++Complete wound healing.
+Some improvement in wound healing.
~No difference.

Foam compared with silicone. One fair-quality trial[107] and one poor-quality cohort study[108] compared a polymer or hydrocellular foam with a silicone dressing (see Table 14). Complete wound healing was similar for foam and silicone dressings in both studies.

Table 14. Local wound applications: Comparisons of different wound dressings – *foam compared with silicone*

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Wound Applications Compared	Outcome Measures and Treatment Effect	Benefit: Wound Improve-ment
Meaume 2003[107] Trial Fair N=38/38 Nursing facility	II	83 years (66-92) years Female: 84% Elderly	8 weeks	A: Hydropolymer foam dressing B: Silicone dressing	Complete wound healing A: 50% B: 44% (p-value NR) Harms (adverse events): A:15% B: 6% More tissue damage, maceration, leakage in A	~
Viamontes 2003[108] Observational Poor N=1891/1891 Nursing facility	NR	83 years (29-106) Female: NR General	Mean 71 days	A: Hydrocellular foam dressing B: Silicone dressing	Complete wound healing: A: 53% B: 50% (NS; p-value NR) Infection: A: 3% B: 9% (NS) Harms – skin stripping: A: < 1% B: 2%	~

NA = not applicable; NPUAP = National Pressure Ulcer Advisory Panel; NR = not reported; NS = not significant
[a]Pressure ulcer stage indicates NPUAP staging unless otherwise stated. Non-NPUAP staging was converted to the equivalent NPUAP stage where possible.
++Complete wound healing.
+Some improvement in wound healing.
~No difference.

Radiant Heat Compared With Other Dressings

Two good-quality trials[109,110] and two fair-quality trials[111,112] of patients with stage III or IV ulcers compared a radiant heat dressing to hydrocolloid dressings,[109] alginate dressings,[110] or "standard care,"[111,112] which included a variety of other dressings, including gauze, alginates, foam, hydrocolloids, and hydrogels (see Table 15). Overall, these studies indicated that radiant heat dressings accelerate the rate of healing compared with other types of dressings. One good-quality and two fair-quality studies measured rates of wound closure and overall found faster healing rates with radiant heat over periods of 4 to 8 weeks. A meta-analysis of the three trials reporting complete wound healing results indicated similar outcomes with radiant heat compared with other dressings (pooled RR 1.32, 95% CI, 0.88 to 1.98, $I^2 = 0.0\%$ p=0.985) (Figure 6).

Table 15. Local wound applications: Comparisons of different wound dressings – *radiant heat*

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Wound Applications Compared	Outcome Measures and Treatment Effect	Benefit: Wound Improvement
Kloth 2002[111] Trial Fair N= 53/40 Hospital and 7 nursing facilities	III and IV	78 years (NR) Female: 63% General	4 weeks	A: Semi-occlusive heated dressing B: Standard care	Complete wound healing: A: 48% B: 36% (p-value NR) Reduction in mean surface area: A: 69% B: 50% (p=0.11) Healing rate: A: 0.52 cm^2 per week B: 0.23 cm^2 per week (p<0.02) Harms: NR	+
Price 2000[110] Trial Good N=58/50 Multiple (hospital, nursing facility, community)	(Bergstrom stage 3, 4)	73 years (NR) Female: 64% General	6 weeks	A: Radiant heat dressing B: Standard care	Complete wound healing: A: 12% B: 8% (NS; p-value NR) Wound surface area reduction: (% of initial area) A: 75% B: 40% (p=0.078) Time to reduce wound size to 25% of original area: A: 33 days B: 38 days (p=0.058). No difference between groups in pain scores at weeks 1 or 6. Harms: No evidence that heat therapy was linked with deterioration in skin condition.	~

Table 15. Local wound applications: Comparisons of different wound dressings – *radiant heat* (continued)

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Wound Applications Compared	Outcome Measures and Treatment Effect	Benefit: Wound Improvement
Thomas 2005[109] Trial Good N=41/39 Nursing facility	(III, IV; Lazarus 1994)	76 years (NR) Female: 32% General	12 weeks	A: Radiant heat dressing B: Hydrocolloid	Complete wound healing: A: 57% B: 44% (p=0.46) Harms: NR	~
Whitney 2001[112] Trial Fair N=40/29 Multiple: (acute care, community, and nursing facility)	III, IV	58 years (NR) Female: 38 % Mixed (Diabetes, SCI)	8 weeks	A: Noncontact normothermic wound therapy (heated dressing) B: Standard care	Complete wound healing: A: 53% B: 43% (p-value NR) Linear rate of healing (mean): A: 0.012cm^2 per day B: 0.004 cm^2 per day (p=0.01)	+

NPUAP = National Pressure Ulcer Advisory Panel; NR = not reported; NS = not significant

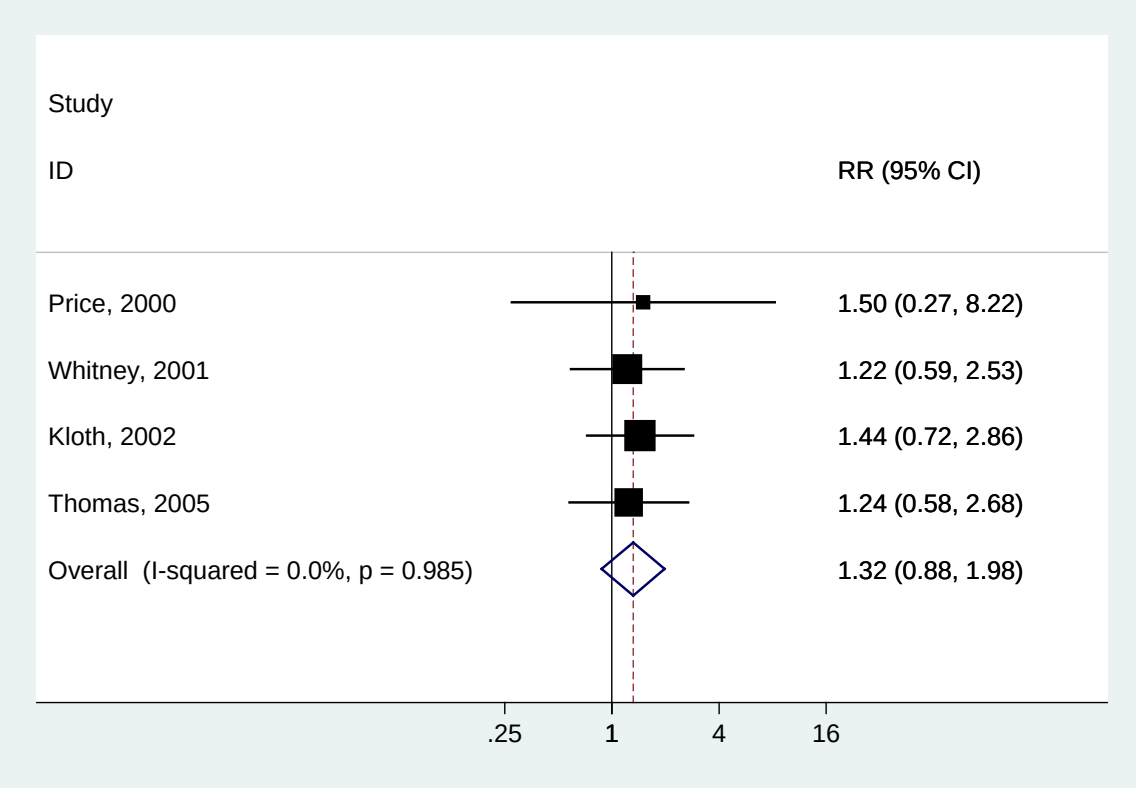
[a]Pressure ulcer stage indicates NPUAP staging unless otherwise noted. Non-NPUAP staging was converted to the equivalent NPUAP stage where possible.

++Complete wound healing.

+Some improvement in wound healing.

~No difference.

Figure 6. Radiant heat compared with other dressings: Pooled results



Other Comparisons

Several studies evaluated dressings that did not fall into the general dressing categories listed above. A good-quality trial[113] compared wrap therapy – dressing stage II-III ulcers with food wrap or polyethylene sheets – to usual care, which typically involved the use of hydrocolloid, hydrogel, or foam dressings. Complete wound healing and time to healing were similar in both groups. Another good-quality trial[114] compared an activated charcoal dressing with a hydrocolloid dressing and found no significant difference in healing outcomes among patients with stage III ulcers. A fair-quality trial[115] compared "advanced" wound dressings, including hydrogel, foam, or transparent film, with "standard" dressings, including gauze, alginates, or hydrocolloids. Specific dressings were chosen based on ulcer characteristics. In 58 community-dwelling patients, complete healing was 54 percent in the advanced dressing group and 30 percent in the standard group, though this difference was not significant. A fair-quality trial[116] compared a honey dressing with a bactericidal dressing and found significantly more complete healing (20 percent vs. 0 percent) and better PUSH scores with the honey dressing over a 5-week period (see Table 16).

Table 16. Local wound applications: Comparisons of different wound dressings – *other comparisons*

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Wound Applications Compared	Outcome Measures and Treatment Effect	Benefit: Wound Improvement
Bito 2012[113] Trial Good N=66/64 Hospitals	II-III	81 years (NR) Female: 52% General,50 years or older	8 weeks	A: Wrap therapy (food wrap or polyethylene sheets) B: Usual care (hydrocolloid, hydrogel, foam dressings)	Complete wound healing: A: 52% B: 46% (p-value NR) Time to healing: A: 60 days B: 58 days (no statistical difference) Harms: Skin complications in both groups. 17% with wrap therapy, incidence NR with usual care.	~
Kerihuel 2010[114] Trial Good N=60/39 Hospitals (inpatients and outpatients)	III (Yarkony IIc, IV)	81 years (NR) Female: 76% General	4 weeks	A: Charcoal (Actisorb) B: Hydrocolloid (DuoDerm)	Wound area reduction: A: 27% B: 19% (NS, p-value NR) Harms: A: 7% (infection, pruritus) B: 16% (maceration/exudation, infection, wound aggravation, overgranulation, eczema)	~
Small 2002[115] Trial Fair N=58/41 Community	(Stirling scale, Waterlow 1996 - II, III, IV)	Median 77 years (19-97) Female: 60% Population: NR	6 weeks	A: Advanced wound care: Hydrogel dressing Foam dressing Transparent film dressing B: Standard care	Complete wound healing (all stage II ulcers): A: 54% B: 30% (p-value NR) Harms: None	~
Yapucu Gunes 2007[116] Trial Fair N=36/26 Hospital	II or III	66 years (NR) Female: 35% General	5 weeks	A: Honey dressing B: Exthoxy-diamino-acridine + nitrofurazone dressing	Complete wound healing: A: 20% B: 0% (p< 0.05) Mean decrease in ulcer size: A: 56% B:13% (p< 0.001) Harms NR	++

NPUAP = National Pressure Ulcer Advisory Panel; NR = not reported; NS = not significant

[a]Pressure ulcer stage indicates NPUAP staging unless otherwise noted. Non-NPUAP staging was converted to the equivalent NPUAP stage where possible.

++Complete wound healing.

+Some improvement in wound healing.

~No difference.

Topical Therapies

Comparisons of topical therapies are described below and in Tables 17-23.

Enzymes

Five trials – one good-quality, two fair-quality, and two poor-quality – evaluated topical debriding enzymes and found that enzymes, particularly collagenase, are associated with improved wound improvement and possibly reduced pain. A good-quality trial[117] compared collagenase ointment with a hydrocolloid dressing in patients with stage III ulcers and found no significant difference in ulcer healing, but improved pain in the collagenase group. In a fair-quality trial,[118] the same investigators found similar healing outcomes for collagenase applied every 24 hours compared with every 48 hours, though pain outcomes were better with the every 24 hour application. Another fair-quality trial compared collagenase with fibrinolysin plus DNAase and found a nonsignificant difference favoring collagenase in necrotic wound area reduction (47 percent vs. 36 percent).[119] A fair-quality trial[120] found no significant differences in complete wound healing or wound area reduction when comparing topical collagenase with papain/urea, but necrotic tissue debridement was better with papain/urea. A poor-quality trial[121] reported shorter healing times and more complete healing (92 percent vs. 64 percent) with collagenase compared with hydrocolloid after 16 weeks. A poor-quality trial[122] found nonsignificant differences in wound area reduction when comparing Varidase (streptokinase and streptodornase) with zinc oxide (19 percent vs. 2 percent) over 8 weeks.

Table 17. Local wound applications: Topical therapies – *enzymes*

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (range) Sex Population	Followup	Wound Applications Compared	Outcomes Measured and Treatment Effect	Benefit: Wound Improvement
Agren 1985[122] Trial Poor N=28/28 Multiple (Hospitals/ outpatient)	III	Median 84 years (46-92) Female: 71% Elderly	8 weeks	A: Streptokinase/ streptodornase B: Zinc oxide	Complete wound healing: NR Disappearance of necrotic tissue: A: 43% B: 50% (p-value NR) Wound area reduction (median): A:18.7% B: 2.4% (p-value NR) Harms: Streptokinase/ streptodornase treatment discontinued in 3 patients due to toxic skin reaction, necrosis, or infection	~

Table 17. Local wound applications: Topical therapies – *enzymes* (continued)

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Wound Applications Compared	Outcomes Measured and Treatment Effect	Benefit: Wound Improvement
Alvarez 2000[120] Trial Fair N=22/21 Nursing facility	Partial thickness-II: 1 vs. 2 Full thickness-III-IV	Median 82 years (53-90) Female: 57% Elderly	4 weeks	A: Collagenase debriding ointment B: Papain urea debriding ointment	Overall wound response (0=wound deteriorated, 1=no change, 2=minimal change, 3=average improvement, 4=significant improvement, 5=necrotic tissue resolved) A: 1.1 B: 4.5 (p<0.01) Healing time (mean time to 50% granulation): A: 28 days B: 6.8 days (p-value NR) Reduction in wound area from baseline: A: 33.9% B: 55.4% (NS; p-value NR) Harms (bacterial count at 4 weeks): A: log 5.0 CFU/mL B: log 4.6 CFU/mL (NS, p>0.05)	**+ (papain superior)**

Table 17. Local wound applications: Topical therapies – *enzymes* (continued)

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Wound Applications Compared	Outcomes Measured and Treatment Effect	Benefit: Wound Improvement
Burgos 2000[117] Trial Good N=43/37 Hospitals	III	80 years (55-96) Female: 54% Over 55	12 weeks	A: Collagenase ointment B: Hydrocolloid	Complete wound healing: A: 17% B: 16% (p=0.45) Wound area reduction: A: 44% B: 28% (p=0.37) Pain improved more with A (p=0.001) No significant difference in bacterial colonization or total cost. Harms: A: 6% (dermatitis) B: 5% (erythema)	~
Muller 2001[121] Trial Poor N=24/23 Hospital	(Grade IV, method NR)	73 years (65-79) Female: 100% Post-hip surgery	16 weeks	A: Collagenase ointment B: Hydrocolloid (DuoDerm)	Complete wound healing: A: 92% B: 64% (p<0.005) Mean time to wound healing with collagenase: A: 10 weeks B: 14 weeks (p<0.005) Harms: NR	++
Pullen 2002[119] Trial Fair N=135/78 Hospital	I, II, IV	79 years (NR) Female: 48% Elderly	4 weeks	A: Collagenase B: Fibrinolysin and deoxyribonuclease (DNAse)	Wound debridement (decrease in necrotic wound area): A: 46.7% B: 36.1% (p=0.11) Harms: no adverse events evaluated as related to study medication	~

NPUAP = National Pressure Ulcer Advisory Panel; NR = not reported; NS = not significant

[a]Pressure ulcer stage indicates NPUAP staging unless otherwise noted. Non-NPUAP staging was converted to the equivalent NPUAP stage where possible.

++Complete wound healing.

+Some improvement in wound healing.

~No difference.

Phenytoin

Three studies (two good, one poor) comparing topical phenytoin to other local wound applications provided inconsistent evidence on the effectiveness of phenytoin. A good-quality trial[72] found more complete healing of stage I and II ulcers after 8 weeks with hydrocolloid compared with phenytoin (74 percent vs. 40 percent); this effect was seen primarily in the stage I ulcers. Another good-quality trial[123] reported nonsignificant differences in PUSH scores and wound volume reduction (48 percent vs. 36 percent) with phenytoin solution compared to saline gauze in stage II ulcers. One poor-quality trial[124] found shorter time to complete wound healing for stage II ulcers with phenytoin compared with either a hydrocolloid dressing or topical antibiotic ointment (35 vs. 52 vs. 54 days).

Table 18. Local wound applications: Topical therapies – *phenytoin*

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Wound Applications Compared	Outcomes Measured and Treatment Effect	Benefit: Wound Improvement
Hollisaz 2004[72] Trial Good N=83/83 Nursing facility or home	I, II	37 years (NR) Female: 0% Spinal cord injury	8 weeks	A: Hydrocolloid B: Phenytoin cream C: Saline gauze	Complete wound healing: A: 74% B: 40% C: 27% (p<0.01) A > B and C for stage I and gluteal A > C for stage II and ischial No difference for sacral Harms: NR	–
Rhodes, 2001[124] Trial Poor N=47/39 Nursing facility	II	78 years (60-101) Female: 8% Elderly	8 weeks or complete wound healing	A: Topical Phenytoin B: Collagen Dressing (DuoDerm) C: Triple antibiotic ointment	Mean time to complete wound healing: Shorter for A compared with B or C (p=0.005) A: 35 days (p=0.011 vs. C; p=0.020 vs. B) B: 52 days C: 54 days Harms: None	+
Subbanna 2007[123] Trial Good N=28/26 Hospital	II	33 Years (10-55) Female: 12% Spinal cord injury	15 days	A: Phenytoin solution B: Sterile gauze	Complete wound healing: NR Reduction in ulcer size: A: 47.8% B: 36.0% (p=0.13) Harms: None	~

NPUAP = National Pressure Ulcer Advisory Panel; NR = not reported

[a]Pressure ulcer stage indicates NPUAP staging unless otherwise noted. Non-NPUAP staging was converted to the equivalent NPUAP stage where possible.

++Complete wound healing.

+Some improvement in wound healing.

~No difference.

Dextranomer

Two trials, one good and one poor quality, provided evidence that dextranomer paste may be inferior to other local wound applications. A good-quality trial[125] comparing dextranomer paste to a calcium alginate dressing measured partial healing and wound area reduction after 8 weeks in patients with stage III and IV ulcers and found significantly faster wound surface area reduction with alginate. A poor-quality study[126] found greater wound area reduction with a hydrogel dressing compared with dextranomer paste (35 percent vs. 7 percent) after 3 weeks.

Table 19. Local wound applications: Topical therapies – *dextranomer*

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Wound Applications Compared	Outcomes Measured and Treatment Effect	Benefit: Wound Improvement
Colin 1996[126] Trial Poor N=135/135 Six centers	All stages	79years (25-98) Female: 54% General	3 weeks	A: Hydrogel (IntraSite) B: Dextranomer paste (Debrisan)	Median reduction in wound area: A: 35% B: 7% (p=0.03) Harms: 1 report of pain in B	+
Sayag 1996[125] Trial Good N=92/60 Nursing facility and dermatology centers	III, V	81 years (60-96) Female: 74% Elderly, limited mobility	8 weeks	A: Calcium alginate B: Dextranomer	Complete wound healing: NR >75% reduction in wound area: A: 32% B:13% (p-value NR) Minimum 40% reduction in wound area: A: 74% B: 42% (p=0.002) Mean wound surface area reduction: A: 2.39 cm^2 B: 0.27 cm^2 (p<0.0001) Harms: Local adverse events A: 8% B: 33%	–

NPUAP = National Pressure Ulcer Advisory Panel; NR = not reported
++Complete wound healing.
+Some improvement in wound healing.
~No difference.

Collagen

Evidence from three trials (one good, two poor) provided evidence that topical collagen is not superior to other local wound applications. A good-quality trial[127] comparing topical collagen to a hydrocolloid dressing found similar complete wound healing for both treatments (51 percent vs. 50 percent) for stage II and III ulcers over 8 weeks. One poor-quality trial[128] of 24 patients found no significant difference in wound area reduction over 3 weeks between topical collagen and placebo (59 percent vs. 46 percent). Another poor-quality trial comparing a collagen and cellulose matrix (Promogran) to petrolatum gauze showed no significant difference in complete wound healing between treatments (90 percent vs. 70 percent) over 8 weeks.[129]

Table 20. Local wound applications: Topical therapies – *collagen*

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage [a]	Mean Age (range) Sex Population	Followup	Wound Applications Compared	Outcomes Measured and Treatment Effect	Benefit: Wound Improvement
Graumlich 2003[127] Trial Good N=65/54 Nursing facility	II, III	81 years (NR) Female: 63% Elderly	8 weeks	A: Topical collagen B: Hydrocolloid	Complete wound healing: A: 51% B: 50% (p=0.89) Mean area healed per day: A: 6 mm^2 B: 6 mm^2 (p=0.94) Harms: None	~
Nisi 2005[129] Trial Poor N=80/80 Hospital, plastic surgery unit	II, III, IV	45 years (35-86) Female: 34% General	2-8 weeks	A: Protease modulating matrix (collagen + cellulose: Promogran) B: Daily iodine and saline wash, petrolatum-soaked gauze	Complete wound healing: A: 90% B: 70% (p=0.59) Length of hospitalization A:360 days B:1164 days (p-value NR) Harms: None	~
Zeron 2007[128] Trial Poor N=24/24 Hospital	NR	79 years (65-90) Female: 21% Elderly	3 weeks	A: Collagen-polyvinylpyrro-lidone (clg-pvp) B: Placebo	Mean reduction in ulcer size: A: 3.4 to 1.14 cm (58.5%) B: 2.9 to 1.58 cm (45.5%) (NS; p-value NR) Harms: NR	~

NPUAP = National Pressure Ulcer Advisory Panel; NR = not reported; NS = not significant

[a]Pressure ulcer stage indicates NPUAP staging unless otherwise noted. Non-NPUAP staging was converted to the equivalent NPUAP stage where possible.

++Complete wound healing.

+Some improvement in wound healing.

~No difference.

Antimicrobials

Although topical antimicrobials are commonly used in pressure ulcer treatment, we found few studies in the post-1985 time frame comparing antimicrobials to placebos or other interventions. The three studies we identified evaluated different antimicrobial formulations and provided insufficient evidence to draw conclusions about effectiveness. One poor-quality trial[124] found similar time to stage II ulcer healing with a triple antibiotic ointment compared with a hydrocolloid dressing (54 vs. 52 days), but inferior to topical phenytoin (35 days) (see Table 18). A poor-quality trial[130] with stage I and II ulcers found more complete healing over 4 weeks with oxyquinoline ointment compared with A&D ointment, though this benefit was seen only with stage II ulcers (45 percent vs. 22 percent). A fair-quality trial[131] found no significant differences in ulcer healing when comparing silver sulfadiazine cream to a silver mesh dressing (Table 21).

Table 21. Local wound applications: Topical therapies – *antimicrobials*

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Wound Applications Compared	Outcomes Measured and Treatment Effect	Benefit: Wound Improvement
Chuangsuwa-nich 2011[131] Trial Fair N=40/40 Hospital	II or IV	66 years (NR) Female: 58% Mixed (inpatients and outpatients)	8 weeks	A: Silver mesh dressing B: Silver sulfadiazine cream	Complete wound healing: NR Wound surface area at 8 weeks: A: 7.96 cm^2 B: 18.22 cm^2 (p=0.09) Healing rate: A: 37% B: 25% (p=0.51) Harms: NR	~
Gerding 1992[130] Trial Poor N=74/74 Nursing facility	I or II (Shea)	Age: NR Female: NR Population: frail, elderly, chronically ill	28 days or until wound resolution	A: Oxyquinoline-containing ointment (DermaMend) B: Vitamin A&D ointment	Complete wound healing: A: Stage I: 58.5% Stage II: 44.5% B: Stage I: 57.1% Stage II: 21.8%, (p<0.03) Healing time (days to resolution): A: Stage I: 6.2 Stage II: 7.8 B: Stage I: 7.3 Stage II: 13.0 (p<0.05) Harms: NR	++

NPUAP = National Pressure Ulcer Advisory Panel; NR = not reported.

[a]Pressure ulcer stage indicates NPUAP staging unless otherwise noted. Non-NPUAP staging was converted to the equivalent NPUAP stage where possible.

++Complete wound healing.

+Some improvement in wound healing.

~No difference.

Maggot Therapy

Three poor-quality observational studies[132-134] evaluating maggot therapy for the debridement and healing of pressure ulcers provide insufficient evidence regarding the effectiveness of this treatment due to poor study quality. All studies found benefits for maggot therapy, including greater wound area reduction[132,133] and faster time to complete wound healing,[134] when comparing healing in patients receiving maggot therapy either to healing during a period of usual care before maggot therapy was implemented, or to patients not receiving maggot therapy. None of the studies adequately accounted for selection bias or potential confounders.

Table 22. Local wound applications: Topical therapies – *maggot therapy*

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Wound Applications Compared	Outcomes Measured and Treatment Effect	Benefit: Wound Improve-ment
Sherman 1995[132] Observational Poor N=8/8 Setting NR	II-IV	58 years (44-68) Female: 0% Spinal cord injury	3 to 4 weeks	A: Maggot therapy B: Usual care (premaggot therapy)	Wound surface area: A: 22% reduction B: 22% increase (p<0.001) Harms: No infection or discomfort with maggot therapy	+
Sherman 2002[133] Observational Poor N=103/67 Hospital	III-IV	64 years (26-91) Female: NR General	2 to 19 weeks	A: Maggot therapy B: Usual care	Complete wound healing: A: 39% B: 21% (p=0.058) Wound surface area: A: 33% reduction B: 45% increase (p<0.05) Harms: Pain reported in 2 of 50 patients treated with maggots.	+
Wang 2010[134] Observational Poor N=18/18 Hospital	NR	48 years (32-55) Female: 33% spinal cord injury	2 to 6 months	A: Maggot therapy B: Usual care	Time to complete wound healing: A: 19 days B: 31 days (p=0.04) Harms: NR	+

NPUAP = National Pressure Ulcer Advisory Panel; NR = not reported

[a]Pressure ulcer stage indicates NPUAP staging unless otherwise noted. Non-NPUAP staging was converted to the equivalent NPUAP stage where possible.

++Complete wound healing.

+Some improvement in wound healing.

~No difference.

Other

Several topical therapies were evaluated in single trials that provided insufficient evidence to draw conclusions about effectiveness. One poor-quality trial[135] found more complete wound healing over 6 months in 22 patients treated with resin salve compared with a hydrocolloid

dressing (92 percent vs. 44 percent). A fair-quality trial found greater wound area reduction with a combination of a zinc-based ointment and vitamin A-based spray (Dermagran) compared with either the ointment or spray alone, or to placebo (91 percent vs. 26 percent vs. 7 percent vs. 5 percent), in stage I-IV ulcers over 6 weeks.[136] We identified several single-study evaluations of plant-derived and other nonpharmaceutical topical treatments,[137-140] but all were small and poor quality. Similarly, evaluations of hyaluronate[141] and ketanserin[142] were limited to single, poor-quality trials, and evaluation of hydrogenated castor oil, and balsam peru castor oil trypsin (BCT) ointment[143] was limited to a single, retrospective cohort study.

Table 23. Local wound applications: Topical therapies – plant-derived and other **nonpharmaceutical treatments**

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Wound Applications Compared	Outcomes Measured and Treatment Effect	Benefit: Wound Improvement
Felzani 2011[141] Trial Poor N=59/50 Hospital	(EPUAP I-III)	56 years (NR) Female: 58% Inpatients	15 days	A: Lysine hyaluronate acid B: Sodium hyaluronate acid	Complete wound healing: Stage I (n=20) A: 90% B: 70% (p<0.05) Stage II (n=20) A: 70% B: 40% (p<0.02) Stage III (n=10; 14 ulcers) A: 71% B: 29% (p<0.01) Harms: NR	**++ (lysine superior)**
Guthrie 1989[136] Trial Fair N=128/105 Nursing facility	I-IV (Shea I-IV)	78 years (NR) Female: 81% Population: general	6 weeks	A: Dermagran spray B: Dermagran ointment C: Dermagran spray + ointment D: Placebo	Wound area reduction: A: 7% B: 26% C: 91% D: 5% (p<0.05) Harms: None	**+**
Hsu 2000[140] Trial Poor N=32/32 Hospital	Grade 2 or higher (Shea)	72 years (NR) Female: 59% Mixed, general, dementia, spinal cord injury	3 weeks	A: Sheng-Ji-San formula and routine medical care B: Routine medical care	Complete wound healing: A: 1/24 (4%) B: 0/8 Change in wound surface area: A: -33.8% (p<0.005) B: +2.9% (NS; p-value NR) Harms: NR	~
Kuflik 2001[137] Trial Poor N=19/18 NR	I, II	Age: NR Female: NR Elderly, immobile	6 weeks	A: Resurfix ointment B: Petrolatum ointment	Complete wound healing: A: 50% B: 22% (p-value NR) Harms: None	~

Table 23. Local wound applications: Topical therapies – plant-derived and other nonpharmaceutical treatments (continued)

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Wound Applications Compared	Outcomes Measured and Treatment Effect	Benefit: Wound Improvement
LeVasseur 1991[138] Trial Poor N=34/21 Hospital and nursing facility	I, II (Shea)	82 years (NR) Female: 52% Elderly	6 weeks	A: F14001 (active based cream) B: Placebo (nonactive based cream)	Complete wound healing: NR (unclear) Healing time A: 18 days B: 29 days (p=0.08) Significant reduction in ulcer size in both groups but no difference between groups. Harms: NR	~
Narayanan 2005[143] Observational Fair N=861/861 Nursing facility	I and II	10% under 60 years; 10% 60-69 years; 22% 70-79 years; 36% 80-89 years; 21% 90 years or older Female: 67% General	4 weeks	A: BCT ointment (hydrogenated castor oil and trypsin) B: BCT ointment + other C: Other (includes another topical wound dressing or prescriptive product)	Complete wound healing, adjusted (95% CI) A: 58.6% (45.8 to 71.4) B: 42.8% (35.0 to 50.7) C: 37.1% (33.2 to 41.0) (p<0.05 for A vs. B or C) Findings similar, but NS, when Stage I or II ulcers analyzed separately. Harms: NR	++
Shamimi Nouri 2008[139] Trial Poor N=18/18 Hospital	NR	47 years (NR) Female: 22% Mixed, inpatients	2 months	A: Topical semelil B: Conventional treatment	Wound area reduction: A: 78.3% B: 6.3% (p<0.001) Harms: None	+

Table 23. Local wound applications: Topical therapies – plant-derived and other nonpharmaceutical treatments (continued)

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Wound Applications Compared	Outcomes Measured and Treatment Effect	Benefit: Wound Improvement
Sipponen 2008[135] Trial Poor N=37/22 Hospital	(Grade system NR: II-IV)	77 years (58-98) Female: 59% General	6 months	A: Resin Salve (Norway spruce) B: Hydrofiber bandage	Complete wound healing: A: 92% B: 44% (p=0.003) Harms: MRSA (1 patient in each group)	++
Tytgat 1988[142] Trial Poor N=16/16 NR	NR	59 years (36-75) Female: 50% Multiple sclerosis	3 weeks	A: Ketanserin 2% B: Placebo	Reduction in wound area: A: 81% B: 16% ("significant", p-value NR) Harms: None	+

MRSA = methicillin-resistant Staphylococcus aureus; NPUAP = National Pressure Ulcer Advisory Panel; NR = not reported; NS = not significant

[a]Pressure ulcer stage indicates NPUAP staging unless otherwise noted. Non-NPUAP staging was converted to the equivalent NPUAP stage where possible.

++Complete wound healing.

+Some improvement in wound healing.

~No difference.

Biological Agents

Comparisons of different biological agents are described below and in Tables 24-26.

Platelet-Derived Growth Factor

Four studies (one fair, three poor) compared platelet-derived growth factor (PDGF) or platelet gel compared with placebo and provided evidence of better wound improvement with PDGF for stage III and IV ulcers. One fair-quality trial[144]comparing PDGF to placebo in stage III and IV ulcers found higher rates of complete wound healing over 16 weeks (23 percent vs. 0 percent). A poor-quality trial found greater wound depth reduction over 4 weeks (86 percent vs. 65 percent) with PDGF.[145,146] One poor-quality trial[147] found better ulcer volume reduction (71 percent vs. 17 percent), but no significant difference in complete wound healing (38 percent vs. 14 percent) with PDGF. Comparison of different doses indicated that 100 mcg/g per day produced similar or better results than higher or lower doses. A poor-quality trial of platelet gel for stage III and IV ulcers showed no significant difference in ulcer volume reduction over 14 weeks compared with usual care with alginate or topical antimicrobials.[148]

Table 24. Local wound applications: Biological agents – *platelet-derived growth factor*

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Wound Applications Compared	Outcome Measures and Treatment Effects	Benefit: Wound Improvement
Mustoe 1994[147] Trial Poor N=52/41 Nursing facility, hospitals	III, IV	72 years (NR) Female: 66% Elderly	28 days (5-month followup)	PDGF spray A: 100 μg/mL 1x daily B: 300 μg/mL 1x daily C: Placebo	Complete wound healing at 5 months: A: 38% B: 21% C:14% (NS; p-value NR) Wound volume reduction at 4 weeks: A: 71% B: 2 6%; C: 17% (p=0.056) Harms (1 event each): tunneling of ulcer, exuberant granulation tissue, erythema with purulent drainage in A; infection in B.	+
Rees 1999[144] Trial Fair N=124/124 Multi-center	III, IV	49 years (NR) Female: 16% General	16 weeks	PDGF (Becaplermin gel) A:100 μg/g 1x daily + placebo 1x daily B: 300 μg/g 1x daily + placebo 1x daily C: 100 μg/g 2x daily D: Placebo 2x daily	Complete wound healing: A: (23%, B: (19%) C: (3%) D: (0%) (p=0.005 and 0.008 for A and B vs. placebo) 90% wound healing significant for A and B vs. placebo (p=.0021 and 0.014) Harms: Similar in all groups (worsening ulcer, infection, sepsis)	++

Table 24. Local wound applications: Biological agents – *platelet-derived growth factor* (continued)

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Wound Applications Compared	Outcome Measures and Treatment Effects	Benefit: Wound Improvement
Robson 1992a;[146] Robson 1992b[145] Trial Poor N=20/20 Hospital	III, IV	33 (22-35) years Female: NR Spinal cord injury	28 treatment days (29 day trial)	A: Platelet derived recombinant growth factor BB (rPDGF-BB) 1 µg/ml 1x daily B: rPDGF-BB10 µg/ml 1x daily, C: 100 µg/ml rPDGF-BB 1x daily D: Placebo	Complete wound healing: NR Ulcer depth reduction: C:14.1% of day 0 depth D:34.9% of day 0 depth (p<0.05) Wound volume reduction: C: (6.4% of day 0 volume) D: 21.8% of day 0 volume (p=0.16) Harms: None	+
Scevola 2010[148] Trial Poor N=13/11 Hospital	III, IV	NR Female: 23% Spinal cord injury	14 weeks	A: Allogeneic platelet gel 2x weekly for 8 weeks B: Usual care (iodine or alginate + zinc oxide or silver sulfadiazine)	No significant differences in ulcer volume reduction (p=0.76) or infection (p-value NR). Harms: None (HCV, HBV, HIV infection) observed	~

HBV = hepatitis B virus; HCV = hepatitis C virus; NPUAP = National Pressure Ulcer Advisory Panel; NR = not reported; NS = not significant; PDGF = platelet-derived growth factor

[a]Pressure ulcer stage indicates NPUAP staging unless otherwise noted. Non-NPUAP staging was converted to the equivalent NPUAP stage where possible.

++Complete wound healing.

+Some improvement in wound healing.

~No difference.

Other Growth Factors

Other growth factors were evaluated in single studies that provided insufficient evidence to draw conclusions about effectiveness. A good-quality trial found better complete wound healing in stage II, III, and IV ulcers with nerve growth factor compared with placebo (44 percent vs. 6 percent) over 14 weeks.[149] A good-quality trial comparing a fibroblast-derived dermal replacement system (Dermagraft) to no dermal replacement found no significant difference in complete wound healing (11 percent vs. 13 percent), ulcer area or volume reduction, or wound infection in stage III ulcers over 24 weeks.[150] A poor-quality trial of fibroblast growth factor did find better partial (> 70 percent) wound healing compared with placebo (60 percent vs. 29 percent) in stage III and IV ulcers over 1 month.[151] Another poor-quality trial found no significant difference in complete wound healing (75 percent vs. 71 percent) or ulcer volume reduction with fibroblast growth factor compared with placebo. Studies of TGF-beta and GM-CSF were limited to single, poor-quality studies.[152-154] A poor-quality trial comparing varying

doses of interleukin 1β to placebo found no differences in wound volume reduction over 29 days.[155]

Table 25. Local wound applications: Biological agents – *other growth factors*

Author Year Quality Study Type Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Wound Applications Compared	Outcome Measures and Treatment Effects	Benefit: Wound Improvement
Hirshberg 2001[152] Trial Poor N=14/8 Wound care clinic	III, IV	44 years (NR) Female: 43% General	16 weeks	TGF-beta gel A:1.0 µg/cm^2 1x daily B: 2.5 µg/cm^2 1x daily C: Placebo gel 1x daily	No significant differences in ulcer size, volume, or closure. Harms: NR	~
Landi 2003[149] Trial Good N=38/36 Nursing facility	II, III, IV	80 years (73-93) years Female: 72% General	6 weeks	A: Nerve growth factor (murine) 1x daily B: Placebo 1x daily	Complete wound healing: A: 44% B: 6% (p=0.009) Ulcer area reduction: A: 73% B: 48% (p=0.022) Harms: None	**++**
Payne 2004[150] Trial Good N=34/10 (34 analyzed) Multi-center	III	69 years (NR) Female: 32% General	24 weeks	A: Fibroblast-derived dermal replacement (Dermagraft) up to 2x weekly and conventional therapy B: Conventional therapy with no dermal replacement	Complete wound healing (week 24): A: 11% B: 13% (NS; p-value NR) Ulcer area reduction (week 12): A: 50% B: 34% (NS; p-value NR) Ulcer volume reduction (at study discontinuation) : A: 41% B: 17% (NS; p-value NR) Wound infections: A: 17% B: 19% (NS; p-value NR) Harms: Similar adverse event rates in A (42%) vs. B (58%).	~

Table 25. Local wound applications: Biological agents – *other growth factors* (continued)

Author Year Quality Study Type Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Wound Applications Compared	Outcome Measures and Treatment Effects	Benefit: Wound Improvement
Robson 1992c[151] Trial Poor N=50/49 Hospital	III, IV	38 years (NR) Female 20% Spinal cord injury	30 days	A: Recombinant basic fibroblast growth factor (bFGF) 1 µg/cm^{2}1x daily B: bFGF 10 µg/cm^2 1x daily C: bFGF 5 µg/cm^2 1x daily D: Placebo 1x daily	Complete wound healing: NR > 70% decrease in wound volume: A,B,C: 60% D: 29% (p<0.05) No significant differences between different bFGF dosage groups. Harms: None	+
Robson 1994[155] Trial Poor N=26/24 Hospital	III, IV	NR (18 and over) Female: NR Spinal cord pathology	29 days	A: Interleukin 1β (IL-1β) 0.01 µg/cm^2/day B: IL-1β 0.1 µg/cm^2/day C: IL-1β 1.0 µg/cm^2/day D: Placebo	Wound volume reduction: No significant differences across comparison groups. Harms: NR	~
Robson 2000;[153] Payne 2001[154] Trial Poor N=61/61 Hospital	III, IV	50 years (NR) Female: NR Spinal cord injury	35 days (1 year followup)	A: GM-CSF 1x daily B: bFGF 1x daily C: GM-CSF 1x daily for 10 days, then bFGF 1x daily for 25 days D: Placebo 1x daily	Complete wound healing at 35 days: A: 67% B: 75% C: 68% D: 71% (p=0.69) Complete wound healing at 1 year: NS >85% healing at 35 days (p-value vs. placebo): Any cytokine therapy: p=0.03 A: p=0.22 B: p=0.02 C: p=0.10 Ulcer volume reduction: A: 63% B: 75% C: 68% D: 71% (NS) Harms: NR	~

bFGF = basic fibroblast growth factor; GM-CSF = granulocyte-macrophage colony-stimulating factor; TGF- beta = transforming growth factor beta; NPUAP = National Pressure Ulcer Advisory Panel; NR = not reported; NS = not significant

[a]Pressure ulcer stage indicates NPUAP staging unless otherwise noted. Non-NPUAP staging was converted to the equivalent NPUAP stage where possible.

++Complete wound healing.

+Some improvement in wound healing.

~No difference.

Macrophage Suspension

Two poor-quality cohort studies provided insufficient evidence to judge the effectiveness of macrophage suspensions in the treatment of pressure ulcers (see Table 26). One study comparing injected macrophage suspension to standard care (as prescribed by a wound care team) for stage III and IV ulcers found more complete wound healing in the macrophage-treated group (70 percent vs. 13 percent) with a median healing time of 87 days.[156] The other poor-quality cohort study also found more complete wound healing (27 percent vs. 6 percent) with macrophage treatment compared with usual care over 12 months.[157]

Table 26. Local wound applications: Biological agents – *macrophage suspensions*

Author Year Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Wound Applications Compared	Outcome Measures and Treatment Effects	Benefit: Wound Improvement
Danon 1997[157] Observational Poor N=199/199 Hospital	All stages	80 years (NR) Female: 53% Elderly	12 months	A: Macrophages (1x application) B: Usual care (variable dressings and topical applications)	Complete wound healing: A: 27% B: 6% (p<0.001) Harms: NR	++
Zuloff-Shani 2010[156] Observational Poor N=104/100 Hospital	III, IV (EPUAP	78 years (NR) Female: 56% Elderly	12 months	A: Activated macrophage suspension (AMS) as needed according to wound condition B: Standard of care	Complete wound healing (all patients): A: 70% B: 13% (p<0.001) Complete wound healing (leg ulcer subset): A: 70% B: 18% (p<0.001) No significant difference in healing time between treatments. Harms: None	++

NPUAP = National Pressure Ulcer Advisory Panel; NR = not reported

[a]Pressure ulcer stage indicates NPUAP staging unless otherwise noted. Non-NPUAP staging was converted to the equivalent NPUAP stage where possible.

++Complete wound healing.

+Some improvement in wound healing.

~No difference.

Evidence About the Comparative Effectiveness of Local Wound Applications by Subgroup-Analysis (Key Question 1a, 1b, and 1c)

Few studies conducted subgroup analyses by ulcer characteristics. A fair-quality trial of transparent MVP dressings found that the benefit of those dressings over gauze in patients with stage III ulcers was seen only in the less severe ulcers within that stage.[89] A good-quality study demonstrated better outcomes with hydrocolloid compared with gauze for gluteal and ischial, but not sacral ulcers.[72] In that same study, hydrocolloid was superior to phenytoin in stage I but not

stage II ulcers, and in gluteal but not other ulcers.[72] Another fair-quality study found faster healing with phenytoin compared with hydrocolloid in stage II ulcers. A fair-quality study found that the benefit of radiant heat dressings compared with standard care, in terms of rate of healing, was more prominent with larger (> 5 cm^2) wounds.[111] Another fair-quality trial found that the benefit of radiant heat over other dressings was observed for both stage III and IV ulcers.[158] A poor-quality study found that the benefit of oxyquinoline ointment over A&D ointment was seen in stage II but not stage I ulcers[130]

A poor-quality study comparing macrophage treatment to standard care found similar benefits for macrophage treatment in the entire study sample, those with diabetes, and those with ulcers of the leg compared with other locations.[156]

Indirect comparisons across studies to evaluate the possibility that treatment effectiveness is modified by ulcer, patient, or setting characteristics are limited by the fact that there were relatively few studies evaluating any given treatment comparison and by the fact that aside from ulcer stage and location, patient age and gender, and study setting, few variables were reported consistently across studies. In the 10 studies comparing hydrocolloid with gauze dressings, there was no clear pattern to suggest variation in findings by ulcer, patient, or setting characteristics. The same is true for other treatment comparisons, all of which had fewer studies.

Local Wound Applications: Harms (Key Question 2)

Harms of local wound applications for pressure ulcers were measured in 36 studies. Since most studies were small, the rates of harms reported in studies that did measure them and statistical comparisons of harms across treatment groups were not reported. Harms commonly measured and reported included skin irritation and inflammation, as well as tissue damage and maceration. Commonly measured, but infrequently occurring, harms included infection, pain, bleeding, tissue overgranulation, and wound deterioration.

Wound Dressings

Hydrocolloid

Harms were measured in 14 studies evaluating hydrocolloid dressings in samples ranging from 7 to 199 patients.[73,75,79,92,93,98,99,103,105,114,117,127,159,160] Commonly reported harms included skin reactions (inflammation, erythema), maceration, pain, wound deterioration, and overgranulation, with rates of harms ranging from 0 to 16 percent. In a fair-quality study comparing a triangular with oval hydrocolloid dressing in 96 patients, wound deterioration and skin reactions were observed in 4 percent with the triangular dressing and 31 percent with the oval dressing over 10 days.[92]

Hydrogel

Harms measured in five studies of hydrogel dressings in samples ranging from 10 to 135 patients[79,84,85,93,126] occurred in 0 to 12 percent of patients and included skin irritation and wound deterioration.

Foam

Harms of foam dressings measured in four trials (five publications) with sample sizes ranging from 40 to 199 patients[76,98,99,103,107] occurred in 1 to 30 percent and included bleeding, overgranulation, wound deterioration, maceration, and tissue damage. A large, poor-quality

cohort study of 1,891 patients with 3,969 ulcers reported a 3 percent infection rate and less than 1 percent rate of skin stripping with foam dressings.[108]

Transparent Film

Harms were measured for transparent film dressings in two studies with sample sizes ranging from 72 to 77 patients.[89,95] One study reported no harms[95] while the other reported a 14 percent rate of wound deterioration.[89]

Alginate

Harms of alginate dressings measured in four studies with sample sizes ranging from 7 to 110 patients[105,106,110,125,161] occurred in 0 to 11 percent of patients and included infection, overgranulation, skin irritation, maceration, bleeding, and wound deterioration.

Silicone

In a large poor-quality cohort study of 1,891 patients with 3,969 ulcers, infections were reported in 9 percent of patients and skin stripping occurred in 2 percent of patients managed with silicone dressings.[108]

Radiant Heat

One study including 50 patients reported on skin condition after use of radiant heat dressings.[110] Inflammation occurred in 11 percent and maceration in 4 percent, though similar rates were observed with the use of alginate dressings in that study.

Comparative Harms

In most studies reporting harms of dressings, rates were qualitatively similar between treatment arms; most studies were small and did not report statistical testing of differences in harms. A poor-quality study comparing hydrocolloid with hydrogel in 90 patients reported wound deterioration in 10 percent and 1.5 percent respectively,[93] although another poor-quality study reported similar rates of skin complications comparing hydrocolloid to hydrogel dressings (12 percent vs. 14 percent).[79] A poor-quality study with 40 patients found no harms with hydrocolloid but six adverse outcomes among 20 patients (30 percent) with a polyurethane foam dressing.[99] However, a fair-quality study with 40 patients found similar rates of harms (0.5 to 1 percent) comparing a hydrocolloid with a hydrocellular foam dressing.[98] A fair-quality trial with 38 patients found more tissue damage and maceration with a polymeric foam dressing compared with a silicone dressing.[107] However, a large cohort study with 1891 patients found no significant differences in infection or skin stripping with foam compared with silicone.[108] A study of radiant heat compared with alginate dressings found no significant differences in skin complications.[110]

Topical Therapies

Enzymes

One good-quality, one fair-quality, and one poor-quality study evaluating collagenase with sample sizes ranging from 37 to 135 patients reported harms – primarily pain, skin inflammation and necrosis – in 0 to 6 percent of patients.[117,120,162] Harms occurred at the same rate in a study comparing collagenase applied every 24 hours with every 48 hours.[118] A single, fair-quality study evaluating fibrinolysin plus DNAase found no harms attributable to the treatment.[119] A

poor-quality study reported discontinuation of topical streptokinase/streptodornase in 3 of 14 patients due to skin reactions, necrosis, or infection.[122]

Phenytoin

One good-quality and one poor-quality study including a total of 71 patients reported no adverse effects from topical phenytoin.[123,124]

Dextranomer

In a good-quality trial with 92 patients,[125] harms occurred in 22 percent of patients treated with dextranomer paste and included infection, bleeding, overgranulation, and skin irritation, though most adverse reactions were considered minor and did not necessitate stopping treatment.

Collagen

One good-quality and one poor-quality study with 145 patients reported no adverse events with topical collagen.[127,129]

Antimicrobials

A fair-quality trial with 45 patients[124] found no adverse events associated with triple antibiotic ointment. A poor-quality series[163] reported no adverse effects of silver sulfadiazine cream in 21 patients.

Biological Agents

Platelet-Derived Growth Factor

One fair-quality and one poor-quality study with 137 patients reported on harms (systemic or local infection, or worsening ulcer) of PDGF and platelet gel and found no significant differences compared with placebo.[144,148]

Other Growth Factors

No systemic or local harms were observed in a good-quality study of nerve growth factor with 37 patients.[149] No significant differences were found in overall adverse events in a study of 34 patients comparing fibroblast-derived dermal replacement with usual care.[150] Harms were not measured in studies of other growth factors.

Macrophage Suspension

A poor-quality cohort study of macrophage suspension including 100 patients reported no adverse events attributable to treatment.[156]

Evidence About the Harms Related to Local Wound Applications by Subgroups According to Pressure Ulcer Characteristics (Key Question 2a), Patient Characteristics (Key Question 2b), or Setting (Key Question 2c)

No studies reported subgroup analyses to evaluate harms by ulcer, patient, or setting characteristics. Indirect comparisons across studies to evaluate differential rates of harm by ulcer, patient, or setting characteristics were not possible due to the inconsistency of harm reporting and the infrequent occurrence of specific adverse events.

Effectiveness of *Surgery*

Pressure ulcers that have progressed to advanced stages often become chronic and do not completely heal with conservative measures. Surgical debridement and vascularized soft-tissue reconstructions are commonly used when nonhealing is observed or the wound has progressed to an advanced stage despite appropriate conservative management. Frail and debilitated elders and patients with sensory and motor deficits are at greatest risk for developing such advanced grade pressure ulcers. Surgical intervention is generally conducted by plastic and reconstructive surgeons and range from local debridement of necrotic and nonviable tissue in the wound bed to direct closure, skin grafting, and closure with soft tissue flaps. The flap is a section of soft tissue that is placed over the open wound and may be harvested from skin (cutaneous), fascia (fasciocutaneous), or muscle (myocutaneous) from nonaffected parts of the body. Direct closure is rarely indicated due to high risk of failure from increased tension at the closure site.[164] Skin grafting is generally used for shallow nonhealing ulcers that have a well-vascularized wound bed. This procedure is also rarely used due to high risk of failure from mechanical strain.[164] Most commonly, soft tissue flaps are harvested and used to surgically close the wound. Ideally, the tissue chosen should have adequate blood supply for healing and adequate thickness to meet the need of the surgical site.[164]

Description of Studies

To determine the effectiveness of surgery in the treatment of pressure ulcers we included controlled trials, observational studies with at least two comparative groups, and intervention series if the population was large and the study was conducted at multiple sites. We found one poor-quality trial[165] and one fair-quality retrospective intervention series that met our inclusion criteria.[166] Given the paucity of evidence, we expanded our inclusion to retrospective series from a single site if the population was large and provided comparative data. We found an additional three fair-quality studies, one with two publications.[167-170] The total number of included studies was five, including one trial and four observational studies.

Details extracted from intervention series studies are included in Table 27 and the trial details are included in the evidence tables (see Appendix H, Table H-7). The assessments of the quality rating criteria used for each study are provided in Appendix H, Table H-8.

The single trial was small (n=60), whereas on average the retrospective studies were of moderate size, ranging from 59 to 201 patients and accounting for 69 to 380 pressure ulcers. The retrospective studies ranged from 5 to 20 years of followup.

The *populations* in studies of surgical interventions for pressure ulcers included elderly nursing home patients and spinal cord injured or neurologically impaired younger adults (mean ages 34-50). All studies enrolled patients with advanced pressure ulcers, stage III or IV NPUAP equivalent.

The *intervention* for all patients was some form of surgical repair of the pressure ulcer, either through primary closure, or soft tissue flap (cutaneous, fasciocutaneous, or myocutaneous). The one trial compared the use of CO_2 laser with knife or electric knife for wound closure by local transposition of tissue or skin graft.[165] One study only considered patients with ischial pressure ulcers.[170] For other intervention series, different approaches were compared.

The *outcomes* for the trial were operative time, blood loss, infection rate, hospitalization days, and failure rate.[165] The outcomes for intervention series were wound healing, recurrence rates.

The harms for intervention series studies included wound dehiscence, infection, reoperative rates, and other complications of the surgery.

The *settings* were hospitals or rehabilitation centers. The single trial was conducted in Argentina. The intervention series were from the United States, Canada, Australia, and Japan.

Key Points

- Evidence was inconclusive to determine if one approach to closure of stage III to IV pressure ulcers is superior to another due to quality of the studies and heterogeneity in patient populations and surgical procedures (strength of evidence: insufficient).
- Sacral pressure ulcers have lower recurrence rates after surgery than ischial pressure ulcers (strength of evidence: low).
- Spinal cord injured patients had higher rates of recurrent pressure ulcer after surgical flap closure than other patients with pressure ulcers (strength of evidence: low).
- Reoperation due to recurrence or flap failure ranged from 12 to 24 percent (strength of evidence: low).
- Wound dehiscence is more common if bone is removed at time of surgical procedure (strength of evidence: low).
- Complication rates after surgery are higher for ischial ulcers than for sacral or trochanteric ulcers (strength of evidence: low).

Detailed Analysis

Evidence About the Comparative Effectiveness of Surgery (Key Question 1)

Determining the effectiveness of surgical techniques for treatment of pressure ulcers was limited to poor-quality intervention series. One poor-quality trial and four fair-quality intervention series including a total of 620 patients accounting for 1,057 pressure ulcers provided evidence on the effectiveness of surgical techniques to treat stage III or IV pressure ulcers. Overall sacral pressure ulcers have lower recurrence rates than ischial pressure ulcers and spinal cord injured patients are at the greatest risk of recurrence. Evidence is inconclusive to determine optimal types of soft tissue flap or how this might vary depending on the anatomical site of the pressure ulcer.

We found only one, poor-quality randomized trial (n=60) comparing one surgical technique with another.[165] CO_2 laser was compared with knife or electric knife for wound closure by local transposition of tissue or skin graft.[165] The study reported significant reduction in operative blood loss (2.1 +/- 0.1 cm^3/cm^2 vs. 2.6 +/- 0.1 cm^3/cm^2), operative time (39+/-5 minutes vs. 45 +/- 7 minutes), hospital days (68 percent fewer days), and infection rate (11/30, 37 percent vs. 14/30, 47 percent) with laser surgery. Although the study was poor quality, it suggested a laser knife may be superior to standard wound closure. Further studies would be needed to determine if this is accurate.

We found five retrospective series, all rated fair quality, evaluating long-term results of surgeries performed for patients with advanced (primarily stage III-IV) pressure ulcers (n=560, nPU=997).[166-170] Two were conducted at multiple sites[166,167] and two were conducted at single sites.[168-170] The combined results provide low strength of evidence that sacral pressure ulcers have lower recurrence rates than ischial pressure ulcers and insufficient evidence to determine optimal surgical procedure.

The smallest retrospective series (n=53, nPU=69) conducted in Japan analyzed outcomes of paraplegic patients, mean age 50 years, treated with fasciocutaneous or myocutaneous flaps over an average followup period of 44 months.[167] It was unclear if the study included all surgically treated patients with ischial or sacral pressure ulcers during the five years of chart review.[167] There was a trend toward greater recurrence rate in ischial compared with sacral pressure ulcers (50 percent vs. 70 percent) and toward better 36-month pressure ulcer free survival rates with fasciocutaneous compared with myocutaneous flaps (68 percent vs. 43 percent), although the difference was not significant.

Two of the three larger retrospective studies reported on recurrence rate and found overall pressure ulcer recurrence rates of 19 percent[166] and 33 percent.[168] The publication by Kierney, et al. was a retrospective study of patients from two centers treated with surgical repair of stage III or IV pressure ulcers between October 1977 and December 1989. They reported on 158 patients with 268 pressure ulcers, mean age 35 years, with mean followup of 3.7 years. They found that cutaneous flaps had the highest recurrence (12/44, 27 percent), compared with fasciocutaneous (8/54, 15 percent) and myocutaneous flaps (13/99, 13 percent).[166] Sacral sites had the least recurrence (8/69, 12 percent) with similar recurrence rates in ischial and trochanteric sites (32/15, 21 percent and 11/49, 22 percent respectively).[166]

Schryvers, et al. conducted a single center retrospective study of patients treated with surgical repair of stage III to IV pressure ulcers between 1976 and 1996, with mean followup of 5.3 years for patients with more than three ulcers and 9.3 years for patients with one ulcer.[168] They reported 380 pressure ulcers in 148 patients, mean age 41 years (range: 16-91). The overall ulcer recurrence rate was 33 percent, greatest with ischial ulcers (84/249, 34 percent). Trochanteric ulcers were the slowest to heal (97-105.6 days). Time to complete healing was similar between the different surgical procedures (primary closure 52-97 days, fasciocutaneous flap 52-100 days, myocutaneous 44-105 days).

Foster, et al. evaluated fasciocutaneous and different types of myocutaneous flaps in 201 patients with 280 pressure ulcers, age 50 (range: 16-90), considered healing at 1 month to be flap success and reported overall flap success of 89 percent (248/280). In patients treated for ischial ulcers, they found that gluteal thigh (fasciocutaneous) and inferior gluteus maximus island (myocutaneous) flaps demonstrated the best healing at 93 and 94 percent while V-Y hamstring and tensor fascia latae flaps (both myocutaneous) had the least success at 58 and 50 percent respectively (Table 27).[169,170]

Table 27. Surgery: Comparative effectiveness of intervention series

Author Year Study Type Quality N Patients/nPU Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Surgical Intervention	Outcomes Measured[a] and Treatment Effect[a]
Foster 1997[170] Observational Fair N=87;/ nPU=112 Hospital	Stage III-IV ischial	49 years (16-90) Female: 26% General (90% spinal cord injury)	11 months (1 month to 9 years)	Myocutaneous flap Fascio-cutaneous flap	Healed wound by 1-month post surgery: inferior gluteus maximus island flap 32/34 (94%) vs. inferior gluteal thigh flap 25/27 (93%) vs. V-Y hamstring 7/12 (58%) vs. tensor fascia latae 6/12 (50%) Harms (n): Complications in 37%: Slight wound edge dehiscence (16); partial flap necrosis (10); wound infection (5); wound dehiscence requiring reoperation (5); aspiration pneumonia (1); intraoperative myocardial infarction (1); deep venous thrombosis (1)
Foster 1997[169] Observational Fair N=201/ nPU=280 Hospital	Stage III-IV pelvic and trochanteric	50 years (16-90) Female: 35% General (90% spinal cord injury)	12 months (1 month to 9 years)	Myocutaneous flap Fascio-cutaneous flap	Healed wound by 1-month post surgery) 248/280 (89%) Ischial: 94/113 (83%) Sacral: 86/94 (91%) Trochanter 68/73 (93%) Complications: Iscial: 47/113 (42%) Sacral: 19/94 (20%) Trochanter: 11/73 (15%)
Kierney1998[166] Observational Fair N=158/ nPU=268 Hospital	Stage III-IV pelvic and trochanteric	35 years (NR) Female: 22% General (84% spinal cord injury/spina bifida)	3.7 years (1 month to 15.5 years)	Primary closure split-thickness skin graft Cutaneous flap Limberg flap Fascio-cutaneous flap Myocutaneous flap Other	Recurrence rates: Overall patient: 25% Overall pressure ulcer: 19% Sacral: 12% Ischial: 21%, Trochanter: 22% FLAPS: Cutaneous 12/44 (27%) Limberg 2/11 (18%) Fasciocutaneous 8/54 (15%) Myocutaneous 13/99 (13%) Spinal cord injured/spina bifida: 20-24% vs. others: 5% Harms: NR

Table 27. Surgery: Comparative effectiveness of intervention series (continued)

Author Year Study Type Quality N Patients/nPU Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Surgical Intervention	Outcomes Measured[a] and Treatment Effect[a]
Schryvers 2000[168] Observational Fair N=168/ nPU=598 Hospital	Stage III-IV (communicate with muscle, bone, or joint) pelvic and trochanteric	41 years (16-91) Female: 22% Spinal cord injury	1976-1996 (length of time from surgery to recurrence ranged from 2 months to 3 years)	Primary closure vs. fascio-cutaneous vs. myocutaneous flap closure	Complete healing , days from surgery: primary closure: n=65, 67.3 days cutaneous/fasciocutaneous: n=237, 59.1 days myocutaneous: n=86, 82.2 days Recurrence rates: Ischial 84/249 (34%) Sacral 24/82 (29%) Trochanteric 16/90 (18%) Complications: (suture line dehiscence) in 31% overall Ischial: 30% Sacral: 30% Trochanteric: 35% Primary closure: 25/75 (34%) Cutaneous flap: 66/253 (26%) Myocutaneous flap: 39/93 (42%)
Yamamoto 1997[167] Observational Fair N=53/ nPU=69 Hospital	NR pelvic	50 years (17-75) Female: 9% Paraplegic	3 years 6 months (range 4 months to 5 years 4 months)	Fascio-cutaneous vs. myocutaneous flap	Recurrence rates: Ischial: 22/45 (48.9%) fasciocutaneous 27.8% vs. myocutaneous 63% Sacral: 5/24 (20.8%) fasciocutaneous17.4% vs. myocutaneous 1/1 (100%) Percent PUFS: at 36 months: overall: sacral 70% vs. ischial 50% (p=0.28) Ischial: fasciocutaneous 67.5% vs. myocutaneous 42.5%, p=0.055 No comparison of sacral sores by muscle flap group due to small sample size Harms: NR

NPUAP = National Pressure Ulcer Advisory Panel; NR = not reported; PUFS = pressure ulcer free survival

[a]Pressure ulcer stage indicates NPUAP staging unless otherwise noted. Non-NPUAP staging was converted to the equivalent NPUAP stage where possible.

Evidence About the Comparative Effectiveness of Surgery by Subgroups According to Pressure Ulcer Characteristics (Key Question 1a)

Three retrospective studies considered site of ulcer as risk for recurrence and found that regardless of surgical repair technique, recurrence occurred more commonly in ischial pressure ulcers compared with sacral ulcers.[166-168] There was conflicting evidence on trochanteric ulcers with one study finding a similar recurrence rate as ischial ulcers (22 percent vs. 21 percent)[166] and one study finding a lower recurrence rate (18 percent vs. 34 percent).[168] Two studies reported on post-surgical healing with one finding that trochanteric surgeries were the slowest to heal[168] and one finding that healing at one month post-surgery was best for trochanteric ulcers (93 percent) compared with sacral or ischial ulcers (83 percent and 91 percent).[169] One study evaluating ischial pressure ulcers considered size of the wound at surgery[170] and found that smaller sized ulcers (average 59.6 cm^2) were less likely to be fully healed at 1 month compared with larger sized ulcers (average 82.9 cm^2). However, the authors were uncertain if this was related to sample size differences per group (21 vs. 91) or other risk factors for pressure ulcers. They noted that 71 percent of patients with small ulcers had more than one risk factor for pressure ulcers, but did not report this result for patients in the group with large ulcers.[169,170]

Evidence About the Comparative Effectiveness of Surgery by Subgroups According to Patient Characteristics (Key Question 1b)

Most studies enrolled neurologically compromised patients—primarily spinal cord injured through trauma, tumor, or congenitally— with the average age of 34 to 50 years. One study compared recurrence rates between patients with spinal cord impairment and other patients, and found no significant difference between paraplegia (38/160, 24 percent), quadriplegia (7/35, 20 percent), and spina bifida (3/13, 23 percent). However, spinal cord injured patients had a higher risk of recurrence compared with patients with multiple sclerosis (0/9, 0 percent) or other conditions causing immobility (3/51, 6 percent).[166]

Evidence About the Comparative Effectiveness of Surgery by Subgroups According to Settings (Key Question 1c)

One study (n=158, nPU=268) reported long-term data on pressure ulcer recurrence when surgical debridement and closure are supplemented with patient rehabilitation and education.[166] The investigators provided a complete perioperative rehabilitation program that included nutrition, social work, physical therapy, wheelchair and mechanical device maintenance, and detailed skin care education. Pressure ulcer recurrence rates were lower than similar long-term studies (19 percent vs. 33 percent to 39 percent), however no study directly compared patients who received this treatment with those who did not.

Surgery: Harms (Key Question 2)

Three retrospective observational studies, one with two publications, reported on harms associated with surgical techniques for the treatment of pressure ulcers.[168-171] One of the studies examined a subset of patients with ischial pressure ulcers also included in the larger study.[169,170] Two of the studies reported overall complication rate ranging from 28 to 37 percent.[168,169] The most common harm was wound dehiscence. One study (n=148, nPU=380) was a 20-year chart review of all patients treated at a single center with wound closure or flap procedure for advanced pressure ulcers.[168] The mean followup ranged from 5.3 years for those with more than three admissions to 9.3 years of followup for those with one admission. The overall dehiscence

rate was 31 percent. The type of procedure influenced the occurrence of wound dehiscence, with myocutaneous flaps causing the greatest incidence of dehiscence at each site (trochanter 17/43, 41 percent; sacral 5/7, 71 percent; ischial 17/43, 39 percent). Rates of dehiscence were higher when bone was excised due to osteomyelitis detected at surgery, most notably at the trochanteric (16/22, 73 percent) and sacral sites (8/14, 57 percent).[168] One 16-year chart review at a single center (n=201, nPU=280) also reported on wound dehiscence but separated those with slight dehiscence in which the wound had complete healing within 1 month of surgery and those with significant dehiscence that affected the ability for the wound to heal.[169] The review reported 10 percent slight dehiscence (27/280) and 3 percent significant dehiscence (9/280) but did not report analysis based on site or surgical procedure. A subset from this study of repairs to ischial pressure ulcers, the type most commonly associated with recurrence, were analyzed in a different report (n=87, nPU=112).[169] In this smaller cohort there was 14 percent slight dehiscence (16/112) and 4 percent significant dehiscence (5/112).[169] Partial flap necrosis was found in 10 patients (9 percent) who had myocutaneous flaps using tensor fascia latae, gracilis, or V-Y hamstring grafts.[169] Need for reoperation from the other studies ranged from 12 to 16 percent but these other studies did not analyze based on surgical intervention.[168,169] Other harms associated with primary closure or flap repair included osteomyelitis or infection (5 percent to 16 percent),[168,169] donor site graft loss (2 percent),[169] and one case each of intraoperative myocardial infarction, aspiration pneumonia, and deep vein thrombosis.[169]

In summary, there was moderate evidence that complications associated with primary closure or flap repair of advanced pelvic pressure ulcers are common, ranging from 28 to 37 percent, with wound dehiscence being the most common. Wound dehiscence may be more common if bone is removed at the time of surgery. Evidence was inconclusive to determine if one type of repair performs better or worse than another or how this is related to site of ulcer given the quality of the studies and the heterogeneity of the populations and surgical procedures. Reoperation due to recurrence or flap failure ranged from 12 to 24 percent.

Evidence About the Harms Related to Surgery by Subgroups According to Pressure Ulcer Characteristics (Key Question 2a), Patient Characteristics (Key Question 2b), or Setting (Key Question 2c)

All of the studies reporting on harms associated with surgical techniques for the treatment of pressure ulcers enrolled patients with advanced, stage III-IV, pressure ulcers with a scarcity of evidence on comparative features of the pressure ulcers. One study considered site of pressure ulcer and type of surgical procedure and found greater dehiscence at trochanteric sites (31/90, 35 percent) compared with sacral or ischial sites (25/82, 30 percent and 74/249, 30 percent respectively).[168] The study also considered dehiscence if bone was excised at the time of surgery (indicative of osteomyelitis), and found that rates of dehiscence were higher, most notably at the trochanteric (16/22, 73 percent) and sacral sites (8/14, 57 percent).[168] One study examining a subset of patients with ischial pressure ulcers found that the overall complication rate, as well as wound dehiscence and partial flap necrosis, were all greater than the overall population.[169,170]

No studies reported on differences in harms according to patient characteristics, patient care settings, or features of patient care settings.

Effectiveness of *Adjunctive Therapies*

Adjunctive therapies refer to pressure ulcer interventions used in addition to standard wound care, where standard care includes pressure relief and local wound applications. The term

adjunctive suggests that these are secondary treatments used to complement or enhance the effect of a primary therapeutic modality. Although many of the therapies described as adjunctive are used as standalone treatments, all are used in conjunction with standard wound care including dressings and standard pressure ulcer relief practices. We use the term adjunctive because it has become the standard label for this group of treatments among researchers and clinicians. Adjunctive therapies include electrical stimulation, electromagnetic therapy, light therapy, laser therapy, hydrotherapy, vibration, shock wave, and hyperbaric oxygen.

Description of Studies

We found six systematic reviews (SR) which were used only as background, 34 trials (three good-quality trials, 29 fair-quality trials, and two poor-quality trials), and five observational studies (two fair-quality and three poor-quality studies) evaluating adjunctive therapies that met our inclusion criteria. Poor-quality studies were considered only if there was a paucity of evidence from higher-quality studies and none met this requirement.[172-175]

Sample sizes in the trials ranged from 6 to 198 patients and study duration from 7 days to 16 weeks.

Details extracted from each study are included in the evidence tables (see Appendix H, Table H-9). The assessments of the quality rating criteria used for each study are provided in Appendix H, Table H-10.

The *populations* varied with many enrolling an elderly general population and others a younger neurologically compromised group. Sizes and stages of pressure ulcers varied across studies. (See Appendix C for NPUAP scale equivalents.)

Interventions included electrical stimulation (12 studies including one study with two publications, one SR), electromagnetic therapy (four studies, two SRs), therapeutic ultrasound (four studies, one SR), negative pressure wound therapy (five studies, two SRs), light therapy (six studies), laser therapy (three studies plus one direct study included in ultrasound), hydrotherapy (two studies), vibration (one study with two publications), shock wave therapy (one study), and hyperbaric oxygen (one study). Interventions varied in treatment dose, frequency, duration, and set up. All used standard wound care in conjunction with the adjunctive therapy.

The *comparator* was either sham treatment (placebo) or standard care.

The *outcomes* varied across studies, but most evaluated the percent change in wound surface area, complete wound healing, or time to healing as primary or secondary outcomes. Some studies used scales such as the Pressure Ulcer Scale for Healing (PUSH) and Pressure Sore Status Tool.[176]

Study *settings* included hospitals and rehabilitation centers, with fewer outpatient clinics and home health. The studies were conducted in the United States, Nigeria, India, Israel, Canada, Scandinavia, Serbia, Greece, Netherlands, and Switzerland.

Direct evidence comparing one intervention with another was limited. Our ability to derive indirect evidence from comparisons across studies was also limited due to variability in study population, design, outcomes measured, and sample size. Study data and the quality assessment of each study are presented in evidence tables (see Appendix H, Evidence Table H-10)

Key Points

Key Question 1

Electrical Stimulation

- Electrical stimulation was beneficial in accelerating the rate of healing of stage II, III, and IV pressure ulcers based on one good-quality and eight fair-quality randomized trials (strength of evidence: moderate).
- Evidence about the effect of electrical stimulation on complete wound healing was inconclusive due to heterogeneous findings across studies (strength of evidence: insufficient).

Electromagnetic Therapy

- Wound improvement of stage II, III, or IV pressure ulcers was similar with electromagnetic therapy compared to sham treatment based on four randomized trials. (strength of evidence: low).

Therapeutic Ultrasound

- Wound improvement was similar with ultrasound compared to standard care or sham treatment based on three randomized trials (strength of evidence: low).

Negative Pressure Wound Therapy

- Wound improvement was similar with negative pressure wound therapy compared to standard care over 4 to 6 weeks of therapy based on two randomized trials and one observational study (strength of evidence: low).

Light Therapy

- Light therapy was similar to sham light therapy in producing complete wound healing, based on two randomized trials (strength of evidence: low).
- Light therapy reduces wound surface area more than standard care or sham light therapy based on four randomized trials and one observational study (strength of evidence: low).

Laser Therapy

- Wound improvement was similar with laser therapy compared to sham treatment or standard care based on four randomized trials (strength of evidence: low).

Hydrotherapy

- Evidence on the effectiveness of hydrotherapy was insufficient based on two randomized trials evaluating different treatment modalities (one of whirlpool therapy and one of pulsatile lavage) (strength of evidence: insufficient)

Key Question 2

Harms of Adjunctive Therapies

- The most common adverse effect of electrical stimulation was local skin irritation (strength of evidence: low).
- There is a lack of studies evaluating harms of electromagnetic therapy, ultrasound, negative pressure wound therapy, and hydrotherapy.
- Light therapy caused no significant adverse events based on four randomized studies (strength of evidence: low).
- Short-term use of laser therapy caused no significant adverse events based on three randomized studies (strength of evidence: low).

Subgroups

- Frail elderly patients experience more adverse events with electrical stimulation compared with a younger population (strength of evidence: low).

Detailed Analysis

Evidence About the Comparative Effectiveness of Adjunctive Therapies (Key Question 1)

Electrical Stimulation

Electrical stimulation therapy is the delivery of direct electric current through the wound bed using surface electrodes. All equipment is designed to provide high-voltage pulsed currents with variable intensity (voltage) and frequency (pulses per second or Hz). The electrodes either surround the wound or one electrode is placed directly on the wound and a second placed at a distant site. Electrical stimulation is believed to promote cell growth and differentiation.

We found no direct evidence comparing electrical stimulation to other interventions for the treatment of pressure ulcers. Nine randomized trials, one good quality[177] and eight fair quality,[178-185] provided evidence regarding the effect of direct electrical stimulation compared with sham treatments. Overall, electrical stimulation increased the rate of healing in stage II, III, and IV pressure ulcers. However, the evidence was insufficient to determine its effect on complete wound healing, due to heterogeneity of findings across studies.

Sample sizes ranged from 7 to 80 patients, accounting for 16 to 192 pressure ulcers. Most were of a duration ranging from 20 days to 16 weeks. One 8-week study followed patients to day 147[179] whereas the rest did not follow patients beyond the study duration. Each study enrolled patients with different sizes and stages of pressure ulcers. One study did not report ulcer stage[181] and one reported ulcers as stage II or III but did not report the scale being used.[185] Age and comorbid conditions varied from young paraplegics to frail elders. Interventions varied in treatment dose, frequency, duration, and set up but all used electrical stimulation sham as the comparator. Most studies evaluated the percent change in wound surface area as the primary outcome. A trend of greater reduction in wound surface area in the treatment group was seen across studies except for one study that found no significant difference.[181] In the one study that followed patients for an additional 90 days after treatment, this trend was lost after day 45 and no significant differences were noted at the end of followup[179] (Table 28).

Six studies of electrical stimulation evaluated complete wound healing as either a primary or secondary outcome.[177,179,182-185] We did not pool the findings of these six studies using meta-analysis because of statistical heterogeneity of results and inconsistent direction of the estimated effect measures across studies. A small good-quality study of patients with stage II, III, IV, or unstageable ulcers found no significant difference in complete wound healing at 3 months.[177] All stage II ulcers (treatment n=4, sham n=1) completely healed at 3 months. For all other ulcers, there was an increase in the percentage of ulcers completely healed in the treatment group (5/15, 33.3 percent) compared with the sham group (1/14, 7.1 percent), but no statistical difference between groups.[177] Two fair-quality studies also found no significant difference in complete healing.[179,183] Three fair-quality studies enrolling elderly patients found an increase in complete wound healing in the electrical stimulation group compared with the sham treatment at 4-8 weeks (14/49 [28.9 percent] vs. 11/49 [23.4 percent], 9/9 [100 percent] vs. 0/7 [0 percent], and 25/43 [58 percent] vs. 1/31 [3 percent] respectively).[177,182,184,185] Two of these studies found a high percentage of completely healed ulcers in the treatment group compared with a very low percentage in the sham group, inconsistent with the results of other trials. Notably, the duration of active treatment for most studies (20 days to 90 days) may not have been long enough to allow for complete healing. One methodologically fair-quality study[186] reported on healing rate without providing appropriate primary data or statistical analysis and did not add to the body evidence.

In summary, studies did not demonstrate an effect of electrical stimulation on complete wound healing compared with sham treatment, but indicated that electrical stimulation may be superior to sham treatment in accelerating the rate of wound healing. These findings are consistent with the findings of two prior systematic reviews of electrical stimulation for pressure ulcers.[10,187]

Table 28. Adjunctive therapies: Electrical stimulation

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Outcomes Measured and Treatment Effect	Benefit: Wound Improvement
Adegoke 2001[178] Trial Fair N=7/6 Hospital	Stage IV	44 years (22-60) Female: NR Spinal cord injury	4 weeks	Wound surface area percent change: 22.2% vs. 2.6% (p-value not reported) Harms: NR	+
Adunsky 2005[179] Trial Fair N=63/38 Hospital	Stage III	71 years (NR) Female: 35% 86% elderly, 14% spinal cord injury	8 weeks/day 147	Complete healing day 147: 25.7% vs. 35.7%, (p=0.39) Mean time to complete closure: 67 vs. 102 days (p=0.16) Harms: excessive granulation (2). No serious adverse events related to treatment.	~

Table 28. Adjunctive therapies: Electrical stimulation (continued)

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Outcomes Measured and Treatment Effect	Benefit: Wound Improvement
Ahmad, 2008[180,188] Trial Fair N=60 NR	Stage II	39 years (NR) Female: 53% NR	5 weeks	Wound surface area percent change: 91% vs. 25-28% (p<0.001) Harms: NR	+
Baker 1996[181] Trial Fair N=80 nPU=192/185 Hospital and outpatient	NR	36 years (19-76) Female: 18% Spinal cord injury	4 weeks	Wound surface area percent change per week: Active A: 36.4 Active B: 29.7 Sham: 32.7% (NS; p-value NR) Harms: NR	~
Gentzkow 1991[182] Trial Fair N=39 nPU=49/40 Hospital and home	Stage III - IV	63 years (29-91) Female: 45% General	4 weeks/8 weeks for safety	Complete healing percent: 49.8% vs. 23.4% (p=0.042) Harms: None	++
Griffin 1991[183] Trial Fair N=20/17 Hospital rehabilitation center	Stage II, III, IV	Age: 29 years (10-74) Female: 0% Spinal cord injury	20 days	Wound surface area median percent change: 80% vs. 52% (p=0.05) Complete healing: Stage II: 2/2 vs. 2/2 Stage III: 1/5 vs. 0/6 Stage IV: 0/1 vs. 0/1 (p-values NR) Harms: NR	+

Table 28. Adjunctive therapies: Electrical stimulation (continued)

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Outcomes Measured and Treatment Effect	Benefit: Wound Improvement
Houghton 2010[177] Trial Good N=34 Home care	Stage II, III, IV	Age: 50 years (23-79) Female: 41% Spinal cord injury	3 months	Wound surface area percent change: 70% vs. 36% (p=0.048) Complete healing: Stage II: complete healing in both groups at 3 months Stage III, IV< or X: 5/15 (33.3%) vs. 1/14 (7.1%, p=0.55) Harms: persistent red area or burn under active electrode after treatment .	+
Kloth 1988[184] Trial Fair N=16 NR	Stage IV	Age: 66 years (20-89) Female: NR Intact nervous system	4-16 weeks (mean 7 weeks)	Wound surface area percent change per week: 44.8% decrease vs. 11.6% increase (p-value NR) Complete healing: 100% vs. 0% (p-value NR) Harms: NR	++
Wood 1993[185] Trial Fair N=71 nPU=74 Acute care or rehabilitation centers	Stage II or III	Age: 75 years (25-99) Female: 42% General	8 weeks	Wound surface area more than 80% decrease: 72.9% vs. 12.9% (p<0.0001 for decrease in surface area) Complete healing: 58% vs. 3% (p-value NR)	++

NPUAP = National Pressure Ulcer Advisory Panel; NR = not reported; NS = not significant

[a]Pressure ulcer stage indicates NPUAP staging unless otherwise noted. Non-NPUAP staging was converted to the equivalent NPUAP stage where possible.

++Complete wound healing.

+Some improvement in wound healing.

~No difference.

Electromagnetic Therapy

Electromagnetic therapy (EMT) is the delivery of energy composed of an electric field and a magnetic field without direct contact on the skin surface. It is theorized that the electromagnetic field alters the cell membrane, potentially promoting transport across the cell membrane, which is thought to promote healing.[189]

We found no direct evidence comparing electromagnetic therapy with other interventions for the treatment of pressure ulcers. We identified four fair-quality randomized controlled trials assessing the effectiveness of EMT compared with no EMT or sham EMT in the treatment of stage II - IV pressure ulcers.[189-192,193]

A trend in the direction of improvement with EMT was found but the significance is called into question. Two studies found a trend toward benefit for EMT in complete wound healing of stage II-III pressure ulcers (85 percent vs. 0 percent[190] and 87 percent vs. 67 percent[192]) but, the difference was not statistically significant (RR 10.00 [95% CI, 0.70 to 143.06] and 7.00 [95% CI, 0.41 to 12016] respectively. Two small, fair- quality studies reported a lower time to complete healing with EMT. One study enrolled stage II and III ulcers and found healing in all stage II ulcers and only those treated with EMT in stage III ulcers (stage II ulcers: 13 days vs. 31.5 days; stage III ulcers: 43 days vs. no complete healing).[192] The other study reported a significant difference in the average healing time for stage III-IV ulcers (10.80+/- 4.06 days vs. 18.85 +/- 9.75 days). However their success in completely healing all of these advanced ulcers calls into question their results.[193] The rate of healing is dependent on the initial size of the ulcer, which was not balanced between the active and control groups. Differences in baseline wound area may have introduced bias for this outcome. One fair-quality randomized trial[191] enrolled 12 patients (nPU=24) with neurologic disorders and stage III or IV pressure ulcers and compared EMT with sham EMT over an average of 30 sessions. No significant difference in improvement of ulcer stage was found between the two groups at the completion of the study (p=0.649).

Our findings of no significant difference in wound improvement despite a trend toward improvement with EMT are consistent with a prior Cochrane review on the topic of electromagnetic therapy for the treatment of pressure ulcers[194] However, two additional systematic reviews report on the trend toward improvement with EMT without statistical analysis of the data.[10,189] The clinical significance of this trend remains unknown.

Therapeutic Ultrasound

Therapeutic ultrasound is the generation of low-frequency sound waves transmitted through soft tissue and created when electrical energy causes deformation of a piezoelectric crystal located in a transducer. The ability of the sound waves to travel through tissue depends on characteristics of the ultrasound and the tissues through which it travels. Both thermal and nonthermal effects of ultrasound are theorized to improve wound healing based primarily on in-vitro studies.[195]

We found two randomized trials comparing the effectiveness of ultrasound with sham ultrasound (US)[196-198] and one randomized trial comparing the combination of ultrasound and ultraviolet light with laser therapy or standard wound care.[199]

Limited evidence found no significant difference in complete wound healing ,although a trend toward improvement with US was seen. All trials were small, had different treatment regimens, and different followup periods. The fair-quality randomized study comparing the combination of ultrasound and ultraviolet-C (UVC) light with laser therapy or standardized wound care enrolled 20 patients comprising 22 wounds and analyzed 16 patients comprising 18 wounds.[199] All patients received standard wound care. Six wounds per group were analyzed after receiving either alternating days of ultrasound or UVC 5 days per week, laser therapy 3 days per week, or no additional intervention. For the outcome of complete wound healing, the US/UVC group showed the fastest healing, averaging 4 weeks (range 2-6 weeks) compared with the control group that averaged 7 weeks (range 4-13) and the laser group that averaged 11 weeks (range 3-20). The mean percentage change per week in wound surface area was 53.5 percent for

the US/UVC group, 32.4 percent for the control group, and 23.7 percent for the laser group. Although there was a trend toward benefit with ultrasound, no significant difference in complete wound healing was found between US/UV therapy and laser therapy. Given that there is only one small, underpowered study assessing this comparison, there is insufficient evidence to determine if a difference exists in the comparative effectiveness of the combination of US/UVC compared with laser therapy.

Of the two randomized studies (n=128) comparing ultrasound with sham ultrasound, neither study found a significant difference in the complete healing of wounds (76 percent vs. 47 percent[196] and 40 percent vs. 44 percent[197]) and rate of healing. One small pilot study randomized six stage III or IV pressure ulcers in five patients to receive either ultrasound or sham ultrasound.[200] They reported a decrease in wound size in the ultrasound group with no change in the sham group, but did not provide specific data to allow comparative analysis for an effect size and therefore do not add to the body of evidence. Our finding of no benefit in wound improvement with therapeutic ultrasound for pressure ulcers is consistent with two prior systematic reviews.[10,201]

Negative Pressure Wound Therapy

Negative pressure wound therapy (NPWT) involves the use of devices that provide a vacuum seal to a wound producing a negative pressure.[202] This causes the wound to contract in size while maintaining a moist environment designed to optimize wound healing.[202] The negative pressure applied to the wound removes excess interstitial fluid which reduces concentrations of inhibitory factors while increasing blood flow. This effect, as well as the actual disruption of the extracellular matrix of the wound, is believed to promote wound healing.[202] The devices include a vacuum pump, drainage tubing, and foam or gauze dressings that are sealed with an adhesive film.

We found evidence on the effectiveness of NPWT from two fair-quality trials and one observational study. There was no evidence of benefit in wound improvement with NPWT.

We found direct evidence from one 6-week, fair-quality trial comparing negative pressure wound therapy to a system of wound gel products in 28 patients.[203] Six patients did not complete the study and were not included in analysis. No significant difference was found in complete healing at 6 weeks (NPWT, 2/20 [10 percent] and topical gel, 2/15 [13 percent]). No significant difference was found in reduction of ulcer volume at 6 weeks (NPWT 52 percent and topical gel 42 percent).[203] We found no other direct evidence comparing vacuum assisted devices to other interventions for the treatment of pressure ulcers.

One fair-quality randomized trial[204] and one fair-quality retrospective cohort study[205] compared NPWT with standard wound care in patients with spinal cord injuries and stage III or IV pressure ulcers. The trial randomized 24 patients and analyzed 22 patients and found no significant difference in mean time to 50 percent reduction in wound volume (NPWT 27 days [standard deviation (SD)=10 days]; control 28 days, [SD=10 days], p=0.9).[204] The retrospective cohort study used data collected on U.S. veterans. Patients treated with NPWT were matched with patients treated with standard wound care within each participating site based on demographic variables and ulcer surface area on day 1. Ulcers were classified as healing if the wound surface area decreased and as nonhealing if the wound surface area increased. No significant differences were found in percentage of patients demonstrating healing (NPWT 70 percent vs. standard care 67 percent) or nonhealing (NPWT 30 percent vs. standard care 33 percent). No significant difference was found for percentage of reduction in wound surface area in those classified as healing (NPWT 43 +/- 22 percent vs. standard care 50 +/- 26 percent).

Based on these three studies, there was low evidence that negative pressure wound therapy provides no benefit in wound improvement over 4-6 weeks. There was insufficient evidence to determine if NPWT provides any benefit in healing over a longer duration due to short duration of studies. These findings are consistent with a prior systematic review.[10]

Light Therapy

Light therapy involves the delivery of electromagnetic energy to the wound surface to promote healing. In the treatment of pressure ulcers, light therapy involves the delivery of energy from the infrared, visible (wavelength 380-760 nm), and ultraviolet spectrums. There are three types of ultraviolet radiation based on the wavelength of the light transmitted. Ultraviolet-A is the longest wavelength and has the ability to penetrate the deepest. It is the most common type of ultraviolet radiation transmitted to the earth's surface and is responsible for immediate tanning effect. Ultraviolet-B is the medium wavelength radiation, able to penetrate to more superficial layers of the skin and is most associated with burning and the development of skin cancers. The shortest wavelength radiation is derived from ultraviolet-C light and is considered the most damaging.[206] Polarized light involves the use of a crystal that causes the visible electromagnetic wave to vibrate in one direction only. A laser is a device that amplifies light and is notable for its high degree of spatial and temporal coherence.[207] We have grouped polarized, infrared, and ultraviolet light, and classified these as light therapy. We have considered laser therapy as an independent class.

We found no direct evidence comparing light therapy with other adjunctive interventions in the treatment of pressure ulcers. We found four fair-quality randomized trials[208-212] and one fair-quality observation study[198] comparing light therapy with either sham light therapy or standard care in patients with pressure ulcers of the pelvis or lower extremity. Patients were of a general population and had stage I-IV pressure ulcers. Studies were 2-12 weeks in duration. All five studies evaluated change in wound surface area or ulcer size while two studies also measured complete healing and time to complete healing.[208,209]

We found low-strength evidence of a reduction in wound surface area in pressure ulcers receiving light therapy but no evidence of benefit in complete wound healing. Three trials (n=262) and one observational study (n=55) found a significant difference in reduction in ulcer size[208-210,212] while one trial (n=164) found no significant difference. Both studies that measured complete healing of patients with stage II-IV ulcers (n=327) found no significant difference between those receiving light therapy compared with sham light therapy (44 percent vs. 40 percent[208] and 54 percent vs. 60 percent[209]). Similarly, no significant difference was found in time to complete healing in either study (see Table 29).

Table 29. Adjunctive therapies: Light therapy compared with standard wound care or sham light therapy

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean age (Range) Sex Population	Followup	Outcomes Measured and Treatment Effect	Benefit: Wound Improvement
Dehlin 2003[208] Trial Fair N=198/164 8 geriatric centers inpatient/outpatient	Stage II-IV	84 years (65-105) Female: 65% General	12 weeks	Complete healing: 44% vs. 40%, p=0.93 Reduction ulcer size: p=0.18 Time until total healing: p=0.93 Harms related or possibly related to treatment: tingling (1); pain (2); bleeding (1); redness (1)	~
Dehlin 2007[209] Trial Fair N=181/163 8 geriatric centers inpatient/ outpatient	Stage III	84 years (65-105) Female: 61% General	12 weeks	Normalized reduction in ulcer size at week 12: 0.79 vs. 0.50 (p=0.039) Normalized weekly reduction in ulcer size over time 15.1% vs. 10.9% (p-value not reported) Rate of normalized reduction in PU size (p=0.12) Percent totally healed ulcers: 54.4% vs. 59.5%, (p=0.52) Time to totally healed ulcers (p=0.58) Harms possibly related to treatment: 9 patients in each group had skin symptoms (mainly tingling)	+
Durovic 2008[210] Trial Fair N=48/40 NR	Stage I-III	65 years (NR) Female: 45% General	4 weeks	Wound surface area change: 4.29 cm^2 reduction (p=0.01) vs. 3.82 cm^2 increase (p=0.001) Harms : NR	+

Table 29. Adjunctive therapies: Light therapy compared with standard wound care or sham light therapy (continued)

Author Year Study Type Quality Number Enrolled/ Completed Setting	Pressure Ulcer Stage[a]	Mean age (Range) Sex Population	Followup	Outcomes Measured and Treatment Effect	Benefit: Wound Improvement
Iordanou 2002[211] Observational Fair N=55 Hospital	Stage I-IV	Age: 67 years (37-85) Sex: NR General	2 weeks	Wound surface area change: 0.58 cm^2 reduction ($p \leq 0.001$) vs. 0.06 cm^2 reduction ($p \leq 0.007$) Harms not reported	+
Schubert 2001[212] Trial Fair N=67 / 59 Hospital	Stage II-III	Age: 85 years (NR) Female: 64% General	10 weeks	Wound surface area per week: 29.8% vs. 20.0%; Healing rate: 49% higher for active group ($p<0.05$). Harms: None	+

NPUAP = National Pressure Ulcer Advisory Panel; NR = not reported; NS = not significant; PU = pressure ulcer
[a]Pressure ulcer stage indicates NPUAP staging unless otherwise noted. Non-NPUAP staging was converted to the equivalent NPUAP stage where possible.
++Complete wound healing.
+Some improvement in wound healing.
~No difference.

Laser Therapy

We found one randomized trial comparing laser therapy with another adjunctive therapy for the treatment of pressure ulcers[199] and three randomized trials comparing laser therapy with standard wound care, to standard wound care alone, or sham laser therapy (Table 30).[213-215] Trials included 16-86 patients, lasted 5-16 weeks, and used different treatment regimens. Two studies enrolled an elderly population with stage III ulcers[213,214] and two enrolled a younger population with spinal cord injuries and stage II-IV pressure ulcers.[199,215]

We found low-strength evidence that laser therapy did not produce wound improvement. The fair-quality randomized study comparing the combination of ultrasound and UVC light with laser therapy or standardized wound care enrolled 20 patients and found faster healing in the US/UVC group (4 weeks) compared with standard therapy (7 weeks) or laser treatment (11 weeks). The mean percentage change per week in wound surface area was 54 percent with US/UVC, 32 percent with standard care, and 24 percent with laser treatment.[199] Although a trend toward benefit with ultrasound, at 12 weeks, no significant difference in complete wound healing was found between US/UV therapy and laser therapy (RR=1.44, 95% CI, 0.85 to 2.64).[216]

Two studies (n=102) found no significant difference in reduction in wound size between treatment groups.[213,214] Two studies (n=124/nPU=143) found no significant difference in complete wound healing.[214,215] One study found no significant difference in time to complete healing.[215]

Our findings are consistent with those of a prior systematic review that found no improvement in wound healing with the use of laser therapy to treat pressure ulcers.[217]

Table 30. Adjunctive therapies: Laser therapy compared with standard wound care or sham laser therapy

Author Year Study Type Quality Sample Size Setting	Pressure Ulcer Stage[a]	Mean Age (Range) Sex Population	Followup	Outcomes Measured and Treatment Effect	Benefit: Wound Improvement
Lucas 2000[213] Trial Fair N=16 Nursing facility	Stage III pelvic and lower extremity	88 years (72-95) Female: 88% General population	6 weeks	Wound surface area median percent change: 83% vs. 95%, NS Harms: None	~
Lucas 2003[214] Trial Fair N=86 Nursing facility	Stage III pelvic and lower extremity	82) years (49-100 Female: 63% General population	6 weeks	Absolute and relative reduction in wound size: NS (p=0.23, p=0.42) Complete wound healing: 18/36 (50%) vs. 15/43 (35%) Wound surface area change: 6/36 (17%) vs. 2/43 (5%) Developed stage IV ulcer: 3/37 (8%) vs. 5/44 (11%), p=0.72 Harms: None	~
Taly 2004[215] Trial Good N subjects=35, N pressure ulcers=64 Hospital rehabilitation ward	Stage II-IV pelvic and lower extremity (2 elbow)	32 years 8-65) Female: 23% Patients with spinal cord injury	5 weeks	Complete healing: 18/35 pressure ulcers vs. 14/29 pressure ulcers (p=0.80) Time to complete healing: 2.45 weeks vs. 1.78 weeks (p=0.33) Harms: None	~

NPUAP = National Pressure Ulcer Advisory Panel; NR = not reported; NS = not significant

[a]Pressure ulcer stage indicates NPUAP staging unless otherwise noted. Non-NPUAP staging was converted to the equivalent NPUAP stage where possible.

++Complete wound healing.

+Some improvement in wound healing.

~No difference.

Hydrotherapy

Hydrotherapy uses water with or without additives to cleanse the wound and to promote healing. It is frequently provided in the form of whirlpool therapy whereby the body or body part is immersed in the pool avoiding direct contact of the jet stream on the wound so as not to disturb granulation tissue. Pulsatile lavage is a form of hydrotherapy in which a gentle stream of normal saline is applied to the wound directly. The treatment uses a device with a disposable tip for each treatment to minimize risk of contamination.

We found evidence on hydrotherapy from two fair-quality trials, one on whirlpool therapy[218] and one on pulsatile lavage.[219] Both studies enrolled patients with stage III-IV pressure ulcers. The whirlpool study was set at an acute care facility and enrolling a general population and the pulsatile lavage study set at a rehabilitation center and enrolling men with spinal cord injuries. Only the pulsatile lavage study was able to compare to a sham treatment and both studies considered change in wound size over time as the outcome of interest. The hydrotherapy group from both studies showed a trend toward greater wound improvement over time (whirlpool 58.33

vs. 27.78 percent; $p<0.05$; -0.33 cm^3/week in wound volume with pulsatile lavage vs. sham) however none reported on complete wound healing. Given the paucity of evidence and the heterogeneity of the available studies, the evidence is insufficient to draw any conclusions of the effectiveness of hydrotherapy on the treatment of pressure ulcers.

Other Adjunctive Therapies

Evidence was limited to a single study on vibration therapy therapy,[220,221] extracorporeal shock wave therapy,[222] and hyperbaric oxygen.[223] Due to study quality, size, and duration, evidence was insufficient to report on comparative effectiveness of these treatments. We elected to perform an additional search specifically on hyperbaric oxygen at the recommendation of our technical expert panel given that this has been an adjunctive therapy commonly used in the treatment of wounds. Our search revealed no additional studies that met our inclusion criteria. The single study on hyperbaric oxygen from our original search was designed to determine if a synergistic effect occurred with electrical stimulation by comparing hyperbaric oxygen alone with the combination of hyperbaric oxygen and electrical stimulation on the healing rates of stage III or IV pressure ulcers.[223] Subjects were assigned to receive either hyperbaric oxygen alone twice daily or hyperbaric oxygen twice daily and electrical stimulation five days per week. All wounds diminished in size over time, with no significant difference between the two groups.

Evidence About the Comparative Effectiveness of Adjunctive Therapies by Subgroups According to Pressure Ulcer Characteristics (Key Question 1a), Patient Characteristics (Key Question 1b), or Setting (Key Question 1c)

Electrical Stimulation

Most studies of electrical stimulation enrolled patients with pelvic and lower extremity pressure ulcers and did not perform subgroup analysis to determine if a difference existed in treatment effectiveness based on anatomic site. Comparison of the results of electrical stimulation studies by ulcer stage (II, III, and IV) and by patients enrolled did not provide evidence of differential effectiveness by ulcer stage.[177-180,183,184]

Most studies enrolled a general population and did not perform subgroup analysis to allow comparison of treatment effectiveness based on unique patient characteristics. Four trials enrolled only patients with spinal cord injuries and the results were consistent with the overall body of evidence.[177,178,181,183] We found similar results in studies that enrolled a younger population (mean age $\leq$ 51 years)[177,180,181,183] compared with an older population (mean age >51 years).[178,179,182,184,185]

Most studies were conducted in a hospital or rehabilitation center,[178,179,183,185] with one study conducted in a home care setting[177] and the others in a combination of settings[181,182] or not reported.[180,184] Findings did not differ based on setting. See Table 30.

Electromagnetic Therapy

One trial of EMT (n=30) randomized patients based on baseline stage of ulcer (II or III) to receive either EMT or sham. There was no significant difference in outcomes between the groups, based on baseline ulcer stage.[192] The two trials of EMT enrolled different patient populations in different settings, but both had similar findings of no significant effect of EMT.[190,192]

Therapeutic Ultrasound

The two randomized trials comparing ultrasound with sham therapy included a mixed population of hospitalized and nursing facility patients of varying stages of pressure ulcers without subgroup analysis to determine if a difference exists based on features of the pressure ulcer, patient, or care setting.[196,197]

Negative Pressure Wound Therapy

There was a lack of studies evaluating the comparative effectiveness of NPWT according to features of the pressure ulcers or characteristics of the patient resulting in insufficient evidence to draw any conclusions. One retrospective cohort study reported on the effectiveness of patients being treated with NPWT compared with standard wound care in the home care setting.[224] The Outcome Concepts System was used to identify patients being treated at home for pressure ulcers and the study considered the outcomes of acute care hospitalization and emergent care rates between January 1, 2003, and December 31, 2004. Patient characteristics were similar in both groups. Sixty patients were treated with NPWT while 2,288 patients were treated with standard wound care.[224] Of this small group treated with NPWT, a significantly lower percentage of NPWT patients were hospitalized (35 percent vs. 48 percent, $p<0.05$), fewer required emergent care services (0 percent vs. 8 percent, $p<0.01$), and fewer required hospitalization for a wound-related problem (5 percent vs. 14 percent, $p<0.01$).[224] No other study evaluated the outcomes of hospitalization or emergent care needs. Given the small sample size in the NPWT group and given that outcomes of wound healing were not assessed, there was insufficient evidence that NPWT in the home setting provided significant benefit.

Light Therapy

Few studies performed subgroup analysis to determine if treatment strategies differed according to features of the pressure ulcers, patient characteristics, or patient care settings. Two studies performed subgroup analysis to determine if differences in outcomes existed based on body mass index.[208,209] One study of patients with stage III-IV NPUAP ulcers found a larger reduction in ulcer size for patients with a body mass index <20 (3.3 cm^2 vs. 2.5 cm^2, $p<0.01$)[208] but a subsequent study of stage III NPUAP ulcers found no significant difference in this subgroup.[209]

Laser Therapy

No studies performed subgroup analysis to determine if treatment strategies differed according to features of the pressure ulcers, patient characteristics, or patient care settings. Two studies (n=51/nPU=80) enrolled younger patients with spinal cord injuries and found no evidence of benefit in complete wound healing. This was consistent with the overall body of evidence that included a mixed population.[199,215]

Adjunctive Therapies: Harms (Key Question 2)

We found 14 trials and two observational studies evaluating the harms of adjunctive therapies (electrical stimulation [three studies], electromagnetic therapy [one study], ultrasound [three studies], negative pressure [two studies], light therapy [four studies], and laser therapy [three studies]). We found no direct evidence comparing one intervention to another and reporting on comparative harms. Indirect evidence of comparative harms was difficult to derive due to variability in study population, study design, outcomes measured, and sample size.

Electrical Stimulation

Three studies reported on harms associated with the use of direct electrical current in the treatment of pressure ulcers compared with sham electrical stimulation.[177,179,182] Overall withdrawal was high in the Adunsky study, which enrolled hospitalized frail elders with stage III pressure ulcers in Israel (overall withdrawal 25/63, 40 percent). Fifteen patients withdrew due to adverse events, (11 of 15 [73 percent] in the treatment group), mostly due to clinical (8/15) or ulcer deterioration (4/15). In two other studies, however, withdrawal occurred in only one spinal cord injured patient.[177,182] The most commonly reported adverse event was skin irritation. Adunsky reported two cases of excessive granulation (5.2 percent) and two cases of a local irritation when the current was combined with topical sulphadiazine ointment on the wound, believed to be due to the effect of electrical stimulation on the silver ions in the ointment.[179]

Electromagnetic Therapy

One small randomized study (n=30) reported no adverse effects.[192]

Therapeutic Ultrasound

Three studies reported on overall withdrawal, which ranged from 12.5 percent to 32.5 percent, mostly due to death or discharge from the care setting and not related to the intervention.[196,198,199] One study reported that 2 of 45 patients in the ultrasound group (4.4 percent) complained of pain associated with ultrasound but no other adverse events were reported.[198]

Negative Pressure Wound Therapy

No controlled studies comparing NPWT to standard care reported on harms. One intervention series of 17 patients with sacral ulcers, stage unknown, reported an overall withdrawal of eight (47 percent), three (18 percent) due to death not attributed to the intervention and five (29 percent) due to need for surgery due to incomplete healing. One retrospective cohort study compared patients being treated with NPWT with patients being treated with standard wound care in the home care setting[224] and reported on emergent care or hospitalization for wound infection, deteriorating wound status, or new lesion/ulcer.[224] Compared with patients receiving standard care, a significantly lower percentage of NPWT patients were hospitalized for wound related issues (3/60 [5 percent] vs. 310/2288 [14 percent], $p<0.01$) or required emergent care for wound related issues (0/60 [0 percent] vs. 189/2288 [8 percent], $p<0.01$).[224] Of note, the U.S. Food and Drug Administration reclassified nonpowered devices intended for NPWT as a class II (special controls) device to ensure safety and effectiveness in administration due to reported risk of infection and bleeding. No harms were reported in the one study evaluated on NPWT in the pressure ulcer population.[225]

Light Therapy

Four studies reported on overall withdrawal from studies of light therapy, ranging from 17 to 19 percent, with none believed to be directly related to the treatment.[208-210,212] Two studies specifically evaluated adverse events,[208,209] with similar number of events occurring in both the light therapy and the sham light therapy groups, and considered unrelated to the treatment. The most common reported adverse event was tingling or pain in or around the wound (n=12 of 327 patients, 3.7 percent). One patient had bleeding in the wound and one patient reported redness.[208]

Laser Therapy

Four studies compared laser therapy with either standard care or sham laser therapy in the treatment of stage II-IV pressure ulcers.[199,213-215] No treatment-related adverse events were reported in three studies[199,213,214] and one study reported excessive granulation tissue in one of 64 ulcers, the only treatment-related adverse event that was observed.[215] One study evaluated the progression to stage IV ulcers in patients with stage III ulcers and found that during the 6-week study, no significant differences existed between groups in the development of stage IV ulcers (5/44 [11 percent] vs. 337 [8 percent], p=0.72).[214]

Evidence About the Harms Related to Adjunctive Therapies by Subgroups According to Pressure Ulcer Characteristics (Key Question 2a), Patient Characteristics (Key Question 2b), or Setting (Key Question 2c)

There was insufficient evidence due to a lack of reporting to determine if differences in harms of any adjunctive therapies exist based on features of the pressure ulcers.

One study of electrical stimulation enrolled hospitalized frail elders with stage III pressure ulcers in Israel and had a high rate of overall withdrawal (25/63, 40 percent) and a high rate of withdrawal due to adverse events (15/63, 24 percent).[179] The two other studies reporting on harms associated with electrical stimulation enrolled younger patients, many of whom had spinal cord injuries, and found a very low overall withdrawal or withdrawal due to adverse events.[177,182] This difference may be due to the patient age and comorbid features. However, there may have been other differences in treatment delivery, patient populations, or harms assessment that accounted for the observed differences across studies.

There was insufficient evidence to determine if differences existed in harms of any adjunctive therapies based on patient care settings.

Discussion

Treatment for pressure ulcers involves a variety of different modalities intended to: alleviate the conditions contributing to ulcer development (support surfaces, repositioning, nutritional support); protect the wound from contamination, create a clean wound environment, promote tissue healing (local wound applications, debridement, wound cleansing, and a variety of adjunctive therapies); and surgically repair the wound. We evaluated evidence addressing the comparative effectiveness and harms in treatment categories where significant uncertainty exists about the best therapeutic options: support surfaces, nutritional supplements, local wound applications (dressings, topical therapies, and biological agents), surgical interventions, and adjunctive therapies. We also attempted to discern whether the balance of benefits and harms for different treatment options varied according to characteristics of the pressure ulcer, the patient, or the setting in which care was being delivered.

Key Findings and Strength of Evidence

We identified evidence addressing a variety of different support surfaces, including air-fluidized (AF) beds, alternating pressure (AP) beds and chair cushions, and low-air-loss (LAL) beds. Other types of support surfaces were evaluated only in small, single studies. We found evidence of moderate strength that wound improvement was better on AF beds from studies that compared AF beds to other support surfaces, including standard hospital beds. Studies found no difference in wound improvement when different types of AP mattresses were compared. (moderate strength of evidence. Evidence about the effectiveness of AP seat cushions was insufficient as only two studies with very different population were identified.) There was low-strength evidence that AP beds or LAL beds led to similar wound improvement when compared to other surfaces, usually standard mattresses. The reported harms of different support surface options were minimal, though harms were infrequently and inconsistently reported in support surface studies.

Studies of nutritional support evaluated protein-containing nutritional supplementation and specific nutrient supplementation with vitamins or minerals, such as ascorbic acid (vitamin C) or zinc. Studies provided moderate strength of evidence that protein supplementation results in wound improvement. There was low strength of evidence indicating similar results with vitamin C compared to placebo. Evidence about zinc supplementation was insufficient to draw conclusions. There was insufficient evidence to adequately describe the harms of nutritional supplementation in this patient population.

A wide variety of modern wound dressings have been compared with each other or to standard care, usually with gauze dressings. We found low-strength evidence that hydrocolloid dressings are superior to gauze and moderate-strength evidence that hydrocolloid and foam (hydrocellular or polyurethane) dressings produced similar wound improvement. Evidence about the comparative effectiveness of other dressings – hydrogels, transparent films, silicone, and alginates – was insufficient to draw conclusions. We found moderate-strength evidence from four studies that radiant heat dressings accelerated the rate of healing compared with other dressings, of stage III and IV ulcers but we did not find evidence of a benefit of radiant heat dressings in terms of complete wound healing.

The most commonly evaluated topical therapies were debriding enzymes (primarily collagenase), phenytoin solution, dextranomer paste, and collagen applications. There was low-strength evidence that dextranomer is less effective than wound dressings. Evidence about

enzymes and phenytoin was inconsistent, and insufficient to draw conclusions. Collagen applications did not appear to produce wound improvement compared with standard care, based on low-strength evidence.

The most commonly evaluated biological agent was platelet-derived growth factor (PDGF), for which there was low-strength evidence of benefit compared with placebo in promoting wound improvement in severe (stage III or IV) ulcers. There was insufficient evidence about the effectiveness of other biological agents.

There was moderate-strength evidence that the most common harms of wound dressings and topical agents were dermatologic complications, including irritation, inflammation, and maceration. However, variability across studies precluded an estimate of adverse events for specific dressings or topical therapies, and evidence was insufficient to determine whether certain types of dressings or topical therapies were more likely to cause these complications than others. Few harms were reported with biological agents, but the evidence about the harms of these agents was insufficient to reach conclusions about adverse event rates. Evidence was insufficient to make conclusions about the effectiveness or harms of local wound applications across different ulcer or patient characteristics, or settings.

Surgical interventions for pressure ulcers identified in studies meeting our inclusion criteria were primarily surgical flaps, most commonly myocutaneous and fasciocutaneous flaps. Studies of surgical interventions were nearly all observational, and most were conducted in single centers. There was insufficient evidence that one approach to closure of stage III to IV pressure ulcers is superior to others due to heterogeneity in patient populations and surgical procedures. There was low strength of evidence that sacral ulcers had a lower rate of ulcer recurrence when compared with ischial ulcers; that a higher rate of recurrent ulcers was found among patients with spinal cord injury compared with others; that a greater wound dehiscence rates occurs with surgeries in which bone is removed as part of the operation; and that more adverse events occur with surgery for ischial compared with sacral or trochanteric ulcers. Surgical flap failures requiring reoperation ranged from 12 to 24 percent.

Adjunctive therapies identified in our review included electrical stimulation, electromagnetic therapy, ultrasound, negative pressure wound therapy, hydrotherapy, light therapy, and laser therapy. Evidence about other adjunctive therapies—including vibration, shock wave, and hyperbaric oxygen—was limited to small, single studies. There was moderate-strength evidence that electrical stimulation improved healing rates, but insufficient evidence about the effect of electrical stimulation on complete wound healing due to heterogeneous findings across studies. Low-strength evidence indicated that the most common adverse effect of electrical stimulation was local skin irritation; and that harms were more common in frail elderly compared with younger populations. There was also low-strength evidence indicating that electromagnetic therapy, therapeutic ultrasound, and negative pressure wound therapy were similar to sham treatment or standard care in wound improvement; there was insufficient evidence to evaluate the harms of those adjunctive therapies due to a lack of reporting of harms. Light therapy provided benefit in terms of wound area reduction but not in terms of complete wound healing, and was not associated with significant adverse events, based on low-strength evidence. There was low-strength evidence that laser therapy was not associated with significant adverse events, but also that it did not provide wound improvement over sham or standard treatment. There was insufficient evidence to draw conclusions about hydrotherapy due to the paucity of studies.

Findings in Relationship to What Is Already Known

Treatments for Pressure Ulcers have been described and evaluated with varying degrees of rigor in the past (e.g., Lyder, 2003[4]) A recent systematic review by Reddy, and colleagues, published in December 2008, evaluated 103 randomized trials published during or prior to August 2008.[10] The review included studies evaluating support surfaces, nutritional supplements, wound dressings, biological agents, and adjunctive therapies. Our review included evaluations of those treatment categories and additionally evaluated surgical interventions. We included observational studies of pressure ulcer treatments, included assessments of treatment harms, and expanded the search to include studies published through June 2012. and assessed treatment harms, in studies published through June 2012. Our review also included observational studies in addition to clinical trials, in an effort to more comprehensively review the relevant literature.

The findings of this prior systematic review were qualitatively similar to ours, with a few exceptions. In the support surface category, Reddy and colleagues reported that AP surfaces and low-air-loss beds were not superior to standard, nonpowered surfaces, which is similar to our findings.[10] They did not, however, report specifically on AF beds, as only one of the five studies of AF beds we included in our review were retrieved in their literature search. Our finding that there was moderate-strength evidence that AF beds were more effective than other surfaces in achieving wound area reduction is based on the finding from these additional studies. Additional systematic reviews on the use of support surfaces have been published by the Cochrane Collaboration. A recent report[48] updated earlier versions[226-228] and separated out treatment from prevention. This review summarized 18 trials (observational studies were not included). This review, like ours, found some limited evidence that AF beds lead to reductions in pressure ulcer size, and no significant effect of LAL beds on healing. Unlike our review, this review reported some benefit from the use of sheepskins, but this is based on a study that was excluded from our review because it was published in 1964.

Finally, the authors of this review found, as we did, that the evidence base was weak, with studies that were small, had serious methodological limitations, and often did not report key elements such as variance data, p-values, and the characteristics of the surfaces used as the comparators.

Reddy and colleagues reported that overall, nutritional supplements did not provide benefit in terms of ulcer healing, but that protein supplementation may provide wound healing benefit.[10] Our findings were similar; we found moderate-strength evidence that protein supplementation accelerates wound healing, but studies did not provide evidence of an effect on complete wound healing. The Cochrane Collaboration published a 2008 systematic review on nutritional interventions to treat and prevent pressure ulcers but the authors were unable to draw conclusions about the effectiveness of nutritional interventions in the treatment of pressure ulcers due to the small number and poor quality of the available studies.[229]

We found to wound dressings and topical therapies, indicating that there was limited evidence to support the use of certain dressings and topical therapies over others, in terms of wound improvement, were similar to the conclusions drawn by Reddy, et al.[10] Our finding that hydrocolloid dressings are likely to be superior to gauze in promoting wound improvement was similar to the conclusion in two other systematic reviews. A review by Chaby, et al. also found equivalence between hydrocolloid and foam dressings in promoting wound improvement, a finding supported by our meta-analysis of 8 studies comparing those dressing types. Both Reddy, et al. and Chaby, et al. highlighted a study demonstrating the superiority of alginate dressings to dextranomer paste; we also found dextranomer paste to be inferior to dressing but considered the

evidence for this to be low-strength.[10] We did find moderate-strength evidence that radiant heat dressings accelerated the rate of wound area reduction, but we did not find evidence of a benefit of radiant heat dressings in terms of complete wound healing. Similar to Reddy, et al., we found a potential benefit, based on low-strength evidence, for platelet-derived growth factor in promoting wound improvement with stage III and IV ulcers.[10]

We found evidence to evaluate the comparative effectiveness of eight adjunctive therapies used in the treatment of pressure ulcers. Of these, none demonstrated consistent effectiveness in complete wound healing. Electrical stimulation, electromagnetic therapy, and light therapy did show a tendency for wound improvement while the other adjunctive therapies showed no evidence of effectiveness. Our findings are consistent with the findings of two prior systematic reviews of electrical stimulation for pressure ulcers,[10,187] two systematic reviews of therapeutic ultrasound,[10,201] one prior systematic review of negative pressure wound therapy,[10] and two systematic reviews of laser therapy.[10,217] Our findings of no significant difference in wound improvement with electromagnetic therapy (EMT) are consistent with those of a prior Cochrane review.[161] Although a trend toward improvement in rate of healing with EMT has been observed, consistent with prior systematic reviews,[10,189] we found that the clinical significance of this trend remains unknown.

Applicability

The applicability of our findings to real-world clinical settings is supported by several features of the body of literature we reviewed. First, the populations studied included a broad representation of patients with pressure ulcers—elderly patients, general populations of patients with limited mobility, patients with spinal cord injury—cared for in a wide variety of settings, including hospitals, nursing homes, wound care clinics, and at home. Second, the interventions represented most of the therapeutic modalities commonly used in clinical settings. Comparators were also commonly used therapies and often included standard care as defined by local practice patterns. In some studies this included use of comparators that may not be considered best practices, such as standard hospital beds and plain gauze dressings. However, as these treatment strategies remain in use in many settings, both in the United States and other countries, we retained these studies in our review.

Other features of the studies we identified, however, limit the applicability of our findings. First, the outcome in many studies was wound size (area, volume, or depth) reduction, as opposed to complete wound healing. Although wound size reduction is a reasonable measure of therapeutic effect, in clinical practice the goal of therapy is almost always complete wound healing, making wound size reduction a surrogate outcome with less clinical significance than complete wound healing. A principal reason for findings of wound size reduction without complete wound healing was the short duration of most trials. Complete healing takes time. Interventions lasting only a few weeks (as was the case for most of the trials included in our review) are less likely to achieve complete wound healing than interventions carried out for periods long enough for complete healing to occur, as they would be in clinical practice. A second reason that applicability is limited is that the treatment of pressure ulcers in clinical practice often involves multiple concurrent therapies, such as support surfaces, nutritional supplementation, biological or topical therapies, and adjunctive interventions. No studies compared one combination of concurrent or sequential therapies with another, and no conclusions can be drawn regarding the effectiveness of one compared with another.

A second issue affecting applicability is that treatment of pressure ulcers is typically multimodal and often involves the sequential use of different therapies. In practice, the relevant question is often not "which therapy works best" but rather "which combination of therapies works best" and "when is a specific treatment indicated." Most comparative studies of pressure ulcer treatments examined head-to-head comparisons of single treatment modalities. Although contextual data and cointerventions were sometimes reported, integrating those data to answer questions about treatment combinations and timing was difficult.

Studies of surgery are additionally limited by the fact that most were observational and conducted in one or, at most, a few centers. Because surgical technique and quality is often operator- and/or site-dependent, and because outcomes are influenced by local practices, staffing, and other features of the environment, it is difficult to generalize the findings of studies of surgery included in this review.

Implications for Clinical and Policy Decisionmaking

The limitations in applicability discussed above, as well as the limitations of the evidence base discussed below, make it difficult to draw firm conclusions with implications for clinical and policy decisionmaking. Notably, we generated no findings that were supported by high strength of evidence, and only a few findings supported by moderate-strength evidence. Most findings were based on low-strength evidence, and for many issues there was insufficient evidence to draw any conclusions.

Findings supported by moderate strength of evidence deserve consideration but must be examined critically. For example, the finding that AF beds promote wound improvement compared with other surfaces might warrant consideration of this technology. However, it is important to point out that although the five studies of these beds had consistent findings, they are somewhat dated and most compared AF beds to standard beds, rather than to other specialized options. Decisions about investments in support surfaces would benefit from head-to-head trials of current technologies that measured effectiveness in terms of complete wound healing, not only reduction in wound size. Nutritional supplementation may provide benefit in terms of wound improvement, though the effects of nutritional supplementation were not dramatic, and it was not clear from the studies in our review whether nutritional supplementation was beneficial to all patients or to those with evidence of nutritional deficiencies. Nutritional support is commonly prescribed for ill or debilitated patients with evidence of malnutrition; whether this affects ulcer healing, and whether patients without evidence of malnutrition might benefit from nutritional supplementation, is not clear.

Decisions about dressings and topical applications are often guided by matching the primary functions of different dressings (e.g., absorbent, hydrating) with the primary considerations for treatment of individual ulcers (e.g., dryness, contamination risk, exudate). Given the wide array of options, comparative effectiveness and harms data have great potential to guide individualized decisionmaking. We found limited evidence, however, to provide such guidance. Overall, we did not find substantial evidence to support certain local wound applications over others. There was evidence to suggest that radiant heat improved the pace of wound healing, but not complete wound healing per se. Some biological agents showed promise for the treatment of severe ulcers, but the evidence was not substantial, and in light of the cost of these agents, more and better evidence is likely needed before they are widely adopted.

Surgery is typically reserved for refractory ulcers unlikely to heal with conservative management. Evidence about surgery is limited to mainly single-center observational studies.

While we found some evidence to inform decisions and expectations about which ulcers will fare best with surgical intervention, and which surgeries are likely to produce the lowest complication rates, the influence of those findings on clinical decisionmaking should be tempered by the low quality of the studies that produced the findings, and the potentially limited generalizability of the findings across sites and surgeons.

Adjunctive therapies include therapies that are variably used in the treatment of pressure ulcers. Our review revealed moderate-strength evidence that electrical stimulation may accelerate healing but did not otherwise produce findings that would support greater use of adjunctive therapies for the goal of wound healing.

Limitations of the Comparative Effectiveness Review Process

The most important potential limitation of our review is that important studies whose findings might influence clinical and policy decisionmaking may not have been identified. We conducted a comprehensive, broadly inclusive search that produced 7,274 study titles and abstracts. Although we excluded studies published before 1985, we do not believe that important studies of therapies used in current practice were missed; the general consistency of our findings with those of other systematic reviews, which included studies published prior to 1985, provides some assurance that our review was not biased by our time frame selection. Although we did not include foreign-language studies, we identified these studies and, based on review of their abstracts, found that none would have altered our conclusions. Our review focused on clinical outcomes of pressure ulcer treatments, particularly wound improvement. Other outcomes, such as ease of use and nursing/staff time, might also influence treatment decisions but were beyond the scope of our review. Finally, we excluded studies of the treatment of nonpressure ulcers. To the extent that evidence for interventions studied in other types of wounds, including venous ulcers, is applicable to the treatment of pressure ulcers, our review may have underestimated the quantity and quality of the body of evidence for these interventions.

There may have been biased reporting of results in the literature such that only selected studies were published and retrievable, and that published studies may have been affected by conflicts of interest. Reporting bias and conflicts of interest are concerns with any systematic review. We were not able to conduct quantitative analyses to evaluate the possibility of reporting bias for most of our findings, because the heterogeneity across studies in our review, and in many cases the lack of key information needed to perform quantitative syntheses, generally precluded meaningful comparison of effect sizes. Mitigating against the likelihood of reporting bias in our review, however, is the fact that the majority of studies in our review were small (most fewer than 100 patients, many fewer than 50), and most reported no significant effect of the intervention. Reporting bias typically results in selective publication of larger studies and/or those with positive findings, and studies biased by conflict of interests would also be more likely to report positive findings. We also conducted gray literature searches to look for unpublished data and did not find evidence of unreported studies.

We took several measures to guard against the influence of bias in our identification and evaluation of studies. Abstracts were reviewed by at least two team members, including a clinician/senior investigator. Studies were extracted based on prespecified data elements, extraction done by one team member was checked by another, and quality rating of studies performed by two team members and disagreements adjudicated by consensus. Rating of elements of strength of evidence was discussed and calibrated among team members.

Limitations of the Evidence Base

The main limitation of the evidence base in our review was poor study quality. Most trials did not specify randomization method, did not conceal allocation, even when this might be possible, and did not mask outcomes assessment. Most studies did use intention-to-treat analyses. Most studies were small, and many were underpowered to detect significant differences. Studies were also highly variable in terms of patient populations, ulcer characteristics (e.g., anatomic site, duration, stage), interventions (even within a given intervention category, e.g., different types of foam dressings), and comparators (especially variability in implementation of standard, or usual, care), limiting our ability to combine or compare results across studies.

Another major limitation of the evidence base relates to the most common outcome measure, wound size reduction. Comparing changes in the size of pressure ulcers poses several measurement issues. For example, reduction in the size of larger and smaller pressure ulcers is hard to compare. Healing could involve "bridges" that split a large ulcer into two. Measurement in person or from tracings or photographs can be difficult, especially when measurement and photographic techniques are not standardized across studies.

Studies rarely described whether interventions were carried out as planned and in a manner conducive to maximizing potential effectiveness. Lack of documentation of treatment fidelity limited our ability to determine whether findings indicated lack of treatment effectiveness or problems with treatment implementation.

Finally, a major limitation of studies in our review was the duration of interventions and followup periods, typically a few weeks. Many pressure ulcers, especially more severe ulcers, may take months, or even years to heal. Many of the studies in our review were implemented over a period that did not necessarily allow for complete ulcer healing and therefore detection of significant differences in ulcer healing across groups. One strength in this body of literature was that most studies did use intention-to-treat analyses.

Research Gaps

The major gaps in research identified by our review relate to the limitations of the evidence base as described above. Future studies with larger sample sizes, more rigorous adherence to methodological standards for clinical trials or observational studies, longer followup periods, standardization of comparators, and more standardized and clinically meaningful outcome measures (including more patient-centered outcomes such as quality of life and pain) are needed to inform clinical practice and policy. Inclusion of information about cointerventions, and the timing of studied interventions in relation to other interventions, would improve the applicability of study findings. Similarly, stratification of findings by patient characteristics (e.g., comorbidities, ulcer stage) would help determine the applicability of different interventions for specific patients and situations. It is particularly important for future studies to report findings according to ulcer stage, as the rate of healing, conditions necessary to promote healing, and therefore treatment choices may differ for partial and full thickness ulcers. Decisions about defining other aspects of patient populations, interventions, comparators, outcomes, study timing and duration, and study settings should be guided by clinical practice, expertise, and factors most relevant to decision makers, including patients, clinicians, and policymakers.

For several interventions, there was insufficient evidence to reach conclusions due to small sample sizes or mixed results across studies. These interventions included AP beds compared

with other surfaces, topical debriding enzymes, phenytoin, and growth factors. Future studies could clarify the comparative effectiveness of these interventions and identify possible reasons for disparate results. For other interventions, findings indicated a possible benefit, but the strength of evidence was low due to study quality, duration, sample size, and measured outcomes (wound size reduction rather than complete wound healing). These interventions include platelet-derived growth factor and light therapy. Future studies are needed to confirm or refute the effectiveness of these interventions.

As mentioned, further study is warranted comparing AF beds with more modern support surfaces and evaluating comparative effectiveness in terms of complete wound healing. Similarly, in light of findings suggesting a benefit for radiant heat dressings and electrical stimulation in terms of wound healing rate, further study should compare these technologies with other treatments, with sufficient followup to evaluate complete wound healing. There was limited evidence to support the use of nutritional supplements as a component of pressure ulcer care, but few studies examined whether supplementation might have a differential effect for patients with and without baseline nutritional deficiencies. Future studies could address this issue.

Hyperbaric oxygen therapy is one clinical area that our TEP identified as high priority but for which we found limited evidence. Although studies and systematic reviews have evaluated this treatment in chronic wounds generally, its utility among patients with pressure ulcers specifically has undergone limited evaluation.

Conclusions

Choices of treatments for pressure ulcer are often guided by product availability, local practice patterns, and individualized decisionmaking based on specific patients and the features of a given pressure ulcer. Our review did not generate many findings to guide those choices based on evidence.

We found limited evidence to draw firm conclusions about the best approaches for treating pressure ulcers. This finding is consistent with that of a prior systematic review addressing most of the same treatment categories included in our review.[10] We found evidence from five studies indicating greater wound improvement with AF beds over other support surfaces, from four studies indicating a benefit of radiant heat dressings over other dressings, and from nine studies indicating a benefit of electrical stimulation. However, the benefit observed in all cases was wound size reduction or better healing rates, rather than completely healed wounds, and evidence for the benefit of support surfaces in promoting wound improvement was based primarily on comparisons of AF beds with hospital beds that may not be considered the standard of care in the field. The balance of costs and potential harms of those technologies against the benefits observed is unclear.

Studies generally did not provide evidence to support the use of one type of commonly used wound dressing over another. There was evidence that hydrocolloid and foam dressings performed similarly, but evidence for other dressing types – hydrogels, alginates, transparent films, and silicone dressings – compared with each other or with standard gauze dressings was limited. Similarly, there was low-strength or insufficient evidence to judge the balance of effectiveness and harms for nutritional supplementation, topical therapies, biological agents, surgical interventions, and adjunctive therapies other than electrical stimulation .

Advancing pressure ulcer care will require more rigorous study to solidify the evidence base for this widely used set of treatments.

Results are summarized below in Table 31.

Table 31. Summary of evidence: Pressure ulcer treatment strategies – limpact of pressure ulcer treatment strategies on wound improvement and harms

Key Question and Treatment Strategy	Strength of Evidence	Conclusion
Key Question 1. In adults with pressure ulcers, what is the comparative effectiveness of treatment strategies for improved health outcomes, including but not limited to: complete wound healing, healing time, reduced wound surface area, pain, and prevention of serious complications of infection?		
Support		
Air-fluidized beds	Moderate	Air-fluidized beds produced better healing in terms of reduction in ulcer size compared with other surfaces (5 studies conducted in the late 1980s and 1990s).
Alternating pressure beds	Moderate	Complete wound healing and reduction in ulcer size were similar across different brands and types of alternating pressure beds (4 studies).
Alternating pressure beds compared with other surfaces	Low	Wound improvement was similar for alternating pressure beds when compared with air, fluid, or standard beds (4 studies).
Alternating pressure chair cushions	Insufficient	Evidence about alternating pressure chair cushions did not permit conclusions due to differences in the patient populations studied (2 studies).
Low-air-loss beds	Low	Wound improvement was similar for low-air-loss beds compared with foam surfaces (4 studies) and for low-air-loss beds compared with low-air-loss bed overlays (1 study).
Nutrition		
Protein-containing nutritional supplements	Moderate	When used in addition to other measures for treating pressure ulcers, protein-containing nutritional supplementation resulted in wound improvement (12 studies).
Vitamin C	Low	Vitamin C used as a single nutritional supplement did not result in wound improvement (1 study).
Zinc	Insufficient	The evidence did not allow conclusions as to whether zinc supplementation improves pressure ulcer healing (1 study).
Local Wound Applications		
Hydrocolloid dressings compared with conventional care	Low	Wound improvement was superior with hydrocolloid compared with gauze dressings (10 studies).
Hydrocolloid compared with foam	Moderate	Wound improvement was equivalent with hydrocolloid and foam dressings (8 studies).
Comparisons of different wound dressings	Insufficient	Evidence regarding the comparative effectiveness of hydrogel (compared with standard care or other dressing types; 7 studies), transparent film (4 studies), silicone (2 studies), and alginate dressings (1 study) was inconclusive due to limitations in the number, size, and quality of studies.
Radiant heat compared with other dressings (healing rate)	Moderate	Radiant heat dressings produced more rapid wound healing rates than other dressings for stage III and IV ulcers (4 studies).
Radiant heat compared with other dressings (complete wound healing)	Moderate	Radiant heat dressings were similar to other dressings in terms of complete wound healing of stage III and IV ulcers (4 studies).
Debriding enzymes compared with dressings or other topical therapies	Insufficient	Evidence about the effectiveness of collagenase and other debriding enzymes was inconclusive due to differences in the enzymes studied and outcomes measured (5 studies).

Table 31. Summary of evidence: Pressure ulcer treatment strategies – Iimpact of pressure ulcer treatment strategies on wound improvement and harms (continued)

Key Question and Treatment Strategy	Strength of Evidence	Conclusion
Key Question 1. In adults with pressure ulcers, what is the comparative effectiveness of treatment strategies for improved health outcomes, including but not limited to: complete wound healing, healing time, reduced wound surface area, pain, and prevention of serious complications of infection? (continued)		
Local Wound Applications		
Dextranomer paste compared with wound dressings	Low	Dextranomer paste was inferior to wound dressings (alginate, hydrogel) in promoting wound area reduction (2 studies).
Topical collagen compared with hydrocolloid dressings or standard care	Low	Wound improvement was similar with topical collagen applications compared with hydrocolloid dressings or standard care (3 studies).
Topical phenytoin	Insufficient	Three studies of the effectiveness of topical phenytoin used different comparators and produced inconsistent results.
Maggot therapy	Insufficient	Evidence about the effectiveness of maggot therapy was inconclusive due to poor study quality (3 studies).
Platelet-derived growth factor	Low	Platelet-derived growth factor was superior to placebo in producing wound improvement in stage III and IV pressure ulcers (4 studies).
Biological agents other than platelet-derived growth factor (fibroblast, nerve, and macrophage suspension)	Insufficient	Evidence about the effectiveness of other biological agents used for the treatment of pressure ulcers was inconclusive due to limitations in the number, size, and quality of studies (7 studies of various biological agents).
Surgery		
Surgical techniques	Insufficient	Evidence was inconclusive as to whether one approach to closure of stage III to IV pressure ulcers was superior to others due to poor-quality studies and heterogeneity in patient populations and surgical procedures (4 studies).
Adjunctive		
Electrical stimulation	Moderate	Electrical stimulation was beneficial in accelerating the rate of healing of stage II, III, and IV pressure ulcers (9 studies).
Electromagnetic therapy	Low	Wound improvement of stage II, III, or IV pressure ulcers was similar with electromagnetic therapy compared with sham treatment (4 studies).
Therapeutic ultrasound	Low	Wound improvement was similar with ultrasound compared with standard care or sham treatment (3 studies).
Negative pressure wound therapy	Low	Wound improvement was similar with negative pressure wound therapy compared with standard care (3 studies).
Hydrotherapy	Insufficient	Evidence on the effectiveness of hydrotherapy was insufficient based on 2 randomized trials evaluating different treatment modalities (1 of whirlpool therapy and 1 of pulsatile lavage).
Light therapy (complete wound healing)	Low	Light therapy was similar to sham light therapy in producing complete wound healing based on 2 randomized trials.
Light therapy (wound surface area reduction)	Low	Light therapy reduced wound surface area over time compared with standard care or sham light therapy (5 studies).
Laser therapy	Low	Wound improvement was similar with laser therapy compared with sham treatment or standard care (4 studies).

Table 31. Summary of evidence: Pressure ulcer treatment strategies – Iimpact of pressure ulcer treatment strategies on wound improvement and harms (continued)

Key Question and Treatment Strategy	Strength of Evidence	Conclusion
Key Question 1a. Does the comparative effectiveness of treatment strategies differ according to features of the pressure ulcers, such as anatomic site or severity at baseline?		
Support		
Support, all strategies	Insufficient	Only 4 studies reported results by ulcer stage or location, and the interventions, characteristics, and results varied and did not permit conclusions.
Nutrition		
Nutrition, all strategies	Insufficient	Only 3 of the 16 studies analyzed results by ulcer characteristics, and the impact on the conclusion was inconsistent.
Local Wound Applications		
Local wound Applications, all strategies	Insufficient	Few studies conducted subgroup analyses by ulcer characteristics (7 studies). Indirect comparisons of results across studies were limited due to heterogeneity of studies.
Surgery		
Sacral compared with ischial pressure ulcers	Low	Sacral pressure ulcers had lower recurrence rates after surgery than ischial pressure ulcers (4 studies).
Adjunctive		
Adjunctive, all strategies	Insufficient	Evidence did not permit determination as to whether the effectiveness of adjunctive therapies varied based on pressure ulcer characteristics due to heterogeneity of studies (6 studies).
Key Question 1b. Does the comparative effectiveness of treatment strategies differ according to patient characteristics, including but not limited to: age, race/ethnicity, body weight, specific medical comorbidities, and known risk factors for pressure ulcers, such as functional ability, nutritional status, or incontinence?		
Support		
Support, all strategies	Insufficient	No studies were identified that allowed conclusions about the impact of patient characteristics on the effectiveness of different support surfaces in pressure ulcer wound improvement. Indirect comparisons of results across studies were limited due to heterogeneity of studies.
Nutrition		
Nutrition, all strategies	Insufficient	Evidence did not permit determination as to whether patient characteristics, including baseline nutritional status, modified the effect of nutritional support on pressure ulcer healing due to a limited number of studies reporting outcomes by baseline nutritional status (2 studies).
Local Wound Applications		
Local wound applications, all strategies	Insufficient	Studies generally did not report outcomes by patient characteristics, including incontinence and mobility (1 study). Indirect comparisons of results across studies were limited due to heterogeneity of studies.
Surgery		
Surgical flap closure	Low	Spinal cord–injured patients had higher rates of recurrent pressure ulcer after surgical flap closure than other patients with pressure ulcers (1 study).

Table 31. Summary of evidence: Pressure ulcer treatment strategies – Iimpact of pressure ulcer treatment strategies on wound improvement and harms (continued)

Key Question and Treatment Strategy	Strength of Evidence	Conclusion
Adjunctive		
Electrical stimulation	Low	The effectiveness of electrical stimulation was similar in spinal-cord–injured patients compared with others (4 studies).
Electromagnetic therapy Therapeutic ultrasound Negative pressure wound therapy Light therapy Laser therapy	Insufficient	Evidence did not permit determination as to whether the effectiveness of electromagnetic therapy compared with sham electromagnetic therapy (2 studies), ultrasound therapy compared with sham ultrasound therapy, negative pressure wound therapy, light therapy, or laser therapy varied based on patient characteristics due to heterogeneity of studies and lack of reporting of specific patient characteristics.
Key Question 1c. Does the comparative effectiveness of treatment strategies differ according to patient care settings, such as home, nursing facility, or hospital, or according to features of patient care settings, including but not limited to nurse/patient staffing ratio, staff education and training in wound care, the use of wound care teams, and home caregiver support and training?		
Support		
Support, all strategies	Insufficient	Only 1 study provided data on results by setting and none provided information on setting characteristics. Indirect comparisons of results across studies were limited due to heterogeneity of studies.
Nutrition		
Nutrition, all strategies	Insufficient	No studies reported results by patient care settings. Indirect comparisons of results across studies were limited due to heterogeneity of studies.
Local Wound Applications		
Local wound applications, all strategies	Insufficient	No studies reported results by patient care settings. Indirect comparisons of results across studies were limited due to heterogeneity of studies.
Surgery		
Surgery, all strategies	Insufficient	No studies reported results by patient care settings. Indirect comparisons of results across studies were limited due to heterogeneity of studies.
Adjunctive		
Electrical stimulation	Low	Electrical stimulation produced similar results in a hospital compared with a rehabilitation center (9 studies).
Electromagnetic therapy Therapeutic ultrasound Negative pressure wound therapy Light therapy Laser therapy	Insufficient	Due to a lack of studies comparing different settings, evidence did not permit determination as to whether the effectiveness of electromagnetic therapy compared with sham electromagnetic therapy (2 studies), ultrasound therapy compared with sham ultrasound therapy, negative pressure wound therapy, light therapy, or laser therapy varied based on features of the patient care settings.

Table 31. Summary of evidence: Pressure ulcer treatment strategies – Iimpact of pressure ulcer treatment strategies on wound improvement and harms (continued)

Key Question and Treatment Strategy	Strength of Evidence	Conclusion
Key Question 2. What are the harms of treatments for pressure ulcers?		
Harms: Support		
Support, all strategies	Insufficient	Few of the identified studies (7 out of 24) explicitly addressed harms attributable to support surfaces. In those where harms were mentioned, most reported no significant differences in harms across the different support surfaces. However, as the harms studied were different and were associated with different support surfaces, we were unable to summarize across studies.
Harms: Nutrition		
Nutrition, all strategies	Insufficient	Harms or adverse events were reported in about half of the studies (8 of 16), but the studies reported different harms, did not describe the harm, or did not specify if it was related to treatment.
Harms: Local Wound Applications		
Dressings and topical therapies	Moderate	Harms reported with dressings and topical therapies for pressure ulcers most commonly included skin irritation and inflammation and tissue damage and maceration. Variability in study populations, interventions, adverse event measurement, and reporting precluded an estimate of adverse event rates for dressings and topical therapies (30 studies).
Dressings and topical therapies	Insufficient	Evidence was inconclusive as to whether specific dressing types or topical therapies were associated with fewer harms than others due to poor study quality and differential reporting of harms across studies (7 studies).
Biological agents	Insufficient	Few harms were reported with biological agents, but evidence did not permit determination of the incidence of harms due to lack of precision across studies (5 studies).
Harms: Surgery		
Recurrence or flap failure	Low	Reoperation due to recurrence or flap failure ranged from 12 to 24 percent (2 studies).
Harms: Adjunctive		
Electrical stimulation	Low	The most common adverse effect of electrical stimulation was local skin irritation (3 studies).
Electromagnetic therapy Therapeutic ultrasound Negative pressure wound therapy	Insufficient	Due to a lack of reporting, evidence did not permit conclusions about the harms of electromagnetic therapy (1 study), ultrasound (3 studies), or negative pressure wound therapy (2 studies).
Light therapy	Low	Light therapy caused no significant adverse events based on 4 randomized studies (4 studies).
Laser therapy	Low	Short-term use of laser therapy caused no significant adverse events based on 3 randomized studies (4 studies in all).

Table 31. Summary of evidence: Pressure ulcer treatment strategies – limpact of pressure ulcer treatment strategies on wound improvement and harms (continued)

Key Question and Treatment Strategy	Strength of Evidence	Conclusion
Key Question 2a. Do the harms of treatment strategies differ according to features of the pressure ulcers, such as anatomic site or severity at baseline?		
Harms: Support		
Support, all strategies	Insufficient	None of the identified studies reported if differences in harms of support surfaces varied based on features of the pressure ulcers. Indirect comparisons of harms across studies were limited due to heterogeneity of studies.
Harms: Nutrition		
Nutrition, all strategies	Insufficient	No studies reported harms by ulcer characteristics. Indirect comparisons of harms across studies were limited due to heterogeneity of studies.
Harms: Local Wound Applications		
Local wound applications, all strategies	Insufficient	No studies reported harms by ulcer characteristics. Indirect comparisons of harms across studies were limited due to heterogeneity of studies.
Harms: Surgery		
Surgery, all strategies	Low	Wound dehiscence was more common if bone was removed at time of surgical procedure (1 study).
Ischial ulcer surgery	Low	Complication rates after surgery were higher for ischial ulcers than for sacral or trochanteric ulcers (2 studies).
Harms: Adjunctive		
Adjunctive, all strategies	Insufficient	Due to a lack of reporting, there was inconclusive evidence to determine if differences in harms of any adjunctive therapies varied based on features of the pressure ulcers (3 studies of electrical stimulation).
Key Question 2b. Do the harms of treatment strategies differ according to patient characteristics, including age, race/ethnicity, body weight, specific medical comorbidities, and known risk factors for pressure ulcers, such as functional ability, nutritional status, or incontinence?		
Harms: Support		
Support, all strategies	Insufficient	None of the identified studies reported if differences in harms of support surfaces varied based on patient characteristics. Indirect comparisons of harms across studies were limited due to heterogeneity of studies.
Harms: Nutrition		
Nutrition, all strategies	Insufficient	No studies reported harms by patient characteristics. Indirect comparisons of harms across studies were limited due to heterogeneity of studies.
Harms: Local Wound Applications		
Local wound applications, all strategies	Insufficient	No studies reported harms by patient characteristics. Indirect comparisons of harms across studies were limited due to heterogeneity of studies.
Harms: Surgery		
Surgery, all strategies	Insufficient	No studies reported harms by patient characteristics. Indirect comparisons of harms across studies were limited due to a lack of studies and reporting.
Harms: Adjunctive		
Electrical stimulation	Low	Frail elderly patients experienced more adverse events with electrical stimulation compared with a younger population (3 studies).

Table 31. Summary of evidence: Pressure ulcer treatment strategies – limpact of pressure ulcer treatment strategies on wound improvement and harms (continued)

Key Question and Treatment Strategy	Strength of Evidence	Conclusion
Key Question 2c. Do the harms of treatment strategies differ according to patient care settings, such as home, nursing facility, or hospital, or according to features of patient care settings, including but not limited to nurse/patient staffing ratio, staff education and training in wound care, the use of wound care teams, and home caregiver support and training?		
Harms: Support		
Support, all strategies	Insufficient	None of the identified studies reported if differences in harms of support surfaces varied by patient care setting. Indirect comparisons of harms across studies were limited due to heterogeneity of studies.
Harms: Nutrition		
Nutrition, all strategies	Insufficient	No studies reported harms by patient care setting. Indirect comparisons of harms across studies were limited due to heterogeneity of studies.
Harms: Local Wound Applications		
Local wound applications, all strategies	Insufficient	No studies reported harms by patient care setting. Indirect comparisons of harms across studies were limited due to heterogeneity of studies.
Harms: Surgery		
Surgery, all strategies	Insufficient	No studies reported harms by patient care setting. Indirect comparisons of harms across studies were limited due to heterogeneity of studies and surgical procedures.
Harms: Adjunctive		
Adjunctive, all strategies	Insufficient	No studies reported harms by patient care setting. Indirect comparisons of harms across studies were limited due to heterogeneity of studies and a lack of studies comparing different settings.

References

1. Bergstrom N, Bennett MA, Carlson CE, et al. Pressure Ulcer Treatment. Clin Pract Guidel Quick Ref Guide Clin. 1994;15.
2. Graves N, Birrell F, Whitby M. Effect of pressure ulcers on length of hospital stay. Infect Control Hosp Epidemiol. 2005;26(3):293-7. PMID: 15796283.
3. Vangilder C, Macfarlane GD, Meyer S. Results of nine international pressure ulcer prevalence surveys: 1989 to 2005. Ostomy Wound Manage. 2008;54(2):40-54. PMID: 18382042.
4. Lyder CH. Pressure ulcer prevention and management. JAMA. 2003 Jan 8;289(2):223-6. PMID: 12517234.
5. NPUAP. Pressure Ulcer Prevention and Treatment: Clinical Practice guidline. National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel. 2009.
6. Thomas DR, Rodeheaver GT, Bartolucci AA, et al. Pressure ulcer scale for healing: derivation and validation of the PUSH tool. The PUSH Task Force. Adv Wound Care. 1997;10(5):96-101. PMID: 9362591.
7. Bates-Jensen BM, Vredevoe DL, Brecht ML. Validity and reliability of the Pressure Sore Status Tool. Decubitus. 1992 Nov;5(6):20-8. PMID: 1489512.
8. Methods Guide for Effectiveness and Comparative Effectiveness Reviews. AHRQ Publication No. 10(12)-EHC063-EF. Rockville, MD: Agency for Healthcare Research and Quality; April 2012. Chapters available at: www.effectivehealthcare.ahrq.gov.
9. Institute of Medicine. Finding What Works in Health Care: Standards for Systematic Reviews. Washington, DC: The National Academy of Sciences; 2011.
10. Reddy M, Gill SS, Kalkar SR, et al. Treatment of pressure ulcers: a systematic review. JAMA. 2008 Dec 10;300(22):2647-62. PMID: 19066385.
11. Downs SH, Black N. The feasibility of creating a checklist for the assessment of the methodological quality both of randomised and non-randomised studies of health care interventions. JECH. 1998;52(6):377-84. PMID: 9764259.
12. Harris RP, Helfand M, Woolf SH, et al. Current methods of the US Preventive Services Task Force: a review of the process. Am J Prev Med. 2001;20(3 Suppl):21-35. PMID: 11306229.
13. USPSTF. U.S. Preventive Services Task Force Procedures Manual. 2008 July 2008;No. 08-05118-EF:Section 4: Evidence Report Development.
14. Higgins JP, Thompson SG. Quantifying heterogeneity in a meta-analysis. Stat Med. 2002 Jun 15;21(11):1539-58. PMID: 12111919.
15. DerSimonian R, Laird N. Meta-analysis in clinical trials. Control Clin Trials. 1986 Sep;7(3):177-88.
16. Atkins D, Chang S, Gartlehner G, et al. Assessing applicability when comparing medical interventions: Agency for Healthcare Research and Quality and the Effective Health Care Program. J Clin Epidemiol. 2011;64(11):1198-207. PMID: 21463926.
17. NPUAP. Pressure Ulcer Prevention and Treatment: Clinical Practice guidline. In: Panel NPUA, editor. Ver. 01/29/2007 ed: National Pressure Ulcer Advisory Panel; 2007.
18. Russell L, Reynolds TM, Carr J, et al. Randomised controlled trial of two pressure-relieving systems. J Wound Care. 2000(a) Feb;9(2):52-5. PMID: 11933280.
19. Russell L, Reynolds T, Carr J, et al. A comparison of healing rates on two pressure-relieving systems. Br J Nurs. 2000(b) Dec 8-2001 Jan 10;9(22):2270-80. PMID: 12271193.
20. Evans D, Land L, Geary A. A clinical evaluation of the Nimbus 3 alternating pressure mattress replacement system. J Wound Care. 2000 Apr;9(4):181-6. PMID: 11933303.

21. Land L, Evans D, Geary A, et al. A clinical evaluation of an alternating-pressure mattress replacement system in hospital and residential care settings. J Tissue Viability. 2000 Jan;10(1):6-11. PMID: 10839090.

22. Mecocci P, von Strauss E, Cherubini A, et al. Cognitive impairment is the major risk factor for development of geriatric syndromes during hospitalization: results from the GIFA study. Dement Geriatr Cogn Disord. 2005;20(4):262-9. PMID: 16103670.

23. Devine B. Alternating pressure air mattresses in the management of established pressure sores. J Tissue Viability. 1995;5(3):94-8.

24. Izutsu T, Matsui T, Satoh T, et al. Effect of rolling bed on decubitus in bedridden nursing home patients. Tohoku J Exp Med. 1998 Feb;184(2):153-7. PMID: 9605022.

25. Clark M, Donald I. A randomised controlled trial comparing the healing of pressure sores upon two pressure-redistributing seat cushions. Proceedings of the 7th European European Conferences on Advances in Wound Management 18-20 November. Harrogate, UK; 1998: 122-5.

26. Caley L, Jones S, Freer J, et al. Randomized Prospective Trial: Treatment Outcomes and Cost-Effectiveness of Two Types of Low-Air-Loss Therapy. 9th Annual Clinical Symposium on Pressure Ulcer and Wound Management. Nashville, TN. October 1994:1-2.

27. Day A, Leonard F. Seeking quality care for patients with pressure ulcers. Decubitus. 1993 Jan;6(1):32-43. PMID: 8427642.

28. Flemming K, Cullum N. Therapeutic ultrasound for pressure sores. Cochrane Database Syst Rev. 2000(4):CD001275. PMID: 11034707.

29. Mulder G, Taro N, Seeley J, et al. A study of pressure ulcer response to low air loss beds vs. conventional treatment. J Geriatr Dermatol. 1994;2(3):87-91.

30. Warner DJ. A clinical comparison of two pressure-reducing surfaces in the management of pressure ulcers. Decubitus. 1992 May;5(3):52-5, 8-60, 2-4. PMID: 1596352.

31. Groen HW, Groenier KH, Schuling J. Comparative study of a foam mattress and a water mattress. J Wound Care. 1999 Jul;8(7):333-5. PMID: 10776222.

32. Branom R, Rappl LM. "Constant force technology" versus low-air-loss therapy in the treatment of pressure ulcers.[Erratum appears in Ostomy Wound Manage 2001 Nov;47(11):6]. Ostomy Wound Manage. 2001 Sep;47(9):38-46. PMID: 11889743.

33. Keogh A, Dealey C. Profiling beds versus standard hospital beds: effects on pressure ulcer incidence outcomes. J Wound Care. 2001 Feb;10(2):15-9. PMID: 12964222.

34. Rosenthal MJ, Felton RM, Nastasi AE, et al. Healing of advanced pressure ulcers by a generic total contact seat: 2 randomized comparisons with low air loss bed treatments. Arch Phys Med Rehabil. 2003 Dec;84(12):1733-42. PMID: 14669176.

35. Russell L, Reynolds TM, Towns A, et al. Randomized comparison trial of the RIK and the Nimbus 3 mattresses. Br J Nurs. 2003(a) Feb 27-Mar 12;12(4):254, 6-9. PMID: 12671572.

36. Nixon J, Nelson EA, Cranny G, et al. Pressure relieving support surfaces: a randomised evaluation. Health Technol Assess. 2006 Jul;10(22):iii-iv, ix-x, 1-163. PMID: 16750060.

37. Thompson P, Anderson J, Langemo D, et al. Support Surfaces: Definitions and Utilization for Patient Care. Adv Skin Wound Care. 2008;21(6):264-6. PMID: 18525248.

38. Makhsous M, Lin F, Knaus E, et al. Promote pressure ulcer healing in individuals with spinal cord injury using an individualized cyclic pressure-relief protocol. Adv Skin Wound Care. 2009 Nov;22(11):514-21. PMID: 20026933.

39. Malbrain M, Hendriks B, Wijnands P, et al. A pilot randomised controlled trial comparing reactive air and active alternating pressure mattresses in the prevention and treatment of pressure ulcers among medical ICU patients. J Tissue Viability. 2010 Feb;19(1):7-15. PMID: 20079647.

40. Valente SA, Greenough Iii WB, DeMarco SL, et al. More expensive surfaces are not always better. Kuwait Medical Journal. 2012;44(1):40-5.

41. Ochs RF, Horn SD, van Rijswijk L, et al. Comparison of air-fluidized therapy with other support surfaces used to treat pressure ulcers in nursing home residents. Ostomy Wound Manage. 2005 Feb;51(2):38-68. PMID: 15699554.

42. Ferrell BA, Osterweil D, Christenson P. A randomized trial of low-air-loss beds for treatment of pressure ulcers. JAMA. 1993;269(4):494-7. PMID: 8338511.

43. Allman RM, Walker JM, Hart MK, et al. Air-fluidized beds or conventional therapy for pressure sores. A randomized trial. Ann Intern Med. 1987 Nov;107(5):641-8. PMID: 3310792.

44. Jackson BS, Chagares R, Nee N, et al. The effects of a therapeutic bed on pressure ulcers: an experimental study. J Enterostomal Ther. 1988 Nov-Dec;15(6):220-6. PMID: 3204209.

45. Strauss MJ, Gong J, Gary BD, et al. The cost of home air-fluidized therapy for pressure sores. A randomized controlled trial. J Fam Pract. 1991 Jul;33(1):52-9. PMID: 2056290.

46. Munro BH, Brown L, Heitman BB. Pressure ulcers: one bed or another? Geriatr Nurs. 1989;10(4):190-2. PMID: 2777121.

47. McInnes E, National Institite for Clinical E. The use of pressure-relieving devices (beds, mattresses and overlays) for the prevention of pressure ulcers in primary and secondary care. J Tissue Viability. 2004 Jan;14(1):4-6, 8, 10 passim. PMID: 14768130.

48. McInnes E, Jammali-Blasi A, Bell-Syer SE, et al. Support surfaces for pressure ulcer prevention. Cochrane Database Syst Rev. 2011;4:CD001735. PMID: 21491384.

49. Langemo D, Thompson P, Hanson D, et al. Topical anesthesia for pressure ulcer treatment. Adv Skin Wound Care. 2008 Aug;21(8):364-9. PMID: 18679084.

50. Pinchcofsky-Devin GD, Kaminski MV. Correlation of pressure sores and nutritional status. J Am Geriatr Soc. 1986;34(6):435-40. PMID: 3084610.

51. Allman RM, Laprade CA, Noel LB, et al. Pressure sores among hospitalized patients. Ann Intern Med. 1986 Sep;105(3):337-42. PMID: 3740674.

52. European Pressure Ulcer Advisory Panel and National Pressure Ulcer Advisory Panel. Prevention and treatment of pressure ulcers: quick reference guide. Washington, DC: National Pressure Ulcer Advisory Panel; 2009.

53. Cereda E, Gini A, Pedrolli C, et al. Disease-specific, versus standard, nutritional support for the treatment of pressure ulcers in institutionalized older adults: a randomized controlled trial. J Am Geriatr Soc. 2009 Aug;57(8):1395-402. PMID: 19563522.

54. Ter Riet G, Kessels AGH, Knipschild PG. Randomized clinical trial of ascorbic acid in the treatment of pressure ulcers. J Clin Epidemiol. 1995;48(12):1453-60. PMID: 8543959.

55. Leigh B, Desneves K, Rafferty J, et al. The effect of different doses of an arginine-containing supplement on the healing of pressure ulcers. J Wound Care. 2012;21(3):150-6. PMID: 22399084.

56. Meaume S, Kerihuel JC, Constans T, et al. Efficacy and safety of ornithine alpha-ketoglutarate in heel pressure ulcers in elderly patients: results of a randomized controlled trial. J Nutr Health Aging. 2009 Aug;13(7):623-30. PMID: 19621198.

57. Van Anholt RD, Sobotka L, Meijer EP, et al. An arginine- and micronutrient-enriched nutritional supplement accelerates pressure ulcer healing and reduces wound care in non-malnourished patients. EWMA Journal. 2010 49, 2010;10(2):45.

58. Benati G, Delvecchio S, Cilla D, et al. Impact on pressure ulcer healing of an arginine-enriched nutritional solution in patients with severe cognitive impairment. Arch Gerontol Geriatr Suppl. 2001;7:43-7. PMID: 11431045.

59. Desneves KJ, Todorovic BE, Cassar A, et al. Treatment with supplementary arginine, vitamin C and zinc in patients with pressure ulcers: a randomised controlled trial. Clin Nutr. 2005 Dec;24(6):979-87. PMID: 16297506.

60. Lee SK, Posthauer ME, Dorner B, et al. Pressure ulcer healing with a concentrated, fortified, collagen protein hydrolysate supplement: a randomized controlled trial. Adv Skin Wound Care. 2006 Mar;19(2):92-6. PMID: 16557055.

61. Myers SA, Takiguchi S, Slavish S, et al. Consistent wound care and nutritional support in treatment. Decubitus. 1990 Aug;3(3):16-28. PMID: 2119183.

62. Ohura T, Nakajo T, Okada S, et al. Evaluation of effects of nutrition intervention on healing of pressure ulcers and nutritional states (randomized controlled trial). Wound Repair Regen. 2011 May-Jun;19(3):330-6. PMID: 21539650.

63. Chernoff R. The effect of a high protein fomula (Replete) on decubitus ulcer healing in long term tube fed institutionalized patients. J Am Diet Assoc. 1990;90(130).

64. Spungen AM, Koehler KM, Modeste-Duncan R, et al. 9 clinical cases of nonhealing pressure ulcers in patients with spinal cord injury treated with an anabolic agent: a therapeutic trial. Adv Skin Wound Care. 2001 May-Jun;14(3):139-44. PMID: 11905979.

65. Omote S, Sugama J, Sanada H, et al. Healing process of pressure ulcers after a change in the nutrition regimen of bedridden elderly: a case series. Jpn J Nurs Sci. 2005;2(2):85-93.

66. Breslow RA, Hallfrisch J, Guy DG, et al. The importance of dietary protein in healing pressure ulcers. J Am Geriatr Soc. 1993;41(4):357-62. PMID: 8463519.

67. Brewer S, Desneves K, Pearce L, et al. Effect of an arginine-containing nutritional supplement on pressure ulcer healing in community spinal patients. J Wound Care. 2010 Jul;19(7):311-6. PMID: 20616774.

68. Houston S, Haggard J, Williford J, Jr., et al. Adverse effects of large-dose zinc supplementation in an institutionalized older population with pressure ulcers [4]. J Am Geriatr Soc. 2001;49(8):1130-2. PMID: 11555083.

69. Yamamoto T, Fujioka M, Kitamura R, et al. Evaluation of nutrition in the healing of pressure ulcers: are the EPUAP nutritional guidelines sufficient to heal wounds. European Pressure Ulcer Advisory Panel. Wounds. 2009;21(6):153-7.

70. Barnes P, Jr., Sauter TE, Zaheri S. Subnormal prealbumin levels and wound healing. Tex Med. 2007 Aug;103(8):65-8. PMID: 19113064.

71. Frias Soriano L, Lage Vazquez MA, Maristany CP-P, et al. The effectiveness of oral nutritional supplementation in the healing of pressure ulcers. J Wound Care. 2004 Sep;13(8):319-22. PMID: 15469215.

72. Hollisaz MT, Khedmat H, Yari F. A randomized clinical trial comparing hydrocolloid, phenytoin and simple dressings for the treatment of pressure ulcers [ISRCTN33429693]. BMC Dermatol. 2004;4(1):18. PMID: 15601464.

73. Alm A, Hornmark AM, Fall PA, et al. Care of pressure sores: a controlled study of the use of a hydrocolloid dressing compared with wet saline gauze compresses. Acta Derm Venereol Suppl (Stockh). 1989;149:1-10. PMID: 2694713.

74. Xakellis. Hydrocolloid versus saline-gauze dressings in treating pressure ulcers: a cost-effectiveness analysis. Arch Phys Med Rehabil. 1992;73:463-9. PMID: 1580775.

75. Chang KW, Alsagoff S, Ong KT, et al. Pressure ulcers--randomised controlled trial comparing hydrocolloid and saline gauze dressings. Med J Malaysia. 1998 Dec;53(4):428-31. PMID: 10971989.

76. Colwell JC, Foreman MD, Trotter JP. A comparison of the efficacy and cost-effectiveness of two methods of managing pressure ulcers. Decubitus. 1993 Jul;6(4):28-36. PMID: 8297488.

77. Gorse GJ, Messner RL. Improved pressure sore healing with hydrocolloid dressings. Arch Dermatol. 1987 Jun;123(6):766-71. PMID: 3555355.

78. Kim YC, Shin JC, Park CI, et al. Efficacy of hydrocolloid occlusive dressing technique in decubitus ulcer treatment: a comparative study. Yonsei Med J. 1996 Jun;37(3):181-5. PMID: 8826783.

79. Mulder GD, Altman M, Seeley JE, et al. Prospective randomized study of the efficacy of hydrogel, hydrocolloid, and saline solution -- moistened dressings on the management of pressure ulcers. Wound Repair Regen. 1993;1(4):213-8. PMID: 17166097.

80. Neill K, Conforti C, Kedas A, et al. Pressure sore response to a new hydrocolloid dressing. Wounds. 1989;1:173-85.

81. Winter A, Hewitt H. Testing a hydrocolloid. Nurs Times. 1990 Dec 12-8;86(50):59-62. PMID: 2255648.

82. Matzen S, Peschardt A, Alsbjorn B. A new amorphous hydrocolloid for the treatment of pressure sores: a randomised controlled study. Scand J Plast Reconstr Surg Hand Surg. 1999 Mar;33(1):13-5. PMID: 10207960.

83. Kaya AZ, Turani N, Akyuz M. The effectiveness of a hydrogel dressing compared with standard management of pressure ulcers. J Wound Care. 2005 Jan;14(1):42-4. PMID: 15656468.

84. Thomas DR, Goode PS, LaMaster K, et al. Acemannan hydrogel dressing versus saline dressing for pressure ulcers. A randomized, controlled trial. Adv Wound Care. 1998 Oct;11(6):273-6. PMID: 10326343.

85. Parnell LKS, Ciufi B, Gokoo CF. Preliminary use of a hydrogel containing enzymes in the treatment of stage II and stage III pressure ulcers. Ostomy Wound Manage. 2005 Aug;51(8):50-60. PMID: 16234576.

86. Yastrub DJ. Relationship between type of treatment and degree of wound healing among institutionalized geriatric patients with stage II pressure ulcers... reprinted with permission from the author and Nurse Practitioner Associates for Continuing Education. Care Manag J. 2004;5(4):213-8.

87. Payne WG, Posnett J, Alvarez O, et al. A prospective, randomized clinical trial to assess the cost-effectiveness of a modern foam dressing versus a traditional saline gauze dressing in the treatment of stage II pressure ulcers. Ostomy Wound Manage. 2009 Feb;55(2):50-5. PMID: 19246785.

88. Kraft MR, Lawson L, Pohlmann B, et al. A comparison of Epi-Lock and saline dressings in the treatment of pressure ulcers. Decubitus. 1993 Nov;6(6):42-4, 6, 8. PMID: 8286026.

89. Sebern MD. Pressure ulcer management in home health care: efficacy and cost effectiveness of moisture vapor permeable dressing. Arch Phys Med Rehabil. 1986 Oct;67(10):726-9. PMID: 3533007.

90. Kurzuk-Howard G, Simpson L, Palmieri A. Decubitus ulcer care: a comparative study. West J Nurs Res. 1985 Feb;7(1):58-79. PMID: 3850687.

91. Oleske DM, Smith XP, White P, et al. A randomized clinical trial of two dressing methods for the treatment of low-grade pressure ulcers. J Enterostomal Ther. 1986 May-Jun;13(3):90-8. PMID: 3519718.

92. Day A, Dombranski S, Farkas C, et al. Managing sacral pressure ulcers with hydrocolloid dressings: results of a controlled, clinical study. Ostomy Wound Manage. 1995 Mar;41(2):52-4, 6, 8 passim. PMID: 7598778.

93. Darkovich SL, Brown-Etris M, Spencer M. Biofilm hydrogel dressing: a clinical evaluation in the treatment of pressure sores. Ostomy Wound Manage. 1990 Jul-Aug;29:47-60. PMID: 2202317.

94. Motta G, Dunham L, Dye T, et al. Clinical efficacy and cost-effectiveness of a new synthetic polymer sheet wound dressing. Ostomy Wound Manage. 1999 Oct;45(10):41, 4-6, 8-9. PMID: 10687651.

95. Brown-Etris M, Milne C, Orsted H, et al. A prospective, randomized, multisite clinical evaluation of a transparent absorbent acrylic dressing and a hydrocolloid dressing in the management of Stage II and shallow Stage III pressure ulcers. Adv Skin Wound Care. 2008 Apr;21(4):169-74. PMID: 18385577.

96. Bale S, Squires D, Varnon T, et al. A comparison of two dressings in pressure sore management. J Wound Care. 1997 Nov;6(10):463-6. PMID: 9455271.

97. Honde C, Derks C, Tudor D. Local treatment of pressure sores in the elderly: amino acid copolymer membrane versus hydrocolloid dressing. J Am Geriatr Soc. 1994 Nov;42(11):1180-3. PMID: 7525682.

98. Seeley J, Jensen JL, Hutcherson J. A randomized clinical study comparing a hydrocellular dressing to a hydrocolloid dressing in the management of pressure ulcers. Ostomy Wound Manage. 1999 Jun;45(6):39-44, 6-7. PMID: 10655861.

99. Banks V, Bale SE, Harding KG. Comparing two dressings for exuding pressure sores in community patients. J Wound Care. 1994(a);3(4):175-8.

100. Banks V, Bale S, Harding K. The use of two dressings for moderately exuding pressure sores. J Wound Care. 1994(b);3(3):132-4.

101. Brod M, McHenry E, Plasse TF, et al. A randomized comparison of poly-hema and hydrocolloid dressings for treatment of pressure sores. Arch Dermatol. 1990 Jul;126(7):969-70. PMID: 2193631.

102. Bale S, Hagelstein S, Banks V, et al. Costs of dressings in the community. J Wound Care. 1998(b) Jul;7(7):327-30. PMID: 9791356.

103. Thomas S, Banks V, Bale S, et al. A comparison of two dressings in the management of chronic wounds. J Wound Care. 1997 Sep;6(8):383-6. PMID: 9341430.

104. Bale S, Banks V, Haglestein S, et al. A comparison of two amorphous hydrogels in the debridement of pressure sores. J Wound Care. 1998 (a) Feb;7(2):65-8. PMID: 9543975.

105. Belmin J, Meaume S, Rabus M-T, et al. Sequential treatment with calcium alginate dressings and hydrocolloid dressings accelerates pressure ulcer healing in older subjects: a multicenter randomized trial of sequential versus nonsequential treatment with hydrocolloid dressings alone. J Am Geriatr Soc. 2002 Feb;50(2):269-74. PMID: 12028208.

106. Meaume S, Vallet D, Morere MN, et al. Evaluation of a silver-releasing hydroalginate dressing in chronic wounds with signs of local infection.[Erratum appears in J Wound Care. 2005 Nov;14(10):479]. J Wound Care. 2005 Oct;14(9):411-9. PMID: 16240620.

107. Meaume S, Van De Looverbosch D, Heyman H, et al. A study to compare a new self-adherent soft silicone dressing with a self-adherent polymer dressing in stage II pressure ulcers. Ostomy Wound Manage. 2003 Sep;49(9):44-51. PMID: 14581709.

108. Viamontes L, Temple D, Wytall D, et al. An evaluation of an adhesive hydrocellular foam dressing and a self-adherent soft silicone foam dressing in a nursing home setting. Ostomy Wound Manage. 2003 Aug;49(8):48-52, 4-6, 8. PMID: 14631663.

109. Thomas DR, Diebold MR, Eggemeyer LM. A controlled, randomized, comparative study of a radiant heat bandage on the healing of stage 3-4 pressure ulcers: a pilot study. J Am Med Dir Assoc. 2005 Jan-Feb;6(1):46-9. PMID: 15871870.

110. Price P, Bale S, Crook H, et al. The effect of a radiant heat dressing on pressure ulcers. J Wound Care. 2000 Apr;9(4):201-5. PMID: 11933306.

111. Kloth LC, Berman JE, Nett M, et al. A randomized controlled clinical trial to evaluate the effects of noncontact normothermic wound therapy on chronic full-thickness pressure ulcers. Adv Skin Wound Care. 2002 Nov-Dec;15(6):270-6. PMID: 12477979.

112. Whitney JD, Salvadalena G, Higa L, et al. Treatment of pressure ulcers with noncontact normothermic wound therapy: healing and warming effects. J Wound Ostomy Continence Nurs. 2001 Sep;28(5):244-52. PMID: 11557928.

113. Bito S, Mizuhara A, Oonishi S, et al. Randomised controlled trial evaluating the efficacy of wrap therapy for wound healing acceleration in patients with NPUAP stage II and III pressure ulcer. 2012;2:e000371. PMID: 22223842.

114. Kerihuel JC. Effect of activated charcoal dressings on healing outcomes of chronic wounds. J Wound Care. 2010 May;19(5):208, 10-2, 14-5. PMID: 20505594.

115. Small N, Mulder M, Mackenzie MJ, et al. A comparative analysis of pressure sore treatment modalities in community settings. Curationis. 2002 Feb;25(1):74-82. PMID: 12096575.

116. Yapucu Gunes U, Eser I. Effectiveness of a honey dressing for healing pressure ulcers. J Wound Ostomy Continence Nurs. 2007 Mar-Apr;34(2):184-90. PMID: 17413836.

117. Burgos A, Gimenez J, Moreno E, et al. Collagenase ointment application at 24- versus 48-hour intervals in the treatment of pressure ulcers. A randomised multicentre study. Clin Drug Investig. 2000;19(6):399-407.

118. Burgos A, Gimenez J, Moreno E, et al. Cost, efficacy, efficiency and tolerability of collagenase ointment versus hydrocolloid occlusive dressing in the treatment of pressure ulcers. A comparative, randomised, multicentre study. Clin Drug Investig. 2000;19(5):357-65.

119. Pullen R, Popp R, Volkers P, et al. Prospective randomized double-blind study of the wound-debriding effects of collagenase and fibrinolysin/deoxyribonuclease in pressure ulcers. Age Ageing. 2002 Mar;31(2):126-30. PMID: 11937475.

120. Alvarez OM, Fernandez-Obregon A, Rogers RS, et al. Chemical debridement of pressure ulcers: a prospective, randomized, comparative trial of collagenase and papain/urea formulations. Wounds. 2000;12(2):15-25.

121. Muller E, van Leen MW, Bergemann R. Economic evaluation of collagenase-containing ointment and hydrocolloid dressing in the treatment of pressure ulcers. Pharmacoeconomics. 2001;19(12):1209-16. PMID: 11772156.

122. Agren MS, Stromberg HE. Topical treatment of pressure ulcers. A randomized comparative trial of Varidase and zinc oxide. Scand J Plast Reconstr Surg. 1985;19(1):97-100. PMID: 3895409.

123. Subbanna PK, Margaret Shanti FX, George J, et al. Topical phenytoin solution for treating pressure ulcers: a prospective, randomized, double-blind clinical trial. Spinal Cord. 2007 Nov;45(11):739-43. PMID: 17279096.

124. Rhodes RS, Heyneman CA, Culbertson VL, et al. Topical phenytoin treatment of stage II decubitus ulcers in the elderly. Ann Pharmacother. 2001 Jun;35(6):675-81. PMID: 11408983.

125. Sayag J, Meaume S, Bohbot S. Healing properties of calcium alginate dressings. J Wound Care. 1996 Sep;5(8):357-62. PMID: 8954425.

126. Colin D, Kurring PA, Yvon C. Managing sloughy pressure sores. J Wound Care. 1996 Nov;5(10):444-6. PMID: 9117814.

127. Graumlich JF, Blough LS, McLaughlin RG, et al. Healing pressure ulcers with collagen or hydrocolloid: A randomized, controlled trial. J Am Geriatr Soc. 2003;51(2):147-54. PMID: 12558709.

128. Zeron HM, Krotzsch Gomez FE, Munoz REH. Pressure ulcers: a pilot study for treatment with collagen polyvinylpyrrolidone. Int J Dermatol. 2007 Mar;46(3):314-7. PMID: 17343594.

129. Nisi G, Brandi C, Grimaldi L, et al. Use of a protease-modulating matrix in the treatment of pressure sores. Chir Ital. 2005 Jul-Aug;57(4):465-8. PMID: 16060184.

130. Gerding GA, Browning JS. Oxyquinoline-containing ointment vs. standard therapy for stage I and stage II skin lesions. Dermatol Nurs. 1992 Oct;4(5):389-98. PMID: 1482629.

131. Chuangsuwanich A, Charnsanti O, Lohsiriwat V, et al. The efficacy of silver mesh dressing compared with silver sulfadiazine cream for the treatment of pressure ulcers. J Med Assoc Thai. 2011 May;94(5):559-65. PMID: 21675444.

132. Sherman RA, Wyle F, Vulpe M. Maggot therapy for treating pressure ulcers in spinal cord injury patients. J Spinal Cord Med. 1995 Apr;18(2):71-4. PMID: 7640976.

133. Sherman RA. Maggot versus conservative debridement therapy for the treatment of pressure ulcers. Wound Repair Regen. 2002 Jul-Aug;10(4):208-14. PMID: 12191002.

134. Wang S-y, Wang J-n, Lv D-c, et al. Clinical research on the bio-debridement effect of maggot therapy for treatment of chronically infected lesions. Orthop Surg. 2010;2(3):201-6. PMID: 22009949.

135. Sipponen A, Jokinen JJ, Sipponen P, et al. Beneficial effect of resin salve in treatment of severe pressure ulcers: a prospective, randomized and controlled multicentre trial. Br J Dermatol. 2008 May;158(5):1055-62. PMID: 18284391.

136. Guthrie M, Diakiw J, Zaydon AC, et al. A randomized double-blind clinical study of dermagran dual therapeutic system in the treatment of decubitus ulcers. Wounds. 1989;1(3):142-54.

137. Kuflik A, Stillo JV, Sanders D, et al. Petrolatum versus Resurfix ointment in the treatment of pressure ulcers. Ostomy Wound Manage. 2001 Feb;47(2):52-6. PMID: 11235499.

138. LeVasseur SA, Helme RD. A double-blind clinical trial to compare the efficacy of an active based cream F14001 against a placebo non-active based cream for the treatment of pressure ulcers in a population of elderly subjects. J Adv Nurs. 1991 Aug;16(8):952-6. PMID: 1779084.

139. Shamimi Nouri K, Karimian R, Nasli E, et al. Topical application of Semelil (ANGIPARS(trademark)) in treatment of pressure ulcers: A randomized clinical trial. Daru. 2008;16(SUPPL. 1):54-7.

140. Hsu YC, Chang HH, Chen MF, et al. Therapeutic effect of sheng-ji-san on pressure ulcers. Am J Chin Med. 2000;28(3-4):391-9. PMID: 11154053.

141. Felzani G, Spoletini I, Convento A, et al. Effect of lysine hyaluronate on the healing of decubitus ulcers in rehabilitation patients. Adv Ther. 2011 May;28(5):439-45. PMID: 21499725.

142. Tytgat H, Van Asch H. Topical ketanserin in the treatment of decubitus ulcers: A double-blind study with 2% ketanserin ointment against placebo. Adv Ther. 1988;5(4):143-52.

143. Narayanan S, Van Vleet J, Strunk B, et al. Comparison of pressure ulcer treatments in long-term care facilities: clinical outcomes and impact on cost. J Wound Ostomy Continence Nurs. 2005 May-Jun;32(3):163-70. PMID: 15931146.

144. Rees RS, Robson MC, Smiell JM, et al. Becaplermin gel in the treatment of pressure ulcers: a phase II randomized, double-blind, placebo-controlled study. Wound Repair Regen. 1999 May-Jun;7(3):141-7. PMID: 10417749.

145. Robson MC, Phillips LG, Thomason A, et al. Platelet-derived growth factor BB for the treatment of chronic pressure ulcers. Lancet. 1992 Jan 4;339(8784):23-5. PMID: 1345953.

146. Robson MC, Phillips LG, Thomason A, et al. Recombinant human platelet-derived growth factor-BB for the treatment of chronic pressure ulcers. Ann Plast Surg. 1992;29(3):193-201. PMID: 1524367.

147. Mustoe TA, Cutler NR, Allman RM, et al. A phase II study to evaluate recombinant platelet-derived growth factor-BB in the treatment of stage 3 and 4 pressure ulcers. Arch Surg. 1994 Feb;129(2):213-9. PMID: 8304833.

148. Scevola S, Nicoletti G, Brenta F, et al. Allogenic platelet gel in the treatment of pressure sores: a pilot study. Int Wound J. 2010 Jun;7(3):184-90. PMID: 20455960.

149. Landi F, Aloe L, Russo A, et al. Topical treatment of pressure ulcers with nerve growth factor: a randomized clinical trial. Ann Intern Med. 2003 Oct 21;139(8):635-41. PMID: 14568851.

150. Payne WG, Wright TE, Ochs D, et al. An exploratory study of dermal replacement therapy in the treatment of stage III pressure ulcers. J Appl Res. 2004;4(1):12-23.

151. Robson MC, Phillips LG, Lawrence WT, et al. The safety and effect of topically applied recombinant basic fibroblast growth factor on the healing of chronic pressure sores. Ann Surg. 1992 Oct;216(4):401-6; discussion 6-8. PMID: 1417189.

152. Hirshberg J, Coleman J, Marchant B, et al. TGF-beta3 in the treatment of pressure ulcers: a preliminary report. Adv Skin Wound Care. 2001 Mar-Apr;14(2):91-5. PMID: 11899912.

153. Robson MC, Hill DP, Smith PD, et al. Sequential cytokine therapy for pressure ulcers: clinical and mechanistic response. Ann Surg. 2000 Apr;231(4):600-11. PMID: 10749622.

154. Payne WG, Ochs DE, Meltzer DD, et al. Long-term outcome study of growth factor-treated pressure ulcers. Am J Surg. 2001 Jan;181(1):81-6. PMID: 11248182.

155. Robson LE. Safety and effect of topical recombinant human interleukin-1beta in the management of pressure sores. Wound Repair Regen. 1994 Jul;2(3):177-81. PMID: 17156109.

156. Zuloff-Shani A, Adunsky A, Even-Zahav A, et al. Hard to heal pressure ulcers (stage III-IV): efficacy of injected activated macrophage suspension (AMS) as compared with standard of care (SOC) treatment controlled trial. Arch Gerontol Geriatr. 2010 Nov-Dec;51(3):268-72. PMID: 20034682.

157. Danon D, Madjar J, Edinov E, et al. Treatment of human ulcers by application of macrophages prepared from a blood unit. Exp Gerontol. 1997 Nov-Dec;32(6):633-41. PMID: 9785089.

158. Whitney J, Higa L, Savadalena G, et al. Effect of radiant heat treatment on pressure ulcer healing: preliminary findings. 31st Annual Wound, Ostomy and Continence Conference; 1999.

159. Meaume S, Ourabah Z, Charru P, et al. Optimizing wound care with a new lipido-colloid dressing (Urgotul Duo). Br J Nurs. 2007 Mar 22-Apr 11;16(6):S4, S6, S8 passim. PMID: 17505400.

160. Stoker FM. A major contributor. Evaluation of Comfeel Pressure Relieving Dressing. Prof Nurse. 1990 Sep;5(12):644-53. PMID: 2217219.

161. Moody M. Calcium alginate: a dressing trial. Nurs Stand. 1991;5(50):3-6. PMID: 1911033.

162. Harding KG, Bale S, Stock J, et al. A multi-center comparison of a hydrocellular adhesive dressing and a hydrocolloid dressing in the management of stage II and III pressure ulcers. 9th Annual Symposium on Advanced Wound Care and 6th Annual Medical Research Forum on Wound Repair. 1996.

163. Hindryckx P, De Cuyper C, Hendrickx B, et al. The treatment of infected decubitus ulcers with 1% silver sulfadiazine cream. Curr Ther Res Clin Exp. 1990;48(3):535-9.

164. Sorensen JL, Jorgensen B, Gottrup F. Surgical treatment of pressure ulcers. Am J Surg. 2004 Jul;188(1A Suppl):42-51. PMID: 15223502.

165. Juri H, Palma A, Obeide A. The CO2 laser in the treatment of decubitus ulcer. J Neurol Orth Med Surg. 1986;7(1):29-33. PMID: 3683061.

166. Kierney PC, Engrav LH, Isik FF, et al. Results of 268 pressure sores in 158 patients managed jointly by plastic surgery and rehabilitation medicine. Plast Reconstr Surg. 1998 Sep;102(3):765-72. PMID: 9727442.

167. Yamamoto Y, Tsutsumida A, Murazumi M, et al. Long-term outcome of pressure sores treated with flap coverage. Plast Reconstr Surg. 1997 Oct;100(5):1212-7. PMID: 9326782.

168. Schryvers OI, Stranc MF, Nance PW. Surgical treatment of pressure ulcers: 20-year experience. Arch Phys Med Rehabil. 2000 Dec;81(12):1556-62. PMID: 11128889.

169. Foster RD, Anthony JP, Mathes SJ, et al. Flap selection as a determinant of success in pressure sore coverage. Arch Surg. 1997(a) Aug;132(8):868-73. PMID: 9267271.

170. Foster RD, Anthony JP, Mathes SJ, et al. Ischial pressure sore coverage: A rationale for flap selection. Br J Plast Surg. 1997(b);50(5):374-9. PMID: 9245873.

171. Tavakoli K, Rutkowski S, Cope C, et al. Recurrence rates of ischial sores in para- and tetraplegics treated with hamstring flaps: an 8-year study. Br J Plast Surg. 1999 Sep;52(6):476-9. PMID: 10673925.

172. Feedar JAK, LC. Acceleration of wound healing with high voltage pulsating direct current (abstract). Phys Ther. 1985(65):741.

173. Stefanovska A. Treatment of chronic wounds by means of electric and electromagnetic fields. Part 2. Value of FES parameters for pressure sore treatment. Med Biol Eng Comput. 1993 May;31(3):213-20. PMID: 8412373.

174. Onigbinde AT, Olafimihan KF, Ojoawo A, et al. The effect of ultraviolet radiation (type B) on decubitus ulcers. Internet J Allied Health Sci Pract. 2010;8(1):1-6.

175. Srivastava RN. An innovative, cost-effective, negative pressure device for management of bedsores in traumatic paraplegia. Spine J. 2010;10(9):86S-7S.

176. Berlowitz DR, Ratliff C, Cuddigan J, et al. The PUSH tool: a survey to determine its perceived usefulness. Adv Skin Wound Care. 2005 Nov-Dec;18(9):480-3. PMID: 16365545.

177. Houghton PE, Campbell KE, Fraser CH, et al. Electrical stimulation therapy increases rate of healing of pressure ulcers in community-dwelling people with spinal cord injury. Arch Phys Med Rehabil. 2010 May;91(5):669-78. PMID: 20434602.

178. Adegoke BO, Badmos KA. Acceleration of pressure ulcer healing in spinal cord injured patients using interrupted direct current. Afr J Med Med Sci. 2001 Sep;30(3):195-7. PMID: 14510128.

179. Adunsky A, Ohry A, Group D. Decubitus direct current treatment (DDCT) of pressure ulcers: results of a randomized double-blinded placebo controlled study. Arch Gerontol Geriatr. 2005 Nov-Dec;41(3):261-9. PMID: 15998547.

180. Ahmad ET. High voltage pulsed galvanic stimulation: effect of treatment durations on healing of chronic pressure ulcers. Indian J Physiother Occup Ther. 2008;2(3):1-5. PMID: 21991123.

181. Baker LL, Rubayi S, Villar F, et al. Effect of electrical stimulation waveform on healing of ulcers in human beings with spinal cord injury. Wound Repair Regen. 1996 Jan-Mar;4(1):21-8. PMID: 17129344.

182. Gentzkow GD, Pollack VP, Kloth LC, et al. Improved healing of pressure ulcers using Dermapulse, a new electrical stimulation device. Wounds. 1991;3(5):158-70.

183. Griffin JW, Tooms RE, Mendius RA, et al. Efficacy of high voltage pulsed current for healing of pressure ulcers in patients with spinal cord injury. Phys Ther. 1991 Jun;71(6):433-42; discussion 42-4. PMID: 2034707.

184. Kloth LC, Feedar JA. Acceleration of wound healing with high voltage, monophasic, pulsed current.[Erratum appears in Phys Ther 1989 Aug;69(8):702]. Phys Ther. 1988 Apr;68(4):503-8. PMID: 3258429.

185. Wood JM, Evans PE, 3rd, Schallreuter KU, et al. A multicenter study on the use of pulsed low-intensity direct current for healing chronic stage II and stage III decubitus ulcers. Arch Dermatol. 1993 Aug;129(8):999-1009. PMID: 8352625.

186. Ullah MO. A study to detect the efficacy of Micro-current Electrical Therapy on decubitus wound. J Med Sci. 2007;7(8):1320-4.

187. Gardner SE, Frantz RA, Schmidt FL. Effect of electrical stimulation on chronic wound healing: a meta-analysis. Wound Repair Regen. 1999 Nov-Dec;7(6):495-503. PMID: 10633009.

188. Ahmad ET. High-voltage pulsed galvanic stimulation: effect of treatment duration on healing of chronic pressure ulcers. Ann Burns Fire Disasters. 2008;21(3):124-8. PMID: 21991123.

189. McGaughey H, Dhamija S, Oliver L, et al. Pulsed electromagnetic energy in management of chronic wounds: a systematic review. Phys Ther Rev. 2009;14(2):132-46.

190. Comorosan S, Vasilco R, Arghiropol M, et al. The effect of diapulse therapy on the healing of decubitus ulcer. Rom J Physiol. 1993 Jan-Jun;30(1-2):41-5. PMID: 7982015.

191. Gupta A, Taly AB, Srivastava A, et al. Efficacy of pulsed electromagnetic field therapy in healing of pressure ulcers: A randomized control trial. Neurol India. 2009 Sep-Oct;57(5):622-6. PMID: 19934563.

192. Salzberg CA, Cooper-Vastola SA, Perez FJ, et al. The effects of non-thermal pulsed electromagnetic energy (DIAPULSE) on wound healing of pressure ulcers in spinal cord-injured patients: a randomized, double-blind study. Wounds. 1995 Jan-Feb;7(1):11-6.

193. Ozdemir F, Kasapoglu M, Oymak F, et al. Efficiency of magnetic field treatment on pressure sores in bedridden patients. Balkan Medical Journal. 2011;28(3):274-8.

194. Aziz Z, Flemming K, Cullum NA, et al. Electromagnetic therapy for treating pressure ulcers. Cochrane Database Syst Rev. 2010;11:CD002930. PMID: 21069672.

195. Speed CAC. Therapeutic ultrasound in soft tissue lesions. Rheumatology (Oxford). 2001;40(12):1331-6. PMID: 11752501.

196. McDiarmid T, Burns PN, Lewith GT, et al. Ultrasound and the treatment of pressure sores. Physiotherapy. 1985;71(2):66-70.

197. Ter Riet G, Kessels AGH, Knipschild P. Randomised clinical trial of ultrasound treatment for pressure ulcers. Br Med J. 1995;310(6986):1040-1. PMID: 7728058.

198. Ter Riet G, Kessels AGH, Knipschild P. A randomized clinical trial of ultrasound in the treatment of pressure ulcers. Phys Ther. 1996;76(12):1301-12. PMID: 8959999.

199. Nussbaum EL, Biemann I, Mustard B. Comparison of ultrasound/ultraviolet-C and laser for treatment of pressure ulcers in patients with spinal cord injury. Phys Ther. 1994 Sep;74(9):812-23; discussion 24-5. PMID: 8066108.

200. Maeshige N, Fujiwara H, Honda H, et al. Evaluation of the combined use of ultrasound irradiation and wound dressing on pressure ulcers. J Wound Care. 2010 Feb;19(2):63-8. PMID: 20216490.

201. Sari AA, Flemming K, Cullum NA, et al. Therapeutic ultrasound for pressure ulcers. Cochrane Database Syst Rev. 2009(4).

202. Sullivan N, Snyder DL, Tipton K, et al. Negative Pressure Wound Therapy Devices. Technology Assessment Report. Rockville, Maryland: AHRQ 2009: 494.

203. Ford CN, Reinhard ER, Yeh D, et al. Interim analysis of a prospective, randomized trial of vacuum-assisted closure versus the healthpoint system in the management of pressure ulcers. Ann Plast Surg. 2002 Jul;49(1):55-61; discussion PMID: 12142596.

204. Wanner MB, Schwarzl F, Strub B, et al. Vacuum-assisted wound closure for cheaper and more comfortable healing of pressure sores: a prospective study. Scand J Plast Reconstr Surg Hand Surg. 2003;37(1):28-33. PMID: 12625392.

205. Ho CH, Powell HL, Collins JF, et al. Poor nutrition is a relative contraindication to negative pressure wound therapy for pressure ulcers: preliminary observations in patients with spinal cord injury. Adv Skin Wound Care. 2010 Nov;23(11):508-16. PMID: 20975334.

206. WHO. UV raditation. World Health Organization; 2012.

207. Wikipedia. Laser. Wikipedia: Wikipedia; 2012.

208. Dehlin O, Elmstahl S, Gottrup F. Monochromatic phototherapy in elderly patients: a new way of treating chronic pressure ulcers?.[Erratum appears in Aging Clin Exp Res. 2003 Dec;15(6):519]. Aging Clin Exp Res. 2003 Jun;15(3):259-63. PMID: 14582689.

209. Dehlin O, Elmstahl S, Gottrup F. Monochromatic phototherapy: effective treatment for grade II chronic pressure ulcers in elderly patients. Aging Clin Exp Res. 2007 Dec;19(6):478-83. PMID: 18172370.

210. Durovic A, Maric D, Brdareski Z, et al. The effects of polarized light therapy in pressure ulcer healing. Vojnosanit Pregl. 2008 Dec;65(12):906-12. PMID: 19160985.

211. Iordanou P, Baltopoulos G, Giannakopoulou M, et al. Effect of polarized light in the healing process of pressure ulcers.[Erratum appears in Int J Nurs Pract 2002 Apr;8(2):116]. Int J Nurs Pract. 2002 Feb;8(1):49-55. PMID: 11831427.

212. Schubert V. Effects of phototherapy on pressure ulcer healing in elderly patients after a falling trauma. A prospective, randomized, controlled study. Photodermatol Photoimmunol Photomed. 2001 Feb;17(1):32-8. PMID: 11169174.

213. Lucas C, Coenen CHM, De Haan RJ. The effect of low level laser therapy (LLLT) on stage III decubitus ulcers (pressure sores); A prospective randomised single blind, multicentre pilot study. Lasers Med Sci. 2000;15(2):94-100. PMID: 12928815.

214. Lucas C, van Gemert MJC, de Haan RJ. Efficacy of low-level laser therapy in the management of stage III decubitus ulcers: a prospective, observer-blinded multicentre randomised clinical trial. Lasers Med Sci. 2003;18(2):72-7. PMID: 12928815.

215. Taly AB, Sivaraman Nair KP, Murali T, et al. Efficacy of multiwavelength light therapy in the treatment of pressure ulcers in subjects with disorders of the spinal cord: A randomized double-blind controlled trial. Arch Phys Med Rehabil. 2004 Oct;85(10):1657-61. PMID: 15468027.

216. Akbari Sari A, Flemming K, Cullum NA, et al. Therapeutic ultrasound for pressure ulcers. Cochrane Database Syst Rev. 2009(1)PMID: 16855964.

217. Lucas C, Stanborough RW, Freeman CL, et al. Efficacy of low-level laser therapy on wound healing in human subjects: A systematic review. Lasers Med Sci. 2000;15(2):84-93.

218. Burke DT, Ho CHK, Saucier MA, et al. Effects of hydrotherapy on pressure ulcer healing. Am J Phys Med Rehabil. 1998;77(5):394-8. PMID: 9798830.

219. Ho CH, Bensitel T, Wang X, et al. Pulsatile lavage for the enhancement of pressure ulcer healing: a randomized controlled trial. Phys Ther. 2012;92(1):38-48. PMID: 21949432.

220. Arashi M, Sugama J, Sanada H, et al. Vibration therapy accelerates healing of Stage I pressure ulcers in older adult patients. Adv Skin Wound Care. 2010 Jul;23(7):321-7. PMID: 20562541.

221. Arashi M, Sugama J, Sanada H. Vibration Therapy Accelerates Healing of Stage I Pressure Ulcers in Older Adult Patients. Journal of Wound, Ostomy & Continence Nursing; 2011: S8-S.

222. Larking AM, Duport S, Clinton M, et al. Randomized control of extracorporeal shock wave therapy versus placebo for chronic decubitus ulceration. Clin Rehabil. 2010 Mar;24(3):222-9. PMID: 20156981.

223. Edsberg LE, Brogan MS, Jaynes CD, et al. Topical hyperbaric oxygen and electrical stimulation: exploring potential synergy. Ostomy Wound Manage. 2002 Nov;48(11):42-50. PMID: 12426451.

224. Schwien T, Gilbert J, Lang C. Pressure ulcer prevalence and the role of negative pressure wound therapy in home health quality outcomes. Ostomy Wound Manage. 2005 Sep;51(9):47-60. PMID: 16230764.

225. U.S. Food and Drug Administration. Medical devices; general and plastic surgery devices; classification of non-powered suction apparatus device intended for negative pressure wound therapy. Final rule. Federal Register. 2010/11/26 ed; 2010: 70112-4.

226. Cullum N, Deeks JJ, Fletcher AW, et al. Effectiveness bulletin. Preventing and treating pressure sores. Qual Health Care. 1995;4(4):289-97. PMID: 10156400.

227. Cullum N, Deeks J, Sheldon TA, et al. Beds, mattresses and cushions for pressure sore prevention and treatment. J Tissue Viability. 1999 Oct;9(4):138. PMID: 10808844.

228. Cullum N, Nelson EA, Flemming K, et al. Systematic reviews of wound care management: (5) beds; (6) compression; (7) laser therapy, therapeutic ultrasound, electrotherapy and electromagnetic therapy. Health Technol Assess. 2001;5(9):1-221. PMID: 11368833.

229. Langer G, Schloemer G, Knerr A, et al. Nutritional interventions for preventing and treating pressure ulcers. Cochrane Database Syst Rev. 2003(4):CD003216. PMID: 14583961.

Abbreviations and Acronyms

AF	Air-fluidized
AHCPR	Agency for Health Care Policy and Research
AHRQ	Agency for Healthcare Research and Quality
ANOVA	Analysis of variance
AP	Alternating pressure
BCT	Balsam peru castor oil trypsin
bFGF	Basic fibroblast growth factor
CDC	Center for Disease Control and Prevention
CERs	Comparative Effectiveness Reviews
CHIP	Children's Health Insurance Program
CI	Confidence interval
CLP	Constant low pressure
CO_2	Carbon dioxide
DP	Dextranomer paste
EMT	Electromagnetic therapy
EPC	Evidence-based Practice Center
ET	Electrotherapy
EPUAP	European Pressure Ulcer Advisory Panel
GM-CSF	Granulocyte-macrophage colony-stimulating factor
HBV	Hepatitis B virus
HCV	Hepatitis C virus
ICU	Intensive care unit
LAL	Low-air-loss beds
MVP	Moisture vapor permeable
NPUAP	United States National Pressure Ulcer Advisory Panel
NPWT	Negative pressure wound therapy
NR	Not reported
NS	Not significant
OKG	Ornithine Alpha-Ketoglutarate
PDGF	Platelet -Derived Growth Factor
PICOTS	Populations, Interventions, Comparators, Outcomes, Timing, and Setting
PSST	Pressure Sore Status Tool
PU	Pressure ulcer
PUSH	Pressure Ulcer Scale for Healing
RR	Relative risk
SCI	Spinal cord injury
SIP	Scientific information packet
SR	Systematic review
NPWT	Topical negative pressure
TENS	Transcutaneous Electric Nerve Stimulation
TEP	Technical Expert Panel
TGF-beta	Transforming growth factor beta
US	Ultrasound

USPSTF	United States Preventative Services Task Force
UVC	Ultraviolet C
WHO	World Health Organization

Appendix A. Exact Search Strategy

The following databases have been searched for relevant information:
Search strategies are presented for the original searches. An updated search was conducted on June 5th, 2012.

Medline

Searched: Ovid MEDLINE(R) and Ovid OLDMEDLINE(R) 1946 to August Week 5 2011
Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations September 12, 2011
Date Searched: September 14, 2011
Updated Searches: June 5th, 2012 and October 17th, 2012

1	Pressure Ulcer/dh, dt, nu, rt, rh, su, th, ae, co, in, mo, po, to	4917
2	pressure ulcer/ and (treatment or healing or management or therapy).hw.	1818
3	((pressure ulcer$ or pressure sore$ or bed sore$ or bedsore$ or decubitus ulcer$) adj5 (treat$ or heal$ or manag$ or therap$)).ti,ab.	2244
4	1 or 2 or 3	6047
5	limit 4 to yr="1985 -Current"	4876
6	remove duplicates from 5	4668

EMBASE

Searched: Embase (Elsevier)
Date Searched: September 14, 2011
Updated Search: June 5th, 2012

6	(('pressure ulcer?' OR 'pressure sore?' OR 'bed sore?' OR bedsore? OR decubitus) NEAR/5 (treat* OR heal* OR manag* OR therap* OR surger*)):ab,ti AND [embase]/lim OR ('decubitus'/mj AND ('radiotherapy':de OR 'drug therapy':de OR 'therapy':de OR 'magnetotherapy':de OR 'treatment outcome':de OR 'palliative therapy':de OR 'treatment failure':de OR 'treatment response':de OR 'wound healing impairment':de OR 'healing':de OR 'ulcer healing':de OR 'wound healing':de OR 'wound care':de OR 'wound healing promoting agent':de OR 'vacuum assisted closure':de OR 'surgery':de OR 'ultrasound therapy':de OR 'diet therapy':de OR 'malnutrition':de OR 'debridement':de OR 'wound dressing':de) AND [embase]/lim) AND (1985:py OR 1986:py OR 1987:py OR 1988:py OR 1989:py OR 1990:py OR 1991:py OR 1992:py OR 1993:py OR 1994:py OR 1995:py OR 1996:py OR 1997:py OR 1998:py OR 1999:py OR 2000:py OR 2001:py OR 2002:py OR 2003:py OR 2004:py OR 2005:py OR 2006:py OR 2007:py OR 2008:py OR 2009:py OR 2010:py OR 2011:py)	1,739
5	(('pressure ulcer?' OR 'pressure sore?' OR 'bed sore?' OR bedsore? OR decubitus) NEAR/5 (treat* OR heal* OR manag* OR therap* OR surger*)):ab,ti AND [embase]/lim OR ('decubitus'/mj AND ('radiotherapy':de OR 'drug therapy':de OR 'therapy':de OR 'magnetotherapy':de OR 'treatment outcome':de OR 'palliative therapy':de OR 'treatment failure':de OR 'treatment response':de OR 'wound healing impairment':de OR 'healing':de OR 'ulcer healing':de OR 'wound healing':de OR 'wound care':de OR 'wound healing promoting agent':de OR 'vacuum assisted closure':de OR 'surgery':de OR 'ultrasound therapy':de OR 'diet therapy':de OR 'malnutrition':de OR 'debridement':de OR 'wound dressing':de) AND [embase]/lim)	2,263

4	'decubitus'/mj AND ('radiotherapy':de OR 'drug therapy':de OR 'therapy':de OR 'magnetotherapy':de OR 'treatment outcome':de OR 'palliative therapy':de OR 'treatment failure':de OR 'treatment response':de OR 'wound healing impairment':de OR 'healing':de OR 'ulcer healing':de OR 'wound healing':de OR 'wound care':de OR 'wound healing promoting agent':de OR 'vacuum assisted closure':de OR 'surgery':de OR 'ultrasound therapy':de OR 'diet therapy':de OR 'malnutrition':de OR 'debridement':de OR 'wound dressing':de) AND [embase]/lim	1,528
3	(('pressure ulcer?' OR 'pressure sore?' OR 'bed sore?' OR bedsore? OR decubitus) NEAR/5 (treat* OR heal* OR manag* OR therap* OR surger*)):ab,ti AND [embase]/lim	1,439
2	'radiotherapy':de OR 'drug therapy':de OR 'therapy':de OR 'magnetotherapy':de OR 'treatment outcome':de OR 'palliative therapy':de OR 'treatment failure':de OR 'treatment response':de OR 'wound healing impairment':de OR 'healing':de OR 'ulcer healing':de OR 'wound healing':de OR 'wound care':de OR 'wound healing promoting agent':de OR 'vacuum assisted closure':de OR 'surgery':de OR 'ultrasound therapy':de OR 'diet therapy':de OR 'malnutrition':de OR 'debridement':de OR 'wound dressing':de AND [embase]/lim	2,565,030
1	'decubitus'/mj AND [embase]/lim	3,001

CINAHL

Searched: EBSCOHost CINAHL Plus with Full Text
Date Searched: September 14, 2011
Updated Search: June 5th, 2012

S6	S1 or S2 or S5	Limiters - Published Date from: 19850101-20111231 Search modes - Boolean/Phrase	1197
S5	S3 or S4	Limiters - Search Only Pre-CINAHL Search modes - Boolean/Phrase	22
S4	(AB "pressure ulcer*" or AB "pressure sore*" or AB "bed sore*" or AB "bedsore*" or AB "decubitus ulcer*") and (AB "treat*" or AB "heal*" or AB "manag*" or AB "therapy" or AB "therapies")	Limiters - Exclude MEDLINE records Search modes - Boolean/Phrase	658
S3	(TI "pressure ulcer*" or TI "pressure sore*" or TI "bed sore*" or TI "bedsore*" or TI "decubitus ulcer*") and (TI "treat*" or TI "heal*" or TI "manag*" or TI "therapy" or TI "therapies")	Limiters - Exclude MEDLINE records Search modes - Boolean/Phrase	449
S2	(MM "Pressure Ulcer") and (MW "treatment" or MW "healing" or MW "management" or MW "therapy" or MW "therapeutic")	Limiters - Exclude MEDLINE records Search modes - Boolean/Phrase	
S1	(MH "Pressure Ulcer/CO/DH/DT/MO/NU/RT/RH/SU/TH")	Limiters - Exclude MEDLINE records Search modes - Boolean/Phrase	1013

EBM Reviews

Searched:
EBM Reviews - Cochrane Database of Systematic Reviews 2005 to August 2011,
EBM Reviews - Database of Abstracts of Reviews of Effects 3rd Quarter 2011,
EBM Reviews - Cochrane Central Register of Controlled Trials 3rd Quarter 2011,
EBM Reviews - Health Technology Assessment 3rd Quarter 2011,
EBM Reviews - NHS Economic Evaluation Database 3rd Quarter 2011
Date Searched: September 14, 2011
Updated Search: June 5h, 2012

1	Pressure Ulcer/dh, dt, nu, rt, rh, su, th, ae, co, in, mo, po, to	262
2	Pressure ulcer/ and (treatment or healing or management or therapy).hw.	184
3	((pressure ulcer$ or pressure sore$ or bed sore$ or bedsore$ or decubitus ulcer$) adj5 (treat$ or heal$ or manag$ or therap$)).ti,ab.	363
4	1 or 2 or 3	501
5	limit 4 to yr="1985 -Current"	470
6	remove duplicates from 5	466

ClinicalTrials.gov

Searched 09/15/2011
Update Search 06/05/2012

((NOT ("Recruiting" OR "Not yet recruiting" OR "Available")) [OVERALL-STATUS] AND pressure ulcer* OR decubitus ulcer* OR pressure sore* OR bedsore* OR bed sore* [DISEASE]) [ALL-FIELDS]
Results = 184

Current Controlled Trials

Searched 09/15/2011
Update Search 06/05/2012

Search box: pressure ulcer*, decubitus ulcer*, pressure sore*, bedsore*, bed sore*
Selected all registries with the exception of Nih's ClinicalTrials.gov
Results = 8, which were then edited to treatment trials

ClinicalStudyResults.org

Searched 09/15/2011
Update Search 06/04/2012

Studies Indications or Disease: two searches:
#1: Ulcers, Pressure
#2: Ulcers, Diabetic and Decubitus (bedsores)
Results: neither search returned any results

WHO ICTRP

Searched 09/15/2011
Update Search 06/05/2012

Search terms:
Condition search box, two separate searches: decubitus ulcers, pressure ulcers
Recruitment status: ALL
Results = 79, which were then edited to treatment trials
Notes: search interface gave inconsistent and unexpected results, based on documentation.

ProQuest CSA Conference Papers Index

Searched: ProQuest CSA Conference Papers Index
Date Searched: 9/19/2011
Updated Search: 06/05/2012

Search Query #9 KW=(pressure ulcer* or pressure sore* or bed sore* or bedsore* or decubitus ulcer*) and KW=(treat* or heal* or surger* or surgical* or diet* or nutrition* or manag* or therap* or pressure or mattress* or cushion* or surface* or gel* or bandage* or dressing* or foam* or maggot* or debrid* or silver or saline or vibration* or cream*) and not Q1=(screening or prevention or risk assessment or classification or diabetes mellitus or training or quality of life or animal studies) (Copy Query)

241 Published Works results found in Conference Papers Index
Date Range: 1985 to 2012

ProQuest Dissertations & Theses

Searched 09/16/2011

Search terms:
(decubitus ulcer* or pressure ulcer* or pressure sore* or bedsore* or bed sore*) AND (treat* or therap* or manag* or heal*)

Details of the Search Process

A research Librarian, developed a list of databases to be searched and tested database specific search strategies in collaboration with the research team . Additional references were found by hand-searching the bibliographies of review articles and included studies; letters to the editor and commentaries; and Technical Expert Panel input.

All citations were imported into Thomson Reuters' EndNote X3 (citation management) *and then Distiller Systematic Review Software (screening of abstracts and full text, kappa calculation, data extraction, exclusion reports, and table construction).*

Search Strategy Development Notes

A combination of controlled vocabulary and keywords were employed in the search strategies, with age, study methodology, and date (2002-) limits applied. No language limit was used. Details of the search strategies are given in Appendix A.

List of Databases Searched

Table A-1. Databases searched

Name	Date Searched	Platform Provider
Bibliographic Database Search		
Medline	1947-02/28/2011; Update Search 06/05/2012	OvidSP
Embase	1976-04/11/2011; Update Search 06/05/2012	Elsevier
Cochrane Library/EBM Reviews: Cochrane Central Register of Controlled Trials (CCRCT)	1991-04/11/2011; Update Search 06/05/2012	OvidSP
Cochrane Library/EBM Reviews: Cochrane Database of Systematic Reviews (CDSR)	2005-04/11/2011; Update Search 06/05/2012	OvidSP
Cochrane Library/EBM Reviews: Database of Abstracts of Reviews of Effects (DARE)	1991-04/11/2011; Update Search 06/05/2012	OvidSP
Citation Database Search		
Scopus	1960-04/11/2011; Update Search 06/05/2012	Elsevier
Subject Specific Database Search		
PsycINFO	1806-04/12/2011; Update Search 06/05/2012	OvidSP

Grey Literature (Unpublished Literature) Strategy

In addition to searching bibliographic, citation, and subject-specific databases, additional materials were sought by searching for regulatory information, clinical trial registries, and conference proceedings. Including the following databases and websites:

Table A-2. Grey literature searched

Name	Date Searched	Platform Provider
Clinical Trial Registries		
Clinicaltrials.gov	Original Search 03/02/2011 Update Search 06/05/2012	US National Institutes of Health
Regulatory Agencies		
Drug Approval Package	Original Search 03/02/2011	US Federal Drug

	Update Search 05/052012	Administration
European Public Assessment Reports	Original Search 03/02/2011 Update Search 04/06/2012	European Medicines Agency
Summary Basis of Decision (SBD): Drugs	Original Search 03/02/2011 Update Search 06/05/2012	Health Canada
Conference Proceedings		
Scopus	1960-April 11, 2011; Update Search 06/05/2012	Elsevier

Scientific Information Packets (SIPs)

The Effective Health Care Program Scientific Resource Center requested information about published and unpublished Phase II and above clinical studies, post-marketing studies, and observational studies from pharmaceutical companies. The SIP request deadline had not yet passed when this draft report was written, the final report will be updated with all relevant information derived from SIP submissions.

Hyperbaric Oxygenation Search Strategy

1	Pressure Ulcer/dh, dt, nu, rt, rh, su, th, ae, co, in, mo, po, to	4899
2	pressure ulcer/ and (treatment or healing or management or therapy).hw.	1892
3	((pressure ulcer$ or pressure sore$ or bed sore$ or bedsore$ or decubitus ulcer$) adj5 (treat$ or heal$ or manag$ or therap$)).ti,ab.	2266
4	1 or 2 or 3	6087
5	limit 4 to yr="1985 -Current"	4963
6	remove duplicates from 5	4920
7	hyperbaric$.ti,ab,hw.	1313131
	Hyperbaric Oxygenation/	9635
	7 or 8	1313131
0	6 and 9	24

Appendix B. Inclusion Criteria by PICOTS and Key Question

Table B-1. Pressure ulcer treatment inclusion criteria by PICOTS and Key Question

	Inclusion Criteria	Exclusion Criteria
Populations	Adults aged 18 years and older being treated for existing decubitus ulcers. Subgroups include: sex, race/ethnicity, socioeconomic status, and diverse specific medical comorbidities (e.g., diabetes, end-stage renal disease, dementia), and patients with specific known risk factors for pressure ulcers (e.g., nutritional status, incontinence, peripheral vascular disease, mobility limitations, functional ability).	Wrong population. Children, adolescents, and patients with non pressure-related ulcers, including but not limited to venous ulcers and diabetic foot ulcers, because treatment considerations for these patients may differ significantly from those for pressure ulcers.
Interventions	Treatment for pressure ulcers including but not limited to: support surfaces, nutritional supplementation, wound debridement and cleansing, wound dressings, biologic agents, and surgical repair. Adjunctive therapies including ultrasound, electrical stimulation, vacuum-assisted closure, and hyperbaric oxygen therapy. • For efficacy and effectiveness assessments, all studies of interventions for treatment of pressure ulcers meeting the requirements of the PICOTS and Key Questions were included.	Wrong intervention. Studies of interventions without comparators were excluded but included in KQ2 to evaluate harms.
Comparisons	Usual care, placebo, no treatment, different treatment interventions	Studies with no comparator (included for harms only)
Outcomes	Clinical outcomes: • Complete wound healing • wound surface area reduction • pain • prevention of sepsis, • prevention of osteomyelitis, • recurrence rate and harms of treatment care settings, (including but not limited to nurse/patient staffing ratio, staff education and training in wound care, the use of wound care teams, and home caregiver support and training)	Non- clinical outcomes, cost, comfort, and nursing time.
Settings	Patient-care settings, such as home, nursing facility, or hospitals.	Hospice care facilities.
Timing	No minimum follow up time was required.	Studies published prior to 1985.
Study designs	Randomized and non randomized trials, retrospective and prospective cohort studies, case-control studies, and multicenter intervention series with a population of 100 patients or more.	Single case reports, intervention series with sample sizes less than 100 patients conducted at single sites, articles with no original data; review articles, letter, and editorials. Systematic reviews used for background only.
Treatment Key Questions		
Population Interventions Comparators Outcomes Timing Settings	KQ1:1. In adults with pressure ulcers, what is the comparative effectiveness of treatment strategies for improved health outcomes including but not limited to: complete wound healing, healing time, reduced wound surface area, pain, and prevention of serious complications of infection? • For efficacy and effectiveness assessments, all studies of interventions for treatment of pressure ulcers meeting the requirements of the PICOTS and Key Questions were included. • No minimum followup time was required.	Wrong population. Wrong interventions. Studies without a comparator or studies that reported outcomes only as an adverse event were excluded, but used in the assessment of harms. Wrong outcomes. Hospice care facilities.

	Inclusion Criteria	Exclusion Criteria
Population/ patient, ulcer characteristics	1a. Does the comparative effectiveness of treatment strategies differ according to features of the pressure ulcers, such as anatomic site or severity at baseline?	None.
Population/ patient, characteristics	1b. Does the comparative effectiveness of treatment strategies differ according to patient characteristics, including but not limited to: age; race/ethnicity; body weight; specific medical comorbidities; and known risk factors for pressure ulcers, such as functional ability, nutritional status, or incontinence?	Wrong population.
Settings	1c. Does the comparative effectiveness of treatment strategies differ according to patient care settings such as home, nursing facility, or hospital, or according to features of patient care settings, including but not limited to nurse/patient staffing ratio, staff education and training in wound care, the use of wound care teams, and home caregiver support and training?	Hospice care facilities.
Harms Key Questions		
Population Interventions Comparators Outcomes Timing Settings	KQ 2. What are the harms of treatments for pressure ulcers?	Wrong population. Wrong intervention. Hospice care facilities.
Population/Patient, ulcer characteristics	2a. Do the harms of treatment strategies differ according to features of the pressure ulcers, such as anatomic site or severity at baseline?	Wrong population.
Population/ patient, characteristics	2b. Do the harms of treatment strategies differ according to patient characteristics, including: age, race/ethnicity; body weight; specific medical comorbidities; and knows risk factors for pressure ulcers, such as functional ability, nutritional status, or incontinence?	Wrong population.
Settings	2c. Do the harms of treatment strategies differ according to patient care settings such as home, nursing facility, or hospital, or according to features of patient care settings, including but not limited to nurse/patient staffing ratio, staff education and training in wound care, the use of wound care teams, and home caregiver support and training?	Hospice care facilities.

Appendix C. Stages of Pressure Ulcers

Table C-1. Stages of pressure ulcer equivalency

NPUAP Stage	Description	Yarkony-Kirk	Description	Shea	Description	DeLisa, Mikulic	Description	Torrance	Description
I	Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area.	I	Red area: a. Present longer that 30 minutes, but less than 24 hours b. Present longer than 24 hours	NA	No Equivalent	I	Pressure sore is an acute inflammatory response involving the epidermis An irregular, ill-defined area if soft-tissue erythema accompanies by in duration and heat persists for more than 24 hours. The epidermis remains intact, and the ulcer is reversible.	I	Persistent erythema of the skin
II	Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum-filled blister	II	Epidermis and/or dermis ulcerated with no subcutaneous fat observed	I	Limited to epidermis exposing dermis	II	Pressure sore is a break in or blistering of the epidermis surrounded by erythema and in duration. Potentially, it also is reversible.	II	Blister formation or superficial subcutaneous ulcer

NPUAP Stage	Description	Yarkony-Kirk	Description	Shea	Description	DeLisa, Mikulic	Description	Torrance	Description
III	Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscles are not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling.	III	Subcutaneous fat observed, no muscle observed	II, III	Full-thickness of dermis to junction of subcutaneous fat Fat obliterated, limited by deep fascia undermining of skin	III	Pressure ulcer is an inflammatory fibroblastic response extending through the dermis to the junction with subcutaneous fat. Clinically presents as an irregular, shallow ulcer that has subcutaneous fat at its base and is surrounded by erythema, induration, and heat.	III	Deep subcutaneous ulcer-ulceration progress through the dermis

NPUAP Stage	Description	Yarkony-Kirk	Description	Shea	Description	DeLisa, Mikulic	Description	Torrance	Description
IV	Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often include undermining and tunneling.	IV-V	Muscle/ fascia observed, but no bone observed Bone observed, but no involvement of joint space	IV	Bone at the base of ulceration	IV – muscle V – exposed bone	Pressure ulcer extents through the full thickness of skin into the deep fascia and / or muscle. Its draining, necrotic base is often foul-smelling, and under-mining of the surface tissues may be excessive. Pressure ulcer penetrates the underlying bone, causing osteomyelitis. It has no anatomic limit and is surrounded by erythema and induration. Clinically, it presents as an extensive ulcer with exposed bone, joint, muscle, and/or fascia at its base.	IV	
		VI	Involvement of joint space	V	Closed large cavity through a small sinus			V	

NPUAP Stage	Description	Yarkony-Kirk	Description	Shea	Description	DeLisa, Mikulic	Description	Torrance	Description
Suspected Deep Tissue Injury	Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue found to be painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue.								
Unstageable	Full thickness tissue loss in which the base of the ulcer is covered by slough (yellow, tan, gray, green, or brown) and/or eschar (tan, brown, or black) in the wound bed.								

Appendix D. Included Studies List

Support

1. Allman RM, et al. Air-fluidized beds or conventional therapy for pressure sores. A randomized trial. Annals of Internal Medicine. 1987 Nov;107(5):641-8. PMID: 3310792.

2. Branom R, Rappl LM. "Constant force technology" versus low-air-loss therapy in the treatment of pressure ulcers.[Erratum appears in Ostomy Wound Manage 2001 Nov;47(11):6]. Ostomy Wound Management. 2001 Sep;47(9):38-46. PMID: 11889743.

3. Caley L, et al. Randomized Prospective Trial: Treatment Outcomes and Cost-Effectiveness of Two Types of Low-Air-Loss Therapy. 9th Annual Clinical Symposium on Pressure Ulcer and Wound Management. Nashville, TN. October 1994:1-2.

4. Clark MD, IP. A randomised controlled trial comparing the healing of pressure sores upon two pressure-redistributing seat cushions. Proceedings of the 7th European European Conferences on Advances in Wound Management 18-20 November. Harrogate, UK; 1997. p. 122-5.

5. Day A, Leonard F. Seeking quality care for patients with pressure ulcers. Decubitus. 1993 Jan;6(1):32-43. PMID: 8427642.

6. Devine B. Alternating pressure air mattresses in the management of established pressure sores. Journal of Tissue Viability. 1995;5(3):94-8.

7. Evans D, Land L, Geary A. A clinical evaluation of the Nimbus 3 alternating pressure mattress replacement system. Journal of Wound Care. 2000 Apr;9(4):181-6. PMID: 11933303.

8. Ferrell BA, Osterweil D, Christenson P. A randomized trial of low-air-loss beds for treatment of pressure ulcers. Journal of the American Medical Association. 1993;269(4):494-7. PMID: 8338511.

9. Groen HW, Groenier KH, Schuling J. Comparative study of a foam mattress and a water mattress. Journal of Wound Care. 1999 Jul;8(7):333-5. PMID: 10776222.

10. Izutsu T, et al. Effect of rolling bed on decubitus in bedridden nursing home patients. Tohoku Journal of Experimental Medicine. 1998 Feb;184(2):153-7. PMID: 9605022.

11. Jackson BS, et al. The effects of a therapeutic bed on pressure ulcers: an experimental study. Journal of Enterostomal Therapy. 1988 Nov-Dec;15(6):220-6. PMID: 3204209.

12. Keogh A, Dealey C. Profiling beds versus standard hospital beds: effects on pressure ulcer incidence outcomes. Journal of Wound Care. 2001 Feb;10(2):15-9. PMID: 12964222.

13. Land L, et al. A clinical evaluation of an alternating-pressure mattress replacement system in hospital and residential care settings. Journal of Tissue Viability. 2000 Jan;10(1):6-11. PMID: 10839090.

14. Makhsous M, et al. Promote pressure ulcer healing in individuals with spinal cord injury using an individualized cyclic pressure-relief protocol. Advances in Skin & Wound Care. 2009 Nov;22(11):514-21. PMID: 20026933.

15. Malbrain M, et al. A pilot randomised controlled trial comparing reactive air and active alternating pressure mattresses in the prevention and treatment of pressure ulcers among medical ICU patients. Journal of Tissue Viability. 2010 Feb;19(1):7-15. PMID: 20079647.

16. Mulder G, et al. A study of pressure ulcer response to low air loss beds vs. conventional treatment. Journal of Geriatric Dermatology 1994;2(3):87-91.

17. Munro BH, Brown L, Heitman BB. Pressure ulcers: one bed or another? Geriatric nursing (New York, N.Y.). 1989;10(4):190-2. PMID: 2777121.

18. Nixon J, et al. Pressure relieving support surfaces: a randomised evaluation. Health Technology Assessment (Winchester, England). 2006 Jul;10(22):iii-iv, ix-x, 1-163. PMID: 16750060.

19. Ochs RF, et al. Comparison of air-fluidized therapy with other support surfaces used to treat pressure ulcers in nursing home residents. Ostomy Wound Management. 2005 Feb;51(2):38-68. PMID: 15699554.

20. Rosenthal MJ, et al. Healing of advanced pressure ulcers by a generic total contact seat: 2 randomized comparisons with low air loss bed treatments. Archives of Physical Medicine & Rehabilitation. 2003 Dec;84(12):1733-42. PMID: 14669176.

21. Russell L, et al. A comparison of healing rates on two pressure-relieving systems. British Journal of Nursing. 2000(b) Dec 8-2001 Jan 10;9(22):2270-80. PMID: 12271193.

22. Russell L, et al. Randomised controlled trial of two pressure-relieving systems. Journal of Wound Care. 2000(a) Feb;9(2):52-5. PMID: 11933280.

23. Russell L, Reynolds TM, Towns A, et al. Randomized comparison trial of the RIK and the Nimbus 3 mattresses. British Journal of Nursing; 2003(a). p. 254, 6-9. PMID: 12671572

24. Strauss MJ, et al. The cost of home air-fluidized therapy for pressure sores. A randomized controlled trial. Journal of Family Practice. 1991 Jul;33(1):52-9. PMID: 2056290.

25. Valente SA, et al. More expensive surfaces are not always better. Kuwait Medical Journal. 2012;44(1):40-5.

26. Warner DJ. A clinical comparison of two pressure-reducing surfaces in the management of pressure ulcers. Decubitus. 1992 May;5(3):52-5, 8-60, 2-4. PMID: 1596352.

Nutrition

1. Barnes P, Jr., Sauter TE, Zaheri S. Subnormal prealbumin levels and wound healing. Texas Medicine. 2007 Aug;103(8):65-8. PMID: 19113064.

2. Benati G, et al. Impact on pressure ulcer healing of an arginine-enriched nutritional solution in patients with severe cognitive impairment. Archives of Gerontology & Geriatrics - Supplement. 2001;7:43-7. PMID: 11431045.

3. Breslow RA, et al. The importance of dietary protein in healing pressure ulcers. Journal of the American Geriatrics Society. 1993;41(4):357-62. PMID: 8463519.

4. Brewer S, et al. Effect of an arginine-containing nutritional supplement on pressure ulcer healing in community spinal patients. Journal of Wound Care. 2010 Jul;19(7):311-6. PMID: 20616774.

5. Cereda E, et al. Disease-specific, versus standard, nutritional support for the treatment of pressure ulcers in institutionalized older adults: a randomized controlled trial. Journal of the American Geriatrics Society. 2009 Aug;57(8):1395-402. PMID: 19563522.

6. Chernoff R. The effect of a high protein fomula (Replete) on decubitus ulcer healing in long term tube fed institutionalized patients. Journal of the American Dietetic Association. 1990;90(130).

7. Desneves KJ, et al. Treatment with supplementary arginine, vitamin C and zinc in patients with pressure ulcers: a randomised controlled trial. Clinical Nutrition. 2005 Dec;24(6):979-87. PMID: 16297506.

8. Houston S, et al. Adverse effects of large-dose zinc supplementation in an institutionalized older population with pressure ulcers [4]. Journal of the American Geriatrics Society. 2001;49(8):1130-2. PMID: 11555083.

9. Lee SK, et al. Pressure ulcer healing with a concentrated, fortified, collagen protein hydrolysate supplement: a randomized controlled trial. Advances in Skin & Wound Care. 2006 Mar;19(2):92-6. PMID: 16557055.

10. Leigh B, et al. The effect of different doses of an arginine-containing supplement on the healing of pressure ulcers. Journal of Wound Care. 2012;21(3):150-6. PMID: 22399084.

11. Meaume S, et al. Efficacy and safety of ornithine alpha-ketoglutarate in heel pressure ulcers in elderly patients: results of a randomized controlled trial. Journal of Nutrition, Health & Aging. 2009 Aug;13(7):623-30. PMID: 19621198.

12. Myers SA, et al. Consistent wound care and nutritional support in treatment. Decubitus. 1990 Aug;3(3):16-28. PMID: 2119183.

13. Ohura T, et al. Evaluation of effects of nutrition intervention on healing of pressure ulcers and nutritional states (randomized controlled trial). Wound Repair & Regeneration. 2011 May-Jun;19(3):330-6. PMID: 21539650.

14. Ter Riet G, Kessels AGH, Knipschild PG. Randomized clinical trial of ascorbic acid in the treatment of pressure ulcers. Journal of Clinical Epidemiology. 1995;48(12):1453-60. PMID: 8543959.

15. Van Anholt RD, et al. An arginine- and micronutrient-enriched nutritional supplement accelerates pressure ulcer healing and reduces wound care in non-malnourished patients. EWMA Journal. 2010 49, 2010;10(2):45.

16. Yamamoto T, et al. Evaluation of nutrition in the healing of pressure ulcers: are the EPUAP nutritional guidelines sufficient to heal wounds. European Pressure Ulcer Advisory Panel. Wounds: A Compendium of Clinical Research & Practice. 2009;21(6):153-7.

Local Wound Applications

1. Agren MS, Stromberg HE. Topical treatment of pressure ulcers. A randomized comparative trial of Varidase and zinc oxide. Scandinavian Journal of Plastic & Reconstructive Surgery. 1985;19(1):97-100. PMID: 3895409.

2. Alm A, et al. Care of pressure sores: a controlled study of the use of a hydrocolloid dressing compared with wet saline gauze compresses. Acta Dermato-Venereologica. Supplementum. 1989;149:1-10. PMID: 2694713.

3. Alvarez OM, et al. Chemical debridement of pressure ulcers: a prospective, randomized, comparative trial of collagenase and papain/urea formulations. Wounds: A Compendium of Clinical Research & Practice. 2000;12(2):15-25.

4. Bale S, et al. A comparison of two amorphous hydrogels in the debridement of pressure sores. Journal of Wound Care. 1998(a)Feb;7(2):65-8. PMID: 9543975.

5. Bale S, Hagelstein S, Banks V, et al. Costs of dressings in the community. Journal of Wound Care. 1998(b) Jul;7(7):327-30. PMID: 9791356.

6. Bale S, et al. A comparison of two dressings in pressure sore management. Journal of Wound Care. 1997 Nov;6(10):463-6. PMID: 9455271.

7. Banks V, Bale S, Harding K. The use of two dressings for moderately exuding pressure sores. Journal of Wound Care. 1994(b);3(3):132-4.

8. Banks V, Bale SE, Harding KG. Comparing two dressings for exuding pressure sores in community patients. Journal of Wound Care. 1994(a);3(4):175-8.

9. Belmin J, et al. Sequential treatment with calcium alginate dressings and hydrocolloid dressings accelerates pressure ulcer healing in older subjects: a multicenter randomized trial of sequential versus nonsequential treatment with hydrocolloid dressings alone. Journal of the American Geriatrics Society. 2002 Feb;50(2):269-74. PMID: 12028208.

10. Bito S, et al. Randomised controlled trial evaluating the efficacy of wrap therapy for wound healing acceleration in patients with NPUAP stage II and III pressure ulcer. BMJ Open. 2012;2:e000371. PMID: 22223842.

11. Brod M, et al. A randomized comparison of poly-hema and hydrocolloid dressings for treatment of pressure sores. Archives of Dermatology. 1990 Jul;126(7):969-70. PMID: 2193631.

12. Brown-Etris M, et al. A prospective, randomized, multisite clinical evaluation of a transparent absorbent acrylic dressing and a hydrocolloid dressing in the management of Stage II and shallow Stage III pressure ulcers. Advances in Skin & Wound Care. 2008 Apr;21(4):169-74. PMID: 18385577.

13. Burgos A, et al. Collagenase ointment application at 24- versus 48-hour intervals in the treatment of pressure ulcers. A randomised multicentre study. Clinical Drug Investigation. 2000;19(6):399-407.

14. Burgos A, et al. Cost, efficacy, efficiency and tolerability of collagenase ointment versus hydrocolloid occlusive dressing in the treatment of pressure ulcers. A comparative, randomised, multicentre study. Clinical Drug Investigation. 2000;19(5):357-65.

15. Chang KW, et al. Pressure ulcers--randomised controlled trial comparing hydrocolloid and saline gauze dressings. Medical Journal of Malaysia. 1998 Dec;53(4):428-31. PMID: 10971989.

16. Chuangsuwanich A, et al. The efficacy of silver mesh dressing compared with silver sulfadiazine cream for the treatment of pressure ulcers. Journal of the Medical Association of Thailand. 2011 May;94(5):559-65. PMID: 21675444.

17. Colin D, Kurring PA, Yvon C. Managing sloughy pressure sores. Journal of Wound Care. 1996 Nov;5(10):444-6. PMID: 9117814.

18. Colwell JC, Foreman MD, Trotter JP. A comparison of the efficacy and cost-effectiveness of two methods of managing pressure ulcers. Decubitus. 1993 Jul;6(4):28-36. PMID: 8297488.

19. Danon D, et al. Treatment of human ulcers by application of macrophages prepared from a blood unit. Experimental Gerontology. 1997 Nov-Dec;32(6):633-41. PMID: 9785089.

20. Darkovich SL, Brown-Etris M, Spencer M. Biofilm hydrogel dressing: a clinical evaluation in the treatment of pressure sores. Ostomy Wound Management. 1990 Jul-Aug;29:47-60. PMID: 2202317.

21. Day A, et al. Managing sacral pressure ulcers with hydrocolloid dressings: results of a controlled, clinical study. Ostomy Wound Management. 1995 Mar;41(2):52-4, 6, 8 passim. PMID: 7598778.

22. Felzani G, et al. Effect of lysine hyaluronate on the healing of decubitus ulcers in rehabilitation patients. Advances in Therapy. 2011 May;28(5):439-45. PMID: 21499725.

23. Gerding GA, Browning JS. Oxyquinoline-containing ointment vs. standard therapy for stage I and stage II skin lesions. Dermatology Nursing. 1992 Oct;4(5):389-98. PMID: 1482629.

24. Gorse GJ, Messner RL. Improved pressure sore healing with hydrocolloid dressings. Archives of Dermatology. 1987 Jun;123(6):766-71. PMID: 3555355.

25. Graumlich JF, et al. Healing pressure ulcers with collagen or hydrocolloid: A randomized, controlled trial. Journal of the American Geriatrics Society. 2003;51(2):147-54. PMID: 12558709.

26. Guthrie M, et al. A randomized double-blind clinical study of dermagran dual therapeutic system in the treatment of decubitus ulcers. Wounds: A Compendium of Clinical Research and Practice. 1989;1(3):142-54.

27. Harding KG, et al. A multi-center comparison of a hydrocellular adhesive dressing and a hydrocolloid dressing in the management of stage II and III pressure ulcers. 9th Annual Symposium on Advanced Wound Care and 6th Annual Medical Research Forum on Wound Repair. 1996.

28. Hindryckx P, et al. The treatment of infected decubitus ulcers with 1% silver sulfadiazine cream. Current Therapeutic Research - Clinical and Experimental. 1990;48(3):535-9.

29. Hirshberg J, et al. TGF-beta3 in the treatment of pressure ulcers: a preliminary report. Advances in Skin & Wound Care. 2001 Mar-Apr;14(2):91-5. PMID: 11899912.

30. Hollisaz MT, Khedmat H, Yari F. A randomized clinical trial comparing hydrocolloid, phenytoin and simple dressings for the treatment of pressure ulcers [ISRCTN33429693]. BMC Dermatology. 2004;4(1):18. PMID: 15601464.

31. Honde C, Derks C, Tudor D. Local treatment of pressure sores in the elderly: amino acid copolymer membrane versus hydrocolloid dressing. Journal of the American Geriatrics Society. 1994 Nov;42(11):1180-3. PMID: 7525682.

32. Hsu YC, et al. Therapeutic effect of sheng-ji-san on pressure ulcers. American Journal of Chinese Medicine. 2000;28(3-4):391-9. PMID: 11154053..

33. Kaya AZ, Turani N, Akyuz M. The effectiveness of a hydrogel dressing compared with standard management of pressure ulcers. Journal of Wound Care. 2005 Jan;14(1):42-4. PMID: 15656468.

34. Kerihuel JC. Effect of activated charcoal dressings on healing outcomes of chronic wounds. Journal of Wound Care. 2010 May;19(5):208, 10-2, 14-5. PMID: 20505594.

35. Kim YC, et al. Efficacy of hydrocolloid occlusive dressing technique in decubitus ulcer treatment: a comparative study. Yonsei Medical Journal. 1996 Jun;37(3):181-5. PMID: 8826783.

36. Kloth LC, et al. A randomized controlled clinical trial to evaluate the effects of noncontact normothermic wound therapy on chronic full-thickness pressure ulcers. Advances in Skin & Wound Care. 2002 Nov-Dec;15(6):270-6. PMID: 12477979.

37. Kraft MR, et al. A comparison of Epi-Lock and saline dressings in the treatment of pressure ulcers. Decubitus. 1993 Nov;6(6):42-4, 6, 8. PMID: 8286026.

38. Kuflik A, et al. Petrolatum versus Resurfix ointment in the treatment of pressure ulcers. Ostomy Wound Management. 2001 Feb;47(2):52-6. PMID: 11235499.

39. Kurzuk-Howard G, Simpson L, Palmieri A. Decubitus ulcer care: a comparative study. Western Journal of Nursing Research. 1985 Feb;7(1):58-79. PMID: 3850687.

40. Landi F, et al. Topical treatment of pressure ulcers with nerve growth factor: a randomized clinical trial. Annals of Internal Medicine. 2003 Oct 21;139(8):635-41. PMID: 14568851.

41. LeVasseur SA, Helme RD. A double-blind clinical trial to compare the efficacy of an active based cream F14001 against a placebo non-active based cream for the treatment of pressure ulcers in a population of elderly subjects. Journal of Advanced Nursing. 1991 Aug;16(8):952-6. PMID: 1779084.

42. Matzen S, Peschardt A, Alsbjorn B. A new amorphous hydrocolloid for the treatment of pressure sores: a randomised controlled study. Scandinavian Journal of Plastic & Reconstructive Surgery & Hand Surgery. 1999 Mar;33(1):13-5. PMID: 10207960.

43. Meaume S, et al. Optimizing wound care with a new lipido-colloid dressing (Urgotul Duo). British Journal of Nursing. 2007 Mar 22-Apr 11;16(6):S4, S6, S8 passim. PMID: 17505400.

44. Meaume S, et al. Evaluation of a silver-releasing hydroalginate dressing in chronic wounds with signs of local infection.[Erratum appears in J Wound Care. 2005 Nov;14(10):479]. Journal of Wound Care. 2005 Oct;14(9):411-9. PMID: 16240620.

45. Meaume S, et al. A study to compare a new self-adherent soft silicone dressing with a self-adherent polymer dressing in stage II pressure ulcers. Ostomy Wound Management. 2003 Sep;49(9):44-51. PMID: 14581709.

46. Moody M. Calcium alginate: a dressing trial. Nursing Standard. 1991;5(50):3-6. PMID: 1911033.

47. Motta G, et al. Clinical efficacy and cost-effectiveness of a new synthetic polymer sheet wound dressing. Ostomy Wound Management. 1999 Oct;45(10):41, 4-6, 8-9. PMID: 10687651.

48. Mulder GD, et al. Prospective randomized study of the efficacy of hydrogel, hydrocolloid, and saline solution -- moistened dressings on the management of pressure ulcers. Wound Repair & Regeneration. 1993;1(4):213-8. PMID: 17166097.

49. Muller E, van Leen MW, Bergemann R. Economic evaluation of collagenase-containing ointment and hydrocolloid dressing in the treatment of pressure ulcers. Pharmacoeconomics. 2001;19(12):1209-16. PMID: 11772156.

50. Mustoe TA, et al. A phase II study to evaluate recombinant platelet-derived growth factor-BB in the treatment of stage 3 and 4 pressure ulcers. Archives of Surgery. 1994 Feb;129(2):213-9. PMID: 8304833.

51. Narayanan S, et al. Comparison of pressure ulcer treatments in long-term care facilities: clinical outcomes and impact on cost. Journal of Wound, Ostomy, & Continence Nursing. 2005 May-Jun;32(3):163-70. PMID: 15931146.

52. Neill K, et al. Pressure sore response to a new hydrocolloid dressing. Wounds: A Compendium of Clinical Research & Practice. 1989;1:173-85.

53. Nisi G, et al. Use of a protease-modulating matrix in the treatment of pressure sores. Chirurgia Italiana. 2005 Jul-Aug;57(4):465-8. PMID: 16060184.

54. Oleske DM, et al. A randomized clinical trial of two dressing methods for the treatment of low-grade pressure ulcers. Journal of Enterostomal Therapy. 1986 May-Jun;13(3):90-8. PMID: 3519718.

55. Parnell LKS, Ciufi B, Gokoo CF. Preliminary use of a hydrogel containing enzymes in the treatment of stage II and stage III pressure ulcers. Ostomy Wound Management. 2005 Aug;51(8):50-60. PMID: 16234576.

56. Payne WG, et al. Long-term outcome study of growth factor-treated pressure ulcers. American Journal of Surgery. 2001 Jan;181(1):81-6. PMID: 11248182.

57. Payne WG, et al. A prospective, randomized clinical trial to assess the cost-effectiveness of a modern foam dressing versus a traditional saline gauze dressing in the treatment of stage II pressure ulcers. Ostomy Wound Management. 2009 Feb;55(2):50-5. PMID: 19246785.

58. Payne WG, et al. An exploratory study of dermal replacement therapy in the treatment of stage III pressure ulcers. Journal of Applied Research. 2004;4(1):12-23.

59. Price P, et al. The effect of a radiant heat dressing on pressure ulcers. Journal of Wound Care. 2000 Apr;9(4):201-5. PMID: 11933306.

60. Pullen R, et al. Prospective randomized double-blind study of the wound-debriding effects of collagenase and fibrinolysin/deoxyribonuclease in pressure ulcers. Age & Ageing. 2002 Mar;31(2):126-30. PMID: 11937475.

61. Rees RS, et al. Becaplermin gel in the treatment of pressure ulcers: a phase II randomized, double-blind, placebo-controlled study. Wound Repair & Regeneration. 1999 May-Jun;7(3):141-7. PMID: 10417749.

62. Rhodes RS, et al. Topical phenytoin treatment of stage II decubitus ulcers in the elderly. Annals of Pharmacotherapy. 2001 Jun;35(6):675-81. PMID: 11408983.

63. Robson LE. Safety and effect of topical recombinant human interleukin-1beta in the management of pressure sores. Wound Repair & Regeneration. 1994 Jul;2(3):177-81. PMID: 17156109.

64. Robson MC, et al. Sequential cytokine therapy for pressure ulcers: clinical and mechanistic response. Annals of Surgery. 2000 Apr;231(4):600-11. PMID: 10749622.

65. Robson MC, et al. The safety and effect of topically applied recombinant basic fibroblast growth factor on the healing of chronic pressure sores. Annals of Surgery. 1992 Oct;216(4):401-6; discussion 6-8. PMID: 1417189.

66. Robson MC, et al. Recombinant human platelet-derived growth factor-BB for the treatment of chronic pressure ulcers. Annals of Plastic Surgery. 1992;29(3):193-201. PMID: 1524367.

67. Robson MC, et al. Platelet-derived growth factor BB for the treatment of chronic pressure ulcers. Lancet. 1992 Jan 4;339(8784):23-5. PMID: 1345953.

68. Sayag J, Meaume S, Bohbot S. Healing properties of calcium alginate dressings. Journal of Wound Care. 1996 Sep;5(8):357-62. PMID: 8954425.

69. Scevola S, et al. Allogenic platelet gel in the treatment of pressure sores: a pilot study. International Wound Journal. 2010 Jun;7(3):184-90. PMID: 20455960.

70. Sebern MD. Pressure ulcer management in home health care: efficacy and cost effectiveness of moisture vapor permeable dressing. Archives of Physical Medicine & Rehabilitation. 1986 Oct;67(10):726-9. PMID: 3533007.

71. Sebern MD. Cost and efficacy of pressure ulcer management in a metropolitan visiting nurse association. Decubitus. 1989 Aug;2(3):58-9. PMID: 2775474.

72. Seeley J, Jensen JL, Hutcherson J. A randomized clinical study comparing a hydrocellular dressing to a hydrocolloid dressing in the management of pressure ulcers. Ostomy Wound Management. 1999 Jun;45(6):39-44, 6-7. PMID: 10655861.

73. Shamimi Nouri K, et al. Topical application of Semelil (ANGIPARS(trademark)) in treatment of pressure ulcers: A randomized clinical trial. Daru. 2008;16(SUPPL. 1):54-7.

74. Sherman RA, Wyle F, Vulpe M. Maggot therapy for treating pressure ulcers in spinal cord injury patients. Journal of Spinal Cord Medicine; 1995. p. 71-4. PMID: 7640976

75. Sherman RA. Maggot versus conservative debridement therapy for the treatment of pressure ulcers. Wound Repair & Regeneration. 2002 Jul-Aug;10(4):208-14. PMID: 12191002.

76. Sipponen A, et al. Beneficial effect of resin salve in treatment of severe pressure ulcers: a prospective, randomized and controlled multicentre trial. British Journal of Dermatology. 2008 May;158(5):1055-62. PMID: 18284391.

77. Small N, et al. A comparative analysis of pressure sore treatment modalities in community settings. Curationis. 2002 Feb;25(1):74-82. PMID: 12096575.

78. Stoker FM. A major contributor. Evaluation of Comfeel Pressure Relieving Dressing. Professional Nurse. 1990 Sep;5(12):644-53. PMID: 2217219.

79. Subbanna PK, et al. Topical phenytoin solution for treating pressure ulcers: a prospective, randomized, double-blind clinical trial. Spinal Cord. 2007 Nov;45(11):739-43. PMID: 17279096.

80. Thomas DR, Diebold MR, Eggemeyer LM. A controlled, randomized, comparative study of a radiant heat bandage on the healing of stage 3-4 pressure ulcers: a pilot study. Journal of the American Medical Directors Association. 2005 Jan-Feb;6(1):46-9. PMID: 15871870.

81. Thomas DR, et al. Acemannan hydrogel dressing versus saline dressing for pressure ulcers. A randomized, controlled trial. Advances in Wound Care. 1998 Oct;11(6):273-6. PMID: 10326343.

82. Thomas S, et al. A comparison of two dressings in the management of chronic wounds. Journal of Wound Care. 1997 Sep;6(8):383-6. PMID: 9341430.

83. Tytgat H, Van Asch H. Topical ketanserin in the treatment of decubitus ulcers: A double-blind study with 2% ketanserin ointment against placebo. Advances in Therapy. 1988;5(4):143-52.

84. Viamontes L, et al. An evaluation of an adhesive hydrocellular foam dressing and a self-adherent soft silicone foam dressing in a nursing home setting. Ostomy Wound Management. 2003 Aug;49(8):48-52, 4-6, 8. PMID: 14631663.

85. Wang S-y, Wang J-n, Lv D-c, et al. Clinical research on the bio-debridement effect of maggot therapy for treatment of chronically infected lesions. Orthopaedic Audio-Synopsis Continuing Medical Education [Sound Recording]; 2010. p. 201-6. PMID: 22009949

86. Whitney JD, et al. Treatment of pressure ulcers with noncontact normothermic wound therapy: healing and warming effects. Journal of Wound, Ostomy, & Continence Nursing. 2001 Sep;28(5):244-52. PMID: 11557928.

87. Winter A, Hewitt H. Testing a hydrocolloid. Nursing Times. 1990 Dec 12-8;86(50):59-62. PMID: 2255648.

88. Xakellis. Hydrocolloid versus saline-gauze dressings in treating pressure ulcers: a cost-effectiveness analysis. Arch Phys Med Rehabil. . 1992;73:463-9. PMID: 1580775.

89. Yapucu Gunes U, Eser I. Effectiveness of a honey dressing for healing pressure ulcers. Journal of Wound, Ostomy, & Continence Nursing. 2007 Mar-Apr;34(2):184-90. PMID: 17413836.

90. Yastrub DJ. Relationship between type of treatment and degree of wound healing among institutionalized geriatric patients with stage II pressure ulcers... reprinted with permission from the author and Nurse Practitioner Associates for Continuing Education. Care Management Journals. 2004;5(4):213-8.

91. Zeron HM, Krotzsch Gomez FE, Munoz REH. Pressure ulcers: a pilot study for treatment with collagen polyvinylpyrrolidone. International Journal of Dermatology. 2007 Mar;46(3):314-7. PMID: 17343594.

92. Zuloff-Shani A, et al. Hard to heal pressure ulcers (stage III-IV): efficacy of injected activated macrophage suspension (AMS) as compared with standard of care (SOC) treatment controlled trial. Archives of Gerontology & Geriatrics. 2010 Nov-Dec;51(3):268-72. PMID: 20034682. Surgery:

Surgery

1. Foster RD, et al. Flap selection as a determinant of success in pressure sore coverage. Archives of Surgery. 1997 Aug;132(8):868-73. PMID: 9267271.

2. Foster RD, et al. Ischial pressure sore coverage: A rationale for flap selection. British Journal of Plastic Surgery. 1997;50(5):374-9. PMID: 9245873.

3. Juri H, Palma A, Obeide A. The CO2 laser in the treatment of decubitus ulcer. Journal of Neurological and Orthopaedic Medicine and Surgery. 1986;7(1):29-33.

4. Kierney PC, et al. Results of 268 pressure sores in 158 patients managed jointly by plastic surgery and rehabilitation medicine. Plastic & Reconstructive Surgery. 1998 Sep;102(3):765-72. PMID: 9727442.

5. Schryvers OI, Stranc MF, Nance PW. Surgical treatment of pressure ulcers: 20-year experience. Archives of Physical Medicine & Rehabilitation. 2000 Dec;81(12):1556-62. PMID: 11128889.

6. Yamamoto Y, et al. Long-term outcome of pressure sores treated with flap coverage. Plastic & Reconstructive Surgery. 1997 Oct;100(5):1212-7. PMID: 9326782.

Adjunctive

1. Adegoke BO, Badmos KA. Acceleration of pressure ulcer healing in spinal cord injured patients using interrupted direct current. African Journal of Medicine & Medical Sciences. 2001 Sep;30(3):195-7. PMID: 14510128.

2. Adunsky A, Ohry A, Group D. Decubitus direct current treatment (DDCT) of pressure ulcers: results of a randomized double-blinded placebo controlled study. Archives of Gerontology & Geriatrics. 2005 Nov-Dec;41(3):261-9. PMID: 15998547.

3. Ahmad ET. High voltage pulsed galvanic stimulation: effect of treatment durations on healing of chronic pressure ulcers. Indian Journal of Physiotherapy & Occupational Therapy. 2008;2(3):1-5. PMID: 21991123.

4. Ahmad ET. High-voltage pulsed galvanic stimulation: effect of treatment duration on healing of chronic pressure ulcers. Annals of Burns & Fire Disasters. 2008;21(3):124-8. PMID: 21991123.

5. Arashi M, Sugama J, Sanada H. Vibration Therapy Accelerates Healing of Stage I Pressure Ulcers in Older Adult Patients. Journal of Wound, Ostomy & Continence Nursing; 2011. p. S8-S.

6. Arashi M, et al. Vibration therapy accelerates healing of Stage I pressure ulcers in older adult patients. Advances in Skin & Wound Care. 2010 Jul;23(7):321-7. PMID: 20562541.

7. Baker LL, et al. Effect of electrical stimulation waveform on healing of ulcers in human beings with spinal cord injury. Wound Repair & Regeneration. 1996 Jan-Mar;4(1):21-8. PMID: 17129344.

8. Burke DT, et al. Effects of hydrotherapy on pressure ulcer healing. American Journal of Physical Medicine and Rehabilitation. 1998;77(5):394-8. PMID: 9798830.

9. Comorosan S, et al. The effect of diapulse therapy on the healing of decubitus ulcer. Romanian Journal of Physiology (Bucuresti). 1993 Jan-Jun;30(1-2):41-5. PMID: 7982015.

10. Dehlin O, Elmstahl S, Gottrup F. Monochromatic phototherapy in elderly patients: a new way of treating chronic pressure ulcers?.[Erratum appears in Aging Clin Exp Res. 2003 Dec;15(6):519]. Aging-Clinical & Experimental Research. 2003 Jun;15(3):259-63. PMID: 14582689.

11. Dehlin O, Elmstahl S, Gottrup F. Monochromatic phototherapy: effective treatment for grade II chronic pressure ulcers in elderly patients. Aging-Clinical & Experimental Research. 2007 Dec;19(6):478-83. PMID: 18172370.

12. Durovic A, et al. The effects of polarized light therapy in pressure ulcer healing. Vojnosanitetski Pregled. 2008 Dec;65(12):906-12. PMID: 19160985.

13. Edsberg LE, et al. Topical hyperbaric oxygen and electrical stimulation: exploring potential synergy. Ostomy Wound Management. 2002 Nov;48(11):42-50. PMID: 12426451.

14. Feedar JAK, LC. Acceleration of wound healing with high voltage pulsating direct current (abstract). Phys Ther. 1985(65):741.

15. Ford CN, et al. Interim analysis of a prospective, randomized trial of vacuum-assisted closure versus the healthpoint system in the management of pressure ulcers. Annals of Plastic Surgery. 2002 Jul;49(1):55-61; discussion PMID: 12142596.

16. Gentzkow GD, et al. Improved healing of pressure ulcers using Dermapulse, a new electrical stimulation device. Wounds: A Compendium of Clinical Research and Practice. 1991;3(5):158-70.

17. Griffin JW, et al. Efficacy of high voltage pulsed current for healing of pressure ulcers in patients with spinal cord injury. Physical Therapy. 1991 Jun;71(6):433-42; discussion 42-4. PMID: 2034707.

18. Gupta A, et al. Efficacy of pulsed electromagnetic field therapy in healing of pressure ulcers: A randomized control trial. Neurology India. 2009 Sep-Oct;57(5):622-6. PMID: 19934563.

19. Ho CH, et al. Pulsatile lavage for the enhancement of pressure ulcer healing: a randomized controlled trial. Physical Therapy. 2012;92(1):38-48. PMID: 21949432.

20. Ho CH, et al. Poor nutrition is a relative contraindication to negative pressure wound therapy for pressure ulcers: preliminary observations in patients with spinal cord injury. Advances in Skin & Wound Care. 2010 Nov;23(11):508-16. PMID: 20975334.

21. Houghton PE, et al. Electrical stimulation therapy increases rate of healing of pressure ulcers in community-dwelling people with spinal cord injury. Archives of Physical Medicine & Rehabilitation. 2010 May;91(5):669-78. PMID: 20434602.

22. Iordanou P, et al. Effect of polarized light in the healing process of pressure ulcers.[Erratum appears in Int J Nurs Pract 2002 Apr;8(2):116]. International Journal of Nursing Practice. 2002 Feb;8(1):49-55. PMID: 11831427.

23. Kloth LC, Feedar JA. Acceleration of wound healing with high voltage, monophasic, pulsed current.[Erratum appears in Phys Ther 1989 Aug;69(8):702]. Physical Therapy. 1988 Apr;68(4):503-8. PMID: 3258429.

24. Larking AM, et al. Randomized control of extracorporeal shock wave therapy versus placebo for chronic decubitus ulceration. Clinical Rehabilitation. 2010 Mar;24(3):222-9. PMID: 20156981.

25. Lucas C, Coenen CHM, De Haan RJ. The effect of low level laser therapy (LLLT) on stage III decubitus ulcers (pressure sores); A prospective randomised single blind, multicentre pilot study. Lasers in Medical Science. 2000;15(2):94-100. PMID: 12928815.

26. Lucas C, van Gemert MJC, de Haan RJ. Efficacy of low-level laser therapy in the management of stage III decubitus ulcers: a prospective, observer-blinded multicentre randomised clinical trial. Lasers in Medical Science; 2003. p. 72-7. PMID: 12928815.

27. Maeshige N, et al. Evaluation of the combined use of ultrasound irradiation and wound dressing on pressure ulcers. Journal of Wound Care. 2010 Feb;19(2):63-8. PMID: 20216490.

28. McDiarmid T, et al. Ultrasound and the treatment of pressure sores. Physiotherapy. 1985;71(2):66-70.

29. Nussbaum EL, Biemann I, Mustard B. Comparison of ultrasound/ultraviolet-C and laser for treatment of pressure ulcers in patients with spinal cord injury. Physical Therapy. 1994 Sep;74(9):812-23; discussion 24-5. PMID: 8066108.

30. Onigbinde AT, Adedoyin RA, Ojoawo OA, et al. Effects of ultraviolet radiation (type B) on wound exudates, appearance and depth description. Technology & Health Care; 2010. p. 297-302. PMID: 21209478

31. Ozdemir F, et al. Efficiency of magnetic field treatment on pressure sores in bedridden patients. Balkan Medical Journal. 2011;28(3):274-8.

32. Salzberg CA, et al. The effects of non-thermal pulsed electromagnetic energy (DIAPULSE) on wound healing of pressure ulcers in spinal cord-injured patients: a randomized, double-blind study. Wounds: A Compendium of Clinical Research & Practice. 1995 Jan-Feb;7(1):11-6.

33. Schubert V. Effects of phototherapy on pressure ulcer healing in elderly patients after a falling trauma. A prospective, randomized, controlled study. Photodermatology, Photoimmunology & Photomedicine. 2001 Feb;17(1):32-8. PMID: 11169174.

34. Schwien T, Gilbert J, Lang C. Pressure ulcer prevalence and the role of negative pressure wound therapy in home health quality outcomes. Ostomy Wound Management. 2005 Sep;51(9):47-60. PMID: 16230764.

35. Srivastava RN. An innovative, cost-effective, negative pressure device for management of bedsores in traumatic paraplegia. Spine Journal. 2010;10(9):86S-7S.

36. Stefanovska A. Treatment of chronic wounds by means of electric and electromagnetic fields. Part 2. Value of FES parameters for pressure sore treatment. Medical & Biological Engineering & Computing; 1993. p. 213-20. PMID: 8412373

37. Taly AB, et al. Efficacy of multiwavelength light therapy in the treatment of pressure ulcers in subjects with disorders of the spinal cord: A randomized double-blind controlled trial. Archives of Physical Medicine & Rehabilitation. 2004 Oct;85(10):1657-61. PMID: 15468027.

38. Ter Riet G, Kessels AGH, Knipschild P. Randomised clinical trial of ultrasound treatment for pressure ulcers. British Medical Journal. 1995;310(6986):1040-1. PMID: 7728058.

39. Ter Riet G, Kessels AGH, Knipschild P. A randomized clinical trial of ultrasound in the treatment of pressure ulcers. Physical Therapy. 1996;76(12):1301-12. PMID: 8959999.

40. Ullah MO. A study to detect the efficacy of Micro-current Electrical Therapy on decubitus wound. Journal of Medical Sciences; 2007. p. 1320-4.

41. Wanner MB, et al. Vacuum-assisted wound closure for cheaper and more comfortable healing of pressure sores: a prospective study. Scandinavian Journal of Plastic & Reconstructive Surgery & Hand Surgery. 2003;37(1):28-33. PMID: 12625392.

42. Wood JM, et al. A multicenter study on the use of pulsed low-intensity direct current for healing chronic stage II and stage III decubitus ulcers. Archives of Dermatology. 1993 Aug;129(8):999-1009. PMID: 8352625.

Appendix E. Excluded Studies List

1. [various innovations in the management of decubitus ulcer]. Kango Gijutsu - Japanese Journal of Nursing Art; 1986. p. 594-600 PMID: 3636507 **exclusion reason -** not relevant.
2. [prevention and treatment of decubitus ulcers]. Soins; La Revue de Reference Infirmiere; 1989. p. 32-6 PMID: 2602966 **exclusion reason -** not relevant.
3. About pressure ulcers. Nursing; 1989. p. 76 PMID: 2771256 **exclusion reason -** background.
4. Electromagnetic energy hastens healing of pressure ulcers. Geriatrics; 1991. p. 16 **exclusion reason -** unable to find.
5. For your information: Pressure ulcers. Missouri Medicine; 1991. p. 633-4 PMID: 1836047 **exclusion reason -** background.
6. Pressure ulcers in adults. Pennsylvania Nurse; 1992. p. 7, 10 PMID: 1508557 **exclusion reason -** background.
7. Platelet derived growth factors: New impulses in wound healing. Therapiewoche; 1993. p. 1380-1381 **exclusion reason -** not relevant.
8. Cutinova(registered trademark) cavity - innovative hydroactive wounddressing, specifically for treatment of deep and complicated wounds. H+G Zeitschrift fur Hautkrankheiten; 1994. p. 678 **exclusion reason -** not relevant.
9. Care of chronic wounds: Leg ulcer and decubitus. Physical wound cleansing. Krankenhaus Arzt; 1995. p. 409-410 **exclusion reason -** not relevant.
10. Decubitus ulcers in geriatrics: The significance of hydrocolloid dressings. Revue du Praticien - Medecine Generale; 1996. p. 38-39 **exclusion reason -** not relevant.
11. Pressure ulcer treatment: Quick reference guide for clinicians. Journal of Pharmaceutical Care in Pain & Symptom Control; 1996. p. 93-124 **exclusion reason -** background.
12. Pressure sores -- part ii: Management of pressure related tissue damage. International Journal of Nursing Practice; 1997. p. 1 **exclusion reason -** no original data.
13. Special report: Pressure-reducing support surfaces in the prevention and treatment of pressure ulcers: Group 3 technologies and continuous rotational devices. Part iii. Tecnologica MAP Supplement; 1998. p. 20-1 PMID: 10183371 **exclusion reason -** unable to find.
14. Special report: Prevention and treatment of pressure ulcers: Group 2 technologies. Part ii. Tecnologica MAP Supplement; 1998. p. 17-9 PMID: 10183370 **exclusion reason -** unable to find.
15. Special report: Pressure-reducing support surfaces in the prevention and treatment of pressure ulcers: Group 1 technologies. Part i. Tecnologica MAP Supplement; 1998. p. 43-5 PMID: 10183362 **exclusion reason -** unable to find.
16. Making the right dressing choice: What the survey said. Community Nurse; 1999. p. 41 PMID: 10732576 **exclusion reason -** no original data.
17. Improve pressure ulcer outcomes with protocols. Homecare Quality Management; 1999. p. 11 **exclusion reason -** no original data.
18. Vacuum-assisted closure for chronic wound healing. Tecnologica MAP Supplement; 2000. p. 19-20 PMID: 11503769 **exclusion reason -** unable to find.
19. Sequential moist wound healing in decubitus and leg ulcers. Vasomed; 2000. p. 35 **exclusion reason -** not relevant.
20. [decubitus ulcer. Biological wound treatment stimulates the healing process]. MMW Fortschritte der Medizin; 2001. p. 59 PMID: 11420836 **exclusion reason -** not relevant.
21. Aggressive nutrition intervention. Staff training is key to ensuring positive outcomes. Health Care Food & Nutrition Focus; 2001. p. 12 PMID: 11213747 **exclusion reason -** no original data.
22. Uf tests potential remedy for pressure ulcers in elderly. Florida Nurse; 2001. p. 32-32 **exclusion reason -** no original data.
23. [mepentol, the first product for the prevention and treatment of grade i pressure ulcers]. Revista de Enfermeria; 2002. p. 41 PMID: 13677759 **exclusion reason -** not relevant.
24. [chronic decubitus, ulcus cruris. Maggots feed for wound healing]. MMW Fortschritte der Medizin; 2002. p. 69 PMID: 11847894 **exclusion reason -** not relevant.
25. The pressure sore alleviation project. Journal of Tissue Viability; 2002. p. 77 PMID: 12001329 **exclusion reason -** wrong intervention.
26. [new product for support of wound healing in decubitus ulcer. Decusin]. Krankenpflege Journal; 2003. p. 40 PMID: 12718268 **exclusion reason -** not relevant.
27. Summaries for patients. Nerve growth factor improves healing of pressure ulcers of the foot. Annals of Internal Medicine; 2003. p. I10 PMID: 14568874 **exclusion reason -** no original data.
28. [new collagen powder for wound healing + cost control]. Krankenpflege Journal; 2004. p. 260 PMID: 15675418 **exclusion reason -** not relevant.
29. [bedridden patients at high risk for decubitus ulcer. Skin oil prevents decubitus wounds]. MMW Fortschritte der Medizin; 2004. p. 62 PMID: 15357488 **exclusion reason -** not relevant.
30. [knowing how to choose the best support surface for the prevention and treatment of decubitus ulcers?]. Revue de L'Infirmiere; 2004. p. 22-4 PMID: 15984746 **exclusion reason -** background.
31. Item no. 50: Complications of immobility on decubitus. Prevention and management: Bedsore. Annales de Dermatologie et de Venereologie; 2005. p.

7S11-7S15 PMID: 18984232 **exclusion reason -** not relevant.
32. Radiant heat bandages for stage 3-4 pressure ulcers. Caring for the Ages; 2005. p. 27-27 **exclusion reason -** unable to find.
33. New equip pressure ulcer standard. Primary Intention: The Australian Journal of Wound Management; 2005. p. 117-117 PMID: 2009041343 **exclusion reason -** not relevant.
34. [efficacy of mepentol supported by scientific evidence]. Revista de Enfermeria; 2007. p. 6-7 PMID: 17957968 **exclusion reason -** not relevant.
35. Patient information. Preventing and treating pressure sores. Advance for Nurse Practitioners; 2007. p. 29 PMID: 19998955 **exclusion reason -** background.
36. Facility lowers rate of pressure ulcers, specifically on heel: Use of boot proves to be a step in right direction. Briefings on Patient Safety; 2009. p. 3-5 **exclusion reason -** no original data.
37. Selected excerpt from best practice statement: Optimizing the use of versivarg xcrg gelling foam dressing. Ostomy Wound Management; 2009. p. 3-18 **exclusion reason -** unable to find.
38. Therapeutic mattresses for pressure ulcer management. Critical Care Nurse; 2009. p. 91-91 **exclusion reason -** no original data.
39. Fall: Court sees deviations from nursing standards. Legal Eagle Eye Newsletter for the Nursing Profession; 2009. p. 2-2 **exclusion reason -** background.
40. The effect of stochastic electrical noise on hard-to-heal wounds. Journal of Wound Care; 2011. p. 96-103 **exclusion reason -** not relevant.
41. Tratamiento de las ãlceras con acupuntura acupuncture treatment in ulcers. Agora de Enfermeria; 2011. p. 27-30 **exclusion reason -** not relevant.
42. Methods guide for effectiveness and comparative effectiveness reviews. Ahrq publication no. 10(12)-ehc063-ef. Rockville, MD: Agency for Healthcare Research and Quality; April 2012 PMID: 21433403 **exclusion reason -** background.
43. Abe, N., M. Noguchi, M. Hayashi, T. Watanabe and H. Kushima. The use of bilobed and trilobed gluteal perforator-based island flaps for the repair of sacral pressure ulcers. Japanese Journal of Plastic and Reconstructive Surgery; 1994. p. 1111-1116 **exclusion reason -** not relevant.
44. Acarturk, T. O. Treatment of large ischial ulcers communicating with the hip joint with proximal femoral resection and reconstruction with a combined vastus lateralis, vastus intermedius and rectus femoris musculocutaneous flap. Journal of Plastic, Reconstructive & Aesthetic Surgery: JPRAS; 2009. p. 1497-502 PMID: 18718837 **exclusion reason -** not relevant.
45. Adams, J., L. Teague and J. Mahoney. The impact of pressure ulcers on patient quality of life: Validation of the cardiff wound impact questionnaire... Symposium on advanced wound care and wound healing society meeting, april 28-may 1, 2007, tampa convention center, tampa, florida. Wounds: A Compendium of Clinical Research & Practice; 2007. p. A26-A26 **exclusion reason -** background.
46. Adelson, R., K. Hepburn, R. Reed and A. Dawson. Effective dissemination of the ahcpr guideline: Prevention and early management of pressure ulcers [abstract]. Abstract Book/Association for Health Services Research; 1997. p. 167-168 **exclusion reason -** background.
47. Aggarwal, A., S. S. Sangwan, R. C. Siwach and K. M. Batra. Gluteus maximus island flap for the repair of sacral pressure sores. Spinal Cord; 1996. p. 346-50 PMID: 8963988 **exclusion reason -** not relevant.
48. Agreda, J. J. S., J. T. Bou, J. Posnett, J. V. Soriano, L. San Miguel and J. M. M. Santos. An approach to the economic impact of the treatment of pressure ulcers in spain [spanish]. Gerokomos; 2007. p. 43-52 **exclusion reason -** background.
49. Aguilo Sanchez, S., L. Figueiras Mareque, A. Quintilla Gatnau and L. Veiga Bogo. Traditional dressings or cures in a moist environment? [spanish]. Revista Rol de Enfermería; 2001. p. 50-54 **exclusion reason -** not relevant.
50. Ahluwalia, R., D. Martin and J. L. Mahoney. The operative treatment of pressure wounds: A 10-year experience in flap selection. International Wound Journal; 2009. p. 355-8 PMID: 19912392 **exclusion reason -** not relevant.
51. Ahluwalia, R., D. Martin and J. L. Mahoney. The operative treatment of pressure wounds: A 10-year experience in flap selection. International Wound Journal; 2010. p. 103-6 PMID: 20529150 **exclusion reason -** not relevant.
52. Akan, I. M., M. G. Ulusoy, B. T. Bilen and M. R. Kapucu. Modified bilateral advancement flap: The slide-in flap. Annals of Plastic Surgery; 1999. p. 545-8 PMID: 10340865 **exclusion reason -** not relevant.
53. Akbari Sari, A., K. Flemming, N. A. Cullum and U. Wollina. Therapeutic ultrasound for pressure ulcers. Cochrane Database of Systematic Reviews; 2009 PMID: 16855964 **exclusion reason -** Systematic Review, not directly used.
54. Akguner, M., C. Karaca, A. Atabey, A. Menderes and H. Top. Surgical treatment for ischial pressure sores with gracilis myocutaneous flap. Journal of Wound Care; 1998. p. 276-8 PMID: 9697459 **exclusion reason -** not relevant.
55. Akiyama, M., Y. Ohnishi, T. Henta, S. Tajima, A. Ishibashi and A. Kawada. An evaluation of actosin ointment against superficial cutaneous blood flow: A laser doppler flowmetric study. Acta Dermatologica - Kyoto; 1998. p. 171-176 **exclusion reason -** wrong outcome.
56. Allman, R. M. The impact of pressure ulcers on health care costs and mortality. Advances in Wound Care; 1998. p. 2 PMID: 9729946 **exclusion reason -** no original data.
57. Allman, R. M., A. M. Damiano and M. J. Strauss. Pressure ulcer status and post-discharge health care resource utilization among older adults with activity

limitations. Advances in Wound Care; 1996. p. 38-44 PMID: 8845997 **exclusion reason -** wrong outcome.
58. Allman, R. M., C. A. Laprade, L. B. Noel, J. M. Walker, C. A. Moorer, M. R. Dear and C. R. Smith. Pressure sores among hospitalized patients. Annals of Internal Medicine; 1986. p. 337-42 PMID: 3740674 **exclusion reason -** background.
59. Alterescu, V. The financial costs of inpatient pressure ulcers to an acute care facility. Decubitus; 1989. p. 14-23 PMID: 2775470 **exclusion reason -** background.
60. Alvarez, M. L. Delivering positive outcomes fromnegative pressure wound therapy (npwt). Wound Repair and Regeneration; 2011. p. A10 **exclusion reason -** not relevant.
61. Alvarez, O. M., A. Fernandez-Obregon, R. S. Rogers, L. Bergamo, J. Masso and M. Black. A prospective, randomized, comparative study of collagenase and papain-urea for pressure ulcer debridement. Wounds: A Compendium of Clinical Research & Practice; 2002. p. 293-301 **exclusion reason -** no original data.
62. Amione, P., E. Ricci, F. Topo, L. Izzo, R. Pirovano, V. Rega, C. Cocci and M. Masina. Comparison of allevyn adhesive and biatain adhesive in the management of pressure ulcers. Journal of Wound Care; 2005. p. 365-70 PMID: 16178291 **exclusion reason -** wrong outcome.
63. Anderson, C. and L. Rappl. Lateral rotation mattresses for wound healing. Ostomy Wound Management; 2004. p. 50-4, 56, 58 passim PMID: 15259801 **exclusion reason -** wrong outcome.
64. Ao, M., O. Mae, Y. Namba and K. Asagoe. Perforator-based flap for coverage of lumbosacral defects. Plastic & Reconstructive Surgery; 1998. p. 987-91 PMID: 9514331 **exclusion reason -** not relevant.
65. Apelqvist, J. and G. Ragnarson Tennvall. Cavity foot ulcers in diabetic patients: A comparative study of cadexomer iodine ointment and standard treatment. An economic analysis alongside a clinical trial. Acta Dermato-Venereologica; 1996. p. 231-5 PMID: 8800307 **exclusion reason -** wrong population.
66. Arboledas Bellon, J. and A. Melero Lopez. Calcium alginate and hydrocellular dressings in the prevention and treatment of pressure ulcers [spanish]. Metas de Enfermería; 2004. p. 28-32 **exclusion reason -** not relevant.
67. Arnold-Long, M., R. Johnson and L. Reed. Negative pressure wound therapy overlay technique with collagen dressings for nonhealing wounds. Journal of Wound, Ostomy, & Continence Nursing; 2010. p. 549-53 PMID: 20838320 **exclusion reason -** not relevant.
68. Aronovitch, S. A comparative, randomized, controlled study to determine safety and efficacy of preventive pressure ulcer systems: Preliminary analysis. The Journal for Prevention and Healing; 1998. p. 15-16 **exclusion reason -** not relevant.
69. Asbjornsen, G., B. Hernaes and G. Molvaer. The effect of transcutaneous electrical nerve stimulation on pressure sores in geriatric patients. Journal of Clinical and Experimental Gerontology; 1990. p. 209-214 **exclusion reason -** not relevant.
70. Aslan, G., D. Tuncali, F. Bingul, L. Ates and N. Yavuz. The "duck" modification of the tensor fascia lata flap. Annals of Plastic Surgery; 2005. p. 637-9 PMID: 15900151 **exclusion reason -** not relevant.
71. Atkins, D., S. Chang, G. Gartlehner, D. I. Buckley, E. P. Whitlock, E. Berliner and D. Matchar. Assessing applicability when comparing medical interventions: Agency for healthcare research and quality and the effective health care program. Journal of clinical epidemiology; 2011. p. 1198-207 PMID: 21463926 **exclusion reason -** background.
72. Atri, S. C., J. Misra, D. Bisht and K. Misra. Use of homologous platelet factors in achieving total healing of recalcitrant skin ulcers. Surgery; 1990. p. 508-12 PMID: 2396195 **exclusion reason -** wrong population.
73. Augeraud, C. and P. Guillain. [comparative study of 4 kinds of dressings]. Soins; La Revue de Reference Infirmiere; 2000. p. 21-4 PMID: 11040822 **exclusion reason -** not relevant.
74. Aziz, Z., K. Flemming, N. A. Cullum and A. Olyaee Manesh. Electromagnetic therapy for treating pressure ulcers. Cochrane Database of Systematic Reviews; 2010. p. CD002930 PMID: 21069672 **exclusion reason -** Systematic Review, not directly used.
75. Baba-Akbari Sari, A., K. Flemming, N. A. Cullum and U. Wollina. Therapeutic ultrasound for pressure ulcers. Cochrane Database of Systematic Reviews; 2006. p. CD001275 PMID: 16855964 **exclusion reason -** Systematic Review, not directly used.
76. Baharestani, M. Early initiation of negative pressure wound therapy* in the treatment of stage iii and iv pressure ulcers: Analyzing the impact of length of home care services. World Union of Wound Healing Societies. Toronto, Canada; 2008 **exclusion reason -** wrong outcome.
77. Baharestani, M. M., D. B. Houliston-Otto and S. Barnes. Early versus late initiation of negative pressure wound therapy: Examining the impact on home care length of stay. Ostomy Wound Management; 2008. p. 48-53 PMID: 19037137 **exclusion reason -** wrong outcome.
78. Baker, R. P., E. M. Brown and H. B. Coakham. Overwhelming cranial and spinal subdural empyema secondary infected sacral decubitus ulcers. British Journal of Neurosurgery; 2003. p. 572-3 PMID: 14756492 **exclusion reason -** not relevant.
79. Balakrishnan, C., S. B. Vanjari and G. Esposito. Tissue expansion in the treatment of pressure ulcers [5]. Plastic and Reconstructive Surgery; 1991. p. 1108 **exclusion reason -** no original data.
80. Bale, S. The management of extensive pressure sores. Journal of Wound Care; 1996. p. 470 PMID: 9117820 **exclusion reason -** not relevant.
81. Bale, S., C. Dealey, T. Defloor, A. Hopkins and F. Worboys. The experience of living with a pressure ulcer. Nursing Times; 2007. p. 42-3 PMID: 17476848 **exclusion reason -** background.

82. Bale, S., T. W. Hahn and P. Gad. Time to healing and health related quality of life in the treatment of pressure ulcers with foam dressings. 12th Conference of the European Wound Management Association; 2002 **exclusion reason -** no original data.
83. Bale, S., N. Tebble, V. Jones and P. Price. The benefits of implementing a new skin care protocol in nursing homes. Journal of Tissue Viability; 2004. p. 44-50 PMID: 15114926 **exclusion reason -** wrong outcome.
84. Ballard, K. and H. Baxter. Vacuum-assisted closure. Nursing Times; 2001. p. 51-2 PMID: 11957602 **exclusion reason -** no original data.
85. Ballard, K. and H. Baxter. Promoting healing in static wounds. Nursing Times; 2001. p. 52 PMID: 11954459 **exclusion reason -** no original data.
86. Ballek, A. Rotational therapy beds: Are they worth the cost? Hospital Materials Management; 1997. p. 18-9 PMID: 10168221 **exclusion reason -** no original data.
87. Banks. Evaluation of a new polyurethane foam dressing. Journal of Wound Care; 1997. p. 266-269 **exclusion reason -** wrong outcome.
88. Banks, K., E. S. Jones, M. S. Law and S. MacAvoy. An effective skin integrity program. Journal of Nursing Staff Development; 1993. p. 93-6 PMID: 8492186 **exclusion reason -** background.
89. Banks, V. Management issues in pressure area care. Journal of Wound Care; 1998. p. 369-70 PMID: 9791370 **exclusion reason -** no original data.
90. Banks, V. Nutrition and pressure area management. Journal of Wound Care; 1998. p. 318-9 PMID: 9697469 **exclusion reason -** background.
91. Banks, V. Pressure sores: Topical treatment and the healing process. Journal of Wound Care; 1998. p. 265-6 PMID: 9677999 **exclusion reason -** no original data.
92. Banks, V., S. Bale and K. Harding. A comparative study to evaluate the effectiveness of lyofoam a in the treatment of superficial pressure sores. 3rd European Conference on Advances in Wound Management; 1993 **exclusion reason -** no original data.
93. Banks, V., S. Bale and K. G. Harding. Superficial pressure sores: Comparing two regimes. Journal of Wound Care; 1994. p. 8-10 **exclusion reason -** duplicate.
94. Baranoski, S. Collaborative roles lead to success in wound healing. Decubitus; 1992. p. 66-8 PMID: 1596354 **exclusion reason -** background.
95. Barnes, E. and J. Malone-Lee. Pressure sores: Tegaderm pouch dressings. Nursing Times; 1985. p. 45-6 PMID: 3853162 **exclusion reason -** no original data.
96. Barnes J, B. K. Management of pressure sores: A comparison of granuflex hydrocolloid dressing and granuflex e hydrocolloid dressing. The Pharmacist and Wound Care; 1992 **exclusion reason -** no original data.
97. Barnes, S. and B. S. Rutland. Air-fluidized therapy as a cost-effective treatment for a "worst case" pressure necrosis. Journal of Enterostomal Therapy; 1986. p. 27-9 PMID: 3633272 **exclusion reason -** not relevant.
98. Barnhart, E. V. and V. Jarvis. Skin integrity, impaired: Pressure ulcer, stage 1b. A standardized nursing care plan. CAET Journal; 1993. p. 15-16 **exclusion reason -** no original data.
99. Barr, J. E. Multi-center evaluation of a new wound dressing. Ostomy Wound Management; 1993. p. 60-4, 66-7 PMID: 8136005 **exclusion reason -** not relevant.
100. Barr, J. E. Managing deep, full-thickness pressure ulcers with a new hydrocolloid/alginate wound filler: Dermasorbtm spiral. Ostomy Wound Management; 1994. p. 4p **exclusion reason -** not relevant.
101. Barr, J. E., A. L. Day, V. A. Weaver and G. M. Taler. Assessing clinical efficacy of a hydrocolloid/alginate dressing on full-thickness pressure ulcers. Ostomy Wound Management; 1995. p. 28-30, 32, 34-6 passim PMID: 7546113 **exclusion reason -** not relevant.
102. Barrett, R., V. Tuttle, E. Whalen, C. Gatchell and A. Dawe. Pressure ulcers and nutritional support: A partnership to improve patient outcomes. Journal of Nursing Care Quality; 2010. p. 145-50 PMID: 19707154 **exclusion reason -** background.
103. Barrois, B., M. Carles, M. Rumeau, L. Tell, J. F. Toussaint, M. Bonnefoy and F. De Vathaire. Efficacy and tolerability of hyaluronan (ialuset(registered trademark)) in the treatment of pressure ulcers: A multicentre, non-randomised, pilot study. Drugs in R and D; 2007. p. 267-273 PMID: 17767392 **exclusion reason -** wrong intervention.
104. Baskov, A. V. [the surgical treatment of decubitus ulcers in patients with spinal cord trauma]. Zhurnal Voprosy Neirokhirurgii Imeni N - N - Burdenko; 2000. p. 7-10 PMID: 10738756 **exclusion reason -** not relevant.
105. Bates-Jensen, B. M. Wound care nurses' judgements on healing time in chronic wounds. Ostomy Wound Management; 1996. p. 36-8, 40, 42 passim PMID: 8826137 **exclusion reason -** background.
106. Bates-Jensen, B. M. A quantitative analysis of wound characteristics as early predictors of healing in pressure sores. University of California, Los Angeles; 1998. p. 236 p **exclusion reason -** not relevant.
107. Bates-Jensen, B. M. Wound characteristics as early predictors of healing in pressure sores... 33rd annual communicating nursing research conference/14th annual win assembly, "building on a legacy of excellence in nursing research," held april 13-15, 2000 at the adam's mark hotel, denver, colorado. Communicating Nursing Research; 2000. p. 191-191 **exclusion reason -** background.
108. Bates-Jensen, B. M., M. Guihan, S. L. Garber, A. S. Chin and S. P. Burns. Characteristics of recurrent pressure ulcers in veterans with spinal cord injury. Journal of Spinal Cord Medicine; 2009. p. 34-42 PMID: 19264047 **exclusion reason -** wrong outcome.
109. Bauer, M. Follow-up and critical review of various surgical techniques for the treatment of

decubitus. Wiener Medizinische Wochenschrift; 1989. p. 586 **exclusion reason -** not relevant.

110. Bauer, N., F. Bushey and D. Amaros. Diffusion of responsibility and pressure ulcers. World Council of Enterostomal Therapists Journal; 2002. p. 9-18 **exclusion reason -** background.

111. Bauerle, J. and K. D. Neander. [use of pulsed electrical stimulation in the therapy of decubitus ulcers]. Krankenpflege Journal; 1996. p. 270-5 PMID: 8717869 **exclusion reason -** not relevant.

112. Bauernfeind, G. and S. Strupeit. [quality assurance by professional wound documentation: Often professional terminology is lacking]. Pflege Zeitschrift; 2009. p. 333-6 PMID: 19555001 **exclusion reason -** background.

113. Bauman, W. A., A. M. Spungen and J. F. Collins. Lack of efficacy of oxandrolone to increase the percent of healed pressure ulcers in persons with sci: Va cooperative study. Journal of Spinal Cord Medicine; 2009. p. 458 **exclusion reason -** wrong intervention.

114. Baxter, C. and P. M. Mertz. Local factors that affect wound healing. Nursing RSA Verpleging; 1992. p. 16, 18-9, 22-3 PMID: 1584283 **exclusion reason -** background.

115. Baxter, H. A comparison of two hydrocolloid sheet dressings. British Journal of Community Nursing; 2000. p. 572, 574, 576-7 PMID: 12066057 **exclusion reason -** wrong outcome.

116. Baxter, H. How a discipline came of age: A history of wound care. Journal of Wound Care; 2002. p. 383-6, 388, 390 passim PMID: 12494830 **exclusion reason -** background.

117. Beaulieu, M. B. [the stages of healing of decubitus ulcers]. Soins; La Revue de Reference Infirmiere; 1995. p. 18-20 PMID: 7716577 **exclusion reason -** background.

118. Bechert, K. Journal of the american college of certified wound specialists: Editorial. Journal of the American College of Certified Wound Specialists; 2010. p. 2 **exclusion reason -** background.

119. Beckel, J. Implementation of a standardized protocol for treating pressure ulcers in a nursing home. Geriatric Nursing; 1992. p. 84-9 PMID: 1321086 **exclusion reason -** not relevant.

120. Beele, H., F. Meuleneire, M. Nahuys and S. L. Percival. A prospective randomised open label study to evaluate the potential of a new silver alginate/carboxymethylcellulose antimicrobial wound dressing to promote wound healing. International Wound Journal; 2010. p. 262-70 PMID: 20529142 **exclusion reason -** wrong intervention.

121. Beitz, J. M. Overcoming barriers to quality wound care: A systems perspective. Ostomy Wound Management; 2001. p. 56-64 PMID: 11889750 **exclusion reason -** background.

122. Beitz, J. M. and L. van Rijswijk. Using wound care algorithms: A content validation study. Journal of Wound, Ostomy, & Continence Nursing; 1999. p. 238-9 PMID: 10795206 **exclusion reason -** wrong intervention.

123. Bejany, D. E., R. Chao, P. E. Perito and V. A. Politano. Continent urinary diversion and diverting colostomy in the therapy of non-healing pressure sores in paraplegic patients. Paraplegia; 1993. p. 242-8 PMID: 8493039 **exclusion reason -** not relevant.

124. Beldon, P. Problems encountered managing pressure ulceration of the sacrum. British Journal of Community Nursing; 2008. p. S6, S8, 10 passim PMID: 19060829 **exclusion reason -** background.

125. Bell, J. The role of pressure-redistributing equipment in the prevention and management of pressure ulcers. Journal of Wound Care; 2005. p. 185-8 PMID: 15835233 **exclusion reason -** no original data.

126. Bell, J. C. and S. D. Matthews. Results of a clinical investigation of four pressure-reduction replacement mattresses. Journal of ET Nursing; 1993. p. 204-10 PMID: 8110886 **exclusion reason -** wrong outcome.

127. Benbow, M. Guidelines for the prevention and treatment of pressure ulcers. Nursing Standard; 2006. p. 42-4 PMID: 16989340 **exclusion reason -** background.

128. Bennett, C., S. S. Thomason, P. Boyle, A. Dammers, H. Lacko, J. Nichols, A. Resulta and C. Watkins. Intensive development of an exportable pressure ulcer prevention and treatment program. Journal of Spinal Cord Medicine; 2009. p. 483 **exclusion reason -** background.

129. Bennett, R. G., P. J. Baran, L. DeVone, H. Bacetti, B. Kristo, M. Tayback and W. B. Greenough Iii. Low airloss hydrotherapy versus standard care for incontinent hospitalized patients. Journal of the American Geriatrics Society; 1998. p. 569-576+654-655 PMID: 9588369 **exclusion reason -** wrong outcome.

130. Bennett, R. G., M. F. Bellantoni and J. G. Ouslander. Air-fluidized bed treatment of nursing home patients with pressure sores. Journal of the American Geriatrics Society; 1989. p. 235-42 PMID: 2918193 **exclusion reason -** wrong outcome.

131. Bennis, S. and S. Davis. An effective approach to treating decubitus ulcers in home healthcare patients. Home Healthcare Nurse; 1994. p. 47-52 PMID: 8113091 **exclusion reason -** wrong population.

132. Benraad, H. B. Treatment of different stages of decubitus ulcers. Pharmaceutisch Weekblad; 1999. p. 1482-1485 **exclusion reason -** background.

133. Benskin, L. Pressure ulcer of one year's duration healed in three weeks through the use of polymeric membrane dressing... 39th annual wound, ostomy and continence nurses annual conference. Journal of Wound, Ostomy & Continence Nursing; 2007. p. S26-S26 **exclusion reason -** not relevant.

134. Berard, P., S. Montandon, D. Jedynak and E. C. Saubier. [trial of a hydrocolloid in occlusive dressings in the treatment of skin wounds, "duoderm"]. Revista de Enfermeria; 1986. p. 17-20 PMID: 3633609 **exclusion reason -** not relevant.

135. Berg, W., C. Lossing, C. Traneroth and A. Gunnarsson. [an effective method for treatment of pressure sores. Total reduction of pressure supersedes

the turning schedule]. Lakartidningen; 1993. p. 585-8 PMID: 8437470 **exclusion reason -** not relevant.

136. Bergemann, R., K. W. Lauterbach, W. Vanscheidt, K. D. Neander and R. Engst. Economic evaluation of the treatment of chronic wounds: Hydroactive wound dressings in combination with enzymatic ointment versus gauze dressings in patients with pressure ulcer and venous leg ulcer in germany. Pharmacoeconomics; 1999. p. 367-77 PMID: 10623365 **exclusion reason -** wrong outcome.
137. Bergstrom, N. Review: Specially designed products to prevent or heal pressure sores are more effective than standard mattresses... Commentary on cullum n, deeks j, sheldon ta et al. Beds, mattresses and cushions for pressure sore prevention and treatment. (cochrane review, latest version 2000). In: Cochrane library. Oxford: Update software]. Evidence Based Nursing; 2000. p. 54-54 **exclusion reason -** Systematic Review, not directly used.
138. Bergstrom, N., M. A. Bennett, C. E. Carlson and e. al. Pressure ulcer treatment. Clinical Practice Guideline - Quick Reference Guide for Clinicians; 1994 **exclusion reason -** background.
139. Bergstrom, N., S. D. Horn, R. J. Smout, S. A. Bender, M. L. Ferguson, G. Taler, A. C. Sauer, S. S. Sharkey and A. C. Voss. The national pressure ulcer long-term care study: Outcomes of pressure ulcer treatments in long-term care. Journal of the American Geriatrics Society; 2005. p. 1721-9 PMID: 16181171 **exclusion reason -** background.
140. Bergstrom, N., R. Smout, S. Horn, W. Spector, A. Hartz and M. R. Limcangco. Stage 2 pressure ulcer healing in nursing homes. Journal of the American Geriatrics Society; 2008. p. 1252-8 PMID: 18482291 **exclusion reason -** background.
141. Bergstrom, N., J. Theodore and M. E. Trumble. Pressure ulcers among home care patients: Whose responsibility are they? Journal of the American Geriatrics Society; 2000. p. 1165-1166 **exclusion reason -** background.
142. Berlemont, M. [extensive resection of the hip for suppurative arthritis in the paraplegic. Evaluation of 170 cases]. Revue de Chirurgie Orthopedique et Reparatrice de l Appareil Moteur; 1985. p. 377-87 PMID: 4081138 **exclusion reason -** not relevant.
143. Berlemont, M. and R. Keromest. [dangers of ischiectomy in ulcers in the paraplegic patient. Review of 236 records]. Revue de Chirurgie Orthopedique et Reparatrice de l Appareil Moteur; 1987. p. 656-64 PMID: 3444945 **exclusion reason -** not relevant.
144. Berlowitz, D. R. Striving for six sigma in pressure ulcer care. Journal of the American Geriatrics Society; 2003. p. 1320-1321 **exclusion reason -** background.
145. Berlowitz, D. R., G. H. Brandeis, J. Anderson and H. K. Brand. Predictors of pressure ulcer healing among long-term care residents. Journal of the American Geriatrics Society; 1997. p. 30-4 PMID: 8994484 **exclusion reason -** wrong intervention.
146. Berlowitz, D. R. and D. M. Brienza. Are all pressure ulcers the result of deep tissue injury? A review of the literature. Ostomy Wound Management; 2007. p. 34-8 PMID: 17978413 **exclusion reason -** background.
147. Berlowitz, D. R. and R. A. Frantz. Implementing best practices in pressure ulcer care: The role of continuous quality improvement. Journal of the American Medical Directors Association; 2007. p. S37-41 PMID: 17336874 **exclusion reason -** background.
148. Berlowitz, D. R. and S. V. Wilking. The short-term outcome of pressure sores. Journal of the American Geriatrics Society; 1990. p. 748-52 PMID: 2370394 **exclusion reason -** background.
149. Berman, J. E., P. R. Sandford, B. S. Sandford, J. F. Collins, W. A. Bauman and A. M. Spungen. Inclusion of undermined wound area improves accuracy of serial assessments based on measured wound surface area. Journal of Spinal Cord Medicine; 2009. p. 458-459 **exclusion reason -** background.
150. Bernabei, R., F. Landi, S. Bonini, G. Onder, A. Lambiase, R. Pola and L. Aloe. Effect of topical application of nerve-growth factor on pressure ulcers. Lancet; 1999. p. 307 PMID: 10440316 **exclusion reason -** no original data.
151. Bernardo, M., C. Wenter, A. March and G. Dona. Pressure sores: Experience and new perspectives of intervention. Geriatria; 1993. p. 325-329 **exclusion reason -** background.
152. Bhanganada, K., V. Kiettiphongthavorn and H. Wilde. The use of super-saturated sucrose solution for chronic skin ulcers (resurrection of an old remedy). Journal of the Medical Association of Thailand; 1986. p. 358-66 PMID: 3760735 **exclusion reason -** wrong intervention.
153. Bialoszewski, D. and M. Kowalewski. Superficially, longer, intermittent ozone theraphy in the treatment of the chronic, infected wounds. Ortopedia Traumatologia Rehabilitacja; 2003. p. 652-8 PMID: 17679848 **exclusion reason -** not relevant.
154. Bielecki, M., R. Skowronski and J. Skowronski. [sacral pressure sores and their treatment]. Chirurgia Narzadow Ruchu i Ortopedia Polska; 2006. p. 51-6 PMID: 17128774 **exclusion reason -** not relevant.
155. Biglari, B., P. H. vd Linden, A. Simon, S. Aytac, H. J. Gerner and A. Moghaddam. Use of medihoney as a non-surgical therapy for chronic pressure ulcers in patients with spinal cord injury. Spinal Cord; 2012. p. 165-9 PMID: 21931331 **exclusion reason -** not relevant.
156. Bih, L. I. and S. Y. Lu. The rehabilitation of pressure sores after myocutaneous flap surgery. Taiwan i Hsueh Hui Tsa Chih - Journal of the Formosan Medical Association; 1989. p. 387-93 PMID: 2794940 **exclusion reason -** not relevant.
157. Bilkay, U., E. Helvaci, C. Tokat, C. Ozek and Y. Akin. [surgical coverage technics of pressure sores and their outcomes]. Ulusal Travma ve Acil Cerrahi Dergisi = Turkish Journal of Trauma & Emergency Surgery: TJTES; 2006. p. 143-9 PMID: 16676254 **exclusion reason -** not relevant.
158. Bill, B., J. Pedersen, E. Call and C. Oberg. Wound dressing shear test method (bench) providing

results equivalent to humans. **exclusion reason -** Scientific Information Packets, not directly used.
159. Bingham, P. Noncontact, low-frequency ultrasound therapy for infected pressure ulcers in a patient with multiple comorbidities... Scientific and clinical abstracts from the 40th annual wound, ostomy and continence nurses annual conference. Journal of Wound, Ostomy & Continence Nursing; 2008. p. S7-S7 **exclusion reason -** no original data.
160. Bizot, E. and E. Longrais. [hygiene of fluidized beds]. Soins; La Revue de Reference Infirmiere; 1985. p. 29-32 PMID: 3854510 **exclusion reason -** background.
161. Blaylock, B. Air support therapy: Ethical considerations. Journal of ET Nursing; 1992. p. 171-3 PMID: 1420530 **exclusion reason -** background.
162. Bliss, M. An update on horizontal support surfaces. Journal of Tissue Viability; 2000. p. 35-6 PMID: 10839096 **exclusion reason -** background.
163. Bliss, M. Pressure sores--demographic perspectives. Journal of Tissue Viability; 2000. p. 106, 109-15 PMID: 11299569 **exclusion reason -** background.
164. Bliss, M. Selection criteria for systematic literature reviews. Journal of Tissue Viability; 2001. p. 173-4; author reply 174-5 PMID: 11949611 **exclusion reason -** background.
165. Bliss, M. The importance of accurate terminology in wound care. Journal of Tissue Viability; 2003. p. 180 PMID: 14606120 **exclusion reason -** background.
166. Bliss, M. Justifying placebo use in clinical trials. Journal of Tissue Viability; 2004. p. 33 PMID: 14768133 **exclusion reason -** background.
167. Bliss, M. and J. M. Thomas. An investigative approach. An overview of randomised controlled trials of alternating pressure supports. Professional Nurse; 1993. p. 437-44 PMID: 8475148 **exclusion reason -** no original data.
168. Bliss, M. R. Managing pressure ulcers. Advances in Wound Care; 1995. p. 6, 8 PMID: 7582343 **exclusion reason -** no original data.
169. Bliss, M. R. Preventing pressure sores in elderly patients: A comparison of seven mattress overlays.[erratum appears in age ageing 1995 nov;24(6):543]. Age & Ageing; 1995. p. 297-302 PMID: 7484486 **exclusion reason -** wrong outcome.
170. Bliss, M. R. Pressure sore protocol. Journal of Wound Care; 1997. p. 248; author reply 249 PMID: 9256734 **exclusion reason -** no original data.
171. Bliss, M. R. Pressure sores and severe sepsis. Hospital Medicine (London); 1999. p. 146 PMID: 10320850 **exclusion reason -** background.
172. Bliss, M. R. Clinical research in patient support systems. 1981. Journal of Tissue Viability; 2003. p. 154-6, 158, 160 passim PMID: 14606118 **exclusion reason -** not relevant.
173. Bliss, M. R. Pressure ulcer care needs medical input. Journal of Wound Care; 2005. p. 354-5 PMID: 16178288 **exclusion reason -** background.
174. Bliss, M. R. and M. Schofield. A pilot leg ulcer clinic in a geriatric day hospital. Age & Ageing; 1993. p. 279-84 PMID: 8213334 **exclusion reason -** not relevant.
175. Blom, M. F. Dramatic decrease in decubitus ulcers. Geriatric Nursing; 1985. p. 84-7 PMID: 3844361 **exclusion reason -** background.
176. Bluestein, D. and A. Javaheri. Pressure ulcers: Prevention, evaluation, and management. American Family Physician; 2008. p. 1186-94 PMID: 19035067 **exclusion reason -** background.
177. Blumen, N., Z. Bar-On, M. Azaria and A. Ohry. [pressure sores: Pathophysiology, prevention, treatment and rehabilitation]. Harefuah; 1992. p. 321-6 PMID: 1572582 **exclusion reason -** not relevant.
178. Bobel, L. M. Nutritional implications in the patient with pressure sores. Nursing Clinics of North America; 1987. p. 379-90 PMID: 3646666 **exclusion reason -** background.
179. Bocchi, A., M. M. Dominici, M. Taglia, E. Caleffi and C. Dominici. [clinical and nursing protocol in the treatment of the decubital ulcers]. Annali Italiani di Chirurgia; 2007. p. 119-24 PMID: 17583121 **exclusion reason -** not relevant.
180. Bocchi, A., S. Traspassi, G. Bianco, F. Castagnetti and F. Papadia. Treatment of decubitus ulcers in patients with spina bifida. Europa Medicophysica; 2002. p. 139-146 **exclusion reason -** wrong population.
181. Bodnar, B. and P. Myron. Portrait of practice: Reducing the prevalence of pressure ulcers. Decubitus; 1992. p. 49-52 PMID: 1558692 **exclusion reason -** background.
182. Bogie, K. M., C. H. Ho and D. D. Terris. Clinical interface. Clinical evidence for new pressure ulcer treatment modalities. Long-Term Care Interface; 2005. p. 43-47 **exclusion reason -** wrong population.
183. Boiko, V. V., I. A. Krivoruchko and D. A. Pasychnyi. [surgical treatment of integumentary tissues of foot and shin using adhesive dermal tension and cryotherapy]. Klinicheskaia Khirurgiia; 2002. p. 33-6 PMID: 11944294 **exclusion reason -** not relevant.
184. Bollero, D., V. Driver, P. Glat, S. Gupta, J. L. Lazaro-Martinez, C. Lyder, M. Ottonello, F. Pelham, S. Vig and K. Woo. The role of negative pressure wound therapy in the spectrum of wound healing. Ostomy Wound Management; 2010. p. 2-18 **exclusion reason -** background.
185. Bolton, L. Hydrocellular dressings versus hydrocolloid dressings... A randomized clinical study comparing a hydrocellular dressing to a hydrocolloid dressing in the management of pressure ulcers. Ostomy Wound Management; 2000. p. 8-8 **exclusion reason -** no original data.
186. Bolton, L. Are silver products safe and effective for chronic wound management? Journal of Wound, Ostomy, & Continence Nursing; 2006. p. 469-77 PMID: 17133133 **exclusion reason -** Systematic Review, not directly used.
187. Bolton, L. Do products affect wound outcomes when using standardized algorithms?... Scientific and clinical abstracts from the 40th annual wound, ostomy and continence nurses annual conference. Journal of

Wound, Ostomy & Continence Nursing; 2008. p. S31-S31 **exclusion reason -** no original data.

188. Bolton, L., S. Girolami, S. Slayton, T. M. Berger, L. Foster, K. T. Whittington, D. Merkle and S. Association for the Advancement of Wound Care Guideline. Assessing the need for developing a comprehensive content-validated pressure ulcer guideline. Ostomy Wound Management; 2008. p. 22-30 PMID: 19037134 **exclusion reason -** background.
189. Bolton, L., P. McNees, L. van Rijswijk, J. de Leon, C. Lyder, L. Kobza, K. Edman, A. Scheurich, R. Shannon, M. Toth and G. Wound Outcomes Study. Wound-healing outcomes using standardized assessment and care in clinical practice. Journal of Wound, Ostomy, & Continence Nursing; 2004. p. 65-71 PMID: 15209428 **exclusion reason -** wrong intervention.
190. Bolton, L. B., N. E. Donaldson, D. N. Rutledge, C. Bennett and D. S. Brown. The impact of nursing interventions: Overview of effective interventions, outcomes, measures, and priorities for future research. Medical Care Research & Review; 2007. p. 123S-43S PMID: 17406015 **exclusion reason -** background.
191. Bolton, L. L. Evidence corner. Wounds heal better with sequential strategies. Wounds: A Compendium of Clinical Research & Practice; 2002. p. A28 **exclusion reason -** not relevant.
192. Bolton, L. L. Evidence corner. Rht: A veterans affairs (va) medical center pilot study on stage iii-iv pressure ulcers. Wounds: A Compendium of Clinical Research & Practice; 2005. p. A22 **exclusion reason -** wrong outcome.
193. Bolton, L. L. Evidence corner. Debriding pressure ulcers with maggot versus conventional therapy. Wounds: A Compendium of Clinical Research & Practice; 2006. p. A19 **exclusion reason -** no original data.
194. Bond, T. K. Consistency in prevention and treatment of pressure ulcers through a wound care team. Nursing Case Management; 1997. p. 203-18 PMID: 9392263 **exclusion reason -** not relevant.
195. Bonnefoy, M., L. Coulon, J. Bienvenu, R. C. Boisson and L. Rys. Implication of cytokines in the aggravation of malnutrition and hypercatabolism in elderly patients with severe pressure sores. Age and Ageing; 1995. p. 37-42 PMID: 7539207 **exclusion reason -** not relevant.
196. Borgman, H. and W. Sellmer. Prophylaxis and therapy of decubitus. Krankenhauspharmazie; 1994. p. 687-691 **exclusion reason -** not relevant.
197. Borgognone, A., T. Anniboletti, F. De Vita, M. Schirosi and P. Palombo. Ischiatic pressure sores: Our experience in coupling a split-muscle flap and a fasciocutaneous flap in a 'criss-cross' way. Spinal Cord; 2010. p. 770-3 PMID: 20309001 **exclusion reason -** not relevant.
198. Borgstrom, P. S., O. Ekberg and A. Lasson. Radiography of pressure ulcers. Acta Radiologica; 1988. p. 581-4 PMID: 3166880 **exclusion reason -** background.
199. Borman, H. and T. Maral. The gluteal fasciocutaneous rotation-advancement flap with v-y closure in the management of sacral pressure sores. Plastic & Reconstructive Surgery; 2002. p. 2325-9 PMID: 12045558 **exclusion reason -** not relevant.
200. Bortolani, A., A. Sanna, D. Barisoni, G. Rigotti and S. Furlan. Review of 150 pressure sores in paraplegics. Rivista Italiana di Chirurgia Plastica; 1990. p. 377-383 **exclusion reason -** not relevant.
201. Bosch, M., R. J. G. Halfens, T. van der Weijden, M. Wensing, R. Akkermans and R. Grol. Organizational culture, team climate, and quality management in an important patient safety issue: Nosocomial pressure ulcers. Worldviews on Evidence-Based Nursing; 2011. p. 4-14 PMID: 20367807 **exclusion reason -** background.
202. Boschnakov, K., J. Tschervenkov and D. Videlov. [the use of skin-muscle flaps in decubitus ulcer treatment]. Zentralblatt fur Chirurgie; 1990. p. 275-8 PMID: 2346063 **exclusion reason -** not relevant.
203. Boshnakov, K. [skin-muscle flaps formed in the gluteal and femoral regions]. Khirurgiia; 1986. p. 29-35 PMID: 3821007 **exclusion reason -** not relevant.
204. Boshnakov, K. and I. Chervenkov. [surgical treatment of decubital wounds in the trochanteric area]. Khirurgiia; 1989. p. 33-8 PMID: 2761176 **exclusion reason -** not relevant.
205. Bou Torra, J.-E., J. J. Soldevilla Agreda, F. Martinez Cuervo and J. Rueda Lopez. [collagen powder dressing in the treatment of pressure ulcer. Multicenter comparative study assessing effectiveness and cost]. Revista de Enfermeria; 2002. p. 50-7 PMID: 13677749 **exclusion reason -** not relevant.
206. Bourdel_Marchasson, I. and M. Barateau, et al. A multi-center trial of the effects of oral nutritional supplementation in critically ill older inpatients. Nutrition; 2000. p. 1-5 **exclusion reason -** wrong population.
207. Bourdel-Marchasson, I. and V. Rondeau. Nutritional intervention trials for preventing and treating pressure ulcer. Nutrition; 2001. p. 155-6 PMID: 11240343 **exclusion reason -** no original data.
208. Bouza Alvarez, C., O. Sanz de Leon and J. Amate Blanco. Effectiveness of special dressings in the treatment of pressure and leg ulcers. Ipe-01/28 (public report) (structured abstract). Health Technology Assessment Database; 2011 **exclusion reason -** no original data.
209. Bouza, C., Z. Saz, A. Munoz and J. M. Amate. Efficacy of advanced dressings in the treatment of pressure ulcers: A systematic review. Journal of Wound Care; 2005. p. 193-9 PMID: 15909431 **exclusion reason -** Systematic Review, not directly used.
210. Bovy, A. [surgical treatment of pressure sores of the heel]. Revue Medicale de Bruxelles; 1986. p. 329-32 PMID: 3526501 **exclusion reason -** not relevant.
211. Boykin, A. and J. Winland-Brown. Pressure sores: Nursing management... Compare hydrocolloid occlusive dressing with povidone-iodine therapy. In: C. A. Tanner, editor Using nursing research.: National League for Nursing; 1989. p. 252-256 **exclusion reason -** unable to find.

212. Boykin, J. V. 5 questions--and answers--about hyperbaric oxygen therapy. Advances in Skin & Wound Care; 2001. p. 232, 234 PMID: 11905969 **exclusion reason -** no original data.
213. Bozzuto, T. M. and C. E. Fife. Adjunctive therapies for wound healing. JAMA; 2000. p. 40; author reply 41 PMID: 10872005 **exclusion reason -** no original data.
214. Braden, B. J. and R. Bryant. Innovations to prevent and treat pressure ulcers. Geriatric Nursing; 1990. p. 182-6 PMID: 2163958 **exclusion reason -** no original data.
215. Bradley, M., N. Cullum, E. A. Nelson, M. Petticrew, T. Sheldon and D. Torgerson. Systematic reviews of wound care management: (2). Dressings and topical agents used in the healing of chronic wounds. Health Technology Assessment (Winchester, England); 1999. p. 1-35 PMID: 10683589 **exclusion reason -** Systematic Review, not directly used.
216. Bradley, M., N. Cullum and T. Sheldon. The debridement of chronic wounds: A systematic review. Health Technology Assessment; 1999. p. iii-73 **exclusion reason -** Systematic Review, not directly used.
217. Bradley, M. D., E. A. Nelson, M. Petticrew, N. A. Cullum and T. Sheldon. Dressings for pressure sores. Cochrane Database of Systematic Reviews; 2009 PMID: 00075320-100000000-00009 **exclusion reason -** background.
218. Brady, S. M. Management of pressure sores with occlusive dressings in a select population. Nursing Management; 1987. p. 47-50 PMID: 3649654 **exclusion reason -** no original data.
219. Brancati, A. [debridement of decubitus ulcers]. Soins; La Revue de Reference Infirmiere; 2011. p. 51 PMID: 21449191 **exclusion reason -** not relevant.
220. Brandeis, G. H., J. N. Morris, D. J. Nash and L. A. Lipsitz. Incidence and healing rates of pressure ulcers in the nursing home. Decubitus; 1989. p. 60-2 PMID: 2787661 **exclusion reason -** not relevant.
221. Brandeis, G. H., J. N. Morris, D. J. Nash and L. A. Lipsitz. The epidemiology and natural history of pressure ulcers in elderly nursing home residents. JAMA; 1990. p. 2905-9 PMID: 2232085 **exclusion reason -** background.
222. Braumann, C., N. Guenther, C. Menenakos, H. Muenzberg, M. Pirlich, H. Lochs and J. M. Mueller. Clinical experiences derived from implementation of an easy to use concept for treatment of wound healing by secondary intention and guidance in selection of appropriate dressings. International Wound Journal; 2011. p. 253-260 **exclusion reason -** wrong population.
223. Braun, J. L., A. N. Silvetti and G. C. Xakellis. Decubitus ulcers: What really works? Patient Care; 1988. p. 22 **exclusion reason -** background.
224. Braun, J. L., A. N. Silvetti and G. C. Xakellis. What really works for pressure sores. Patient Care; 1992. p. 63 **exclusion reason -** background.
225. Bravo, F. G. and H. P. Schwarze. Free-style local perforator flaps: Concept and classification system. Journal of Plastic, Reconstructive & Aesthetic Surgery: JPRAS; 2009. p. 602-8; discussion 609 PMID: 19181580 **exclusion reason -** not relevant.
226. Breite, M. J. Pressure ulcers: The benefits and costs of new therapies. JAMA; 1993. p. 2735; author reply 2735-6 PMID: 8492393 **exclusion reason -** no original data.
227. Brem, H., J. Balledux, T. Bloom, M. D. Kerstein and L. Hollier. Healing of diabetic foot ulcers and pressure ulcers with human skin equivalent: A new paradigm in wound healing. Archives of Surgery; 2000. p. 627-634 PMID: 10843357 **exclusion reason -** wrong population.
228. Brem, H., T. Jacobs, L. Vileikyte, S. Weinberger, M. Gibber, K. Gill, A. Tarnovskaya, H. Entero and A. J. M. Boulton. Wound-healing protocols for diabetic foot and pressure ulcers. Surgical Technology International; 2003. p. 85-92 PMID: 12931288 **exclusion reason -** wrong population.
229. Brem, H. and R. S. Kirsner. Use of graftskin (apligraf) in the treatment of pressure ulcers and acute wounds. Wounds: A Compendium of Clinical Research & Practice; 2000. p. 72A-77 **exclusion reason -** not relevant.
230. Brem, H. and C. Lyder. Protocol for the successful treatment of pressure ulcers. American Journal of Surgery; 2004. p. 9-17 PMID: 15223496 **exclusion reason -** background.
231. Brem, H., M. Tomic-Canic, A. Tarnovskaya, H. P. Ehrlich, E. Baskin-Bey, K. Gill, M. Carasa, S. Weinberger, H. Entero and B. Vladeck. Healing of elderly patients with diabetic foot ulcers, venous stasis ulcers, and pressure ulcers. Surgical Technology International; 2003. p. 161-7 PMID: 12931298 **exclusion reason -** wrong population.
232. Brennan, M. R. and S. Faliks. Honey -- debriding alternative... 41st annual wound, ostomy and continence nurses annual conference, st. Louis, missouri, june 6-10, 2009. Journal of Wound, Ostomy & Continence Nursing; 2009. p. S17-S17 **exclusion reason -** no original data.
233. Brenner, P. and A. Berger. The long-term management of sacral, ischial and trochanteric pressure sores by myocutaneous island flaps and their postoperative course. European Journal of Plastic Surgery; 1987. p. 24-28 **exclusion reason -** not relevant.
234. Breslow, R., J. Hallfrisch, P. B. Moser, M. Maney, D. Muller and A. Goldberg. High calories and protein improve healing of pressure sores in malnourished nursing home patients. Federation of American Societies for Experimental Biology (FASEB) World Meeting. Washington, DC; 1987. p. Paper No. 4042 **exclusion reason -** unable to find.
235. Breslow, R. A. The effect of dietary protein intake on pressure sore healing and nutritional status in nursing home subjects. University of Maryland College Park; 1990. p. 129 p **exclusion reason -** no original data.
236. Brienza, D. M. and M. J. Geyer. Understanding support surface technologies. Advances in Skin & Wound Care; 2000. p. 237-44 PMID: 11075023 **exclusion reason -** background.

237. Brindle, C. T. Wound-product selection and innovations: 3308: Identifying high-risk icu patients: Use of an absorbent soft silicone self-adherent bordered foam dressing to decrease pressure ulcers in the surgical trauma icu patient. Journal of Wound Ostomy & Continence Nursing; 2009. p. Supplement S27 **exclusion reason -** Scientific Information Packets, not directly used.
238. Bristow, J. V., E. H. Goldfarb and M. Green. Clinitron therapy: Is it effective? Geriatric Nursing; 1987. p. 120-4 PMID: 3646981 **exclusion reason -** wrong intervention.
239. Brooks, R. and A. Semlyen. Economic appraisal in pressure sore management. Journal of Wound Care; 1997. p. 491-4 PMID: 9455275 **exclusion reason -** background.
240. Brown Etris, M. A strategy for the management of pressure ulcers in nursing homes. Ostomy Wound Management; 1989. p. 28-32 PMID: 2719804 **exclusion reason -** no original data.
241. Brown Etris, M. A randomized comparative clinical evaluation of a transparent absorbent acrylic dressing and a hydrocolloid dressing on stage ii and iii pressure ulcers. Journal of Wound, Ostomy & Continence Nursing; 2006. p. S53-S53 PMID: 2009188654 **exclusion reason -** not relevant.
242. Brown Etris, M., M. Punchello, D. Shields, H. Barnes, K. Galluzzi, A. Whalen and et al. Interim analysis of a randomized prospective multi-centred 20-week comparison of two wound management systems on pressure ulcers. 31st Annual Wound, Ostomy and Continence Conference; 1999 **exclusion reason -** no original data.
243. Brown, G. Long-term outcomes of full-thickness pressure ulcers: Healing and mortality. Ostomy Wound Management; 2003. p. 42-50 PMID: 14652420 **exclusion reason -** no original data.
244. Brown, G. L. Re: Recombinant human platelet-derived growth factor-bb for the treatment of chronic pressure ulcers. Annals of Plastic Surgery; 1993. p. 192 PMID: 8489189 **exclusion reason -** no original data.
245. Brown-Etris, M. Measuring healing in wounds. Advances in Wound Care; 1995. p. suppl 53-8 PMID: 7627405 **exclusion reason -** background.
246. Brown-Etris, M. and C. T. Milne. Use of a foam dressing with a unique spoke-shaped delivery system on pressure ulcers of the heel and elbow... 39th annual wound, ostomy and continence nurses annual conference. Journal of Wound, Ostomy & Continence Nursing; 2007. p. S30-1 **exclusion reason -** no original data.
247. Brown-Etris, M., M. Punchello and T. O'Connor. Use of a transparent absorbent acrylic dressing on stage ii and iii pressure ulcers. Journal of Wound, Ostomy & Continence Nursing; 2006. p. S53-4 **exclusion reason -** not relevant.
248. Brown-Maher, T. Multidisciplinary approach to chronic wound care: Our 2-year newfoundland and labrador experience. Journal of Cutaneous Medicine & Surgery; 2009. p. S26-8 PMID: 19480748 **exclusion reason -** no original data.
249. Bryant, R. Commentary on abstracts from the literature. Wound. Effects of hydrotherapy on pressure ulcer healing [original article by burke td, ho ch-k, saucier ma, stewart g appears in am j phys med rehabil 1998;77;394-3]. In: J. D. Whitney, editor Journal of Wound, Ostomy & Continence Nursing; 2000. p. 12A-13 **exclusion reason -** background.
250. Buck, D. W., 2nd and V. L. Lewis, Jr. The use of argon beam coagulation in pressure sore reconstruction. Journal of Plastic, Reconstructive & Aesthetic Surgery: JPRAS; 2009. p. 1684-7 PMID: 18977700 **exclusion reason -** not relevant.
251. Bufton, T. Wound care. A home from home. Nursing Times; 1995. p. 66-74 PMID: 7716025 **exclusion reason -** not relevant.
252. Burke, D. T., C. H. Ho and M. A. Saucier. Hydrotherapy effects on pressure ulcer healing [abstract]. Archives of Physical Medicine and Rehabilitation; 1997. p. 1053 **exclusion reason -** no original data.
253. Burrows, C., R. Miller, D. Townsend, R. Bellefontaine, G. Mackean, H. L. Orsted and D. H. Keast. Best practice recommendations for the prevention and treatment of venous leg ulcers: Update 2006. Advances in Skin & Wound Care; 2007. p. 611-21; quiz 622-3 PMID: 17975369 **exclusion reason -** background.
254. Burt, S., L. McDonald and T. Burke. Unexpected outcomes from monochromatic infrared energy (mire). Journal of Wound, Ostomy & Continence Nursing; 2006. p. S26-S26 **exclusion reason -** no original data.
255. Burton, P. Prevention is better than cure. Journal of Community Nursing; 1995. p. 18 **exclusion reason -** background.
256. Cali, T. J. and M. Bruce. Pressure ulcer treatment: Examining selected costs of therapeutic failure. Advances in Wound Care; 1999. p. 8-11 **exclusion reason -** no original data.
257. Call, E., J. Pederson, L. Baker and C. Oberg. Characterization of wound dressings physical properties and their potential impact on prevention of ulceration. 2010 EPUAP Annual Conference; 2010 **exclusion reason -** Scientific Information Packets, not directly used.
258. Campbell, C. and L. C. Parish. The decubitus ulcer: Facts and controversies. Clinics in Dermatology; 2010. p. 527-32 PMID: 20797513 **exclusion reason -** background.
259. Campbell, C. and L. C. Parish. Treatment of decubitus ulcers. SKINmed; 2011. p. 114-5 PMID: 21548518 **exclusion reason -** not relevant.
260. Campbell, K. E. and A. LeMesurier. Hydrocolloid dressings: A case series in wear time and function. Link (17012473); 2004. p. 13-15 **exclusion reason -** wrong population.
261. Candela-Zamora, M. D., M. A. Martin-Gomez, B. Solas-Gomez, C. Fernandez-Perez, M. Martin-Gonzalez, L. Manzanedo-Basilio, S. Navarro-Gorjon, R. Gonzalez-Dugo, S. Rodriguez-Sanchez, M. S. Nunez-Marugan, C. Nosti del Valle, T. Garcia-Acena, S. Cano-Escudero and N. del Prado-Gonzalez. [comparative study of the effectiveness two of

hyperoxygenated fatty acids in the treatment of grade i ulcers in geriatric hospitalized patients]. Enfermeria Clinica; 2010. p. 10-6 **exclusion reason -** not relevant.

262. Cannon, B. C. and J. P. Cannon. Management of pressure ulcers. American Journal of Health-System Pharmacy; 2004. p. 1895-905; quiz 1906-7 PMID: 15487879 **exclusion reason -** background.
263. Capillas Perez, R., V. Cabre Aguilar, A. M. Gil Colome, A. Gaitano Garcia and J. E. Torra i Bou. [comparison of the effectiveness and cost of treatment with humid environment as compared to traditional cure. Clinical trial on primary care patients with venous leg ulcers and pressure ulcers]. Revista de Enfermeria; 2000. p. 17-24 PMID: 10788945 **exclusion reason -** not relevant.
264. Capra, F. and M. Biraghi. Preliminary clinical-iconographic evolution of cadexomer iodine in the topical treatment of decubitus ulcers. Giornale Italiano di Ricerche Cliniche e Terapeutiche; 1990. p. 65-70 **exclusion reason -** not relevant.
265. Carasa, M. and M. Polycarpe. Caring for the chronically critically ill patient: Establishing a wound-healing program in a respiratory care unit. American Journal of Surgery; 2004. p. 18-21 PMID: 15223497 **exclusion reason -** no original data.
266. Carley, P. J. and S. F. Wainapel. Electrotherapy for acceleration of wound healing: Low intensity direct current. Archives of Physical Medicine and Rehabilitation; 1985. p. 443-6 **exclusion reason -** wrong population.
267. Carlton, T. and P. Strasburg. Implementing research: Improving care of patients with pressure ulcers. Communicating Nursing Research; 2009. p. 469-469 **exclusion reason -** wrong outcome.
268. Carr, R. D. and D. E. Lalagos. Clinical evaluation of a polymeric membrane dressing in the treatment of pressure ulcers. Decubitus; 1990. p. 38-42 PMID: 2205233 **exclusion reason -** not relevant.
269. Carroll, P. Pressure ulcers and materiel management: Cost-effective prevention and care. Hospital Materiel Management Quarterly; 1993. p. 38-49 PMID: 10129709 **exclusion reason -** background.
270. Casali, B., P. A. Bonati, G. DelGin and C. Ascari. The use of a blood platelet lysate in the treatment of pressure sores experimental observations. European Wound Management Association Conference. Milan, Italy; 1997 PMID: CN-00319220 **exclusion reason -** not relevant.
271. Casey, G. Three steps to effective wound care. Elderly Care; 1998. p. 14-6 PMID: 10542489 **exclusion reason -** background.
272. Cassell, B. L. Treating pressure sores stage by stage. RN; 1986. p. 36-40 PMID: 3635207 **exclusion reason -** no original data.
273. Cavadas, P. C. Turn-over deepithelialized edge flaps in pressure sore repair. Plastic & Reconstructive Surgery; 1997. p. 921-2 PMID: 9047226 **exclusion reason -** no original data.
274. Ceelen, K. K., A. Stekelenburg, S. Loerakker, G. J. Strijkers, D. L. Bader, K. Nicolay, F. P. Baaijens and C. W. J. Oomens. Compression-induced damage and internal tissue strains are related. J Biomech; 2008. p. 3399-3404 PMID: 19010470 **exclusion reason -** wrong population.
275. Centers for Medicare & Medicaid Services. Decision memo for air-fluidized beds for pressure ulcers (cag-00017r). In: U. S. D. o. H. a. H. Services, editor; 2012 **exclusion reason -** background.
276. Ceolim, M. F., I. E. M. Araujo, M. J. E. Diogo, H. M. Bajay and K. M. Rosa. Comparing hydrocolloid to dry gauze dressings in the treatment of sacral pressure sores. Nursing: A new era for action, international council of nurses icn 22nd quadrennial congress. Geneva, Switzerland: International Council of Nurses; 2001. p. 445 **exclusion reason -** no original data.
277. Cervelli, V., B. De Angelis, L. Lucarini, D. Spallone, A. Balzani, L. Palla, P. Gentile and P. Cerulli. Tissue regeneration in loss of substance on the lower limbs through use of platelet-rich plasma, stem cells from adipose tissue, and hyaluronic acid. Advances in Skin & Wound Care; 2010. p. 262-72 PMID: 20489388 **exclusion reason -** wrong population.
278. Cervo, F. A., A. C. Cruz and J. A. Posillico. Pressure ulcers. Analysis of guidelines for treatment and management. Geriatrics; 2000. p. 55-60; quiz 62 PMID: 10732005 **exclusion reason -** background.
279. Ceschino, M., F. Enrichens and G. Olivero. [the he/neon soft-laser in the treatment of decubitus ulcer]. Minerva Chirurgica; 1988. p. 49-56 PMID: 3283603 **exclusion reason -** not relevant.
280. Chaby, G., P. Senet, M. Vaneau, P. Martel, J. C. Guillaume, S. Meaume, L. Téot, C. Debure, A. Dompmartin, H. Bachelet, H. Carsin, V. Matz, J. L. Richard, J. M. Rochet, N. Sales-Aussias, A. Zagnoli, C. Denis, B. Guillot and O. Chosidow. Dressings for acute and chronic wounds: A systematic review. Archives of Dermatology; 2007. p. 1297-1304 PMID: 17938344 **exclusion reason -** background.
281. Chadwick, P., M. Harrison, C. Morris, A. Bamford and G. Stansby. Avance® negative pressure wound therapy system: A clinical focus. Wounds UK; 2010. p. 114-122 **exclusion reason -** not relevant.
282. Chaiken, N. Making progress with stalled wounds. Pressure ulceration and the use of active leptospermum honey for debridement and healing. Ostomy Wound Management; 2010. p. 12 **exclusion reason -** not relevant.
283. Chambers, J. Topical manuka honey for mrsa-contaminated skin ulcers. Palliative Medicine; 2006. p. 557 PMID: 16903411 **exclusion reason -** not relevant.
284. Chan, D. C. W., D. H. F. Fong, J. Y. Y. Leung, N. G. Patil and G. K. K. Leung. Maggot debridement therapy in chronic wound care. Hong Kong Medical Journal; 2007. p. 382-6 PMID: 17914145 **exclusion reason -** Systematic Review, not directly used.
285. Chan, J. W. H., K. S. Virgo and F. E. Johnson. Hemipelvectomy for severe decubitus ulcers in patients with previous spinal cord injury. American Journal of Surgery; 2003. p. 69-73 PMID: 12531450 **exclusion reason -** not relevant.

286. Chang, J. and N. G. Cuellar. The use of honey for wound care management: A traditional remedy revisited. Home Healthcare Nurse; 2009. p. 308-16; quiz 317-8 PMID: 19448499 **exclusion reason -** no original data.
287. Chapman, B. R., K. J. Mills, L. M. Pearce and T. C. Crowe. Use of an arginine-enriched oral nutrition supplement in the healing of pressure ulcers in patients with spinal chord injuries: An observational study. Nutrition & Dietetics; 2011. p. 208-213 **exclusion reason -** Scientific Information Packets, not directly used.
288. Chapuis, A. and P. Dollfus. The use of a calcium alginate dressing in the management of decubitus ulcers in patients with spinal cord lesions. Paraplegia; 1990. p. 269-71 PMID: 2235034 **exclusion reason -** wrong outcome.
289. Charles, M. A., J. Oldenbrook and C. Catton. Evaluation of a low-air-loss mattress system in the treatment of patients with pressure ulcers. Ostomy Wound Management; 1995. p. 46-8, 50, 52 PMID: 7612140 **exclusion reason -** wrong outcome.
290. Chavarria Leon, G. and L. Cruz Cerdas. Pressure sores: Surgical management in a national rehabilitation centre. Cirugia Plastica Ibero-Latinoamericana; 2002. p. 63-68 **exclusion reason -** not relevant.
291. Chen, Q. Effect of egg albumen combined with infrared ray irradiation to treat patients with bedsore induced by fecal incontinence [chinese]. Chinese Nursing Research; 2004. p. 1550-1551 **exclusion reason -** not relevant.
292. Chen, T. H. Bilateral gluteus maximus v-y advancement musculocutaneous flaps for the coverage of large sacral pressure sores: Revisit and refinement. Annals of Plastic Surgery; 1995. p. 492-7 PMID: 8579267 **exclusion reason -** not relevant.
293. Chen, X., Z. Jiang, Z. Chen and D. Wang. Application of skin traction for surgical treatment of grade iv pressure sore: A clinical report of 160 cases. Spinal Cord; 2011. p. 76-80 PMID: 20644559 **exclusion reason -** not relevant.
294. Chen, Y., X. Mai and Y. Wang. [wound repair with the fasciocutaneous flap of double reverse z-plasty]. Chung-Hua Cheng Hsing Shao Shang Wai Ko Tsa Chih - Chinese Journal of Plastic Surgery & Burns; 1995. p. 126-8 PMID: 7648500 **exclusion reason -** not relevant.
295. Cheneworth, C. C., K. H. Hagglund, B. Valmassoi and C. Brannon. Portrait of practice: Healing heel ulcers. Advances in Wound Care; 1994. p. 44-8 PMID: 7812583 **exclusion reason -** no original data.
296. Cheng, T. J. and Y. B. Tang. Treatment of ischial pressure sores with an inferior gluteus maximus musculocutaneous island flap. British Journal of Plastic Surgery; 1995. p. 521-2 PMID: 7551539 **exclusion reason -** no original data.
297. Cheong, E. C., J. Lim and T. C. Lim. An atrophic, fat-infiltrated gracilis muscle for ischial reconstruction? British Journal of Plastic Surgery; 2005. p. 749-51 PMID: 15927165 **exclusion reason -** not relevant.
298. Cheong, E. C., M. T. C. Wong, W. C. Ong, J. Lim and T. C. Lim. Sensory innervated superior gluteal artery perforator flap for reconstruction of sacral wound defect. Plastic & Reconstructive Surgery; 2005. p. 958-9 PMID: 15731715 **exclusion reason -** not relevant.
299. Cherubino, M., J. P. Rubin, N. Miljkovic, A. Kelmendi-Doko and K. G. Marra. Adipose-derived stem cells for wound healing applications. Annals of Plastic Surgery; 2011. p. 210-5 PMID: 21200308 **exclusion reason -** background.
300. Chin, T. and H. Hyakusoku. A new device: A portable and effective irrigation system for pressure ulcers. Plastic & Reconstructive Surgery; 2003. p. 1973-4 PMID: 14663270 **exclusion reason -** not relevant.
301. Chou, R. and M. Helfand. Challenges in systematic reviews that assess treatment harms. Ann Intern Med; 2005. p. 1090-1099 PMID: 15968034 **exclusion reason -** background.
302. Chuang, W. Management of the fungally infected pressure ulcer. World Council of Enterostomal Therapists Journal; 2007. p. 34-34 **exclusion reason -** no original data.
303. Cid Gonzalez, M., J. A. Garcia Viveros, J. Martinez Florindo and C. Alcon Jimenez. An alternative in the treatment of longstanding pressure ulcers. Use of sucrose in 6 patients [spanish]. Enfermeria Clinica; 2003. p. 177-179 **exclusion reason -** not relevant.
304. Citak, M., M. Backhaus, R. Meindl, G. Muhr and T. Fehmer. Rare complication after vac-therapy in the treatment of deep sore ulcers in a paraplegic patient. Archives of Orthopaedic & Trauma Surgery; 2010. p. 1511-4 PMID: 20306199 **exclusion reason -** not relevant.
305. Clark, M. Pressure sore treatment. 2. Evidence of effectiveness. Journal of Wound Care; 1997. p. 400-2 PMID: 9341434 **exclusion reason -** no original data.
306. Clark, M. Models of pressure ulcer care: Costs and outcomes British Journal of Healthcare Management; 2001. p. 412-416 **exclusion reason -** wrong intervention.
307. Clark, M. Guidelines for seating in pressure ulcer prevention and management. Nursing Times; 2009. p. 40-1 PMID: 19480169 **exclusion reason -** background.
308. Clark, M. Evidence in wound prevention and treatment: Are the 'rules' too hard? Journal of Tissue Viability; 2010. p. 85 PMID: 20699188 **exclusion reason -** background.
309. Clark, M., J. M. G. A. Schols, G. Benati, P. Jackson, M. Engfer, G. Langer, B. Kerry, D. Colin and P. European Pressure Ulcer Advisory. Pressure ulcers and nutrition: A new european guideline. Journal of Wound Care; 2004. p. 267-72 PMID: 15977767 **exclusion reason -** background.
310. Clark M, D. I. P. A randomised controlled trial comparing the healing of pressure sores upon two pressure-redistributing seat cushions. Proceedings of

the 7th European European Conference on Advances in Wound Management; 1997 **exclusion reason -** duplicate.

311. Clark, M. D. A randomised controlled trial comparing the healing of pressure sores upon two pressure-redistributing seat cushions. Proceedings of the 7th European Conferences on Advances in Wound Management. Harrogate, UK; 1998. p. 122-5 **exclusion reason -** no original data.
312. Clegg, A. and L. Richbourg. Multi-site heel ulcer study conducted by nc woc nurses... Scientific and clinical abstracts from the 40th annual wound, ostomy and continence nurses annual conference. Journal of Wound, Ostomy & Continence Nursing; 2008. p. S61-2 **exclusion reason -** wrong outcome.
313. Clegg, J. P. and J. F. Guest. Modelling the cost-utility of bio-electric stimulation therapy compared to standard care in the treatment of elderly patients with chronic non-healing wounds in the uk. Current Medical Research and Opinion; 2007. p. 871-883 PMID: 17407644 **exclusion reason -** wrong outcome.
314. Coerper, S., G. Gottwald, S. Beckert and H. D. Becker. Wound healing and wound treatment 2004 -- the current state... First published in german in zeitung fur wundheilung in 2004 vol 9;1:20-3. EWMA Journal; 2005. p. 4 **exclusion reason -** background.
315. Coggrave, M., H. West and B. Leonard. Topical negative pressure for pressure ulcer management. British Journal of Nursing; 2002. p. S29-36 PMID: 11979189 **exclusion reason -** not relevant.
316. Colin, D. Trials with a new non-stick dressing. Revue de Geriatrie; 1988. p. 199-201 **exclusion reason -** not relevant.
317. Colin, D., P. A. Kurring, D. Quinlan and C. Yvon. The clinical investigation of an amorphous hydrogel compared with a dextranomer paste dressing in the management of sloughy pressure sores. Proceedings of the 5th European Conference on Advances in Wound Management; 1995 **exclusion reason -** no original data.
318. Collins, N. Anabolic agents and wound healing. Advances in Skin & Wound Care; 2001. p. 154-5 PMID: 11905983 **exclusion reason -** no original data.
319. Collins, N. Arginine and wound healing. Advances in Skin & Wound Care; 2001. p. 16-7 PMID: 11905451 **exclusion reason -** no original data.
320. Collins, N. Tube feeding and pressure ulcers. Advances in Skin & Wound Care; 2001. p. 72-3 PMID: 11899909 **exclusion reason -** no original data.
321. Collins, N. Vitamin c and pressure ulcers. Advances in Skin & Wound Care; 2002. p. 186, 188 PMID: 12151986 **exclusion reason -** no original data.
322. Collins, N. Zinc supplementation: Yea or nay? Advances in Skin & Wound Care; 2003. p. 226-30 PMID: 14581813 **exclusion reason -** no original data.
323. Collins, N. Diarrhea and wound healing. Advances in Skin & Wound Care; 2003. p. 175-6 PMID: 12897673 **exclusion reason -** no original data.
324. Collins, N. Vegetarian diets and wound healing. Advances in Skin & Wound Care; 2003. p. 65-6 PMID: 12690229 **exclusion reason -** no original data.
325. Collins, N. Adding vitamin c to the wound management mix. Advances in Skin & Wound Care; 2004. p. 109-12 PMID: 15194971 **exclusion reason -** wrong intervention.
326. Collins, N. The right mix: Using nutritional interventions and an anabolic agent to manage a stage iv ulcer. Advances in Skin & Wound Care; 2004. p. 36, 38-9 PMID: 14752325 **exclusion reason -** not relevant.
327. Compagno G, D. T. P. The use of a hyperproteinic integrator in pressure ulcers management [abstract]. 13th Conference of the European Wound Management Association; 2003 **exclusion reason -** no original data.
328. Conforti, C. Pressure sores: Dressed for successful healing. Nursing; 1989. p. 58-61 PMID: 2927763 **exclusion reason -** no original data.
329. Conner-Kerr, T. and R. A. Isenberg. Retrospective analysis of pulsed radiofrequency energy therapy use in the treatment of chronic pressure ulcers. Advances in skin & wound care; 2012. p. 253-60 PMID: 22610109 **exclusion reason -** wrong intervention.
330. Consortium for Spinal Cord Medicine Clinical Practice, G. Pressure ulcer prevention and treatment following spinal cord injury: A clinical practice guideline for health-care professionals. Journal of Spinal Cord Medicine; 2001. p. S40-101 PMID: 11958176 **exclusion reason -** background.
331. Cooper, P. J., D. G. Gray and J. Mollison. A randomised controlled trial of two pressure-reducing surfaces. Journal of Wound Care; 1998. p. 374-376 **exclusion reason -** wrong population.
332. Cooper, S. M. and E. Young. Topical negative pressure in the treatment of pressure ulcers. Journal of the American Academy of Dermatology; 1999. p. 280 PMID: 10426905 **exclusion reason -** no original data.
333. Cooper, S. M. and E. Young. Topical negative pressure. International Journal of Dermatology; 2000. p. 896-8 PMID: 11168656 **exclusion reason -** no original data.
334. Cope, C., P. Barry, M. Hassall, R. Barnett, M. Richards and J. Vandervord. V-y advancement hamstring myocutaneous island flap repair of ischial pressure ulcers. Australian & New Zealand Journal of Surgery; 1995. p. 412-6 PMID: 7786266 **exclusion reason -** not relevant.
335. Corbi, Y. [prevention and treatment of bedsores. At each stage a precise therapeutic intervention and an adjusted nursing process]. Soins; La Revue de Reference Infirmiere; 1995. p. 29-32 PMID: 7725136 **exclusion reason -** not relevant.
336. Corbyn, C. and A. Rush. Challenges of wound management in bariatric patients. Wounds UK; 2010. p. 62-71 **exclusion reason -** no original data.
337. Correa, G. I., W. O. Calderon, L. A. Burnier, S. E. Danilla, R. G. Roa and L. M. Guzman. Proximal amputation of inferior extremity secondary to recurrent pressure ulcers in patients with spinal cord injuries.[erratum appears in spinal cord. 2008 jul;46(7):530]. Spinal Cord; 2008. p. 135-9 PMID: 17607312 **exclusion reason -** not relevant.

338. Coskunfirat, O. K. and H. E. Ozgentas. Gluteal perforator flaps for coverage of pressure sores at various locations. Plastic & Reconstructive Surgery; 2004. p. 2012-7; discussion 2018-9 PMID: 15253191 **exclusion reason -** not relevant.
339. Court-Tillis, D. Critical path network. Skin flap path incorporates 30-day los for rehabilitation. Hospital Case Management; 1996. p. 135-138 **exclusion reason -** not relevant.
340. Coutts, P., R. G. Sibbald, K. Inman and N. Maltby-Stephens. The use of an adhesive hydrocellular foam compared to a hydrocolloid dressing for the treatment of stage ii and iii pressure ulcers. 13th Annual Symposium on Advanced Wound Care and 10th Annual Medical Research Forum on Wound Repair; 2000 PMID: CN-00296295 **exclusion reason -** not relevant.
341. Cox-Martin, B. and P. Shaw. Development of an outreach service to promote surgical/non-surgical treatment of pressure ulcers. Wounds UK; 2010. p. 54-64 **exclusion reason -** not relevant.
342. Craig, L. D., S. Nicholson, F. A. Silverstone and R. D. Kennedy. Use of a reduced-carbohydrate, modified-fat enteral formula for improving metabolic control and clinical outcomes in long-term care residents with type 2 diabetes: Results of a pilot trial. Nutrition; 1998. p. 529-534 **exclusion reason -** wrong outcome.
343. Crowe, T. and C. Brockbank. Nutrition therapy in the prevention and treatment of pressure ulcers. Wound Practice & Research; 2009. p. 90 **exclusion reason -** no original data.
344. Cruse, J. M., H. Wang, R. E. Lewis, J. Cespedes, R. S. Morrison Iii, W. C. Lineaweaver and S. Dilioglou. Cellular and molecular alterations in spinal cord injury patients with pressure ulcers: A preliminary report. Experimental and Molecular Pathology; 2002. p. 124-131 **exclusion reason -** background.
345. Cubit, K. Get behind it! Sacral dressing may prevent pressure injury in 'at risk' medical patients. **exclusion reason -** Scientific Information Packets, not directly used.
346. Cuddigan, J., C. Dealey and D. Langemo. International pressure ulcer prevention and treatment guidelines. **exclusion reason -** background.
347. Cullen, A. Spinal cord injury: Using maggots to ease the pressure. Wounds UK; 2009. p. 82 **exclusion reason -** wrong intervention.
348. Cullum, N., J. Deeks, T. A. Sheldon, F. Song and A. W. Fletcher. Beds, mattresses and cushions for pressure sore prevention and treatment. Journal of Tissue Viability; 1999. p. 138 PMID: 10808844 **exclusion reason -** Systematic Review, not directly used.
349. Cullum, N., E. A. Nelson, K. Flemming and T. Sheldon. Systematic reviews of wound care management: (5) beds; (6) compression; (7) laser therapy, therapeutic ultrasound, electrotherapy and electromagnetic therapy. Health Technology Assessment (Winchester, England); 2001. p. 1-221 PMID: 11368833 **exclusion reason -** Systematic Review, not directly used.
350. Cullum, N. and E. Petherick. Pressure ulcers. Clinical Evidence; 2008 PMID: 19450317 **exclusion reason -** Systematic Review, not directly used.
351. Cutler, N. R., R. D. Seifert, J. J. Sramek, W. M. Boyd and P. St Clair. Fleroxacin treatment of stage iv pressure ulcers with associated osteomyelitis. Annals of Pharmacotherapy; 1994. p. 117-8 PMID: 8123950 **exclusion reason -** no original data.
352. Cutting, K. F. Revising wound dressing classification. Wounds UK; 2011. p. 135 **exclusion reason -** Scientific Information Packets, not directly used.
353. Cuzzoni, G. and E. Ferrero. The treatment of severe pressure sores in the elderly. Rivista Italiana di Chirurgia Plastica; 1993. p. 361-367 **exclusion reason -** not relevant.
354. D'Agostino Dias, M., B. Fontes, R. S. Poggetti and D. Birolini. Hyperbaric oxygen therapy: Types of injury and number of sessions-review of 1506 cases. Undersea & Hyperbaric Medicine; 2008. p. 53-60 **exclusion reason -** wrong population.
355. Dalla Valle, I., M. P. Ferrari and C. Lia. Anallergic, sterilized lyophilized heterologous collagen and its effect in the treatment of neurogenic decubitus ulcers. Riabilitazione; 1985. p. 37-53 **exclusion reason -** not relevant.
356. Danon, D., O. Frenkel, L. Diamandstein, E. Winkler and A. Orenstein. Macrophage treatment of pressure sores in paraplegia. Journal of Wound Care; 1998. p. 281-3 PMID: 9697460 **exclusion reason -** not relevant.
357. Darouiche, R. O., G. C. Landon, M. Klima, D. M. Musher and J. Markowski. Osteomyelitis associated with pressure sores. Archives of Internal Medicine; 1994. p. 753-8 PMID: 8147679 **exclusion reason -** wrong intervention.
358. Darvall, A. Multi-disciplinary approach to pressure ulcer management in the spinal cord injury population. 2008 **exclusion reason -** not relevant.
359. Dat, A. D., F. Poon, B. T. K. Pham and J. Doust. Aloe vera for treating acute and chronic wounds. Cochrane Database of Systematic Reviews; 2012 PMID: 00075320-100000000-07161 **exclusion reason -** Systematic Review, not directly used.
360. Davidson, J. and L. W. Eremic. Critical care extra. Visible wounds. American Journal of Nursing; 2000. p. 24AA **exclusion reason -** wrong intervention.
361. Davies, P. and M. Rippon. Evidence review: The clinical benefits of safetacrg technology in wound care. Ostomy Wound Management; 2008. p. 4-31 **exclusion reason -** unable to find.
362. de Azevedo, I. B., R. F. Sampaio, J. C. Montes and R. L. Contreras. [treatment of decubitus ulcers with propolis]. Revista Brasileira de Enfermagem; 1986. p. 33-7 PMID: 3648838 **exclusion reason -** not relevant.
363. de la Fuente, S. G., L. S. Levin, J. D. Reynolds, C. Olivares, T. N. Pappas, K. A. Ludwig and C. R. Mantyh. Elective stoma construction improves outcomes in medically intractable pressure ulcers.

Diseases of the Colon & Rectum; 2003. p. 1525-30 PMID: 14605574 **exclusion reason -** wrong intervention.

364. de la Fuente, T. P., I. G. Gonzalez and F. C. Munoz. The igap flap for ischial pressure sore reconstruction in tetraplegic patients. International Journal Of Surgery; 2008. p. e1-e3 PMID: 19059123 **exclusion reason -** no original data.
365. De Laat, E. and T. Van Achterberg. Diagnostics and interventions aimed at wound-related complaints in patients with pressure ulcers: A review of the literature. 16th international nursing research congress.: Sigma Theta Tau International; 2005. p. 1p **exclusion reason -** Systematic Review, not directly used.
366. de Laat, E. H. E. W., W. J. Scholte op Reimer and T. van Achterberg. Pressure ulcers: Diagnostics and interventions aimed at wound-related complaints: A review of the literature. Journal of Clinical Nursing; 2005. p. 464-72 PMID: 15807753 **exclusion reason -** Systematic Review, not directly used.
367. de Laat, E. H. E. W., M. H. W. A. van den Boogaard, P. H. M. Spauwen, D. H. J. M. van Kuppevelt, H. van Goor and L. Schoonhoven. Faster wound healing with topical negative pressure therapy in difficult-to-heal wounds: A prospective randomized controlled trial. Annals of Plastic Surgery; 2011. p. 626-31 PMID: 21629111 **exclusion reason -** not relevant.
368. de Leon, J. Negative pressure wound therapy in pressure ulcer management. Ostomy Wound Management; 2005. p. 3S-8S PMID: 15699557 **exclusion reason -** not relevant.
369. De Luis Roman, D. and R. Aller. Systematic review of nutricional support in pressure ulcer. Anales de Medicina Interna; 2007. p. 342-345 PMID: 18020893 **exclusion reason -** not relevant.
370. Dealey, C. A prevention and management aid. Evaluation of the nimbus ii mattress. Professional Nurse; 1994. p. 798-804 PMID: 7938061 **exclusion reason -** no original data.
371. Dealey, C. Pressure sores and incontinence: A study evaluating the use of topical agents in skin care. Journal of Wound Care; 1995. p. 103-5 PMID: 7600345 **exclusion reason -** wrong population.
372. Dealey, C., R. Brooks, J. Thomson and M. R. Bliss. Pressure area care and estimating the cost of pressure sores. Journal of Wound Care; 1997. p. 134-8 PMID: 9256710 **exclusion reason -** no original data.
373. Dealey C, K. A. A randomized, controlled, parallel-group clinical trial of a new polyurethane foam island dressing versus a hydrocolloid island dressing in the treatment of grade ii and iii pressure sores. Proceedings of the 6th European Conference on Advances in Wound Management; 1995 **exclusion reason -** no original data.
374. Defloor, T. [less frequent turning intervals and yet less pressure ulcers]. Tijdschrift voor Gerontologie en Geriatrie; 2001. p. 174-7 PMID: 11565421 **exclusion reason -** not relevant.
375. DeHart, D. Osteomyelitis associated with pressure sores. Archives of Internal Medicine; 1994. p. 2501 PMID: 7979847 **exclusion reason -** no original data.
376. Delemarle, D. and F. Nadaud. [a joint physical therapy-nursing intervention]. Soins; La Revue de Reference Infirmiere; 2006. p. 26 PMID: 16771284 **exclusion reason -** not relevant.
377. deLeon, J. M., M. Nagel, M. Fudge, A. Lucius and B. Garcia. Use of radiofrequency and negative pressure wound therapy in chronic pressure ulcers. 3rd Congress of the World Union of Wound Healing Societies; 2008 **exclusion reason -** no original data.
378. DelGiorno, T. G., Jr. and C. P. Gross. Advisor forum. Minoxidil for poorly healing ulcers? Clinical Advisor for Nurse Practitioners; 2004. p. 75-75 **exclusion reason -** no original data.
379. Demirseren, M. E., S. Gokrem, O. M. Ozdemir, A. Katircioglu, Z. Can and S. Serel. Hatchet-shaped tensor fascia lata musculocutaneous flap for the coverage of trochanteric pressure sores: A new modification. Annals of Plastic Surgery; 2003. p. 419-22 PMID: 14520072 **exclusion reason -** not relevant.
380. DerSimonian, R. and N. Laird. Meta-analysis in clinical trials. Control Clin Trials. 1986/09/01 ed; 1986. p. 177-88 PMID: 3802833 **exclusion reason -** background.
381. Deshmukh, G. R., D. C. Barkel, D. Sevo and P. Hergenroeder. Use or misuse of colostomy to heal pressure ulcers. Diseases of the Colon & Rectum; 1996. p. 737-8 PMID: 8674363 **exclusion reason -** wrong intervention.
382. Desneves, K. Effect of an arginine-containing supplement on the healing of pressure ulcers in community spinal patients. 2010 Conference of the Australian Wound Management Association (AWMA 2010); 2010 PMID: 20616774 **exclusion reason -** not relevant.
383. Deva, A. K., G. H. Buckland, E. Fisher, S. C. C. Liew, S. Merten, M. McGlynn, M. P. Gianoutsos, M. A. R. Baldwin and P. G. Lendvay. Topical negative pressure in wound management. Medical Journal of Australia; 2000. p. 128-131 **exclusion reason -** not relevant.
384. Di Domenico, G., G. M. Leonardi, M. Mottola, G. Vaccaro and C. Nocera. Platelet gel and wound care: The weight of the platelets concentration in the clinicianthерapeutic practice. Vox Sanguinis; 2009. p. 249 **exclusion reason -** not relevant.
385. Di Giulio, P. [topical treatment of decubitus lesions]. Rivista dell Infermiere; 1985. p. 35-47 PMID: 3933085 **exclusion reason -** not relevant.
386. Di Giulio, P., L. Saiani, D. Laquintana, A. Palese, S. Perli, M. Andreatta, F. Rosa, P. Chini, F. Soraperra, I. Ventura, C. Suriani, S. Romani, M. Zancarli, M. Martini, F. Partel, S. Bassetti, R. Kaisermann, C. Bortolotti, M. Gianordoli, I. Rizzoli, R. Nardelli, E. Pellizzari, E. Valduga, M. Castaman, M. Pordenon, M. Beltrame, C. Bertolo, E. Casasola, P. Del Pin, S. Giolo, E. Marcatti, D. Pecini, M. Rodaro, C. Zanon, L. Stefanon, L. Covre, C. Babbo, I. Martin, A. Roilo, M. Zanutel, S. Sabbadin, L. Boin, A. Caron, E.

Martignago, V. Venturin, A. Greggio, P. Frigo, D. Lazzaron, A. Tonietto, B. Zanin, S. Zorzi, A. Zuanon, D. Salmaso, T. Frison, I. Marin, A. Buosi, E. Fiorese, D. Gasparin, B. Goat, G. Saccardo, O. Simonetto, S. Gomiero, N. Baccara, L. Ghirardello, M. Niolu, S. Silvestri, M. L. Buffon, P. Casson, R. Santantonio, P. Albore, E. Mazzorana, L. Terziariol, G. Bulgarelli, E. Barani, P. Gasparini, S. Migliori, E. Sasso, R. M. Marfisi, G. Tognoni, G. Sgaroni, G. Noro, M. Mattiuzzo and P.-E. Gruppo. [a double blind randomised clinical trial to assess the efficacy of the treatments of the superficial pressure sores]. Assistenza Infermieristica e Ricerca:Air; 2004. p. 201-8 PMID: 15709463 **exclusion reason -** not relevant.

387. Diamant-Berger, F. and C. Kerangall. [treatment of bedsores and trophic wounds with an absorbent dressing]. Soins; La Revue de Reference Infirmiere; 1990. p. 53-8 PMID: 2326677 **exclusion reason -** not relevant.
388. Diaz Caro, I. [specific treatment of sacro-coccygeal ulcers]. Revista de Enfermeria; 2003. p. 54-60 PMID: 14502916 **exclusion reason -** not relevant.
389. Diekmann, J. M., J. M. Smith and J. R. Wilk. A double life for a dental irrigation device. American Journal of Nursing; 1985. p. 1157 PMID: 3850722 **exclusion reason -** no original data.
390. Disa, J. J., J. M. Carlton and N. H. Goldberg. Efficacy of operative cure in pressure sore patients. Plastic & Reconstructive Surgery; 1992. p. 272-8 PMID: 1732895 **exclusion reason -** not relevant.
391. Dissemination, C. f. R. a. Why appraise the evidence: A case study of vitamin c and the healing of pressure sores (structured abstract). Database of Abstracts of Reviews of Effects; 2011 PMID: 00125498-100000000-10871 **exclusion reason -** Systematic Review, not directly used.
392. Dissemination, C. f. R. a. Treatment of pressure ulcers: A systematic review (structured abstract). Database of Abstracts of Reviews of Effects; 2011 PMID: 00125498-100000000-20161 **exclusion reason -** Systematic Review, not directly used.
393. Dissemination, C. f. R. a. A systematic review of the use of hydrocolloids in the treatment of pressure ulcers (structured abstract). Database of Abstracts of Reviews of Effects; 2011 PMID: 00125498-100000000-20667 **exclusion reason -** Systematic Review, not directly used.
394. Dissemination, C. f. R. a. Systematic review of repositioning for the treatment of pressure ulcers (brief record). Database of Abstracts of Reviews of Effects; 2011 PMID: 00125498-100000000-26177 **exclusion reason -** Systematic Review, not directly used.
395. Dissemination, C. f. R. a. A literature assessment of the use of miscellaneous topical agents, growth factors, and skin equivalents for the treatment of pressure ulcers (structured abstract). Database of Abstracts of Reviews of Effects; 2011 PMID: 00125498-100000000-20056 **exclusion reason -** Systematic Review, not directly used.
396. Dissemination, C. f. R. a. Enteral nutritional support in prevention and treatment of pressure ulcers: A systematic review and meta-analysis (structured abstract). Database of Abstracts of Reviews of Effects; 2011 PMID: 00125498-100000000-16575 **exclusion reason -** Systematic Review, not directly used.
397. Dissemination, C. f. R. a. Efficiency of the products for pressure ulcers treatment: A systematic review with meta-analysis (provisional abstract). Database of Abstracts of Reviews of Effects; 2011 PMID: 00125498-100000000-16663 **exclusion reason -** Systematic Review, not directly used.
398. Dissemination, C. f. R. a. Efficacy of advanced dressings in the treatment of pressure ulcers: A systematic review (structured abstract). Database of Abstracts of Reviews of Effects; 2011 PMID: 00125498-100000000-16829 **exclusion reason -** Systematic Review, not directly used.
399. Dissemination, C. f. R. a. Beds, mattresses and cushions for pressure sore prevention and treatment (brief record). Database of Abstracts of Reviews of Effects; 2011 PMID: 00125498-100000000-18754 **exclusion reason -** Systematic Review, not directly used.
400. Dissemination, C. f. R. a. Air-fluidized beds used for treatment of pressure ulcers in the home environment (structured abstract). Database of Abstracts of Reviews of Effects; 2011 PMID: 00125498-100000000-19181 **exclusion reason -** Systematic Review, not directly used.
401. Dissemination, C. f. R. a. The effectiveness of topical negative pressure in the treatment of pressure ulcers: A literature review (structured abstract). Database of Abstracts of Reviews of Effects; 2011 PMID: 00125498-100000000-20816 **exclusion reason -** background.
402. Dobson, J. L. and S. L. Ellis. Creating an optimum healing environment for a grade v pressure ulcer. Journal of Wound Care; 2001. p. 415-20 PMID: 12964290 **exclusion reason -** not relevant.
403. Dolezal, R., M. Cohen and R. C. Schultz. The use of clinitron therapy unit in the immediate postoperative care of pressure ulcers. Annals of Plastic Surgery; 1985. p. 33-6 PMID: 3977238 **exclusion reason -** wrong outcome.
404. Doss, M., S. Martens, J. P. Wood, J. D. Wolff, C. Baier and A. Moritz. Vacuum-assisted suction drainage versus conventional treatment in the management ofpoststernotomy osteomyelitis. European Journal of Cardio-Thoracic Surgery; 2002. p. 934-938 **exclusion reason -** wrong population.
405. Downs, S. H. and N. Black. The feasibility of creating a checklist for the assessment of the methodological quality both of randomised and non-randomised studies of health care interventions. JECH; 1998. p. 377-384 PMID: 9764259 **exclusion reason -** background.
406. Drimmer, M. A. and M. J. Krasna. The vastus lateralis myocutaneous flap. Plastic & Reconstructive Surgery; 1987. p. 560-6 PMID: 3823248 **exclusion reason -** not relevant.
407. Droste, L. R. Pressure ulcer prevention and treatment for high risk polytrauma, spinal cord injured

and acute care patients: Practice innovation using an alternating support surface advanced features... Scientific and clinical abstracts from the 40th annual wound, ostomy and continence nurses annual conference. Journal of Wound, Ostomy & Continence Nursing; 2008. p. S35-S35 **exclusion reason -** wrong population.

408. Dumurgier, C., P. Cottias, G. Pujol, L. Lantieri, F. Gandon and A. Rochebiliere. The invaldes' hospital flap: A report on 48 patients. Lyon Chirurgical; 1993. p. 433-437 **exclusion reason -** not relevant.
409. Dzidic, I. [usefulness of the roho mattress in the prevention and therapy of decubitus ulcers]. Reumatizam; 1991. p. 75-6 PMID: 1806965 **exclusion reason -** not relevant.
410. Dzwierzynski, W. W., K. Spitz, A. Hartz, C. Guse and D. L. Larson. Improvement in resource utilization after development of a clinical pathway for patients with pressure ulcers. Plastic & Reconstructive Surgery; 1998. p. 2006-11 PMID: 9810998 **exclusion reason -** not relevant.
411. Economides, N. G., V. A. Skoutakis, C. A. Carter and V. H. Smith. Evaluation of the effectiveness of two support surfaces following myocutaneous flap surgery. Advances in Wound Care; 1995. p. 49-53 PMID: 7795873 **exclusion reason -** wrong population.
412. Edsberg, L. E., M. S. Brogan, C. D. Jaynes and K. Fries. Reducing epibole using topical hyperbaric oxygen and electrical stimulation. Ostomy Wound Management; 2002. p. 26-9 PMID: 11993057 **exclusion reason -** not relevant.
413. Eginton, M. T., K. R. Brown and e. al. A prospective randomized evaluation of negative-pressure wound dressings for diabetic foot wounds. Annals of Vascular Surgery; 2003. p. 645-649 **exclusion reason -** wrong population.
414. Elizarov, M. N., A. V. Garkavi and A. L. Komissarova. Treatment of purulent-necrotic decubitus ulcers in spinal patients using alginate coating teralgim and algimaf. Sovetskaya Meditsina; 1991. p. 25-26 PMID: 1715609 **exclusion reason -** not relevant.
415. Elizarov, M. N., A. V. Garkavi and S. I. Sen'kevich. [treatment of decubitus ulcer by "algimaf" preparation]. Ortopediia Travmatologiia i Protezirovanie; 1990. p. 47-8 PMID: 2093864 **exclusion reason -** not relevant.
416. El-Sabbagh, A. H. The accordion gracilis muscle flap: A new design for coverage of recurrent and complicated ischeal pressure sores. International Wound Journal; 2011 PMID: 21595831 **exclusion reason -** not relevant.
417. Eltorai, I., G. Glantz and R. Montroy. The use of the carbon dioxide laser beam in the surgery of pressure sores. International Surgery; 1988. p. 54-6 PMID: 3360579 **exclusion reason -** wrong intervention.
418. Esch, B. and G. Raptis. [treatment of decubitus ulcer with crilanomer and dextranomer]. Zeitschrift fur Hautkrankheiten; 1989. p. 1135-8 PMID: 2483786 **exclusion reason -** not relevant.
419. Eshaque, A. K. and N. Nahar. Management of sacral pressure sores with a myocutaneous flap. Contemporary Orthopaedics; 1994. p. 353-6 PMID: 10146777 **exclusion reason -** not relevant.
420. Esmaili, R., E. Zadeh, E. Nasiri, A. Khalilian, O. Dehghani and S. Alipour. Study regarding the effect of calendula officinal is cream in healing of pressure sores. 16th International Conference of Indian Association of Palliative Care (IAPCON 2009) **exclusion reason -** not relevant.
421. Esposito, G., G. Di Caprio, P. Ziccardi and N. Scuderi. Tissue expansion in the treatment of pressure ulcers. Plastic & Reconstructive Surgery; 1991. p. 501-8 PMID: 1998020 **exclusion reason -** not relevant.
422. Esposito, G., P. Ziccardi, G. Di Caprio and N. Scuderi. Reconstruction of ischial pressure ulcers by skin expansion. Scandinavian Journal of Plastic & Reconstructive Surgery & Hand Surgery; 1993. p. 133-6 PMID: 8351494 **exclusion reason -** not relevant.
423. European Pressure Ulcer Advisory Panel and National Pressure Ulcer Advisory Panel. Prevention and treatment of pressure ulcers: Quick reference guide. Washington, DC: National Pressure Ulcer Advisory Panel; 2009 **exclusion reason -** background.
424. Evans, G. R., C. R. Dufresne and P. N. Manson. Surgical correction of pressure ulcers in an urban center: Is it efficacious? Advances in Wound Care; 1994. p. 40-6 PMID: 8149047 **exclusion reason -** not relevant.
425. Evans, G. R., V. L. Lewis, Jr., P. N. Manson, M. Loomis and C. A. Vander Kolk. Hip joint communication with pressure sore: The refractory wound and the role of girdlestone arthroplasty. Plastic & Reconstructive Surgery; 1993. p. 288-94 PMID: 8430143 **exclusion reason -** not relevant.
426. Evans, J. M., K. L. Andrews, D. S. Chutka, K. C. Fleming and S. L. Garness. Pressure ulcers: Prevention and management. Mayo Clinic Proceedings; 1995. p. 789-99 PMID: 7630221 **exclusion reason -** background.
427. EWMA. Systematic review of repositioning for the treatment of pressure ulcers. EWMA Journal; 2010. p. 5-12 **exclusion reason -** Systematic Review, not directly used.
428. Feedar, J. A., L. C. Kloth and G. D. Gentzkow. Chronic dermal ulcer healing enhanced with monophasic pulsed electrical stimulation. Physical Therapy; 1991. p. 639-49 PMID: 1409886 **exclusion reason -** not relevant.
429. Ferrell, B. A., B. M. Artinian and D. Sessing. The sessing scale for assessment of pressure ulcer healing. Journal of the American Geriatrics Society; 1995. p. 37-40 PMID: 7806737 **exclusion reason -** background.
430. Ferrell, B. A., E. Keeler, A. L. Siu, S. H. Ahn and D. Osterweil. Cost-effectiveness of low-air-loss beds for treatment of pressure ulcers. Journals of Gerontology Series A-Biological Sciences & Medical Sciences; 1995. p. M141-6 PMID: 7743399 **exclusion reason -** background.

431. Finnegan, M. J., L. Gazzerro, J. O. Finnegan and P. Lo. Comparing the effectiveness of a specialized alternating air pressure mattress replacement system and an air-fluidized integrated bed in the management of post-operative flap patients: A randomized controlled pilot study. Journal of Tissue Viability; 2008. p. 2-9 PMID: 18293765 **exclusion reason -** wrong population.
432. Flemister, B. G. A pilot study of interface pressure with heel protectors used for pressure reduction. Journal of ET Nursing; 1991. p. 158-61 PMID: 1892946 **exclusion reason -** wrong population.
433. Flemming, K. and N. Cullum. Therapeutic ultrasound for pressure sores. Cochrane Database of Systematic Reviews; 2000. p. CD001275 PMID: 11034707 **exclusion reason -** Systematic Review, not directly used.
434. Fleurence, R. L. Cost-effectiveness of pressure-relieving devices for the prevention and treatment of pressure ulcers. International Journal of Technology Assessment in Health Care; 2005. p. 334-41 PMID: 16110713 **exclusion reason -** background.
435. Foglia, E., U. Restelli, A. M. Napoletano, D. Coclite, E. Porazzi, M. Bonfanti and D. Croce. Pressure ulcers management: An economic evaluation. Journal of Preventive Medicine and Hygiene; 2012. p. 30-36 **exclusion reason -** unable to find.
436. Fox, G. N. Management of pressure ulcers. JAMA; 2003. p. 2210; author reply 2210-1 PMID: 12734129 **exclusion reason -** no original data.
437. Francis, K. D., S. L. Hendler and E. F. Byrne. Semirigid dressings for treatment of pressure sores after spinal cord injury. Archives of Physical Medicine and Rehabilitation World Meeting; 1991 **exclusion reason -** unable to find.
438. Franek, A., E. Franek and J. Grzesik. [electrically enhanced damaged tissues healing. Part ii: Direct and pulse current in soft tissue healing]. Polski Merkuriusz Lekarski; 1999. p. 198-201 PMID: 10835915 **exclusion reason -** not relevant.
439. Franek, A., R. Kostur, A. Polak, J. Taradaj, Z. Szlachta, E. Blaszczak, P. Dolibog, P. Dolibog, B. Koczy and C. Kucio. Using high-voltage electrical stimulation in the treatment of recalcitrant pressure ulcers: Results of a randomized, controlled clinical study. Ostomy Wound Management; 2012. p. 30-44 PMID: 22391955 **exclusion reason -** wrong intervention.
440. Franek, A., R. Kostur, J. Taradaj, E. Blaszczak, Z. Szlachta, P. Dolibog, P. Dolibog and A. Polak. Effect of high voltage monophasic stimulation on pressure ulcer healing: Results from a randomized controlled trial. Wounds: A Compendium of Clinical Research & Practice; 2011. p. 15-23 **exclusion reason -** wrong intervention.
441. Franek, A., R. Kostur, J. Taradaj, E. Blaszczak, Z. Szlachta, P. Dolibog, P. Dolibog and A. Polak. Effect of high voltage monophasic stimulation on pressure ulcer healing: Results from a randomized controlled trial. Wounds: A Compendium of Clinical Research & Practice; 2011. p. 15-23 **exclusion reason -** wrong intervention.
442. Frank, G. C. Wound care means nutritional care. Advance for Long-Term Care Management; 2010. p. 32 **exclusion reason -** background.
443. Franks, P. J. The cost of pressure ulceration. EWMA Journal; 2007. p. 15 **exclusion reason -** wrong intervention.
444. Frantz, R. The effect of tens on healing of pressure ulcers. 4th Annual Meeting of the Wound Healing Society; 1994 **exclusion reason -** no original data.
445. Frantz, R. A. Pressure ulcer costs in long term care. Decubitus; 1989. p. 56-7 PMID: 2505809 **exclusion reason -** wrong intervention.
446. Frantz, R. A., S. Bergquist and J. Specht. The cost of treating pressure ulcers following implementation of a research-based skin care protocol in a long-term care facility. Advances in Wound Care; 1995. p. 36-45 PMID: 7795870 **exclusion reason -** wrong outcome.
447. Frantz, R. A., S. Gardner, P. Harvey and J. Specht. The cost of treating pressure ulcers in a long-term care facility. Decubitus; 1991. p. 37-8, 40, 42 passim PMID: 1908247 **exclusion reason -** wrong intervention.
448. Frantz, R. A., S. Gardner, J. K. Specht and G. McIntire. Integration of pressure ulcer treatment protocol into practice: Clinical outcomes and care environment attributes. Outcomes Management for Nursing Practice; 2001. p. 112-20 PMID: 11898671 **exclusion reason -** no original data.
449. Fratino, L. Treatment of decubitus ulcers and of venous ulcer with intralesion mielogen in elderly patients with or without cancer. ESMO Congress Secretariat. Soldino 22, 6900 Lugano, Switzerland; 1998 **exclusion reason -** wrong population.
450. Freedman, G., C. Cean, V. Duron, A. Tarnovskaya and H. Brem. Pathogenesis and treatment of pain in patients with chronic wounds. Surgical Technology International; 2003. p. 168-79 PMID: 12931299 **exclusion reason -** wrong population.
451. French, E. T. and K. Ledwell-Sifner. [method of documentation in decubitus. Decubitus protocol allows for more effective treatment]. Krankenpflege - Soins Infirmiers; 1992. p. 10-4 PMID: 1740912 **exclusion reason -** not relevant.
452. Frias Soriano, L., M. A. Lage Vazquez, C. P.-P. Maristany, J. M. Xandri Graupera, W. Wouters-Wesseling and L. Wagenaar. The effectiveness of oral nutritional supplementation in the healing of pressure ulcers. Journal of Wound Care; 2004. p. 319-22 PMID: 15469215 **exclusion reason -** not relevant.
453. Frisbie, J. H. Wound healing in acute spinal cord injury: Effect of anticoagulation. Archives of Physical Medicine & Rehabilitation; 1986. p. 311-3 PMID: 3707315 **exclusion reason -** not relevant.
454. Fromantin, I. and C. Routkovsky-Norval. [decubitus ulcers in oncology, first results of a study]. Soins; La Revue de Reference Infirmiere; 2003. p. 22-3 PMID: 12724987 **exclusion reason -** not relevant.

455. Fromantin, I., L. Teot and S. Meaume. [a wound, wound healing ... And many ways to achieve this]. Soins; La Revue de Reference Infirmiere; 2007. p. 15-9 PMID: 18335828 **exclusion reason -** not relevant.
456. Frykberg, R. G., V. R. Driver, D. Carman, B. Lucero, C. Borris-Hale, C. P. Fylling, L. M. Rappl and P. A. Clausen. Chronic wounds treated with a physiologically relevant concentration of platelet-rich plasma gel: A prospective case series. Ostomy Wound Management; 2010. p. 36-44 PMID: 20567053 **exclusion reason -** wrong population.
457. Fu, X., Z. Shen and Y. Chen. [basic fibroblast growth factor (bfgf) and wound healing: A multi-centers and controlled clinical trial in 1024 cases]. Chung-Kuo Hsiu Fu Chung Chien Wai Ko Tsa Chih/Chinese Journal of Reparative & Reconstructive Surgery; 1998. p. 209-11 PMID: 10437068 **exclusion reason -** not relevant.
458. Fuentelsaz Gallego, C., E. Hernandez Faba, C. Bermejo Caja, P. Hermoso Villar, E. Gallart Vive, C. Blasco Garcia, I. B. Cantalejo, J. C. Garcia, P. C. Cortes, T. M. Casbas, A. Z. Yarnoz, R. A. Catalan, P. C. Jimenez, B. E. Zerolo, G. E. Aguilar, G. G. Caminero, R. M. L. Pisa, T. M. Jimenez, E. N. Blanco and R. S. Soler. Review of literature on pressure ulcers in people aged 65 or over. Gerokomos; 2005. p. 166-173 **exclusion reason -** not relevant.
459. Fugazza, G. and F. Bona. [decubitus ulcer in the calcaneus region: Rapid development, difficult recovery]. Minerva Medica; 1996. p. 89-92 PMID: 8668293 **exclusion reason -** not relevant.
460. Furth, P. [example of standardized decubitus therapy (stage i-iii)]. Krankenpflege Journal; 1994. p. 221-4 PMID: 8028260 **exclusion reason -** not relevant.
461. Fuster Puigdomenech, A., S. Moraleda Perez, J. Fernandez Delgado and M. Martinez Moreno. Surgical treatment of bedsores in spinal cord lesions: Descriptive study [spanish]. Rehabilitacion; 1999. p. 316-320 **exclusion reason -** not relevant.
462. Gallois, A., C. Dhelemme, I. Lefebvre, C. Fontalirand, S. Richez and H. Robert. Comparative study of bed sores in a psychiatric hospital. Journal de Pharmacie Clinique; 1988. p. 425-456 **exclusion reason -** not relevant.
463. Garber, S. L. and D. H. Rintala. Pressure ulcers in veterans with spinal cord injury: A retrospective study. Journal of Rehabilitation Research & Development; 2003. p. 433-41 PMID: 15080228 **exclusion reason -** background.
464. Garber, S. L., D. H. Rintala, C. D. Rossi, K. A. Hart and M. J. Fuhrer. Reported pressure ulcer prevention and management techniques by persons with spinal cord injury. Archives of Physical Medicine & Rehabilitation; 1996. p. 744-9 PMID: 8702366 **exclusion reason -** wrong intervention.
465. Garcia Fernandez, F. P., F. Martinez Cuervo, P. L. Pancorbo Hidalgo, J. Rueda Lopez, E. Santamaria Andres, J. J. Soldevilla Agreda and J. Verdu Soriano. Debridement of pressure ulcers and other chronic wounds. Gerokomos; 2005. p. 158-165 **exclusion reason -** not relevant.
466. Garcia Fernandez, F. P., P. L. Pancorbo Hidalgo, J. Verdu Soriano, J. J. Soldevilla Agreda, M. Rodriguez Palma, M. Gago Fornells, F. Martinez Cuervo and J. Rueda Lopez. Efficiency of the products for pressure ulcers treatment: A systematic review with meta-analysis. Gerokomos; 2007. p. 36-48 **exclusion reason -** not relevant.
467. Gardner, S. E., R. A. Frantz, S. Bergquist and C. D. Shin. A prospective study of the pressure ulcer scale for healing (push). Journals of Gerontology Series A-Biological Sciences & Medical Sciences; 2005. p. 93-7 PMID: 15741289 **exclusion reason -** wrong intervention.
468. Gardner, S. E., R. A. Frantz and F. L. Schmidt. Effect of electrical stimulation on chronic wound healing: A meta-analysis. Wound Repair & Regeneration; 1999. p. 495-503 PMID: 10633009 **exclusion reason -** Systematic Review, not directly used.
469. Garg, M., S. Rubayi and J. Z. Montgomerie. Postoperative wound infections following myocutaneous flap surgery in spinal injury patients. Paraplegia; 1992. p. 734-9 PMID: 1448302 **exclusion reason -** not relevant.
470. Gazzerro, L. and M. Finnegan. Comparing the effectiveness of alternating air pressure mattress replacement systems and air fluidized integrated beds in the management of flap and graft patients: Ten case studies... Scientific and clinical abstracts from the 40th annual wound, ostomy and continence nurses annual conference. Journal of Wound, Ostomy & Continence Nursing; 2008. p. S63-S63 **exclusion reason -** no original data.
471. Genecov, D. G., A. M. Schneider, M. J. Morykwas and E. al. A controlled subatmospheric pressure dressing increases the rate of skin graft donor site reepithelialization. Annals of Plastic Surgery; 1998. p. 219-25 **exclusion reason -** not relevant.
472. Genoud, C. and J. Weller. [protocol for the evaluation and treatment of chronic wounds in the home care setting]. Praxis; 2008. p. 317-21 PMID: 18548939 **exclusion reason -** not relevant.
473. GENTILELLO, L., D. A. THOMPSON, A. S. TONNESEN, D. HERNANDEZ, A. S. KAPADIA, S. J. ALLEN, B. A. HOUTCHENS and M. E. MINER. Effect of a rotating bed on the incidence of pulmonary complications in critically ill patients. Critical Care Medicine; 1988. p. 783-786 **exclusion reason -** wrong population.
474. Gentzkow, G. D., G. Alon, G. A. Taler, I. M. Eltorai and R. E. Montroy. Healing of refractory stage iii and iv pressure ulcers by a new electrical stimulation device. Wounds: A Compendium of Clinical Research & Practice; 1993. p. 160-172 **exclusion reason -** wrong outcome.
475. George-Saintilus, E., B. Tommasulo, C. E. Cal, R. Hussain, N. Mathew, Y. Dlugacz, R. Pekmezaris and G. Wolf-Klein. Pressure ulcer push score and traditional nursing assessment in nursing home residents: Do they correlate? Journal of the American Medical Directors Association; 2009. p. 141-4 PMID: 19187884 **exclusion reason -** wrong intervention.

476. Gethin, G. Right track. World of Irish Nursing & Midwifery; 2009. p. 46-46 **exclusion reason -** no original data.
477. Gilchrist, B. Using eggs to treat pressure sores. Nursing Times; 1990. p. 72-72 **exclusion reason -** no original data.
478. Gilchrist, B. and J. Hutchinson. Journal of the wound care society. Does occlusion lead to infection? Nursing Times; 1990. p. 70-1 PMID: 2367232 **exclusion reason -** no original data.
479. Gillespie, C. Keeping pup on a short leash... Scientific and clinical abstracts from the 40th annual wound, ostomy and continence nurses annual conference. Journal of Wound, Ostomy & Continence Nursing; 2008. p. S38-S38 **exclusion reason -** no original data.
480. Giongo, F. and M. Biraghi. New therapeutical prospects in the treatment of decubitus ulcers: The cadexomer iodine. Gazzetta Medica Italiana Archivio per le Scienze Mediche; 1991. p. 67-73 **exclusion reason -** not relevant.
481. Girouard, K., M. B. Harrison and E. VanDenKerkof. The symptom of pain with pressure ulcers: A review of the literature. Ostomy Wound Management; 2008. p. 30-40, 42 PMID: 18493092 **exclusion reason -** Systematic Review, not directly used.
482. Gjersvik, P. [to cure chronic bed sores]. Tidsskrift for Den Norske Laegeforening; 2005. p. 867 PMID: 15815731 **exclusion reason -** not relevant.
483. Glasco, K. and L. M. Rappl. Relating the support surface to improved wound healing and lower costs... 39th annual wound, ostomy and continence nurses annual conference. Journal of Wound, Ostomy & Continence Nursing; 2007. p. S58-S58 **exclusion reason -** no original data.
484. Glover, D. and G. Wicks. Suprasorb x + phmb: The clinical evidence... Polyhexamethylene biguanide. Journal of Wound Care; 2009. p. 15-21 **exclusion reason -** not relevant.
485. Gobbi, P. [patients admitted with decubital lesions: The experience of the milanese hospital in garbagnate]. Assistenza Infermieristica e Ricerca:Air; 2002. p. 22-7 PMID: 11998342 **exclusion reason -** not relevant.
486. Gogia. Effects of high voltage galvanic stimulation on wound healing. Ostomy Wound Manage.; 1992. p. 29-35 **exclusion reason -** wrong population.
487. Goldberg, N. H. Outcomes in surgical intervention. Advances in Wound Care; 1995. p. suppl 69-70 PMID: 7627410 **exclusion reason -** not relevant.
488. Goldstein, R. D., C. D. Hall and R. A. Buzard. A simple method for improving skin graft take in patients on clinitron therapy. Plastic & Reconstructive Surgery; 1987. p. 743 PMID: 3313456 **exclusion reason -** not relevant.
489. Gonzalez Jimenez, F., M. Pareja Illeras, P. Jimenez Lopez and M. Carmona Sanchez. [how to evaluate nursing procedures for bedsores, or decubitus ulcers by means of a codified and computerized record-keeping system]. Revista de Enfermeria; 2005. p. 23-6 PMID: 15768955 **exclusion reason -** not relevant.
490. Gonzalez Monterrubio, G., M. M. T. Martin, N. M. Gomez, E. R. Revilla Trujillo and J. Ruiz Pato. Efficacy of a protocol treatment of decubitus ulcer in critical patients [spanish]. Metas de Enfermería; 1998. p. 27-33 PMID: 2002150876 **exclusion reason -** not relevant.
491. Gonzalez Sarasua, J., A. Perez Arias, A. Fueyo Lorente, J. L. Arranz, F. B. Alzaga and J. G. Campano. Choice of surgical techniques and the prevention of complications in the treatment of pressure sores. Cirugia Plastica Ibero-Latinoamericana; 1992. p. 411-418 PMID: 18158437 **exclusion reason -** no original data.
492. Gonzalez Sarasua, J., S. Perez Lopez, M. Alvarez Viejo, M. Perez Basterrechea, A. Fernandez Rodriguez, A. Ferrero Gutierrez, J. Garcia Gala, Y. Menendez Menendez, D. Escudero Augusto, A. Perez Arias and J. Otero Hernandez. Treatment of pressure ulcers with autologous bone marrow nuclear cells in patients with spinal cord injury. Journal of Spinal Cord Medicine; 2011. p. 301-307 PMID: 21756569 **exclusion reason -** wrong population.
493. Goodman, C. M., V. Cohen, A. Armenta, J. Thornby and D. T. Netscher. Evaluation of results and treatment variables for pressure ulcers in 48 veteran spinal cord-injured patients. Annals of Plastic Surgery; 1999. p. 665-72 PMID: 10382806 **exclusion reason -** not relevant.
494. Gorecki, C., J. Brown, D. Lamping, A. Madill and J. Nixon. Health-related quality of life in pressure ulceration: Development of a conceptual framework. 16th Annual Conference of the International Society for Quality of Life Research. New Orleans; 2009 PMID: 20554279 **exclusion reason -** no original data.
495. Gorecki, C., J. M. Brown, E. A. Nelson, M. Briggs, L. Schoonhoven, C. Dealey, T. Defloor and J. Nixon. Impact of pressure ulcers on quality of life in older patients: A systematic review: Clinical investigations. Journal of the American Geriatrics Society; 2009. p. 1175-1183 **exclusion reason -** background.
496. Gorecki, C., J. Nixon, A. Madill, J. Firth and J. M. Brown. What influences the impact of pressure ulcers on health-related quality of life? A qualitative patient-focused exploration of contributory factors. Journal of tissue viability; 2012. p. 3-12 PMID: 22137874 **exclusion reason -** wrong outcome.
497. Goren, D. Use of omiderm in treatment of low-degree pressure sores in terminally ill cancer patients. Cancer Nursing; 1989. p. 165-9 PMID: 2743299 **exclusion reason -** wrong population.
498. Gosnell, D. J. and C. Pontius. A model of quality assurance for decubitus ulcer monitoring. Decubitus; 1988. p. 24-9 PMID: 3254241 **exclusion reason -** not relevant.
499. Gottrup, F., P. Holstein, B. Jorgensen, M. Lohmann and T. Karlsmar. A new concept of a multidisciplinary wound healing center and a national expert function of wound healing. Archives of

Surgery; 2001. p. 765-72 PMID: 11448387 **exclusion reason -** not relevant.
500. Gottwald, C. [improved management of decubitus ulcer is advantageous to the patient as well as to the economy]. Pflege Zeitschrift; 2000. p. 471-4 PMID: 11022565 **exclusion reason -** not relevant.
501. Gould, W. L., N. Montero, J. Cukic, R. C. Hagerty and T. R. Hester. The "split" gluteus maximus musculocutaneous flap. Plastic & Reconstructive Surgery; 1994. p. 330-6 PMID: 8310025 **exclusion reason -** not relevant.
502. Governa, M., A. Bortolani, Q. Piubello, C. Ghimenton, A. Sanna and D. Barisoni. Spinocellular carcinoma arising from scars (marjolin ulcer): Our experience. Rivista Italiana di Chirurgia Plastica; 1994. p. 151-156 **exclusion reason -** not relevant.
503. Gradon, J. and C. Adamson. Infections of pressure ulcers: Management and controversies. Infectious Diseases in Clinical Practice; 1995. p. 11-16 **exclusion reason -** background.
504. Granick, M. S., A. N. Eisner and M. P. Solomon. Surgical management of decubitus ulcers. Clinics in Dermatology; 1994. p. 71-9 PMID: 8180947 **exclusion reason -** background.
505. Granick, M. S. and D. A. Ladin. The multidisciplinary in-hospital wound care team: Two models. Advances in Wound Care; 1998. p. 80-3 PMID: 9729938 **exclusion reason -** no original data.
506. Granick, M. S. and C. D. Long. Outcome assessment of an in-hospital cross-functional wound care team. Plastic & Reconstructive Surgery; 2004. p. 671-2 PMID: 14758234 **exclusion reason -** no original data.
507. Granick, M. S., J. Posnett, M. Jacoby, S. Noruthun, P. A. Ganchi and R. O. Datiashvili. Efficacy and cost-effectiveness of a high-powered parallel waterjet for wound debridement. Wound Repair & Regeneration; 2006. p. 394-7 PMID: 16939565 **exclusion reason -** wrong population.
508. Graves, N. and A. E. Ashby. The use of opal001 filtrate and cream in the treatment of chronic pressure ulcers. Wound Practice & Research; 2008. p. 22 **exclusion reason -** not relevant.
509. Graves, N., F. Birrell and M. Whitby. Effect of pressure ulcers on length of hospital stay. Infection Control & Hospital Epidemiology; 2005. p. 293-297 PMID: 15796283 **exclusion reason -** background.
510. Gray, D. Pressure ulcer prevention and treatment: The transair range. British Journal of Nursing; 1999. p. 454-8 PMID: 10531827 **exclusion reason -** no original data.
511. Gray, D. G. and M. Smith. Comparison of a new foam mattress with the standard hospital mattress. Journal of Wound Care; 2000. p. 29-31 **exclusion reason -** wrong outcome.
512. Gray, M. Does oral zinc supplementation promote healing of chronic wounds? Journal of Wound, Ostomy, & Continence Nursing; 2003. p. 295-9 PMID: 14615757 **exclusion reason -** background.
513. Gray, M. Does oral supplementation with vitamins a or e promote healing of chronic wounds? Journal of Wound, Ostomy, & Continence Nursing; 2003. p. 290-4 PMID: 14615755 **exclusion reason -** background.
514. Gray, M. Context for woc practice. Pressure ulcer risk assessment, negative pressure wound therapy, and suprapubic catheters. Journal of Wound, Ostomy, & Continence Nursing; 2007. p. 356-8 PMID: 17667081 **exclusion reason -** no original data.
515. Gray, M. Is larval (maggot) debridement effective for removal of necrotic tissue from chronic wounds? Journal of Wound, Ostomy, & Continence Nursing; 2008. p. 378-84 PMID: 18635985 **exclusion reason -** Systematic Review, not directly used.
516. Gray, M. and D. P. Jones. The effect of different formulations of equivalent active ingredients on the performance of two topical wound treatment products. Ostomy Wound Management; 2004. p. 34-8, 40, 42-4 PMID: 15206088 **exclusion reason -** no original data.
517. Gray, M. and C. R. Ratliff. Is hyperbaric oxygen therapy effective for the management of chronic wounds? Journal of Wound, Ostomy, & Continence Nursing; 2006. p. 21-5 PMID: 16444099 **exclusion reason -** Systematic Review, not directly used.
518. Gray, M. and J. D. Whitney. Does vitamin c supplementation promote pressure ulcer healing? Journal of Wound, Ostomy, & Continence Nursing; 2003. p. 245-9 PMID: 14560282 **exclusion reason -** background.
519. Greener, M. Octenidine: Antimicrobial activity and clinical efficacy. Wounds UK; 2011. p. 74-78 **exclusion reason -** wrong outcome.
520. Greer, D. M., J. Morris, N. E. Walsh, A. M. Glenn and J. Keppler. Cost-effectiveness and efficacy of air-fluidized therapy in the treatment of pressure ulcers. Journal of Enterostomal Therapy; 1988. p. 247-51 PMID: 3060503 **exclusion reason -** not relevant.
521. Greer, S. E. and L. C. Argenta. Whither subatmospheric pressure dressing? Annals of Plastic Surgery; 2000. p. 332-336 PMID: 10987538 **exclusion reason -** no original data.
522. Greer, S. E., M. T. Longaker and M. Margiotta. Preliminary results from a multicenter, randomized, controlled study of the use of subatmospheric pressure dressing for pressure ulcer healing. Wound Repair and Regeneration; 1999. p. A255 **exclusion reason -** no original data.
523. Gregor, S., M. Maegele, S. Sauerland, J. F. Krahn, F. Peinemann and S. Lange. Negative pressure wound therapy: A vacuum of evidence? Archives of Surgery; 2008. p. 189-96 PMID: 18283145 **exclusion reason -** Systematic Review, not directly used.
524. Grimm, A., B. Loos and R. E. Horch. [optimizing vacuum therapy in extensively undermined wounds]. Zentralblatt fur Chirurgie; 2006. p. S19-23 PMID: 16575639 **exclusion reason -** not relevant.
525. Grimm, M. R. Stage i pressure ulcers: Catching pressure injury before skin breakdown... Including commentary by ferris mtg. Corp. Ostomy Wound Management; 2009. p. 10-10 **exclusion reason -** no original data.

526. Grinnell, F., K. Toda and A. Takashima. Role of fibronectin in epithelialization and wound healing. Progress in Clinical & Biological Research; 1988. p. 259-72 PMID: 3289046 **exclusion reason -** wrong intervention.
527. Gross, E. B. New treatment option for wounds and pressure ulcers. 2008 **exclusion reason -** no original data.
528. Grosse, W. and H. J. Gerner. [mesalt--a new possibility for wound treatment in decubitus ulcer]. Rehabilitation; 1985. p. 100-2 PMID: 4012022 **exclusion reason -** not relevant.
529. Gude, D. Management of pressure ulcers - what is new? Journal of Mid-life Health; 2011. p. 91-2 PMID: 22408340 **exclusion reason -** background.
530. Guihan, M. Characteristics of veterans with sci hospitalized for the treatment of severe pressure ulcers. 52nd Annual Conference of American Paraplegia Society. Riviera Hotel, Las Vegas, Nevada; 2006 **exclusion reason -** no original data.
531. Guihan, M., S. L. Garber, C. H. Bombardier, R. Durazo-Arizu, B. Goldstein and S. A. Holmes. Lessons learned while conducting research on prevention of pressure ulcers in veterans with spinal cord injury. Archives of Physical Medicine and Rehabilitation; 2007. p. 858-861 PMID: 17601465 **exclusion reason -** wrong intervention.
532. Guirini, J. [commentary on] healing of diabetic foot ulcers and pressure ulcers with human skin equivalent: A new paradigm in wound healing [original article by brem h et al appears in arch surg 2000;135:627-634]. Foot & Ankle Quarterly--The Seminar Journal; 2000. p. 107 **exclusion reason -** wrong population.
533. Gunes, U. Y. A prospective study evaluating the pressure ulcer scale for healing (push tool) to assess stage ii, stage iii, and stage iv pressure ulcers. Ostomy Wound Management; 2009. p. 48-52 PMID: 19471048 **exclusion reason -** wrong intervention.
534. Gunnewicht, B. R. Management of pressure sores in a spinal injuries unit. Journal of Wound Care; 1996. p. 36-9 PMID: 8697127 **exclusion reason -** wrong intervention.
535. Gunningberg, L., C. Lindholm, M. Carlsson and P. O. Sjoden. Risk, prevention and treatment of pressure ulcers - nursing staff knowledge and documentation. Scandinavian Journal of Caring Sciences; 2001. p. 257-263 **exclusion reason -** background.
536. Gupta, N., B. Loong and G. Leong. Comparing and contrasting knowledge of pressure ulcer assessment, prevention and management in people with spinal cord injury among nursing staff working in two metropolitan spinal units and rehabilitation medicine training specialists in a three-way comparison. Spinal Cord; 2012. p. 159-64 PMID: 21894165 **exclusion reason -** wrong intervention.
537. Gupta, S. and A. Gabriel. Improving pressure ulcer outcomes using an algorithmic approach to negative pressure wound therapy. 2008 PMID: 17601465 **exclusion reason -** no original data.
538. Gurcay, E. Pressure sores in patients with spinal cord injuries. Marmara Medical Journal; 2009. p. 162-168 **exclusion reason -** background.
539. Gusenoff, J. A., R. J. Redett and M. Y. Nahabedian. Outcomes for surgical coverage of pressure sores in nonambulatory, nonparaplegic, elderly patients. Annals of Plastic Surgery; 2002. p. 633-40 PMID: 12055434 **exclusion reason -** not relevant.
540. Guthrie, J. Wound care. Using air fluidised therapy. Nursing Times; 1993. p. 82-8 PMID: 8474913 **exclusion reason -** not relevant.
541. Gutierrez, A. Pressure lessons: Choosing the correct specialty mattress is integral to preventing and healing pressure ulcers. Rehab Management: The Interdisciplinary Journal of Rehabilitation; 2002. p. 44 **exclusion reason -** no original data.
542. Haalboom, J. R. E. The guideline 'decubitus' [pressure ulcer] of the dutch college of general practitioners; reaction from internal medicine. Nederlands Tijdschrift voor Geneeskunde; 2000. p. 645-646 **exclusion reason -** background.
543. Hai, H., H. Dai and Y. Xu. [combined treatment of refractory decubitus ulcers]. Chung-Kuo Hsiu Fu Chung Chien Wai Ko Tsa Chih/Chinese Journal of Reparative & Reconstructive Surgery; 2006. p. 909-11 PMID: 17036979 **exclusion reason -** not relevant.
544. Haisfield, M. E., C. Heckman and T. Day. Improving care of pressure sores. Oncology Nursing Forum; 1995. p. 989-90 PMID: 7567624 **exclusion reason -** no original data.
545. Hale, C. Pressure sores: Assessing the cost. Nursing Times; 1990. p. 66-71 PMID: 2113672 **exclusion reason -** not relevant.
546. Hale, J. S. and S. H. Smith. Pressure reduction mattresses versus pressure reduction overlays: A cost analysis. Journal of Enterostomal Therapy; 1990. p. 241-3 PMID: 2122995 **exclusion reason -** not relevant.
547. Halfens, R. J., G. J. Bours and W. Van Ast. Relevance of the diagnosis 'stage 1 pressure ulcer': An empirical study of the clinical course of stage 1 ulcers in acute care and long-term care hospital populations. Journal of Clinical Nursing; 2001. p. 748-57 PMID: 11822846 **exclusion reason -** background.
548. Hallouet, P., J. Eggers and E. Malaquin-Pavan. [care of decubitus ulcers]. Soins; 2007. p. 45-7 PMID: 17983004 **exclusion reason -** not relevant.
549. Hamilton, L., P. Quek, N. Lew, K. Li and R. Topp. Pressure ulcers: An interdisciplinary protocol for prevention and treatment. Perspectives; 1989. p. 9-15 PMID: 2497617 **exclusion reason -** no original data.
550. Hampton. Evaluation of the new cairwave therapy system in one hospital trust. 1997. p. 167-170 **exclusion reason -** no original data.
551. Hampton, S. Efficacy and cost-effectiveness of the thermo contour mattress. British Journal of Nursing; 1999. p. 990-6 PMID: 10711028 **exclusion reason -** wrong outcome.
552. Hampton, S. The pressure ulcer benchmark: Will it improve patient care? Journal of Wound Care;

2001. p. 210-2 PMID: 12964355 **exclusion reason -** not relevant.
553. Hampton, S. Pressure ulcer care: Can we learn from poorer countries? British Journal of Nursing; 2001. p. S4 PMID: 12070395 **exclusion reason -** no original data.
554. Hampton, S. Unisoft: Pressure relief with price relief. Nursing & Residential Care; 2002. p. 434 **exclusion reason -** no original data.
555. Hampton, S. An evaluation of a silicone adhesive shaped heel dressing. British Journal of Nursing; 2010. p. S30-3 PMID: 20335927 **exclusion reason -** not relevant.
556. Hampton, S. Wound care: The science of healing. Nursing in Practice: The Journal for Today's Primary Care Nurse; 2010. p. 60 **exclusion reason -** background.
557. Han, H., J. Few and N. A. Fine. Use of the tumescent technique in presssure ulcer closure. Plastic & Reconstructive Surgery; 2002. p. 711-2 PMID: 12142710 **exclusion reason -** not relevant.
558. Han, H., V. L. Lewis Jr, T. A. Wiedrich and P. K. Patel. The value of jamshidi core needle bone biopsy in predicting postoperative osteomyelitis in grade iv pressure ulcer patients. Plastic and Reconstructive Surgery; 2002. p. 118-122 PMID: 12087241 **exclusion reason -** wrong intervention.
559. Harada, K., K. Yamahara, S. Ohnishi, K. Otani, H. Kanoh, H. Ishibashi-Ueda, N. Minamino, K. Kangawa, N. Nagaya and T. Ikeda. Sustained-release adrenomedullin ointment accelerates wound healing of pressure ulcers. Regulatory Peptides; 2011. p. 21-26 **exclusion reason -** wrong population.
560. Harding, K., K. Cutting and P. Price. The cost-effectiveness of wound management protocols of care. British Journal of Nursing; 2000. p. S6, S8, S10 passim PMID: 12271239 **exclusion reason -** not relevant.
561. Harding, K. G., S. Bale, M. Llewellyn, J. Baggott and K. Robbins. A pilot study of clostridium collagenase (collagenase abc(registered trademark)) ointment in the debridement of dermal ulcers. Clinical Drug Investigation; 1996. p. 139-144 **exclusion reason -** not relevant.
562. Harker, J. Pressure ulcer classification: The torrance system. Journal of Wound Care; 2000. p. 275-277 PMID: 11933341 **exclusion reason -** background.
563. Harris, C., L. Damkat-Thomas and C. E. Black. The superior gluteal artery perforator flap to reconstruct lumbar soft tissue defects in the non-ambulatory patient. Journal of Plastic, Reconstructive and Aesthetic Surgery; 2012. p. 408-409 **exclusion reason -** not relevant.
564. Harris, R. P., M. Helfand, S. H. Woolf, K. N. Lohr, C. D. Mulrow, S. M. Teutsch, D. Atkins and T. U. S. P. S. T. F. Methods Work Group. Current methods of the us preventive services task force: A review of the process. Am J Prev Med; 2001. p. 21-35 PMID: 11306229 **exclusion reason -** background.
565. Harrison, J. E. Polymeric membrane dressings* bring brisk healing to bilateral pressure ulcers. 2008 **exclusion reason -** not relevant.
566. Harrison, M. B., M. Mackey and E. Friedberg. National patient safety goals. Pressure ulcer monitoring: A process of evidence-based practice, quality, and research. Joint Commission Journal on Quality & Patient Safety; 2008. p. 355-359 **exclusion reason -** background.
567. Hartgrink, H. H., J. Wille, P. Konig, J. Hermans and P. J. Breslau. Pressure sores and tube feeding in patients with a fracture of the hip: A rondomized clinical trial. Clinical Nutrition; 1998. p. 287-292 **exclusion reason -** wrong population.
568. Hartling, L., F. A. McAlister, B. H. Rowe, J. Ezekowitz, C. Friesen and T. P. Klassen. Challenges in systematic reviews of therapeutic devices and procedures. Ann Intern Med; 2005. p. 1100-1111 PMID: 15968035 **exclusion reason -** background.
569. Hartmann, M., D. Schulz, C. Gundermann and J. Norgauer. [economic aspects of standardization of modern wound care]. Hautarzt; 2007. p. 970-4 PMID: 17618408 **exclusion reason -** not relevant.
570. Hartoch, R. S., J. G. McManus, S. Knapp and M. F. Buettner. Emergency management of chronic wounds. Emergency Medicine Clinics of North America; 2007. p. 203-21 PMID: 17400082 **exclusion reason -** background.
571. Harvey, C. Wound healing. Orthopaedic Nursing; 2005. p. 143-57; quiz 158-9 PMID: 15902014 **exclusion reason -** background.
572. Hausman, L. L. Cost containment through reducing pressure ulcers. Nursing Management; 1994. p. 88R, 88T, 88V PMID: 8044484 **exclusion reason -** not relevant.
573. Hawkins, E. Using activheal® in a traffic light system wound care formulary. Wounds UK; 2010. p. 177-182 **exclusion reason -** no original data.
574. Hayashi, T., K. Honda, C. Kimura, Y. Yamamoto, A. Oyama and T. Sugihara. Treatment of ischial pressure sores by means of sclerotherapy using absolute ethanol. Annals of Plastic Surgery; 2004. p. 554-9 PMID: 15602252 **exclusion reason -** not relevant.
575. HAYES and Inc. Pressure-reducing support surfaces for pressure ulcers (structured abstract). Health Technology Assessment Database; 2011 **exclusion reason -** unable to find.
576. Heasley, D. D. Evaluation of a silver collagen based amorphous gel in expedience of wound debridement. Journal of Wound, Ostomy & Continence Nursing; 2011. p. S18-S18 **exclusion reason -** wrong population.
577. Helaly, P., E. Vogt and G. Schneider. [wound healing disorders and their enzymatic therapy--a multicenter double-blind study]. Schweizerische Rundschau fur Medizin Praxis; 1988. p. 1428-34 PMID: 2851160 **exclusion reason -** not relevant.
578. Helberg, D., E. Mertens, R. J. Halfens and T. Dassen. Treatment of pressure ulcers: Results of a study comparing evidence and practice. Ostomy

Wound Management; 2006. p. 60-72 PMID: 16896239 **exclusion reason -** background.

579. Heller, B. [a hammock against decubitus ulcer on the heel. 2. Nursing award for treatment of decubitus ulcers]. Pflege Aktuell; 1997. p. 540-1 PMID: 9386546 **exclusion reason -** not relevant.

580. Henderson, C. T., L. S. Trumbore, S. Mobarhan, R. Benya and T. P. Miles. Prolonged tube feeding in long-term care: Nutritional status and clinical outcomes. J Am Coll Nutr; 1992. p. 309-325 PMID: 1619183 **exclusion reason -** background.

581. Henderson, V., D. Anthony and E. P. Tolmie. A study of the prevention and management of pressure sores. Clinical Effectiveness in Nursing; 2002. p. 155-157 **exclusion reason -** no original data.

582. Hendrickson, M. A. Optimizing wound care by integrating negative pressure wound therapy (npwt) adjunctive topical treatments and surgical debridement... 41st annual wound, ostomy and continence nurses annual conference, st. Louis, missouri, june 6-10, 2009. Journal of Wound, Ostomy & Continence Nursing; 2009. p. S15-S15 **exclusion reason -** no original data.

583. Henriques, M. S. and S. C. O. Simoes. [application of honey in the treatment of stage 4 pressure ulcers] [portuguese]. Nursing: Revista de Formacao Continua em Enfermagem; 2008. p. 37-40 **exclusion reason -** not relevant.

584. Hermans, M. H. E. and M. Neto. Reducing heel pressure with a vpf/smt polyurethane support surface. **exclusion reason -** Scientific Information Packets, not directly used.

585. Hermans, M. H. E. and M. Neto. Reducing the chances of pressure ulcers on the occiput. **exclusion reason -** Scientific Information Packets, not directly used.

586. Hermans, M. H. E., M. Neto and S. Warren. Surface modification technology: Increasing envelopment in polyurethane foam pressure relief mattress. **exclusion reason -** Scientific Information Packets, not directly used.

587. Hermans, M. H. E., M. Neto and S. Warren. Surface modification technology results in an increase in envelopment in pressure redistribution mattresses. **exclusion reason -** Scientific Information Packets, not directly used.

588. Hermans, M. H. E., M. Neto and S. Warren. Measuring pinch shear forces on the occiput and the heels using pressure mapping: Results of a study in volunteers. **exclusion reason -** Scientific Information Packets, not directly used.

589. Hermans, M. H. E., S. Warren, K. McCabe, R. Contreras, B. Niederoest and M. Neto. Variable pressure foaming in polyurethane systems shows a clear reduction of pressure in an 'in vevo' test model. **exclusion reason -** Scientific Information Packets, not directly used.

590. Hermans, M. H. E., S. Warren, M. Neto and S. I. Reger. Evaluation of the efficacy of a new mattress technology by mapping the pressure on the trochanter major in healthy volunteers. **exclusion reason -** Scientific Information Packets, not directly used.

591. Hernandez Ortiz, J. A. Prevention and care in pressure ulcers. Where are we? [spanish]. Gerokomos; 2009. p. 132-140 **exclusion reason -** not relevant.

592. Hess, C. T. Managed care and wound care: Proactive strategies for successful outcomes. Ostomy Wound Management; 1996. p. 94, 96, 98 PMID: 8716036 **exclusion reason -** no original data.

593. Hess, C. T. Managing a pressure ulcer. Nursing; 2001. p. 68 PMID: 11216248 **exclusion reason -** no original data.

594. Hewitt, H., Y. Wint, L. Talabere, S. Lopez, E. Bailey, O. Parshad and S. Weaver. The use of papaya on pressure ulcers. American Journal of Nursing; 2002. p. 73-7 PMID: 12473933 **exclusion reason -** no original data.

595. Hey, S. Pressure-sore care and cure. Lancet; 1996. p. 1511 PMID: 8942786 **exclusion reason -** no original data.

596. Heyneman, A., H. Beele, K. Vanderwee and T. Defloor. A systematic review of the use of hydrocolloids in the treatment of pressure ulcers. Journal of Clinical Nursing; 2008. p. 1164-73 PMID: 18416792 **exclusion reason -** Systematic Review, not directly used.

597. Heywood, A. J. and A. A. Quaba. Modified gluteus maximus v-y advancement flaps. British Journal of Plastic Surgery; 1989. p. 263-5 PMID: 2758198 **exclusion reason -** background.

598. Hierner, R. Operative treatment of pressure sores: How and when? Zeitschrift fur Wundheilung; 2005. p. 110-123 **exclusion reason -** background.

599. Hierner, R., M. Flour, M. Notebaert, M. Tombeur, C. Kiekens, H. Degreef, L. Veckman, E. Vandermersch and E. Joosten. Update on plastic surgical management of pressure sores. Chirurgische Gastroenterologie Interdisziplinar; 2006. p. 155-168 **exclusion reason -** background.

600. Hill-Brown, S. Reduction of pressure ulcer incidence in the home healthcare setting: A pressure-relief seating cushion project to reduce the number of community-acquired pressure ulcers. Home Healthcare Nurse; 2011. p. 575-9 PMID: 21956013 **exclusion reason -** wrong population.

601. Hinshaw, J. R., H. R. Herrera, R. J. Lanzafame and R. P. Pennino. The use of the carbon dioxide laser permits primary closure of contaminated and purulent lesions and wounds. Lasers in Surgery & Medicine; 1987. p. 581-3 PMID: 3573932 **exclusion reason -** not relevant.

602. Hirano, A., N. Tanaka and N. Itano. Coccygeal pressure sores in paraplegics. Japanese Journal of Plastic and Reconstructive Surgery; 1990. p. 849-855 **exclusion reason -** not relevant.

603. Hisashige, A. and T. Ohura. Cost-effectiveness of nutritional intervention on healing of pressure ulcers. Clinical Nutrition; 2012 PMID: 22626888 **exclusion reason -** background.

604. Hofman, D., B. Burgess, G. W. Cherry, B. J. Robinson and T. J. Ryan. Management of pressure sores and leg ulcers with duoderm hydroactive gel.

4th Annual Meeting of the European Tissue Repair Society; 1994 **exclusion reason -** no original data.
605. Holman, P. D. Preservation of the lower extremity in the treatment of massive pressure ulcers. Arizona Medicine; 1985. p. 93-9 PMID: 3977620 **exclusion reason -** not relevant.
606. Homma, K., G. Murakami, H. Fujioka, T. Fujita, A. Imai and K. Ezoe. Treatment of ischial pressure ulcers with a posteromedial thigh fasciocutaneous flap. Plastic & Reconstructive Surgery; 2001. p. 1990-6; discussion 1997 PMID: 11743389 **exclusion reason -** not relevant.
607. Hommel, A., K. B. Bjorkelund, K. Thorngren and K. Ulander. A study of a pathway to reduce pressure ulcers for patients with a hip fracture. Journal of Orthopaedic Nursing; 2007. p. 151-159 **exclusion reason -** wrong population.
608. Honaker, J. S., M. R. Forston, E. A. Davis, M. M. Wiesner and J. A. Morgan. Effects of non contact low-frequency ultrasound on healing of suspected deep tissue injury: A retrospective analysis. International Wound Journal; 2012 **exclusion reason -** wrong population.
609. Honda, S. Use of comfeel ulcus sheet and pressure relief dressing in the treatment of pressure sores in patients with spinal cord injuries. Japanese Pharmacology and Therapeutics; 1990. p. 289-296 **exclusion reason -** not relevant.
610. Honda, S., R. Uchida, T. Kimura, T. Moriai, A. Magara, Y. Hayashi, H. Ebata, E. Saito, Y. Ono, M. Ijichi, H. Tanaka, T. Hayashi, T. Noguchi, S. Yoshimi, A. Nakashima and S. Takada. Clinical results of new transparent hydrogel wound dressing clearsite(registered trademark) on decubitus. Japanese Pharmacology and Therapeutics; 1993. p. 543-553 **exclusion reason -** not relevant.
611. Hopkins, A., S. Gooch and F. Danks. A programme for pressure sore prevention and management. Journal of Wound Care; 1998. p. 37-40 PMID: 9510749 **exclusion reason -** wrong outcome.
612. Horch, R. E., D. Nord, M. Augustin, G. Germann, M. Leffler and A. Dragu. [economic aspects of surgical wound therapies]. Chirurg; 2008. p. 518-25 PMID: 18458799 **exclusion reason -** not relevant.
613. Horn, S., S. Sharkey, S. Hudak and W. Spector. Practice-based evidence for pressure ulcer prevention and treatment in nursing homes. World Union Of Wound Healing Societies. Toronto, Canada; 2008 PMID: 20177165 **exclusion reason -** wrong intervention.
614. Horn, S. D. The business case for nursing in long-term care. Policy, Politics, & Nursing Practice; 2008. p. 88-93 PMID: 18650413 **exclusion reason -** not relevant.
615. Hornake, J., M. Forston, E. Davis, M. Wiesner and J. Morgan. Effect of noncontact low frequency ultrasound treatment on suspected deep tissue injury healing. Journal of Wound, Ostomy & Continence Nursing; 2011. p. S8-9 **exclusion reason -** wrong population.
616. Hou, C. L. [myocutaneous flap in the treatment of pressure sores]. Chung-Hua Cheng Hsing Shao Shang Wai Ko Tsa Chih - Chinese Journal of Plastic Surgery & Burns; 1989. p. 30-1, 77 PMID: 2507107 **exclusion reason -** not relevant.
617. House, M. J. Wheelchair seat angle and lumbar support are critical factors for resolution of flexible spinal deformity and decubitus ulcer in persons with spinal cord injury... Platforms, thematic posters, and posters for csm 2007. Journal of Neurologic Physical Therapy; 2006. p. 216-216 **exclusion reason -** not relevant.
618. Hu, K.-x., H.-w. Zhang, F. Zhou, G. Yao, J.-p. Shi, Z. Cheng, L.-f. Wang and Z.-q. Hou. [observation on the therapeutic effects of negative-pressure wound therapy on the treatment of complicated and refractory wounds]. Zhonghua Shao Shang Za Zhi; 2009. p. 249-52 PMID: 19951540 **exclusion reason -** not relevant.
619. Hu, T. W., N. A. Stotts, T. E. Fogarty and N. Bergstrom. Cost analysis for guideline implementation in prevention and early treatment of pressure ulcers. Decubitus; 1993. p. 42-6 PMID: 8318158 **exclusion reason -** not relevant.
620. Hung, S. J., H. C. Chen and F. C. Wei. Free flaps for reconstruction of the lower back and sacral area. Microsurgery; 2000. p. 72-6 PMID: 10702740 **exclusion reason -** not relevant.
621. Hutchinson, J. J. and M. McGuckin. Occlusive dressings: A microbiologic and clinical review. Am J Infect Control; 1990. p. 257-268 PMID: 2206087 **exclusion reason -** background.
622. Hyakusoku, H., M. Murakami and S. Ishimaru. Surgical treatment of decubitus ulcers outside the sacral, ischial and trochanter region. Japanese Journal of Plastic and Reconstructive Surgery; 2003. p. 587-594 **exclusion reason -** not relevant.
623. Ichioka, S., T. Nakatsuka, N. Ohura, M. Shibata and J. Ando. Treating pressure ulcers with artificial dermis graft and new pressure relief air mattress. Chicago 2000 World Congress HQ. Chicago, IL 2000 **exclusion reason -** unable to find.
624. Ichioka, S., N. Ohura and T. Nakatsuka. Benefits of surgical reconstruction in pressure ulcers with a non-advancing edge and scar formation. Journal of Wound Care; 2005. p. 301-5 PMID: 16048214 **exclusion reason -** not relevant.
625. Ichioka, S., N. Ohura, N. Sekiya, M. Shibata and T. Nakatsuka. Regenerative surgery for sacral pressure ulcers using collagen matrix substitute dermis (artificial dermis). Annals of Plastic Surgery; 2003. p. 383-9 PMID: 14520066 **exclusion reason -** not relevant.
626. Ichioka, S., K. Okabe, N. Ohura, H. Yokogawa, M. Nakajima and T. Nakatsuka. Versatility of the limberg flap and the v-y flap (based on a distal perforator) for covering sacral ulcers. Scandinavian Journal of Plastic & Reconstructive Surgery & Hand Surgery; 2007. p. 65-9 PMID: 17605438 **exclusion reason -** not relevant.
627. Ichioka, S., K. Okabe, S. Tsuji, N. Ohura and T. Nakatsuka. Distal perforator-based fasciocutaneous v-y flap for treatment of sacral pressure ulcers. Plastic

& Reconstructive Surgery; 2004. p. 906-9 PMID: 15468397 **exclusion reason -** not relevant.
628. Ichioka, S., K. Okabe, S. Tsuji, N. Ohura and T. Nakatsuka. Triple coverage of ischial ulcers with adipofascial turnover and fasciocutaneous flaps. Plastic & Reconstructive Surgery; 2004. p. 901-5 PMID: 15468396 **exclusion reason -** not relevant.
629. Iglesias, C. P., J. Nixon, G. Cranny, A. Nelson, K. Hawkins, A. Philips, D. J. Torgerson, S. Mason and N. Cullum. The nhs health technology assessment programme. Pressure trial: Cost effectiveness analysis of two alternating pressure surfaces for the prevention of pressure ulcers. EWMA Journal; 2006. p. 38-38 **exclusion reason -** not relevant.
630. Iizaka, S., H. Sanada, Y. Matsui, M. Furue, T. Tachibana, T. Nakayama, J. Sugama, K. Furuta, M. Tachi, K. Tokunaga and Y. Miyachi. Serum albumin level is a limited nutritional marker for predicting wound healing in patients with pressure ulcer: Two multicenter prospective cohort studies. Clinical Nutrition; 2011. p. 738-45 PMID: 21802178 **exclusion reason -** background.
631. Institute of Medicine. Finding what works in health care: Standards for systematic reviews. Washington, DC: The National Academy of Sciences; 2011 **exclusion reason -** background.
632. Iordanou, P., J. Christopoulou, E. Siamaga, E. Evagelou and Z. Vardaki. Factors affecting pressure ulcers healing. ICUs & Nursing Web Journal; 2002. p. 15p **exclusion reason -** background.
633. Iori, I., A. M. Pizzini, D. Arioli, D. Favali and M. C. Leone. [infected pressure ulcers: Evaluation and management]. Infezioni in Medicina; 2009. p. 88-94 PMID: 20428024 **exclusion reason -** not relevant.
634. Isago, T., M. Nozaki, Y. Kikuchi, T. Honda and H. Nakazawa. Negative-pressure dressings in the treatment of pressure ulcers. Journal of Dermatology; 2003. p. 299-305 PMID: 12707466 **exclusion reason -** wrong outcome.
635. Isago, T., K. Shimoda, N. Morita, Y. Takahashi and Y. Tomoyasu. Treatment effects of the vacuum-assisted closure of skin ulcers. Japanese Pharmacology and Therapeutics; 2002. p. 311-317 **exclusion reason -** not relevant.
636. Isenberg, J. S., G. Ozuner and R. J. Restifo. The natural history of pressure sores in a community hospital environment. Annals of Plastic Surgery; 1995. p. 361-5 PMID: 8585677 **exclusion reason -** background.
637. Isenberg, R. Pulsed radio frequency energy therapy in elderly patients with stage iii and stage iv pressure ulcers in long-term care settings. Ostomy Wound Management; 2008. p. 72-73 **exclusion reason -** no original data.
638. Isenberg, R. A. Cell proliferation induction (cpi) wound therapy in long-term care settings: An effective therapy for elderly patients with stage iv pressure ulcers... Scientific and clinical abstracts from the 40th annual wound, ostomy and continence nurses annual conference. Journal of Wound, Ostomy & Continence Nursing; 2008. p. S64-S64 **exclusion reason -** not relevant.
639. Isenberg, R. A. Pulsed radio frequency energy therapy in elderly patients with pressure ulcers in long-term care settings: An analysis of 224 wounds... 41st annual wound, ostomy and continence nurses annual conference, st. Louis, missouri, june 6-10, 2009. Journal of Wound, Ostomy & Continence Nursing; 2009. p. S63-S63 **exclusion reason -** no original data.
640. Ishida, L. H., A. M. Munhoz, E. Montag, H. R. N. Alves, F. L. Saito, H. A. Nakamoto and M. C. Ferreira. Tensor fasciae latae perforator flap: Minimizing donor-site morbidity in the treatment of trochanteric pressure sores. Plastic & Reconstructive Surgery; 2005. p. 1346-52 PMID: 16217478 **exclusion reason -** not relevant.
641. Ismail, H. E. d. A. Versatility of perforator sparing buttock rotation flap in repair of pressure sores. European Journal of Plastic Surgery; 2011. p. 1-7 **exclusion reason -** not relevant.
642. Ito, Y., N. Sumiya, O. Hayakawa, K. Ichikawa, Y. Kato and A. Tunashima. Surgical treatment of sacral pressure sores using an ultrasonic surgical aspirator and a rubber compression fixing. Japanese Journal of Plastic and Reconstructive Surgery; 2003. p. 1165-1172 **exclusion reason -** not relevant.
643. Itoh, M., J. S. Montemayor, Jr., E. Matsumoto, A. Eason, M. H. Lee and F. S. Folk. Accelerated wound healing of pressure ulcers by pulsed high peak power electromagnetic energy (diapulse). Decubitus; 1991. p. 24-5, 29-34 PMID: 1994961 **exclusion reason -** Systematic Review, not directly used.
644. Iusim, M., J. Kimchy, T. Pillar and D. G. Mendes. Evaluation of the degree of effectiveness of biobeam low level narrow band light on the treatment of skin ulcers and delayed postoperative wound healing. Orthopedics; 1992. p. 1023-1026 **exclusion reason -** wrong population.
645. Iverson-Carpenter, M. A descriptive study of the etiologies and defining characteristics of pressure sores. In: R. M. Carroll-Johnson, editor Classification of nursing diagnoses: Proceedings of the eighth conference held in st. Louis, mo, march, 1988.: J.B. Lippincott; 1989. p. 275-280 **exclusion reason -** background.
646. Jack, L. The use of low level laser therapy as a treatment for chronic wounds. Wounds UK; 2006. p. 74-75 **exclusion reason -** not relevant.
647. Jakubietz, R. G., M. G. Jakubietz, D. F. Jakubietz, G. Koehler, P. H. Zeplin, R. H. Meffert and K. Schmidt. Ischial pressure sores: Reconstruction using the perforator-based reverse flow musculocutaneous 180 degrees propeller flap. Microsurgery; 2009. p. 672-5 PMID: 19530083 **exclusion reason -** not relevant.
648. James, H. Tissue viability society. Exploring the role of the tissue viability specialist nurse. Nursing Standard; 1994. p. 60-3 PMID: 7811622 **exclusion reason -** no original data.
649. Jamshed, N. and E. L. Schneider. Is the use of supplemental vitamin c and zinc for the prevention & treatment of pressure ulcers evidence-based? Annals

of Long-Term Care; 2010. p. 28-32 **exclusion reason** - Systematic Review, not directly used.
650. Janssen, P. A., H. Janssen, G. Cauwenbergh, P. De Doncker, K. De Beule, P. Lewi, H. F. Tytgat and C. M. Lapiere. Use of topical ketanserin in the treatment of skin ulcers: A double-blind study. Journal of the American Academy of Dermatology; 1989. p. 85-90 PMID: 2663937 **exclusion reason** - wrong intervention.
651. Jaul, E. Setting up a dedicated pressure ulcer unit in a geriatric ward. Journal of Wound Care; 2003. p. 131-3 PMID: 12715484 **exclusion reason** - wrong intervention.
652. Jedynak, D., S. Montandon and P. Berard. [experimentation with a hydrocolloid in an occlusive bandage in the treatment of cutaneous decubitus ulcers "duoderm"]. Soins; La Revue de Reference Infirmiere; 1985. p. suppl 1-3 PMID: 3848093 **exclusion reason** - not relevant.
653. Jepson, B. A. Relieving the pain of pressure sores. Lancet; 1992. p. 503-4 PMID: 1346867 **exclusion reason** - wrong outcome.
654. Jercinovic, A., R. Karba, L. Vodovnic, A. Stefanovska, P. Kroselj, R. Turk and et al. Low frequency pulsed current and pressure ulcer healing. IEEE Transactions on Rehabilitation Engineering; 1994. p. 225-33 **exclusion reason** - wrong outcome.
655. Jester, J. and V. Weaver. A report of clinical investigation of various tissue support surfaces used for the prevention, early intervention and management of pressure ulcers. Ostomy Wound Management; 1990. p. 39-45 PMID: 2306326 **exclusion reason** - no original data.
656. Jiang, Q. X. [study on close insulin wet compresses in treating bedsores]. Chung-Hua Hu Li Tsa Chih Chinese Journal of Nursing; 1994. p. 274-7 PMID: 7788783 **exclusion reason** - not relevant.
657. Jiburum, B. C., J. U. Achebe and F. C. Akpuaka. Early results of operative closure of pressure sores in traumatic paraplegics. International Surgery; 1995. p. 178-80 PMID: 8530239 **exclusion reason** - not relevant.
658. Johnston, P. J. Improvement in surgical wound status: A process improvement plan. Remington Report; 2006. p. 18-20 **exclusion reason** - not relevant.
659. Johnstone, A. Time -- principles of wound preparation. Journal of Wound, Ostomy & Continence Nursing; 2006. p. S11-S11 **exclusion reason** - unable to find.
660. Jones, J. T., M. A. Stenson, B. D. Spannagel and D. D. Robinson. Treatment of pressure ulcers with nitropaste. Journal of the American Geriatrics Society; 1997. p. 895 PMID: 9215351 **exclusion reason** - wrong outcome.
661. Jones, K. R. Identifying best practices for pressure ulcer management. Journal of Clinical Outcomes Management; 2009. p. 375-381 **exclusion reason** - Systematic Review, not directly used.
662. Jones, K. R. and K. Fennie. Factors influencing pressure ulcer healing in adults over 50: An exploratory study. Journal of the American Medical Directors Association; 2007. p. 378-87 PMID: 17619036 **exclusion reason** - background.
663. Jones, M. L., T. Young and P. Liptrot. Improving pressure ulcer care through designer education. British Journal of Nursing; 2003. p. S28-35 PMID: 14593269 **exclusion reason** - background.
664. Jones, P. L. and A. Millman. A three-part system to combat pressure sores. Geriatric Nursing; 1986. p. 78-82 PMID: 3633222 **exclusion reason** - wrong intervention.
665. Joseph, E. and C. A. Hamori. A prospective, randomized trial of vacuum-assisted closure versus standard therapy of chronic non-healing wounds. Wounds 2000. p. 60-67 **exclusion reason** - not relevant.
666. Josvay, J. and A. Donath. Modified hamstring musculocutaneous flap for the coverage of ischial pressure sores. Plastic & Reconstructive Surgery; 1999. p. 1715-8 PMID: 10323711 **exclusion reason** - not relevant.
667. Josvay, J. and A. Donath. [15 years experience in the surgical treatment of decubitus ulcers of the pelvic region]. Magyar Sebeszet; 2002. p. 301-5 PMID: 12474515 **exclusion reason** - not relevant.
668. Josvay, J., A. Donath, G. Kertesz and A. Klauber. [surgical treatment of decubitus ulcers of the pelvic area in patients with spinal cord injury]. Ideggyogyaszati Szemle; 2003. p. 58-62 PMID: 12690792 **exclusion reason** - not relevant.
669. Josvay, J., M. Sashegyi, P. Kelemen and A. Donath. Clinical experience with the hatchet-shaped gluteus maximus musculocutaneous flap. Annals of Plastic Surgery; 2005. p. 179-82 PMID: 16034250 **exclusion reason** - not relevant.
670. Josvay, J., M. Sashegyi, P. Kelemen and A. Donath. Modified tensor fascia lata musculofasciocutaneous flap for the coverage of trochanteric pressure sores. Journal of Plastic, Reconstructive & Aesthetic Surgery: JPRAS; 2006. p. 137-41 PMID: 16703857 **exclusion reason** - not relevant.
671. Jull, A. B., A. Rodgers and N. Walker. Honey as a topical treatment for wounds. Cochrane Database of Systematic Reviews; 2008. p. CD005083 PMID: 18843679 **exclusion reason** - Systematic Review, not directly used.
672. Jurado Hernandez, R. Multicenter clinical evaluation of a new hydro-polymeric dressing [spanish]. Metas de Enfermería; 2002. p. 12-19 **exclusion reason** - not relevant.
673. Juri, H., A. Palma and A. Obeide. The co2 laser in the treatment of decubitus ulcer. Journal of Neurological and Orthopaedic Medicine and Surgery; 1986. p. 29-33 PMID: 3683061 **exclusion reason** - not relevant.
674. Juszczyk, K., J. G. Gollogly and O. C. Ngiep. Bilateral hip disarticulation in paraplegics. Asian Biomedicine; 2010. p. 125-129 **exclusion reason** - not relevant.
675. Kalava, U. R., S. S. Cha and P. Y. Takahashi. Association between vitamin d and pressure ulcers in older ambulatory adults: Results of a matched case-

control study. Clinical Interventions In Aging; 2011. p. 213-9 PMID: 21966215 **exclusion reason -** wrong intervention.

676. Kallianinen, L. K., J. Hirshberg, B. Marchant and R. S. Rees. Role of platelet-derived growth factor as an adjunct to surgery in the management of pressure ulcers. Plastic & Reconstructive Surgery; 2000. p. 1243-8 PMID: 11083552 **exclusion reason -** not relevant.

677. Kaminski, M. V., Jr., G. Pinchcofsky-Devin and S. D. Williams. Nutritional management of decubitus ulcers in the elderly. Decubitus; 1989. p. 20-30 PMID: 2510755 **exclusion reason -** no original data.

678. Kamolz, L. P., H. Andel and E. al. Use of subatmospheric pressure therapy to prevent burn wound progression in human: First experiences. Burns; 2004. p. 253-258 **exclusion reason -** wrong population.

679. Kanj, L. F., S. V. Wilking and T. J. Phillips. Pressure ulcers. Journal of the American Academy of Dermatology; 1998. p. 517-36; quiz 537-8 PMID: 9555790 **exclusion reason -** background.

680. Kapoor, A., B. Kader and D. R. Berlowitz. Predicting pressure ulcer healing using the minimum data set. 29th Annual Meeting of the Society of General Internal Medicine. Los Angeles, California; 2006 **exclusion reason -** no original data.

681. Karabeg, R., V. Dujso and M. Jakirlic. [application of tensor fascia lata pedicled flap in reconstructing trochanteric pressure sore defects]. Medicinski Arhiv; 2008. p. 300-2 PMID: 19469276 **exclusion reason -** not relevant.

682. Karadag, M. Pressure sores due surgery. SENDROM; 2004. p. 90-94 **exclusion reason -** background.

683. Karadakovan, A. and Z. Basbakkal. Ice therapy for pressure sores. Rehabilitation Nursing; 1997. p. 257-8 PMID: 9341547 **exclusion reason -** not relevant.

684. Karba, R., D. Semrov, L. Vodovnik, H. Benko and R. Savrin. Dc electrical stimulation for chronic wound healing enhancement. Part 1. Clinical study and determination of electrical field distribution in the numerical wound model. Bioelectrochemistry and Bioenergetics; 1997. p. 265-270 **exclusion reason -** wrong outcome.

685. Karrer, S. [topical therapy of ulcers]. Hautarzt; 2005. p. 1165-78; quiz 1179 PMID: 16283127 **exclusion reason -** not relevant.

686. Karrer, S. [how to treat chronic wounds]. MMW Fortschritte der Medizin; 2010. p. 81-3, 85-7; quiz 88 PMID: 20608135 **exclusion reason -** not relevant.

687. Karube, S., T. Inamatu, S. Kuzuhara, K. I. Tabuchi, O. Handa and S. I. Nakase. Clinical evaluation of nasent pad a for the patient with decubitus ulcer. Effectiveness of treatment and prevention. Japanese Pharmacology and Therapeutics; 1988. p. 299-309 **exclusion reason -** not relevant.

688. Kauer, C. and A. Andourah. [perineal complications and gracilis musculocutaneous flap in patients with paraplegia. Apropos of 19 cases]. Annales de Chirurgie Plastique et Esthetique; 1991. p. 347-52 PMID: 1724889 **exclusion reason -** not relevant.

689. Kauer, C. and G. Sonsino. The need for skin and muscle saving techniques in the repair of decubitus ulcers. A consecutive series of 72 patients and 100 ulcers over 5 years (1979/1984). A case report. Scandinavian Journal of Plastic & Reconstructive Surgery; 1986. p. 129-31 PMID: 3775282 **exclusion reason -** background.

690. Kauffmann, G., A. Davis, E. Schulwolf, V. Press, K. Stupay and V. Arora. Ibcd: Development and testing of a checklist to improve quality of care for hospitalized general medical patients. Journal of Hospital Medicine; 2011. p. S117-S118 **exclusion reason -** wrong intervention.

691. Keast, D. H., N. Parslow, P. E. Houghton, L. Norton and C. Fraser. Best practice recommendations for the prevention and treatment of pressure ulcers: Update 2006. Advances in Skin & Wound Care; 2007. p. 447-60; quiz 461-2 PMID: 17762312 **exclusion reason -** background.

692. Kegels, F. Clinical evaluation of honey-based products for lower extremity wounds in a home care setting. Wounds UK; 2011. p. 46-53 **exclusion reason -** wrong population.

693. Keller, H. P. [surgical therapy of decubitus ulcers]. Krankenpflege Journal; 1988. p. 134-6 PMID: 3374072 **exclusion reason -** not relevant.

694. Keller, H. P. [surgical therapy of decubitus ulcers]. Krankenpflege Journal; 1996. p. 266-8 PMID: 8717868 **exclusion reason -** not relevant.

695. Kemp, M. G., D. Kopanke, L. Tordecilla, L. Fogg, S. Shott, V. Matthiesen and B. Johnson. The role of support surfaces and patient attributes in preventing pressure ulcers in elderly patients. Research in Nursing & Health: Wiley Subscription Services, Inc., A Wiley Company; 1993. p. 89-96 **exclusion reason -** wrong outcome.

696. Kerstein, M. D. and E. D. Reis. Current surgical perspectives in wound healing. In: M. D. Kerstein, editor Wounds: A Compendium of Clinical Research & Practice; 2001. p. 53-58 **exclusion reason -** background.

697. Keys, K. A., L. N. Daniali, K. J. Warner and D. W. Mathes. Multivariate predictors of failure after flap coverage of pressure ulcers. Plastic & Reconstructive Surgery; 2010. p. 1725-34 PMID: 20517098 **exclusion reason -** not relevant.

698. Kiemele, L. J. and P. Y. Takahashi. Practical wound management in long-term care. Annals of Long Term Care; 2004. p. 25-32 **exclusion reason -** background.

699. Kierney, P. C., D. D. Cardenas, L. H. Engrav, J. H. Grant and R. P. Rand. Limb-salvage in reconstruction of recalcitrant pressure sores using the inferiorly based rectus abdominis myocutaneous flap. Plastic & Reconstructive Surgery; 1998. p. 111-6 PMID: 9655415 **exclusion reason -** not relevant.

700. Kim, Y. S., D. H. Lew, T. S. Roh, W. M. Yoo, W. J. Lee and K. C. Tark. Inferior gluteal artery perforator flap: A viable alternative for ischial pressure sores. Journal of Plastic, Reconstructive &

Aesthetic Surgery: JPRAS; 2009. p. 1347-54 PMID: 18799379 **exclusion reason -** not relevant.

701. Kimura, T. Conservative treatment of decubitus ulcers for outpatients. IRYO - Japanese Journal of National Medical Services; 1985. p. 735-738+662 **exclusion reason -** not relevant.
702. King, T., R. Gehrke and L. Vazquez. Using enhanced case management to improve wound outcomes. Sci Nursing; 2007. p. 2p **exclusion reason -** no original data.
703. Kingsley, A. and J. Murray. Esprit hr: Something safe to lie on. British Journal of Nursing; 2001. p. S63,S66 PMID: 12070401 **exclusion reason -** no original data.
704. Kinjo, M., N. Nishiyama, K. Egashira, M. Morise, S. Shimazu, H. Nemoto and A. Kakita. Local lipo prostaglandin e1 administrated therapy in the treatment of decubitus ulcer. Therapeutic Research; 1993. p. 144-147 **exclusion reason -** not relevant.
705. Kish, T. D., M. H. Chang and H. B. Fung. Treatment of skin and soft tissue infections in the elderly: A review. American Journal of Geriatric Pharmacotherapy; 2010. p. 485-513 PMID: 21356502 **exclusion reason -** Systematic Review, not directly used.
706. Klein-Meding, C. [management of chronic wounds: Continuity makes the difference]. Pflege Zeitschrift; 2003. p. 164-5 PMID: 12696333 **exclusion reason -** not relevant.
707. Kloth, L. C., J. E. Berman, S. Dumit-Minkel, C. H. Sutton, P. E. Papanek and J. Wurzel. Effects of a normothermic dressing on pressure ulcer healing. Advances in Skin & Wound Care; 2000. p. 69-74 PMID: 11074989 **exclusion reason -** wrong outcome.
708. Kloth, L. C., J. E. Berman, M. J. Nett and P. E. Papanek. Twelve week randomized trial to evaluate noncontact normothermic wound therapy on full-thickness pressure ulcers. Wound Repair and Regeneration; 2001. p. 399 **exclusion reason -** no original data.
709. Knight, A. L. Medical management of pressure sores. Journal of Family Practice; 1988. p. 95-100 PMID: 3292696 **exclusion reason -** background.
710. Knowles, C. and I. Horsey. Clinical evaluation of an electronic pressure-relieving mattress. British Journal of Nursing; 1999. p. 1392-5 PMID: 10887824 **exclusion reason -** no original data.
711. Knudsen, A. M. and S. Gallagher. Care of the obese patient with pressure ulcers. Journal of Wound, Ostomy, & Continence Nursing; 2003. p. 111-8 PMID: 12658239 **exclusion reason -** not relevant.
712. Knudsen, C. W. and K. A. Tonseth. Pressure ulcers--prophylaxis and treatment. Tidsskrift for Den Norske Laegeforening; 2011. p. 464-7 PMID: 21383799 **exclusion reason -** background.
713. Kohr, R. Moist healing versus wet-to-dry. Canadian Nurse; 2001. p. 17-9 PMID: 11865493 **exclusion reason -** no original data.
714. Kolnaar, B. G. and V. G. Chel. [summary of 'decubitus' guideline of the dutch college of family practitioners]. Nederlands Tijdschrift voor Geneeskunde; 2000. p. 646-9 PMID: 10774291 **exclusion reason -** not relevant.
715. Konya, C., H. Sanada, J. Sugama, M. Okuwa and A. Kitagawa. Does the use of a cleanser on skin surrounding pressure ulcers in older people promote healing? Journal of Wound Care; 2005. p. 169-71 PMID: 15835228 **exclusion reason -** wrong intervention.
716. Koonin, A. J. Electro pressure regeneration therapy. Total Health; 2001. p. 42-44 **exclusion reason -** background.
717. Kordestani, S., M. Shahrezaee, M. N. Tahmasebi, H. Hajimahmodi, D. Haji Ghasemali and M. S. Abyaneh. A randomised controlled trial on the effectiveness of an advanced wound dressing used in iran. Journal of Wound Care; 2008. p. 323-7 PMID: 18705234 **exclusion reason -** wrong outcome.
718. Koshima, I., T. Moriguchi, S. Soeda, S. Kawata, S. Ohta and A. Ikeda. The gluteal perforator-based flap for repair of sacral pressure sores. Plastic & Reconstructive Surgery; 1993. p. 678-83 PMID: 8446721 **exclusion reason -** not relevant.
719. Kostur, R., A. Franek, A. Polak, J. Taradaj and Z. Szlachta. Analysis of the effects of pressure ulcer treatment using the existing electrical methods [polish]. Przeglad Flebologiczny; 2007. p. 73-80 **exclusion reason -** not relevant.
720. Krainski, M. M. Pressure ulcers and the elderly. A review of the literature, 1980-1990. Ostomy Wound Management; 1992. p. 22-37 PMID: 1622536 **exclusion reason -** Systematic Review, not directly used.
721. Krajnik, M., Z. Zylicz, I. Finlay, J. Luczak and A. A. van Sorge. Potential uses of topical opioids in palliative care--report of 6 cases. Pain; 1999. p. 121-125 **exclusion reason -** no original data.
722. Kramer, J. D. and M. Kearney. Patient, wound, and treatment characteristics associated with healing in pressure ulcers. Advances in Skin & Wound Care; 2000. p. 17-24 PMID: 11061706 **exclusion reason -** background.
723. Kranke, P., M. Bennett, I. Roeckl-Wiedmann and S. Debus. Hyperbaric oxygen therapy for chronic wounds. Cochrane Database of Systematic Reviews; 2004. p. CD004123 PMID: 15106239 **exclusion reason -** wrong population.
724. Krasner, D. Ahcpr clinical practice guideline number 15, treatment of pressure ulcers: A pragmatist's critique for wound care providers. Ostomy Wound Management; 1995. p. 97S-101S; discussion 102S PMID: 7669206 **exclusion reason -** background.
725. Krastins, K. Pressure ulcer treatment after femoral neck fracture surgery. 21st World Congress of Dermatology. La Rural Convention Center, Buenos Aires (Argentina); 2007 **exclusion reason -** no original data.
726. Krause, T., J. Anders and W. von Renteln-Kruse. [treatment of pressure sores: Rarely based on guidelines]. Zeitschrift fur Arztliche Fortbildung und Qualitatssicherung; 2004. p. 769-74 PMID: 15646563 **exclusion reason -** not relevant.

727. Kravitz, R. Development and implementation of a nursing skin care protocol. Journal of ET Nursing; 1993. p. 4-8 PMID: 8452919 **exclusion reason -** wrong intervention.
728. Kremer, M. and A. Berger. [plastic surgery of para-pelvic decubitus ulcers]. Chirurg; 1999. p. 726-40 PMID: 10427463 **exclusion reason -** not relevant.
729. Kristi Henzel, M., K. M. Bogie, M. Guihan and C. H. Ho. Pressure ulcer management and research priorities for patients with spinal cord injury: Consensus opinion from sci queri expert panel on pressure ulcer research implementation. Journal of Rehabilitation Research and Development; 2011. p. xi-xxxi **exclusion reason -** background.
730. Kroll, S. S. and S. Hamilton. Multiple and repetitive uses of the extended hamstring v-y myocutaneous flap. Plastic & Reconstructive Surgery; 1989. p. 296-302 PMID: 2748743 **exclusion reason -** not relevant.
731. Kroll, S. S. and L. Rosenfield. Perforator-based flaps for low posterior midline defects. Plastic & Reconstructive Surgery; 1988. p. 561-6 PMID: 3279442 **exclusion reason -** not relevant.
732. Krouskop, T. A., R. Williams, M. Krebs, I. Herszkowicz and S. Garber. Effectiveness of mattress overlays in reducing interface pressures during recumbency. Journal of Rehabilitation Research & Development; 1985. p. 7-10 PMID: 3772816 **exclusion reason -** wrong intervention.
733. Kuhn, W., N. J. Luscher, R. de Roche, S. Krupp and G. A. Zach. The neurosensory musculocutaneous tensor fasciae latae flap: Long term results. Paraplegia; 1992. p. 396-400 PMID: 1635788 **exclusion reason -** not relevant.
734. Kuipers, T., G. B. Stark and G. Spilker. [costs and long-term results of plastic surgery treatment of decubitus ulcers in paraplegic patients]. Handchirurgie, Mikrochirurgie, Plastische Chirurgie; 1995. p. 161-5 PMID: 7622133 **exclusion reason -** not relevant.
735. Kumar, R. N., G. V. Gupchup, M. A. Dodd, B. Shah, M. Iskedjian, T. R. Einarson and D. W. Raisch. Direct health care costs of 4 common skin ulcers in new mexico medicaid fee-for-service patients. Advances in Skin & Wound Care; 2004. p. 143-9 PMID: 15194976 **exclusion reason -** background.
736. Kung, L. G., N. J. Luscher and G. A. Zach. [surgical therapy of presacral decubitus ulcer. Indications and technic in 39 consecutive cases]. Handchirurgie, Mikrochirurgie, Plastische Chirurgie; 1986. p. 264-6 PMID: 3770565 **exclusion reason -** not relevant.
737. Kuntscher, M. V., D. Erdmann, L. S. Levin and G. Germann. [role of a sensory innervated plantar fillet free flap for reconstruction of sacral pressure sores in paraplegic patients. Last resort for reconstruction of sacral pressure sores in paraplegics]. Chirurg; 2003. p. 734-8 PMID: 12928794 **exclusion reason -** not relevant.
738. Kurokawa, M., G. Muneuchi and T. Kusaka. The surgical repair of dorsal pressure sores using bilateral overlapping flaps. Japanese Journal of Plastic and Reconstructive Surgery; 1999. p. 317-321 **exclusion reason -** not relevant.
739. Kuwahara, M., H. Tada, K. Mashiba, S. Yurugi, H. Iioka, K. Niitsuma and Y. Yasuda. Mortality and recurrence rate after pressure ulcer operation for elderly long-term bedridden patients. Annals of Plastic Surgery; 2005. p. 629-32 PMID: 15900149 **exclusion reason -** not relevant.
740. Labler, L. and K. Oehy. [vacuum sealing of problem wounds]. Swiss Surgery; 2002. p. 266-72 PMID: 12520846 **exclusion reason -** not relevant.
741. Lagana, G. and E. H. Anderson. Moisture dressings: The new standard in wound care. Journal for Nurse Practitioners; 2010. p. 366-370 **exclusion reason -** background.
742. Lagarde, I. and S. Taurand. [hydrocolloid dressings. Treatment of decubitus ulcers]. Soins; 1996. p. 17-20 PMID: 8954494 **exclusion reason -** not relevant.
743. Lagden, K. and E. Attrell. Evaluation of a hydrofibre dressing in calgary home care wound clinics. CAET Journal; 2000. p. 12-13 **exclusion reason -** not relevant.
744. Laing, T. A., N. Ekpete, S. Oon and S. M. Carroll. Surgical reconstruction of pressure ulcer defects: A single- or two-stage procedure? Journal of Wound, Ostomy, & Continence Nursing; 2010. p. 615-8 PMID: 21052028 **exclusion reason -** wrong intervention.
745. Lanaia, C., M. Novara, G. Campo, A. Micale, P. F. Veroux, A. Turrisi and F. Lanaia. Comfeel wound dressing in the treatment of decubitus ulcer. Acta Chirurgica Italica; 1989. p. 469-477 **exclusion reason -** not relevant.
746. Landi, F., G. Onder, A. Russo and R. Bernabei. Pressure ulcer and mortality in frail elderly people living in community. Archives of Gerontology & Geriatrics; 2007. p. 217-23 PMID: 17317456 **exclusion reason -** background.
747. Landsman, A. S. [commentary on] becaplermin gel in the treatment of pressure ulcers: A phase ii randomized, double-blind, placebo-controlled study [original article by rees rs et al appears in wound rep reg 1999;7(3):141-147]. Foot & Ankle Quarterly--The Seminar Journal; 2000. p. 101 **exclusion reason -** no original data.
748. Langemo, D. Npuap best practices for pressure ulcer care: Abstracts of presentations. Ostomy Wound Management; 2007. p. 24-28 **exclusion reason -** background.
749. Langemo, D., J. Anderson, D. Hanson, S. Hunter, P. Thompson and M. E. Posthauer. Nutritional considerations in wound care. Advances in Skin & Wound Care; 2006. p. 297-8, 300, 303 PMID: 16885642 **exclusion reason -** background.
750. Langemo, D. and S. Baranoski. Key points on caring for pressure ulcers in home care. Home Healthcare Nurse; 2003. p. 309-15 PMID: 12792412 **exclusion reason -** background.
751. Langemo, D., J. M. Black, J. Maklebust and M. E. Posthauer. The npuap: Look who else is turning 20!

Advances in Skin & Wound Care; 2007. p. 84, 88-9 PMID: 17287618 **exclusion reason -** background.
752. Langemo, D., J. Cuddigan, M. Baharestani, C. R. Ratliff, M. E. Posthauer, J. Black and S. Garber. Pressure ulcer guidelines: "Minding the gaps" when developing new guidelines. Advances in Skin & Wound Care; 2008. p. 213-7 PMID: 18453847 **exclusion reason -** background.
753. Langemo, D., P. Thompson, D. Hanson, J. Anderson and S. Hunter. Topical anesthesia for pressure ulcer treatment. Advances in Skin & Wound Care; 2008. p. 364-9 PMID: 18679084 **exclusion reason -** no original data.
754. Langemo, D. K. When the goal is palliative care. Advances in Skin & Wound Care; 2006. p. 148-54 PMID: 16639221 **exclusion reason -** background.
755. Langemo, D. K., J. Black and P. National Pressure Ulcer Advisory. Pressure ulcers in individuals receiving palliative care: A national pressure ulcer advisory panel white paper. Advances in Skin & Wound Care; 2010. p. 59-72 PMID: 20087072 **exclusion reason -** background.
756. Langemo, D. K. and G. Brown. Skin fails too: Acute, chronic, and end-stage skin failure. Advances in Skin & Wound Care; 2006. p. 206-11 PMID: 16641567 **exclusion reason -** background.
757. Langer, C. [decubitus prevention and therapy]. Krankenpflege Journal; 1985. p. 12-3 PMID: 3847660 **exclusion reason -** not relevant.
758. Langer, G., G. Schloemer, A. Knerr, O. Kuss and J. Behrens. Nutritional interventions for preventing and treating pressure ulcers. Cochrane Database of Systematic Reviews; 2003. p. CD003216 PMID: 14583961 **exclusion reason -** Systematic Review, not directly used.
759. Langer, G. and G. Schlomer. [nutrition as intervention in prevention and treatment of decubitus ulcer: Outcomes research]. Pflege Zeitschrift; 2005. p. 368-73 PMID: 16013289 **exclusion reason -** not relevant.
760. Langer, S. W. [testing the efficacy of a material for the relief of pressure in the prevention and treatment of decubitus ulcers]. Krankenpflege Journal; 1996. p. 263-5 PMID: 8717867 **exclusion reason -** not relevant.
761. Lapsley, H. M. and R. Vogels. Cost and prevention of pressure ulcers in an acute teaching hospital. International Journal for Quality in Health Care; 1996. p. 61-6 PMID: 8680818 **exclusion reason -** background.
762. Lari, A. R. and N. Rajacic. One-stage repair of multiple bed sores. British Journal of Plastic Surgery; 1992. p. 540-3 PMID: 1446200 **exclusion reason -** not relevant.
763. Larichev, A. B., A. V. Antoniuk and V. S. Kuz'min. [vacuum-therapy in treatment of festering wounds]. Khirurgiia; 2008. p. 22-6 PMID: 18577940 **exclusion reason -** not relevant.
764. Larson, D. L., K. A. Hudak, W. P. Waring, M. R. Orr and K. Simonelic. Protocol management of late-stage pressure ulcers: A 5-year retrospective study of 101 consecutive patients with 179 ulcers. Plastic & Reconstructive Surgery; 2012. p. 897-904 PMID: 22183500 **exclusion reason -** not relevant.
765. Laudanska, H. and B. Gustavson. In-patient treatment of chronic varicose venous ulcers. A randomized trial of cadexomer iodine versus standard dressings. Journal of International Medical Research; 1988. p. 428-435 **exclusion reason -** wrong population.
766. Lauterbach, S. and A. Pfeiffer. Decubitus: Affliction and relief. Pharmazeutische Zeitung; 2010 **exclusion reason -** not relevant.
767. Laverre, L. [nurse consultant for decubitus ulcers]. Revue de L'Infirmiere; 1990. p. 23-4 PMID: 2091215 **exclusion reason -** not relevant.
768. Lavrinec, P., R. P. Mikus, A. M. Zajec and J. Lavrinec. Nutritional support in patients with chronic wounds and pressure ulcers [slovene]. Obzornik Zdravstvene Nege; 2007. p. 111-124 **exclusion reason -** Systematic Review, not directly used.
769. Lawton, R. L. and V. De Pinto. Bilateral hip disarticulation in paraplegics with decubitus ulcers. Archives of Surgery; 1987. p. 1040-3 PMID: 3619617 **exclusion reason -** not relevant.
770. Lazar, C. C., I. Auquit-Auckbur and P. Y. Milliez. [the total thigh flap in reconstructive surgery]. Annales de Chirurgie Plastique et Esthetique; 2007. p. 144-7 PMID: 17137699 **exclusion reason -** background.
771. Lazovic, G. The surgical treatment of decubitus ulcers in sacral and trochanteric area. 6th Congress of the Balkan Association for Plastic, Reconstructive Aesthetic Surgery. Hotel Gorica, Ohrid; 2009 **exclusion reason -** no original data.
772. Le Chapelain, L., J. P. Fyad, J. M. Beis, M. O. Thisse and J. M. Andre. [early surgery management of pelvic region pressure ulcers versus directed cicatrization in a population of spinal cord injured patients]. Annales de Readaptation et de Medecine Physique; 2001. p. 608-12 PMID: 11788121 **exclusion reason -** not relevant.
773. Leaper, D. Evidence-based wound care in the uk. International Wound Journal; 2009. p. 89-91 **exclusion reason -** background.
774. Lechner, J. L., S. Ksiazekl, J. Chang, S. L. Rozek and J. M. Smith. Carrington dermal wound gel versus current treatments for the healing of decubitus ulcers and other dermal wounds. ASHP Midyear Clinical Meeting; 1991. p. P-294E **exclusion reason -** unable to find.
775. Lee, E.-T. A new wound closure achieving and maintaining device using serial tightening of loop suture and its clinical applications in 15 consecutive patients for up to 102 days. Annals of Plastic Surgery; 2004. p. 436-41 PMID: 15502458 **exclusion reason -** not relevant.
776. Lee, H. B., S. W. Kim, D. H. Lew and K. S. Shin. Unilateral multilayered musculocutaneous v-y advancement flap for the treatment of pressure sore. Plastic & Reconstructive Surgery; 1997. p. 340-5; discussion 346-9 PMID: 9252600 **exclusion reason -** not relevant.

777. Lee, H. J., J. K. Pyon, S. Y. Lim, G. H. Mun, S. I. Bang and K. S. Oh. Perforator-based bilobed flaps in patients with a sacral sore: Application of a schematic design. Journal of Plastic, Reconstructive and Aesthetic Surgery; 2011. p. 790-795 PMID: 21144809 **exclusion reason -** not relevant.
778. Lee, J. T., L. F. Cheng, C. M. Lin, C. H. Wang, C. C. Huang and S. H. Chien. A new technique of transferring island pedicled anterolateral thigh and vastus lateralis myocutaneous flaps for reconstruction of recurrent ischial pressure sores. Journal of Plastic, Reconstructive and Aesthetic Surgery; 2007. p. 1060-1066 PMID: 17493884 **exclusion reason -** not relevant.
779. Lee, J. T., H. T. Hsiao, K. Y. Tung and S. Y. Ou. Gluteal perforator flaps for coverage of pressure sores at various locations [9]. Plastic and Reconstructive Surgery; 2006. p. 2507-2508 PMID: 16772972 **exclusion reason -** no original data.
780. Lee, K. The experience of applying silver-containing hydrofiber dressing on refractory problem wounds. World Council of Enterostomal Therapists Journal; 2009. p. 29-29 **exclusion reason -** not relevant.
781. Lee, M. S., S. R. Seo and J. C. Kim. A (beta)-cyclodextrin, polyethyleneimine and silk fibroin hydrogel containing centella asiatica extract and hydrocortisone acetate: Releasing properties and in vivo efficacy for healing of pressure sores. Clinical and Experimental Dermatology; 2012 **exclusion reason -** wrong population.
782. Lee, S. K. The role of nutrition in treating and healing wounds. Nursing Homes: Long Term Care Management; 2006. p. 26-30 **exclusion reason -** background.
783. Lee, S. K. Healing chronic wounds in long-term care: New technologies to get the job done. Director; 2007. p. 19-23 PMID: 19343863 **exclusion reason -** background.
784. Lee, S.-S., S.-H. Huang, M.-C. Chen, K.-P. Chang, C.-S. Lai and S.-D. Lin. Management of recurrent ischial pressure sore with gracilis muscle flap and v-y profunda femoris artery perforator-based flap. Journal of Plastic, Reconstructive & Aesthetic Surgery: JPRAS; 2009. p. 1339-46 PMID: 18595789 **exclusion reason -** not relevant.
785. Lefemine, V., S. Enoch and D. E. Boyce. Surgical and reconstructive management of pressure ulcers. European Journal of Plastic Surgery; 2009. p. 63-75 **exclusion reason -** background.
786. Legassic, M., D. Keast, D. Wolfe and R. Petrella. Feasibility of an internet clinic for treating and preventing pressure ulcers in persons with spinal cord injury. **exclusion reason -** background.
787. Leigh, I. H. and G. Bennett. Pressure ulcers: Prevalence, etiology, and treatment modalities. A review. American Journal of Surgery; 1994. p. 25S-30S PMID: 8109681 **exclusion reason -** background.
788. Leininger, S. M. The role of nutrition in wound healing. Critical Care Nursing Quarterly; 2002. p. 13-21 **exclusion reason -** background.
789. Lemaire, V., K. Boulanger and O. Heymans. Free flaps for pressure sore coverage. Annals of Plastic Surgery; 2008. p. 631-4 PMID: 18520197 **exclusion reason -** not relevant.
790. LeMaster, K. M. 5 million lives campaign. Reducing incidence and prevalence of hospital-acquired pressure ulcers at genesis medical center. Joint Commission Journal on Quality & Patient Safety; 2007. p. 611-616 **exclusion reason -** background.
791. Leow, M., J. Lim and T. C. Lim. The superior gluteal artery perforator flap for the closure of sacral sores. Singapore Medical Journal; 2004. p. 37-9 PMID: 14976580 **exclusion reason -** not relevant.
792. Lepisto, M., S. Lauri, E. Eriksson and T. Vahlberg. Pressure ulcer patients in long-term care. A follow-up study. Reviews in Clinical Gerontology; 2004. p. 91-103 **exclusion reason -** wrong outcome.
793. Lermusiaux, P., P. Oxeda and G. Lagrave. The surgical treatment of pressure sores in paraplegic patients. Seventy-five cases. Annales de Chirurgie Plastique et Esthetique; 1985. p. 166-170 **exclusion reason -** not relevant.
794. Lesavoy, M. A., T. J. Dubrow, H. N. Korn, M. G. Cedars and D. J. Castro. "Sensible" flap coverage of pressure sores in patients with meningomyelocele. Plastic & Reconstructive Surgery; 1990. p. 390-4; discussion 395-6 PMID: 2304990 **exclusion reason -** background.
795. Lesourd, B. Oral dietary supplements and aged patients. Nutrition Clinique et Metabolisme; 1997. p. 55-60 **exclusion reason -** background.
796. Lessan-Salmassi, D. Treatment of chronic decubital ulcers with fascio-cutaneous and cutaneous flaps in paraplegic patients. Unfallchirurg; 1989. p. 358-362 PMID: 2762823 **exclusion reason -** not relevant.
797. Levine, J. M. Pressure ulcer intervention goes far beyond physiological aspects of care. Caring for the Ages; 2007. p. 21-21 **exclusion reason -** background.
798. Levine, J. M. Historical perspective: The impact of plaster-of-paris splints on pressure ulcer occurrence in world war ii. Advances in Skin & Wound Care; 2008. p. 526-8 PMID: 18981756 **exclusion reason -** background.
799. Levine, J. M. and S. Lebovits. Pearls for practice. Optimizing pressure ulcer care: A checklist for system change. Ostomy Wound Management; 2009. p. 6-6 **exclusion reason -** background.
800. Levine, J. M., M. Peterson and F. Savino. Focus on: Pressure relief & wound care. Implementing the new cms guidelines for wound care. Nursing Homes: Long Term Care Management; 2005. p. 110 **exclusion reason -** background.
801. Levine, J. M. and E. Totolos. Pressure ulcers: A strategic plan to prevent and heal them. Geriatrics; 1995. p. 32-37; quiz 38-9 PMID: 7821827 **exclusion reason -** background.
802. Lewandowicz, E., H. Witmanowski and D. Sobieszek. Selection of surgical technique in treatment of pressure sores. Postepy Dermatologii i Alergologii; 2011. p. 23-29 **exclusion reason -** not relevant.

803. Li, Y.-l., H.-t. Xiao, Q. Qi, Z.-p. Zhou, H. Oka and T. Moriguchi. [clinical efficacy of artery perforator-based flap in the repair of gluteal-sacral pressure sores]. Zhonghua Shao Shang Za Zhi; 2007. p. 32-5 PMID: 17605251 **exclusion reason -** not relevant.
804. Li, Z. Y., Y. Cen, M. J. Gu, H. S. Wang and Y. J. Wang. Rotating muscle flap in the treatment of refractory bedsore at sacrococcygeal region. Journal of Clinical Rehabilitative Tissue Engineering Research; 2007. p. 10376-10377 **exclusion reason -** not relevant.
805. Liddle, B. J. Reporting deaths to the coroner. Pressure sores underreported. BMJ; 1993. p. 1540 PMID: 8518695 **exclusion reason -** background.
806. Lidman, D., A. C. Ek, A. G. Dahllof, J. Eldh, B. Palmer and C. Hultling. [bedsores--etiology, prevention and treatment]. Lakartidningen; 1989. p. 3880-2 PMID: 2811536 **exclusion reason -** not relevant.
807. Lidowski, H. Namp: A system for preventing and managing pressure ulcers. Decubitus; 1988. p. 28-37 PMID: 3254236 **exclusion reason -** no original data.
808. Lievens, P. C. and A. L. Delforge. Efficiency of infrared laser treatment examined in the healing of bedsores. Clinical Laser Monthly; 1992. p. 159-60 PMID: 10148275 **exclusion reason -** no original data.
809. Lile, J. L., M. N. Pase, R. G. Hoffman and M. K. Mace. The neuman systems model as applied to the terminally ill client with pressure ulcers. Advances in Wound Care; 1994. p. 44-8 PMID: 7827747 **exclusion reason -** background.
810. Lim, R., R. Sirett, T. A. Conine and D. Daechsel. Clinical trial of foam cushions in the prevention of decubitis ulcers in elderly patients. Journal of Rehabilitation Research & Development; 1988. p. 19-26 **exclusion reason -** wrong population.
811. Lima, A. C. B. and D. M. Guerra. [evaluation of the cost of treating pressure ulcers in hospitalized patients using industrialized dressings]. Ciencia & Saude Coletiva; 2011. p. 267-77 PMID: 21180834 **exclusion reason -** not relevant.
812. Lin, H., C. Hou, A. Chen and Z. Xu. Treatment of ischial pressure sores using a modified gracilis myofasciocutaneous flap. Journal of Reconstructive Microsurgery; 2010. p. 153-7 PMID: 19902407 **exclusion reason -** not relevant.
813. Lin, H., C. Hou, A. Chen and Z. Xu. Long-term outcome of using posterior-thigh fasciocutaneous flaps for the treatment of ischial pressure sores. Journal of Reconstructive Microsurgery; 2010. p. 355-8 PMID: 20183787 **exclusion reason -** not relevant.
814. Lin, H., C. Hou, Z. Xu and A. Chen. Treatment of ischial pressure sores with double adipofascial turnover flaps. Annals of Plastic Surgery; 2010. p. 59-61 PMID: 19801917 **exclusion reason -** not relevant.
815. Lin, J. Y. and X. H. Wu. [the effect of bactroban cream for treating bedsores]. Contemporary Nurse. Issue; 1997. p. 38-38 **exclusion reason -** not relevant.
816. Lin, M.-T., K.-P. Chang, S.-D. Lin, C.-S. Lai and Y.-L. Yang. Tensor fasciae latae combined with tangentially split vastus lateralis musculocutaneous flap for the reconstruction of pressure sores. Annals of Plastic Surgery; 2004. p. 343-7 PMID: 15385768 **exclusion reason -** not relevant.
817. Linder, R. M. and D. Morris. The surgical management of pressure ulcers: A systematic approach based on staging.[erratum appears in decubitus 1990 aug;3(3):8]. Decubitus; 1990. p. 32-8 PMID: 2357277 **exclusion reason -** background.
818. Lindholm, C., A. Bergsten and E. Berglund. Chronic wounds and nursing care. Journal of Wound Care; 1999. p. 5-10 **exclusion reason -** not relevant.
819. Lipschitz, D. A. Approaches to the nutritional support of the older patient. Clinics in Geriatric Medicine; 1995. p. 715-24 PMID: 8556696 **exclusion reason -** background.
820. Lisito, P., B. Rousson and J. Hocquart. Surgical treatment of pelvic pressure ulcers. Annales de Readaptation et de Medecine Physique; 1986. p. 385-393 **exclusion reason -** not relevant.
821. Liu, G. Progress on prevention and treatment of patients with bed sore [chinese]. Chinese Nursing Research; 2005. p. 2082-2084 **exclusion reason -** background.
822. Liu, Y. Clinical effect on yousuo mixed solution to treat decubitus ulcer [chinese]. Shanxi Nursing Journal; 1999. p. 174-175 **exclusion reason -** not relevant.
823. Liu, Y., Q. Q. Chen and C. L. Hou. Treatment of decubitus ulcers in sacrum region with fasciocutaneous flaps. Chinese Journal of Clinical Rehabilitation; 2002. p. 834+845 **exclusion reason -** not relevant.
824. Liu, Y., X. Zhang and C. Zhang. [clinical typing and surgical principle of pressure sore]. Chung-Kuo Hsiu Fu Chung Chien Wai Ko Tsa Chih/Chinese Journal of Reparative & Reconstructive Surgery; 2007. p. 932-6 PMID: 17933225 **exclusion reason -** not relevant.
825. Livesley, N. J. and A. W. Chow. Infected pressure ulcers in elderly individuals. Clinical Infectious Diseases; 2002. p. 1390-6 PMID: 12439803 **exclusion reason -** background.
826. Livne, M. and M. Steinmann. Pressure ulcer prevention project: An international outcomes report from israel. Outcomes Management; 2002. p. 99-102 PMID: 12134380 **exclusion reason -** background.
827. Ljungberg, S. Comparison of dextranomer paste and saline dressings for management of decubital ulcers. Clinical Therapeutics; 1998. p. 737-43 PMID: 9737833 **exclusion reason -** wrong outcome.
828. Llagostera Pages, M. [care of the skin.]. Atencion Primaria; 2006. p. 65-71 PMID: 17286938 **exclusion reason -** background.
829. Llanos, S., W. Calderon, S. Searle and M. Quintas. Improvement of the bipedicled fascial flap with a cutaneous v and y island for coverage of the heel. Plastic & Reconstructive Surgery; 2006. p. 297-8 PMID: 16816744 **exclusion reason -** no original data.
830. Lloyd-Jones, M. The role of eclypse adherent sacralâ® in managing sacral pressure ulcers. British

Journal of Community Nursing; 2011. p. S38-42 **exclusion reason -** not relevant.
831. Loehne, H. B. A trial of a heel pressure relieving device proves efficacious in a long term care facility, addressing complete heel suspension 24/7 with patient comfort, leading to use throughout the continuum of care... 39th annual wound, ostomy and continence nurses annual conference. Journal of Wound, Ostomy & Continence Nursing; 2007. p. S45-S45 **exclusion reason -** no original data.
832. Loehner, D. Why use a film dressing? Advances in Wound Care; 1995. p. 6 **exclusion reason -** background.
833. Lokhvitskii, S. V. and N. V. Klimova. [the diagnosis and treatment of chronic osteomyelitis in patients with spinal cord trauma]. Vestnik Khirurgii Imeni i - i - Grekova; 1996. p. 60-2 PMID: 8753963 **exclusion reason -** not relevant.
834. Lomas, C. Pct leads by example on community 'never events'. Nursing Times; 2010. p. 1 PMID: 20608436 **exclusion reason -** background.
835. Lontoft, E. and H. Kjeldsen. [long-term results after surgical treatment of pressure sores]. Ugeskrift for Laeger; 1986. p. 1148-9 PMID: 12187948 **exclusion reason -** not relevant.
836. Lopez Rodriguez, L., I. Garrido Diaz, J. Seda Diestro, A. Rodriguez Hurtado and I. Fernandez Cordon. [what to do when there is no evidence]. Revista de Enfermeria; 2007. p. 58-61 PMID: 17380636 **exclusion reason -** background.
837. Lopez, T. C., U. F. Porta, M. D. R. Antunez and M. J. N. Nadal. [the best introduced measures for the prevention and treatment of pressure sores in corporacion sanitaria clinic of barcelona]. Revista de Enfermeria; 2008. p. 34-5 PMID: 18564785 **exclusion reason -** background.
838. Lowthian, P. Pegasus airwave and bi-wave plus. British Journal of Nursing; 1995. p. 1020, 1022-4 PMID: 7580086 **exclusion reason -** background.
839. Lowthian, P. 'Last-resort' dressings for intractable pressures sores. British Journal of Nursing; 1995. p. 1183-4, 1186, 1188-9 PMID: 8696085 **exclusion reason -** background.
840. Lowthian, P. The egerton convertible ii and the elite 3 bed system. British Journal of Nursing; 1996. p. 118, 120-3 PMID: 8680245 **exclusion reason -** background.
841. Lu, C. X. [use of a dufourmentel flap in repairing lumbosacral bed sore (a report of 7 cases)]. Chung-Hua Cheng Hsing Shao Shang Wai Ko Tsa Chih - Chinese Journal of Plastic Surgery & Burns; 1989. p. 197-8, 238 PMID: 2514027 **exclusion reason -** not relevant.
842. Lubin, B. S. and T. Powell. Pressure sores and specialty beds: Cost containment and ensurance of quality care. Journal of ET Nursing; 1991. p. 190-7 PMID: 1954298 **exclusion reason -** background.
843. Lucas, C., R. W. Stanborough, C. L. Freeman and R. J. De Haan. Efficacy of low-level laser therapy on wound healing in human subjects: A systematic review. Lasers in Medical Science; 2000. p. 84-93 **exclusion reason -** Systematic Review, not directly used.
844. Lucich, S. and J. Haan. Ankle foot orthoses in prevention and treatment of heel pressure ulcers: A physical therapy perspective. 2008 **exclusion reason -** no original data.
845. Lucke, K. and C. Jarlsberg. How is the air-fluidized bed best used? American Journal of Nursing; 1985. p. 1338, 1340 PMID: 3852639 **exclusion reason -** background.
846. Lukanc, C., E. Kramer, R. B. King, T. V. Carle and G. M. Yarkony. Duoderm super(tm): A new treatment for pressure sores. **exclusion reason -** unable to find.
847. Lum, C., W. Cheung, P. M. Chow, J. Woo, E. Hui and K. H. Or. Use of a hydrogel in pressure sore management: A randomized, controlled clinical trial. Proceedings of the 5th European Conference on Advances in Wound Management; 1995 **exclusion reason -** no original data.
848. Luscher, N. J. [decubitus ulcers of the pelvic area. Diagnosis and surgical therapy]. Aktuelle Probleme in Chirurgie und Orthopadie; 1989. p. 3-152 PMID: 2567125 **exclusion reason -** not relevant.
849. Luscher, N. J. [value of surgical treatment of decubitus ulcer in geriatric patients]. Therapeutische Umschau; 1991. p. 341-6 PMID: 1871689 **exclusion reason -** not relevant.
850. Luscher, N. J., R. de Roche, S. Krupp, W. Kuhn and G. A. Zach. The sensory tensor fasciae latae flap: A 9-year follow-up. Annals of Plastic Surgery; 1991. p. 306-10; discussion 311 PMID: 1872535 **exclusion reason -** not relevant.
851. Luscher, N. J., W. Kuhn and G. A. Zach. Rhomboid flaps in surgery for decubital ulcers: Indications and results. Annals of Plastic Surgery; 1986. p. 415-21 PMID: 3273059 **exclusion reason -** not relevant.
852. Lyder, C. and L. van Rijswijk. Pressure ulcer prevention and care: Preventing and managing pressure ulcers in long-term care: An overview of the revised federal regulation. Ostomy Wound Management; 2005. p. 2-6 PMID: 16089049 **exclusion reason -** background.
853. Lyder, C. A. E. Chapter 12. Pressure ulcers: A patient safety issues. In: Hughes rg, editor. Patient safety and quality: An evidence-based handbook for nurses. In: P. H. S. Agency for Health Care Policy and Research, U.S. Department of Health and Human Services, editor Rockville, MD; 2008 **exclusion reason -** background.
854. Lyder, C. H. Conceptualization of the stage 1 pressure ulcer. Journal of ET Nursing; 1991. p. 162-5 PMID: 1892947 **exclusion reason -** background.
855. Lyder, C. H. Examining the inclusion of ethnic minorities in pressure ulcer prediction studies. Journal of Wound, Ostomy, & Continence Nursing; 1996. p. 257-60 PMID: 9043271 **exclusion reason -** background.
856. Lyder, C. H. Pressure ulcer prevention and management. Annual Review of Nursing Research;

2002. p. 35-61 PMID: 12092517 **exclusion reason -** Systematic Review, not directly used.
857. Lyder, C. H. Pressure ulcer prevention and management. JAMA; 2003. p. 223-6 PMID: 12517234 **exclusion reason -** background.
858. Lyder, C. H. Is pressure ulcer care evidence based or evidence linked? Journal of Wound Care; 2005. p. 2-3 **exclusion reason -** background.
859. Lyder, C. H. Implications of pressure ulcers and its relation to federal tag 314. Annals of Long Term Care; 2006. p. 19-24 **exclusion reason -** background.
860. Lyder, C. H. Effective management of pressure ulcers. A review of proven strategies. Advance for Nurse Practitioners; 2006. p. 32-7; quiz 38 PMID: 16977895 **exclusion reason -** wrong population.
861. Lyder, C. H. and E. A. Ayello. Annual checkup: The cms pressure ulcer present-on-admission indicator. Advances in Skin & Wound Care; 2009. p. 476-84 PMID: 20026923 **exclusion reason -** background.
862. Lyder, C. H., O. Empleo-Frazier and D. McGee. Evaluating the clinical and economic outcomes of implementing a standardized algorithm to heal stage ii pressure ulcers. Fourth Australian Wound Management Association Conference; 2002 **exclusion reason -** no original data.
863. Lydon, P. The local treatment of pressure sores. Irish Medical Journal; 1994. p. 72-3 PMID: 8056542 **exclusion reason -** no original data.
864. Lyons, Y. J. Wound care--monitoring practice. Nursing Times; 1994. p. 69-78 PMID: 8177778 **exclusion reason -** background.
865. Macario, A. Economic evaluation of noncontact normothermic wound therapy for treatment of pressure ulcers. Expert Review of Pharmacoeconomics & Outcomes Research; 2002. p. 211-7 PMID: 19807413 **exclusion reason -** wrong outcome.
866. Macario, A. and F. Dexter. Is noncontact normothermic wound therapy cost effective for the treatment of stages 3 and 4 pressure ulcers? Wounds: A Compendium of Clinical Research & Practice; 2002. p. 93-106 **exclusion reason -** wrong outcome.
867. Mackey, D. Support surfaces: Beds, mattresses, overlays-oh my! Nursing Clinics of North America; 2005. p. 251-65 PMID: 15924893 **exclusion reason -** background.
868. Maehata, Y., H. Matsuda, Y. Miyajima and M. Takasaki. Experience in use of solcoseryl ointment in elderly patients suffering from decubitus. Japanese Pharmacology and Therapeutics; 1999. p. 99-105 **exclusion reason -** not relevant.
869. Maeshige, N., H. Terashi, M. Aoyama, K. Torii, M. Sugimoto and M. Usami. Effect of ultrasound irradiation on alpha-sma and tgf-beta1 expression in human dermal fibroblasts. Kobe Journal of Medical Sciences; 2011. p. E242-52 PMID: 21937873 **exclusion reason -** wrong intervention.
870. Maguina, P. and R. Kalimuthu. Posterior rectal hernia after vacuum-assisted closure treatment of sacral pressure ulcer. Plastic & Reconstructive Surgery; 2008. p. 46e-47e PMID: 18594380 **exclusion reason -** not relevant.
871. Maida, V., M. Ennis and J. Corban. Wound outcomes in patients with advanced illness. International Wound Journal; 2012 **exclusion reason -** wrong population.
872. Maklebust, J. Treating pressure ulcers in the home. Home Healthcare Nurse; 1999. p. 307-15; quiz 316 PMID: 10562004 **exclusion reason -** background.
873. Maklebust, J. An update on horizontal patient support surfaces. Ostomy Wound Management; 1999. p. 70S-77S; quiz 78S-79S PMID: 10085977 **exclusion reason -** background.
874. Maklebust, J. A., L. Mondoux and M. Sieggreen. Pressure relief characteristics of various support surfaces used in prevention and treatment of pressure ulcers. Journal of Enterostomal Therapy; 1986. p. 85-9 PMID: 3635540 **exclusion reason -** wrong population.
875. Malm, M. and T. Lundeberg. Effect of low power gallium arsenide laser on healing of venous ulcers. Scandinavian Journal of Plastic & Reconstructive Surgery & Hand Surgery; 1991. p. 249-251 **exclusion reason -** wrong population.
876. Mandal, A. Role of topical negative pressure in pressure ulcer management. Journal of Wound Care; 2007. p. 33-5 PMID: 17334144 **exclusion reason -** background.
877. Mandracchia, V. J., S. M. Sanders and J. A. Frerichs. The use of becaplermin (rhpdgf-bb) gel for chronic nonhealing ulcers. A retrospective analysis. Clinics in Podiatric Medicine & Surgery; 2001. p. 189-209, viii PMID: 11344978 **exclusion reason -** no original data.
878. Mandrekas, A. D. and D. P. Mastorakos. The management of decubitus ulcers by musculocutaneous flaps: A five-year experience. Annals of Plastic Surgery; 1992. p. 167-74 PMID: 1567119 **exclusion reason -** not relevant.
879. Manesh, A. O., K. Flemming, N. A. Cullum and H. Ravaghi. Electromagnetic therapy for treating pressure ulcers. Cochrane Database of Systematic Reviews; 2009 **exclusion reason -** Systematic Review, not directly used.
880. Manzanero-Lopez E, P.-L. B. Evaluation of a new dressing in the management of pressure sores. 2nd World Union of Wound Healing Societies Meeting; 2004 **exclusion reason -** no original data.
881. Mao, C. L., A. J. Rivet, T. Sidora and M. T. Pasko. Update on pressure ulcer management and deep tissue injury. Annals of Pharmacotherapy; 2010. p. 325-32 PMID: 20118142 **exclusion reason -** background.
882. Marchina, M. D. and G. Renzi. A new antiseptic preparation used for the disinfection of cutaneous distrophic ulcers. Chronica Dermatologica; 1997. p. 873-885 **exclusion reason -** wrong intervention.
883. Margara, A., G. Merlino, F. Bergamin, M. Borsetti and G. Borsetti. Surgical treatment of pressure sores: Experience in 333 cases. Chirurgia; 2002. p. 143-145 **exclusion reason -** not relevant.
884. Margara, A., G. Merlino, M. Borsetti, F. Bergamin and G. Borsetti. A proposed protocol for the

surgical treatment of pressure sores based on a study of 337 cases. European Journal of Plastic Surgery; 2003. p. 57-61 **exclusion reason -** wrong intervention.
885. Margolis, D. J. Utility of direct current in decubitus ulcers. Archives of Dermatology; 1994. p. 660-1 PMID: 8179350 **exclusion reason -** no original data.
886. Margolis, D. J. and V. L. Lewis. A literature assessment of the use of miscellaneous topical agents, growth factors, and skin equivalents for the treatment of pressure ulcers. Dermatologic Surgery; 1995. p. 145-8 PMID: 7894932 **exclusion reason -** Systematic Review, not directly used.
887. Marinho, A. d. M. [drug combinations in the care of bed sores]. Revista Brasileira de Enfermagem; 1997. p. 257-74 PMID: 9775937 **exclusion reason -** not relevant.
888. Martin, S. J., O. J. Corrado and E. A. Kay. Enzymatic debridement for necrotic wounds. Journal of Wound Care; 1996. p. 310-1 PMID: 8954418 **exclusion reason -** wrong outcome.
889. Martinez Cuervo, F. and E. Pateras Galofre. The effectiveness of hyperoxygenated fatty acids in the care of skin perilesional, the prevention of the pressure ulcers, vascular ulcers and diabetic foot. Gerokomos; 2009. p. 41-46 **exclusion reason -** background.
890. Martinez Cuervo, F., T. Segovia Gomez, F. Alonso Perez, J. Verdu Soriano, J. De Con Redondo and T. Lahuerta Garcia. [evaluation of the clinical effectiveness of the dressing permafoam for the treatment of chronic ulcers]. Revista de Enfermeria; 2005. p. 29-34 PMID: 16060325 **exclusion reason -** not relevant.
891. Masanovic, M. G., C. Roques, S. Meaume and J.-M. Rochet. [supports to help the prevention and treatment of sores]. Soins; La Revue de Reference Infirmiere; 2009. p. 40-3 PMID: 19306559 **exclusion reason -** not relevant.
892. Maslauskas, K., D. Samsanavicius, R. Rimdeika and V. Kaikaris. Surgical treatment of pressure ulcers: An 11-year experience at the department of plastic and reconstructive surgery of hospital of kaunas university of medicine. Medicina (Kaunas, Lithuania); 2009. p. 269-75 PMID: 19423957 **exclusion reason -** not relevant.
893. Masquelet, A. C., J. Y. Nordin and C. Pages. Closure of sacral and ischiatic raw areas with musculo-cutaneous flaps. Presse Medicale; 1985. p. 277-279 PMID: 3157110 **exclusion reason -** not relevant.
894. Mathewson, C., V. K. Adkins, M. A. Lenyoun, A. M. Schmidt and M. L. Jones. Using telemedicine in the treatment of pressure ulcers. Ostomy Wound Management; 1999. p. 58-62 PMID: 10687659 **exclusion reason -** background.
895. Mathiesen, J. [from times gone by--treatment of bed sores]. Tidsskriftet Sykepleien; 1997. p. 29 PMID: 9355644 **exclusion reason -** background.
896. Mathus-Vliegen, E. M. H. Nutritional status, nutrition, and pressure ulcers. Nutrition in Clinical Practice; 2001. p. 286-291 **exclusion reason -** background.
897. Matsumoto, H., Y. Oshima and M. Yoneda. Effect of compressive stress on the extracellular matrix in human fibroblasts and endothelial cells -- relation to body pressure when pressure ulcers develop [japanese]. Journal of Japan Academy of Nursing Science; 2009. p. 3-12 **exclusion reason -** background.
898. Matsumoto, H., Y. Oshima and M. Yoneda. Analysis of specific distribution of ecm degraded-product in wound surface of pressure ulcer [japanese]. Journal of Japan Academy of Nursing Science; 2009. p. 13-23 **exclusion reason -** background.
899. Matsuzaki, K. and N. Kumagai. Minimum invasive surgery for the treatment of pressure sores under local anesthesia. 3rd Congress of the World Union of Wound Healing Societies. Metro Toronto Convention Centre, Toronto, Ontario (Canada); 2008 **exclusion reason -** no original data.
900. Mattie, A. S. and B. L. Webster. Centers for medicare and medicaid services' "never events": An analysis and recommendations to hospitals. Health Care Manager; 2008. p. 338-49 PMID: 19011417 **exclusion reason -** background.
901. Mauckner, P. [the treatment of heel pressure ulcer with v.A.C. Therapy using the new v.A.C. Granufoam "heel-dressing"]. Zentralblatt fur Chirurgie; 2004. p. S104-7 PMID: 15168303 **exclusion reason -** background.
902. Mawson, A. R., F. H. Siddiqui and J. J. Biundo, Jr. Enhancing host resistance to pressure ulcers: A new approach to prevention. Preventive Medicine; 1993. p. 433-50 PMID: 8327423 **exclusion reason -** background.
903. Mayer, S. Nutritional therapy in decubitus. Journal fur Ernahrungsmedizin; 2002. p. 11-12 **exclusion reason -** not relevant.
904. McCormack, J. Double jeopardy: Answers to wound care cost questions. Materials Management in Health Care; 1996. p. 46 PMID: 10156374 **exclusion reason -** background.
905. McCowan, M. and F. Aitken. Pressure sore protocol. Journal of Wound Care; 1997. p. 248; author reply 249 PMID: 9256735 **exclusion reason -** background.
906. McCulloch, J. M. The role of physiotherapy in managing patients with wounds. Journal of Wound Care; 1998. p. 241-4 PMID: 9677994 **exclusion reason -** background.
907. McGaughey, H., S. Dhamija, L. Oliver, A. Porter-Armstrong and S. McDonough. Pulsed electromagnetic energy in management of chronic wounds: A systematic review. Physical Therapy Reviews; 2009. p. 132-146 **exclusion reason -** Systematic Review, not directly used.
908. McGinnis, E. and N. Stubbs. Pressure relieving devices for treating heel pressure ulcers. Cochrane Database of Systematic Reviews; 2009 **exclusion reason -** background.
909. McGinnis, E. and N. Stubbs. Pressure-relieving devices for treating heel pressure ulcers. Cochrane Database of Systematic Reviews; 2011 PMID: 21901698 **exclusion reason -** background.

910. McGregor, J. C. An audit of mortality in patients with pressure sores admitted to a regional plastic surgery unit over a 20-year period (1972-92). Journal of the Royal College of Surgeons of Edinburgh; 1995. p. 313-4 PMID: 8523309 **exclusion reason -** background.
911. McGregor, J. C. and M. M. Hoogbergen. Audit of pressure sores treated in a regional plastic surgery unit (1971-1990). Journal of the Royal College of Surgeons of Edinburgh; 1991. p. 399-401 PMID: 1774709 **exclusion reason -** not relevant.
912. McInnes, E., A. Jammali-Blasi, S. E. Bell-Syer, J. C. Dumville and N. Cullum. Support surfaces for pressure ulcer prevention. Cochrane Database of Systematic Reviews; 2011. p. CD001735 PMID: 21491384 **exclusion reason -** background.
913. McInnes, E. and E. National Institite for Clinical. The use of pressure-relieving devices (beds, mattresses and overlays) for the prevention of pressure ulcers in primary and secondary care. Journal of Tissue Viability; 2004. p. 4-6, 8, 10 passim PMID: 14768130 **exclusion reason -** background.
914. McLeod, A. G. Principles of alternating pressure surfaces. Advances in Wound Care; 1997. p. 30-6 PMID: 9450404 **exclusion reason -** background.
915. McMullen, D. Clinical experience with a calcium alginate dressing. Dermatology Nursing; 1991. p. 216-9, 270 PMID: 1831374 **exclusion reason -** not relevant.
916. McNees, P. Pressure ulcers and other chronic wounds in patients with and patients without cancer: A retrospective, comparative analysis of healing patterns. Ostomy Wound Management; 2007. p. 70-8 PMID: 17293631 **exclusion reason -** wrong outcome.
917. Meaume, S. A randomized controlled study to compare a sequential treatment using alginate-cmc and hydrocolloid dressing or hydrocolloid dressing alone in decubitus ulcer management. 9th European Conference on Advances in Wound Management; 1999 **exclusion reason -** no original data.
918. Meaume, S. [leg and decubitus ulcers, unreserved treatment]. Soins; La Revue de Reference Infirmiere; 2004. p. S5-7 PMID: 15384752 **exclusion reason -** not relevant.
919. Meaume, S. [9--clinical aspects: Decubitus ulcers. Local treatment of decubitus ulcers]. Soins; La Revue de Reference Infirmiere; 2004. p. 23-5 PMID: 15551634 **exclusion reason -** not relevant.
920. Meaume, S. [nursing considerations of bedsore dressings]. Revue de L'Infirmiere; 2010. p. 23-4 PMID: 20536087 **exclusion reason -** not relevant.
921. Meaume, S. and S. Bohbot. [healing of chronic wounds. Use of dressings]. Soins; La Revue de Reference Infirmiere; 1995. p. 10-4 PMID: 7716575 **exclusion reason -** not relevant.
922. Meaume, S., M. Bonnefoy, B. Guihur, C. De Montalembert, F. Remy and S. Bohbot. [decubitus ulcers in the aged. Local care and results of a randomized multicenter study]. Soins; La Revue de Reference Infirmiere; 1996. p. 40-5 PMID: 8954476 **exclusion reason -** not relevant.
923. Meaume, S., N. Faucher, O. Henry and J. Belmin. A randomised controlled study to compare a sequential treatment using alginate-cmc and hydrocolloid dressing to hydrocolloid dressing alone in decubitus ulcers management. 12th Conference of the European Wound Management Association; 2002 **exclusion reason -** no original data.
924. Meaume, S. and E. Gemmen. Cost-effectiveness of wound management in france: Pressure ulcers and venous leg ulcers. Journal of Wound Care; 2002. p. 219-24 PMID: 12096580 **exclusion reason -** background.
925. Meaume, S. and B. Guihur. [local treatments of confirmed decubitus ulcers]. Revue de L'Infirmiere; 1995. p. 30-2, 37-42 PMID: 7659937 **exclusion reason -** not relevant.
926. Meaume, S., F. Hamon-Mekki and L. Teot. [wounds and bedsores 2000]. Soins; La Revue de Reference Infirmiere; 2000. p. 1 PMID: 11040816 **exclusion reason -** background.
927. Meaume, S., J. Sayag, M. Bonnefoy, C. Brasseur, O. Drunat, G. Sebbane and et al. Calcium alginate dressing (algosteril) in the management of full-thickness pressure sores: A controlled, randomized study on elderly patients. Proceedings of the 5th European Conference on Advances in Wound Management; 1995 **exclusion reason -** no original data.
928. Meaume, S., D. Vallet, M. N. Morere and L. Teot. Evaluation of a silver-releasing hydroalginate dressing in chronic wounds with signs of local infection. Zeitschrift fur Wundheilung; 2006. p. 236-245 PMID: 16240620 **exclusion reason -** not relevant.
929. Medeiros, A. B. F., C. H. A. d. F. Lopes and M. S. B. Jorge. [analysis of prevention and treatment of the pressure ulcers proposed by nurses]. Revista Da Escola de Enfermagem Da Usp; 2009. p. 223-8 PMID: 19437876 **exclusion reason -** background.
930. Medina, A., P. G. Scott, A. Ghahary and E. E. Tredget. Pathophysiology of chronic nonhealing wounds. Journal of Burn Care & Rehabilitation; 2005. p. 306-19 PMID: 16006837 **exclusion reason -** background.
931. Meesterberends, E., R. Halfens, C. Lohrmann and R. de Wit. Pressure ulcer guideline development and dissemination in europe. Journal of Clinical Nursing; 2010. p. 1495-503 PMID: 20579194 **exclusion reason -** background.
932. Mehta, A., T. A. Baker, M. Shoup, K. Brownson, S. Amde, E. Doren, S. Shah, P. Kuo and J. Angelats. Biplanar flap reconstruction for pressure ulcers: Experience in patients with immobility from chronic spinal cord injuries. American Journal of Surgery; 2012. p. 303-6; discussion 306-7 PMID: 22364900 **exclusion reason -** not relevant.
933. Mehta, S., R. W. Teasell, B. Foulon, D. E. R. Warburton, S. Connolly, D. L. Wolfe, J. T. C. Hsieh, M. Regan, T. Lam, A. Krassioukov and B. C. Craven. Effectiveness of electrical stimulation therapy in sci: Systematic review. Journal of Spinal Cord Medicine; 2009. p. 478 **exclusion reason -** Systematic Review, not directly used.

934. Meier, K. and L. B. Nanney. Emerging new drugs for wound repair. Expert Opinion on Emerging Drugs; 2006. p. 23-37 PMID: 16503824 **exclusion reason -** background.
935. Meijers, J. M. M., J. M. G. A. Schols, P. A. Jackson, G. Langer, M. Clark and R. J. G. Halfens. Evaluation of the dissemination and implementation of a nutritional guideline for pressure ulcer care. Journal of Wound Care; 2007. p. 201-5 PMID: 17552402 **exclusion reason -** background.
936. Melo, P. G., M. C. Pedrozo, T. D. Felice, R. C. D. Mendes and W. O. Schmitz. The effect of nifedipine gel in the treatment for pressure sores. Latin American Journal of Pharmacy; 2008. p. 410-414 **exclusion reason -** not relevant.
937. Meltem, C., C. Esra, F. Hasan and D. Ali. The gluteal perforator-based flap in repair of pressure sores. British Journal of Plastic Surgery; 2004. p. 342-7 PMID: 15145738 **exclusion reason -** not relevant.
938. Mendonca, D. A., R. Papini and P. E. Price. Negative-pressure wound therapy: A snapshot of the evidence. International Wound Journal; 2006. p. 261-71 PMID: 17199762 **exclusion reason -** background.
939. Meuleneire, F. Local treatment of heel pressure ulcers with a silicone foam dressing. **exclusion reason -** no original data.
940. Michael, J. Topical use of pvp-i (betadine) preparations in patients with spinal cord injury. Drugs Under Experimental & Clinical Research; 1985. p. 107-9 PMID: 3836120 **exclusion reason -** wrong intervention.
941. Michael Rieger, U. Correspondence (letter to the editor): Treatment principles for decubitus ulcers. Deutsches Arzteblatt International; 2011. p. 354-5 PMID: 21655463 **exclusion reason -** background.
942. Miller, S. Can pimecrolimus enhance wound healing? Journal of the American Podiatric Medical Association; 2009. p. 173-4 PMID: 19299357 **exclusion reason -** not relevant.
943. Miller, T., S. Draper and M. White. Development and implementation of an evidenced-based pressure ulcer reduction program in a multi-center health care facility in canada. **exclusion reason -** background.
944. Milne, C., A. Coccarelli and M. Lassy. A comparison of collagenase to hydrogel dressings in wound debridement. Journal of Wound, Ostomy & Continence Nursing; 2011. p. S3-S3 **exclusion reason -** wrong outcome.
945. Milne, C., D. Saucier and G. Motta. A one year evaluation of a variable pressure foaming (vpf) mattress with surface modification technology (smt) for prevention and treatment of pressure ulcers in general medical-surgical patients. **exclusion reason -** Scientific Information Packets, not directly used.
946. Minabe, T. Versatility of the gluteus maximus musculocutaneous flap for repair of pressure sores. Japanese Journal of Plastic and Reconstructive Surgery; 1998. p. 1103-1111 **exclusion reason -** not relevant.
947. Minagawa, T., C. Kimura, R. Shichinohe, O. Ricia and T. Takano. Treatment of trochanteric pressure ulcers with undermined edges using negative pressure wound therapy combined with skin graft. Japanese Journal of Plastic and Reconstructive Surgery; 2006. p. 565-572 **exclusion reason -** not relevant.
948. Minakata, T., S. Kyutoku and S. Kurooka. A pulsatile jet irrigation system for bedside refractory ulcer treatment. Japanese Journal of Plastic and Reconstructive Surgery; 2003. p. 1173-1177 **exclusion reason -** background.
949. Minatel, D. G., A. M. S. Pereira, T. M. Chiaratti, L. Pasqualin, J. C. N. Oliveira, L. B. Couto, R. C. C. Lia, J. M. Cintra, M. F. A. Bezzon and S. C. Franca. Clinical study for the validation of the efficacy of ointment containing barbatimao (stryphnodendron adstringens (mart.) coville)* on healing of decubitus ulcers. Revista Brasileira de Medicina; 2010. p. 250-256 **exclusion reason -** not relevant.
950. Minato, S., T. Nara, R. Koizumi, S. Honjo, K. Kashiwa, H. Suzuki, B. Sodei, N. Shiraishi, A. Kuriyagawa, M. Hakozaki, H. Kimura, E. Okutu and K. Aoyama. Follow-up study of pressure ulcers treated by a musculocutaneous flap, muscle flap and other. Japanese Journal of Plastic and Reconstructive Surgery; 1990. p. 555-562 **exclusion reason -** not relevant.
951. Minato, S., H. Tochinai, K. Aoyama, H. Yamataka and T. Usui. Choice of operative method for decubitus ulcer. Japanese Journal of Plastic and Reconstructive Surgery; 1998. p. 1095-1101 **exclusion reason -** background.
952. Miner, K. J. and N. Salome. Papain-urea chlorophyllin copper complex sodium ointment (puc) and trypsin, balsam peru, and castor oil (tbc) in the treatment and healing of recurrent stage ii and stage iii pressure ulcers. Journal of Wound, Ostomy & Continence Nursing; 2006. p. S11-S11 **exclusion reason -** not relevant.
953. Mirkovitch, V., R. Macarone-Palmieri and L. Sorges. Treatment of skin wounds, open and contaminated with a polyvinyl-alcohol powder. Helvetica Chirurgica Acta; 1987. p. 103-106 **exclusion reason -** not relevant.
954. Mitchell, S. L., D. K. Kiely, A. Lewis and L. A. Lipsitz. The risk factors and impact of survival of feeding tube placement in nursing home residents with severe cognitive impairment. Archives of Internal Medicine; 1997. p. 327-332 **exclusion reason -** wrong population.
955. Mithat Akan, I., N. Sungur, R. Ozdemir, H. Kilinc and O. Sensoz. "Pac man" flap for closure of pressure sores. Annals of Plastic Surgery; 2001. p. 421-5 PMID: 11324886 **exclusion reason -** not relevant.
956. Mitish, V. A., A. M. Svetukhin and S. P. Glyantsev. Pressure sores in pregnancy. British Journal of Plastic Surgery; 1998. p. 573 PMID: 9924423 **exclusion reason -** background.
957. Mitiuk, O. I. [the use of extracorporeal stimulation of venous flow in the treatment of trophic ulcer in elderly and senile patients]. Klinicheskaia Khirurgiia; 1999. p. 22-4 PMID: 10370312 **exclusion reason -** not relevant.

958. Mitsukawa, N., S. Hori and H. Mukai. The surgical treatment of methicillin-resistant staphylococcus aureus-infected pressure sores. Japanese Journal of Plastic and Reconstructive Surgery; 1995. p. 155-159 **exclusion reason -** not relevant.
959. Mittmann, N., B. C. Chan, B. C. Craven, P. K. Isogai and P. Houghton. Evaluation of the cost-effectiveness of electrical stimulation therapy for pressure ulcers in spinal cord injury. Archives of Physical Medicine & Rehabilitation; 2011. p. 866-72 PMID: 21621661 **exclusion reason -** background.
960. Miyachi, Y. Recent trend in pressure ulcer treatment in japan. Japan Medical Association Journal; 2006. p. 62-69 **exclusion reason -** background.
961. Miyachi, Y. and S. Imamura. Improved healing of pressure sores with sugar and povidone-iodine. Current Therapeutic Research - Clinical and Experimental; 1991. p. 81-87 **exclusion reason -** wrong intervention.
962. Miyaji, H., H. Sakurai, M. Kikawada, K. Yamaguchi, A. Kimura, T. Fujiwara, N. Imada, M. Imai, T. Iwamoto and M. Takasaki. [treatment of bedsores--combination of therapies depended the experimental design method]. Nippon Ronen Igakkai Zasshi - Japanese Journal of Geriatrics; 2005. p. 90-8 PMID: 15732367 **exclusion reason -** not relevant.
963. Miyamoto, S., T. Minabe and K. Harii. A gluteal thigh flap based on cruciate anastomosis for the repair of ischial pressure ulcers. Japanese Journal of Plastic and Reconstructive Surgery; 2005. p. 1027-1034 **exclusion reason -** not relevant.
964. Miyauchi, H., T. Shimada, M. Nishii, T. Shikai, H. Hisadome and m. Tashiro. Comparative study for treatment of decubitus using three ointments; reflap, providone iodine sugar and a combination of both ingredients. Skin Research; 1990. p. 547-563 **exclusion reason -** not relevant.
965. Miyazaki, K., K. Yoshioka, M. Hayase, N. Ohkawa, E. Kitazawa and S. Nakade. Wound management for pressure ulcer developed on neurofibroma : Negative pressure therapy using multiple ddressings. **exclusion reason -** no original data.
966. Modenes Casillas, J. C., J. M. Porras Pastor, M. Pelet Larres, S. Camara Diaz, E. Jove Lance, I. Santalo Rios and J. L. Palacio Pellon. Assessment of the satisfaction and effectiveness of the hydrocoloid [sic] dressing sureskin ii in the treatment of acute and chronic wounds [spanish]. Gerokomos; 2006. p. 225-234 **exclusion reason -** not relevant.
967. Mody, G. N., I. A. Nirmal, S. Duraisamy and B. Perakath. A blinded, prospective, randomized controlled trial of topical negative pressure wound closure in india. Ostomy/wound management; 2008. p. 36-46 **exclusion reason -** wrong population.
968. Moher, D., A. Liberati, J. Tetzlaff and D. G. Altman. Preferred reporting items for systematic reviews and meta-analyses: The prisma statement. PLoS Med. 2009/07/22 ed; 2009. p. e1000097 PMID: 19621072 **exclusion reason -** background.
969. Moisidis, E., T. Heath and E. al. A prospective, blinded, randomized, controlled clinical trial of topical negative pressure use in skin grafting. Plastic & Reconstructive Surgery 2004. p. 917-922 **exclusion reason -** wrong population.
970. Mol, B. J. P., M. B. M. Hermans, R. P. M. Lambregts, v. Mortel and G. J. M. Wesseling. Ultraviolet light in the treatment of pressure sores. Nederlands Tijdschrift Fysiotherapie; 1994. p. 28-34 **exclusion reason -** not relevant.
971. Monetta, L. [use of papain in curative nursing actions]. Revista Brasileira de Enfermagem; 1987. p. 66-73 PMID: 3504013 **exclusion reason -** not relevant.
972. Monsbakken, J. A. and S. Wangensteen. [pressure sores--occurrence, prevention and treatment]. Sykepleien; 1986. p. 13-6, 38 PMID: 3633649 **exclusion reason -** not relevant.
973. Montorio, L., G. B. Vicari and M. Ferraro. The use of iruxol cream in the treatment of cutaneous ulceration of various origins. Giornale Italiano di Dermatologia e Venereologia; 1985. p. XXIX-XXXIV **exclusion reason -** not relevant.
974. Moody, M. Tissue viability. Illuminating research. Nursing Times; 1987. p. 62 PMID: 3684650 **exclusion reason -** background.
975. Moody, M. The role of a pressure relief dressing in the prevention and treatment of pressure sores. 3rd European Conference on Advances in Wound Management; 1993 **exclusion reason -** no original data.
976. Moody, M. Review of the stm range of pressure distribution products. British Journal of Nursing; 1998. p. 1078-80 PMID: 9830917 **exclusion reason -** background.
977. Mookhoek, E. J. [pressure sores in a psychiatric hospital: A report of 10 years of systematic decubitus treatment]. Tijdschrift voor Gerontologie en Geriatrie; 1994. p. 54-7 PMID: 8197596 **exclusion reason -** not relevant.
978. Moore, J. H., Jr. The role of plastic surgery in the treatment of pressure ulcers. Topics in Spinal Cord Injury Rehabilitation; 1996. p. 26-36 **exclusion reason -** background.
979. Moore, Z. and S. Cowman. A systematic review of wound cleansing for pressure ulcers. Journal of Clinical Nursing; 2008. p. 1963-72 PMID: 18705777 **exclusion reason -** Systematic Review, not directly used.
980. Moore, Z. and M. Ramanelli. Topical management of infected grade 3 and 4 pressure ulcers. Ewma position document: Management of wound infection. London, United Kingdom: Medical Education Partnership Ltd; 2006. p. 11-13 **exclusion reason -** no original data.
981. Moore, Z. E. and S. Cowman. Repositioning for treating pressure ulcers. Cochrane Database of Systematic Reviews; 2009. p. CD006898 PMID: 19370658 **exclusion reason -** Systematic Review, not directly used.
982. Moore, Z. E. H. and S. Cowman. Wound cleansing for pressure ulcers. Cochrane Database of

Systematic Reviews; 2005. p. CD004983 PMID: 16235386 **exclusion reason -** Systematic Review, not directly used.

983. Morand, J. J. [management of ulcerated graft in patients with joint prosthesis]. Annales de Dermatologie et de Venereologie; 1999. p. 91-5 PMID: 10095905 **exclusion reason -** not relevant.

984. Moreno-Guerin Banos, A., Y. Pelaez Nora, E. Perez-Godoy Diaz and D. Paredes Gonzalez. [approach and control of pressure ulcer infected in the heel]. Revista de Enfermeria; 2008. p. 16-7 PMID: 18497001 **exclusion reason -** not relevant.

985. Morison, M. J. Delayed pressure sore healing can be prevented. Professional Nurse; 1989. p. 332-6 PMID: 2717631 **exclusion reason -** background.

986. Morley, M. Managing decubitus ulcers. Canadian Nurse; 1990. p. 19-20 PMID: 2224819 **exclusion reason -** background.

987. Morris, L. Clinical efficacy of c-view transparent film wound dressing. British Journal of Nursing; 2001. p. 616-20 PMID: 12066036 **exclusion reason -** not relevant.

988. Mosher, B. A., J. Cuddigan, D. R. Thomas and D. M. Boudreau. Outcomes of 4 methods of debridement using a decision analysis methodology. Advances in Wound Care; 1999. p. 81-8 PMID: 10326360 **exclusion reason -** Systematic Review, not directly used.

989. Moss, C., A. E. M. Taylor and S. Shuster. Comparison of cadexomer iodine and dextranomer for chronic venous ulcers. Clinical and Experimental Dermatology: Blackwell Publishing Ltd; 1987. p. 413-418 PMID: 2462473 **exclusion reason -** wrong population.

990. Motta, G., C. Milne and D. Saucier. A prospective evaluation of the bodyzone variable pressure foaming mattress with surface modification technology in hospitalized general medical-surgical patients. **exclusion reason -** Scientific Information Packets, not directly used.

991. Motta, G., C. Milne and D. Saucier. Prevention and treatment of pressure ulcers with a new viscoelastic foam mattress with surface modification technology in general medical-surgical patients. **exclusion reason -** Scientific Information Packets, not directly used.

992. Motta, G. J. The effectiveness of dermagran topical therapy for treating chronic wounds in nursing facility residents. Ostomy Wound Management; 1991. p. 35-8 PMID: 1930582 **exclusion reason -** not relevant.

993. Motta, G. J., K. Martin, P. Miller, M. Marshall and J. Zink. Cost-effective technology for pressure relief. Ostomy Wound Management; 1991. p. 29-37 PMID: 1764157 **exclusion reason -** no original data.

994. Motta, G. J., C. T. Milne and L. Q. Corbett. Impact of antimicrobial gauze on bacterial colonies in wounds that require packing. Ostomy Wound Management; 2004. p. 48-62 PMID: 15356368 **exclusion reason -** not relevant.

995. Motta, G. J., K. Thimsen-Whitaker and M. A. Demoor. Documenting outcomes of wound care. Continuing Care; 1995. p. 16-7 PMID: 10163375 **exclusion reason -** background.

996. Moues, C., C. V. Margreet and E. al. Bacterial load in relation to vacuum-assisted closure wound therapy: A prospective randomized trial. Wound Repair & Regeneration; 2004. p. 11-17 **exclusion reason -** wrong outcome.

997. Mouthuy, B., N. Calteux, B. Bienfait, M. Schoofs, D. Rossillon, G. Verheecke and A. de Coninck. [value of the gluteus maximus musculocutaneous flap in the treatment of sacral and ischiatic ulcers. Apropos of 40 cases]. Annales de Chirurgie Plastique et Esthetique; 1986. p. 143-8 PMID: 2429601 **exclusion reason -** not relevant.

998. Mowlavi, A. and R. E. Brown. Suction lipectomy during flap reconstruction provides immediate and safe debulking of the skin island. Annals of Plastic Surgery; 2003. p. 189-93 PMID: 12897524 **exclusion reason -** background.

999. Muehlberger, T., A. Buschmann and N. Toman. Extended free deep inferior epigastric flap for closure of a thoracolumbar defect. Journal of Reconstructive Microsurgery; 2007. p. 521-2 PMID: 18189211 **exclusion reason -** not relevant.

1000. Muguti, G. I. Early experience with reconstructive surgery at mpilo central hospital, zimbabwe. Journal of the Royal College of Surgeons of Edinburgh; 1990. p. 248-51 PMID: 2231500 **exclusion reason -** not relevant.

1001. Mulder, G. D. A prospective controlled randomized study of the efficacy of clearsite, duoderm, and wet-to-dry gauze dressing in the management of pressure ulcers. 2nd European Conference on Advances in Wound Management; 1992 **exclusion reason -** no original data.

1002. Mulder, G. D., S. F. Albert and R. E. Grimwood. Clinical evaluation of a new occlusive hydrocolloid dressing. Cutis; 1985. p. 396-7, 400 PMID: 3996043 **exclusion reason -** not relevant.

1003. Mulgrew, S., A. Khoo, R. M. Newton, R. Rajan and K. Kumar. Pressure necrosis secondary to negative pressure dressing. Annals of the Royal College of Surgeons of England; 2011. p. e27-8 PMID: 21943441 **exclusion reason -** not relevant.

1004. Mullner, T., L. Mrkonjic, O. Kwasny and V. Vecsei. The use of negative pressure to promote the healing of tissue defects: A clinical trial using the vacuum sealing technique. British Journal of Plastic Surgery; 1997. p. 194-9 PMID: 9176007 **exclusion reason -** not relevant.

1005. Mumcuoglu, K. Y., A. Ingber, L. Gilead, J. Stessman, R. Friedmann, H. Schulman, H. Bichucher, I. Ioffe-Uspensky, J. Miller, R. Galun and I. Raz. Maggot therapy for the treatment of intractable wounds. International Journal of Dermatology; 1999. p. 623-7 PMID: 10487456 **exclusion reason -** not relevant.

1006. Mun, G.-H., Y.-W. Jo, S.-Y. Lim, W.-S. Hyon, S.-I. Bang and K.-S. Oh. Pedicled perforator flap of stellate design. Journal of Plastic, Reconstructive & Aesthetic Surgery: JPRAS; 2008. p. 1332-7 PMID: 18029241 **exclusion reason -** not relevant.

1007. Munter, K. C. and H. Beele. The contop study: Improved healing of delayed healing ulcers with sustained silver-releasing foam dressing versus other silver dressings... 39th annual wound, ostomy and continence nurses annual conference. Journal of Wound, Ostomy & Continence Nursing; 2007. p. S68-S68 **exclusion reason -** no original data.
1008. Munter, K. C., H. Beele, L. Russell, A. Crespi, E. GrÃ¶chenig, P. Basse, N. Alikadic, F. Fraulin, C. Dahl and A. P. Jemma. Effect of a sustained silver-releasing dressing on ulcers with delayed healing: The contop study. Journal of Wound Care; 2006. p. 199-206 **exclusion reason -** wrong intervention.
1009. Muro, T., K. Onishi, N. Inomata, T. Yamada, M. Saze and Y. Maruyama. The vacuum-assisted closure of pressure ulcers - clinical evaluation in combination with bfgf preparation. Japanese Pharmacology and Therapeutics; 2008. p. 325-331 **exclusion reason -** not relevant.
1010. Musalatov, K. A., L. L. Silin, M. N. Elizarov, P. M. Elizarov and A. V. Garkavi. [reconstructive operations on soft tissues in the treatment of bedsores in patients with spinal injuries]. Vestnik Rossiiskoi Akademii Meditsinskikh Nauk; 1995. p. 30-2 PMID: 8601087 **exclusion reason -** not relevant.
1011. Musgrove, E., C. Woodham and P. Dearie. Leg ulceration and clinical effectiveness: Nurse-led clinics. Nursing Standard; 1998. p. 57 **exclusion reason -** background.
1012. Mustoe, T., J. Upton and V. Marcellino. Carcinoma in chronic pressure sores: A fulminant disease process. Plastic and Reconstructive Surgery; 1986. p. 116-121 PMID: 3941833 **exclusion reason -** no original data.
1013. Naber, T. H., T. Schermer, A. de Bree, K. Nusteling, L. Eggink, J. W. Kruimel, J. Bakkeren, H. van Heereveld and M. B. Katan. Prevalence of malnutrition in nonsurgical hospitalized patients and its association with disease complications. American Journal of Clinical Nutrition; 1997. p. 1232-1239 PMID: 9356543 **exclusion reason -** wrong population.
1014. Nae, S., N. Antohi, C. Stingu, V. Stan and S. Parasca. [options for flap coverage in pressure sores]. Chirurgia (Bucuresti); 2010. p. 663-8 PMID: 21141091 **exclusion reason -** not relevant.
1015. Nagano, M., T. Kuroda, E. Tomoe, T. Megumi, Y. Ogata, C. Sakurai, T. Keiko, S. Tomoko and O. Takehiko. Pressure-reducing mattress to help take care of patients with pressure ulcers in large hospitals in japan. Journal of Wound, Ostomy & Continence Nursing; 2006. p. S45-6 **exclusion reason -** wrong outcome.
1016. Nagase, T., T. Hisatomi, I. Koshima, N. Hattori, H. Koyanagi and H. Sanada. Heterotopic ossification in the sacral pressure ulcer treated with basic fibroblast growth factor: Coincidence or side effect? Journal of Plastic, Reconstructive & Aesthetic Surgery: JPRAS; 2007. p. 327-9 PMID: 17293296 **exclusion reason -** no original data.
1017. Nakagawa, K., M. Ishii, H. Kobayashi, D. Tsuruta, Y. Iwamoto, N. Yashiro, I. Ishidoh, T. Hamada, T. Terashima, K. Shindo, S. Suzuki, N. Mizuno, J. Katoh, A. Shoji, S. Kuniyuki, T. Nishimura, Y. Abe, H. Kanetomo and J. Kitajima. Evaluation of the effects of tretinoin tocoferil ointment (olcenon(registered trademark) ointment) in the treatment of decubitus and skin ulcers. Skin Research; 1994. p. 209-219 **exclusion reason -** not relevant.
1018. Nakayama, M. Applying negative pressure therapy to deep pressure ulcers covered by soft necrotic tissue. International Wound Journal; 2010. p. 160-6 PMID: 20455957 **exclusion reason -** wrong outcome.
1019. Namiki, Y., S. Torii, Y. Hayashi, M. Hasegawa and K. Fukuta. Gluteus maximus musculocutaneous v-y advancement flaps for the repair of pressure sores. Japanese Journal of Plastic and Reconstructive Surgery; 1989. p. 21-29 **exclusion reason -** not relevant.
1020. Napier, S. and M. Cook. A case report of rhabdomyolysis and pressure sores following hypotensive anaesthesia and prolonged surgery in the prone position. Anaesthesia; 2011. p. 9 **exclusion reason -** wrong intervention.
1021. National Pressure Ulcer Advisory Panel. Pressure ulcer healing: Controversy to consensus assessment methods and outcomes. Advances in Wound Care; 1995. p. 28/1-28/1 PMID: 1995025293 **exclusion reason -** wrong outcome.
1022. Naylor, W. Malignant wounds: Aetiology and principles of management. Nursing Standard; 2002. p. 45-56 **exclusion reason -** no original data.
1023. Nazarko, L. Negative pressure wound therapy for older residents. Nursing & Residential Care; 2009. p. 69 **exclusion reason -** background.
1024. Neander, K. D. [current aspects of the therapy of chronic wounds]. Zentralblatt fur Chirurgie; 2000. p. 94-9 PMID: 10929657 **exclusion reason -** background.
1025. Neander, K. D. [dermatologic agents for preventing decubitus ulcer: Effectiveness could not be verified by the study]. Pflege Zeitschrift; 2001. p. 261-3 PMID: 12025069 **exclusion reason -** not relevant.
1026. Nelson, D. B. and M. A. Dilloway. Principles, products, and practical aspects of wound care. Critical Care Nursing Quarterly; 2002. p. 33-54 **exclusion reason -** background.
1027. Nelson, E. A. Pressure sore treatment. 3. Clinical guidelines. Journal of Wound Care; 1997. p. 402-4 PMID: 9341435 **exclusion reason -** background.
1028. Nelson, S. E. Pearls for practice. Treating stage iii pressure ulcers... Including commentary by ferris mfg. Corp. Ostomy Wound Management; 2009. p. 6-6 **exclusion reason -** background.
1029. Nemoto, O. and A. Ohkawara. Clinical and bacteriological research of sucrose/povidone-iodine ointment (u-pasta kowa) for pressure sores and skin ulcers. Skin Research; 1996. p. 538-548 **exclusion reason -** not relevant.
1030. Neubert, T. R., M. Fischer and U. Toellner-Bauer. [from national standard to internal "decubitus ulcer" guideline--1: Algorithms promote

transparency]. Pflege Zeitschrift; 2005(a). p. 376-9 PMID: 16013291 **exclusion reason -** background.

1031. Neubert, T. R., M. Fischer and U. Toellner-Bauer. [from national prevention standard to internal "decubitus ulcer" guideline--2: Standardizing wounds and still treating them individually]. Pflege Zeitschrift; 2005(b). p. 445-8 PMID: 16106833 **exclusion reason -** background.

1032. Neumann, V., E. Stoppard, R. Kent, K. Andrews, S. Duport, A. M. Larking, M. Clinton and M. Hardy. Letter to the editor: Re: Randomized control of extracorporeal shock wave therapy versus placebo for chronic decubitus ulceration... Randomized control of extracorporeal shock wave therapy versus placebo for chronic decubitus ulceration. Clinical Rehabilitation; 2010. p. 1148-1149 **exclusion reason -** no original data.

1033. Neves, R. I., S. H. Kahler, D. R. Banducci and E. K. Manders. Tissue expansion of sensate skin for pressure sores. Annals of Plastic Surgery; 1992. p. 433-7 PMID: 1444132 **exclusion reason -** background.

1034. Newton, H. A comprehensive guide to wound management... Clinical resources efficiency support team (1998) clinical guidelines for wound management in northern ireland. Belfast: Crest wound management group. Nursing Times; 2000. p. 17-17 **exclusion reason -** background.

1035. Newton, M. Integrated care pathway: The prevention and management of pressure ulcers. Journal of Tissue Viability; 2003. p. 126-9 PMID: 12889400 **exclusion reason -** background.

1036. Niazi, Z. B. and C. A. Salzberg. Operative repair of pressure ulcers. Clinics in Geriatric Medicine; 1997. p. 587-97 PMID: 9227947 **exclusion reason -** background.

1037. Niazi, Z. B. and C. A. Salzberg. Surgical management of pressure ulcers. Ostomy Wound Management; 1997. p. 44-8, 50-2 PMID: 9385178 **exclusion reason -** background.

1038. Nie, X., J. K. Cai, H. M. Yang, H. A. Xiao, J. H. Wang, N. Wen, Y. J. Zhang and Y. Jin. Successful application of tissue-engineered skin to refractory ulcers. Clinical & Experimental Dermatology; 2007. p. 699-701 PMID: 17725663 **exclusion reason -** not relevant.

1039. Niezgoda, J. A. A comparison of vacuum assisted closure therapy to moist wound care in the treatment of pressure ulcers: Preliminary results of a multicenter trial. 2nd World Union of Wound Healing Societies Meeting; 2004 **exclusion reason -** no original data.

1040. Niezgoda, J. A. Incorporating negative pressure therapy into the management strategy for pressure ulcers. Ostomy Wound Management; 2004. p. 5S-8S PMID: 15632459 **exclusion reason -** wrong population.

1041. Niitsu, F. [nursing technics in home care. 4. Symptoms common among aged patients and their nursing (1). Care of decubitus ulcer]. Kango Gijutsu - Japanese Journal of Nursing Art; 1986. p. 650-3 PMID: 3636517 **exclusion reason -** not relevant.

1042. Nissen, C., W. Gibson, T. Snoder, K. Martin and D. Wassenaar. Focus on research. Partners: A strategy for improving wound and skin care clinical outcomes in long term care. Chart; 1998. p. 5-5 **exclusion reason -** background.

1043. Nixon, J., G. Cranny, A. Nelson, C. Iglesias, A. Phillips, K. Hawkins, D. Torgerson, S. Mason and N. Cullum. The nhs health technology assessment programme. Pressure trial clinical and patient outcomes. EWMA Journal; 2006. p. 38-38 **exclusion reason -** not relevant.

1044. Noda, Y., K. Watanabe, A. Sanagawa, Y. Sobajima and S. Fujii. Physicochemical properties of macrogol ointment and emulsion ointment blend developed for regulation of water absorption. International Journal of Pharmaceutics; 2011. p. 131-6 PMID: 21820500 **exclusion reason -** wrong outcome.

1045. Nohara, Y., M. Mizuno, H. Kamei, M. Yamadaz, K. Fujii, N. Satoh, N. Nitao, A. Renda, T. Yuasa, M. Hamazaki, A. Shimauchi, Y. Hirai, H. Yasui, S. Muramatsu, Y. Noda and K. Furuta. [preparation of a manual treatment of pressure ulcers which draws attention to moisture of the affected part]. Gan to Kagaku Ryoho [Japanese Journal of Cancer & Chemotherapy]; 2003. p. 95-7 PMID: 15311773 **exclusion reason -** not relevant.

1046. Nojima, K. The surgical treatment of sacral pressure ulcers analyses of 92 cases. Tokyo Jikeikai Medical Journal; 2004. p. 441-453 **exclusion reason -** not relevant.

1047. Nord, D. [cost-effectiveness in wound care]. Zentralblatt fur Chirurgie; 2006. p. S185-8 PMID: 16575679 **exclusion reason -** not relevant.

1048. Norton, L., L. Rappl and G. Sibbald. Thinking outside the bed: Managing interface pressure... Including commentary by rappl l. International Journal of Therapy & Rehabilitation; 2005. p. 165 **exclusion reason -** background.

1049. NPUAP. Pressure ulcer prevention and treatment: Clinical practice guidline. In: N. P. U. A. Panel, editor. Ver. 01/29/2007 ed: National Pressure Ulcer Advisory Panel; 2007 **exclusion reason -** background.

1050. NPUAP. Terms and definitions related to support surfaces. National pressure Ulcer Advisory Panel Support Surface Standards Initiative. ver. 01/29/2001 ed: National Pressure Ulcer Advisory Panel; 2007 **exclusion reason -** background.

1051. NPUAP. Pressure ulcer prevention and treatment: Clinical practice guidline. National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel.; 2009 **exclusion reason -** background.

1052. Oberlin, C., B. Azoulay and A. Bhatia. The posterolateral malleolar flap of the ankle: A distally based sural neurocutaneous flap--report of 14 cases. Plastic & Reconstructive Surgery; 1995. p. 400-5; discussion 406-7 PMID: 7624414 **exclusion reason -** not relevant.

1053. Oberringer, M., H. P. Baum, V. Jung, C. Welter, J. Frank, M. Kuhlmann, W. Mutschler and R. G. Hanselmann. Differential expression of heat shock protein 70 in well healing and chronic human wound

tissue. Biochemical & Biophysical Research Communications; 1995. p. 1009-14 PMID: 7575503 **exclusion reason -** background.

1054. O'Brien, S. P., V. Gahtan, S. Wind and M. D. Kerstein. What is the paradigm: Hospital or home health care for pressure ulcers? American Surgeon; 1999. p. 303-6 PMID: 10190350 **exclusion reason -** wrong intervention.

1055. Obuchi, R., S. Matsumoto, Y. Tobari, S. Tsukada and T. Yoshimi. [an iatrogenic incident concerning decubitus ulcer. Decubitus ulcer encountered at clinical scenes: A discussion]. Kangogaku Zasshi - Japanese Journal of Nursing; 1986. p. 899-906 PMID: 3639174 **exclusion reason -** not relevant.

1056. Oechies, J. The treatment of poorly healing wounds with ultraviolet b-c. Physiotherapy Theory and Practice; 1991. p. 259 **exclusion reason -** no original data.

1057. Ohry A, G. O. The effects of bst electro-stimulation on healing of pressure ulcers: Results of a multi-center, double blind, randomized, placebo controlled study [oral presentation no: 66]. 17th Conference of the European Wound Management Association; 2007 **exclusion reason -** not relevant.

1058. Ohura, T., T. Nakajo, T. Moriguchi, H. Oka, M. Tachi, N. Ohura Jr, R. Nogami and S. Murayama. Clinical efficacy of basic fibroblast growth factor on pressure ulcers: Case-control pairing study using a new evaluation method. Wound Repair and Regeneration; 2011. p. 542-551 **exclusion reason -** wrong outcome.

1059. Ohura, T., H. Sanada and Y. Mino. [clinical study using activity-based costing to assess cost-effectiveness of a wound management system utilizing modern dressings in comparison with traditional wound care]. Nippon Ronen Igakkai Zasshi - Japanese Journal of Geriatrics; 2004. p. 82-91 PMID: 14999922 **exclusion reason -** not relevant.

1060. Ohura, T., H. Sanada and Y. Mino. Clinical activity-based cost effectiveness of traditional versus modern wound management in patients with pressure ulcers. Wounds: A Compendium of Clinical Research & Practice; 2004. p. 157 **exclusion reason -** not relevant.

1061. Oien, R. F. Registering ulcer treatment through a national quality register: Rut -- a winning concept for both patients and the health care sector. EWMA Journal; 2009. p. 41-44 **exclusion reason -** background.

1062. Okabe, K., K. Satoh, A. Takushima, T. Eguchi, M. Takushima, A. Niu, M. Minegisi and M. Asatani. Indications and selection of the surgical repair method for recurrent and intractable pressure sores. Japanese Journal of Plastic and Reconstructive Surgery; 1998. p. 933-946 **exclusion reason -** not relevant.

1063. Oliva Torras, E., M. Subirana Casacuberta, M. P. Sebastia, C. Jover Sancho and N. Sola Sole. [care plan for patients in prone decubitus. An experience from practice]. Enfermeria Intensiva; 1995. p. 149-58 PMID: 8715358 **exclusion reason -** not relevant.

1064. Oliveri, L., G. Lavagnino, A. Gliori and G. L. Rossi. Treatment of ulcers: Application of a new product. Rivista Italiana di Chirurgia Plastica; 1991. p. 498-503 **exclusion reason -** not relevant.

1065. Olsen, L., F. L. Kallehave and F. Gottrup. [methods for measurement of wound extent]. Ugeskrift for Laeger; 1994. p. 7345-8 PMID: 7801394 **exclusion reason -** not relevant.

1066. Olshanksy, K. Multivariate predictors of failure after flap coverage of pressure ulcers. Plastic & Reconstructive Surgery; 2011. p. 486-7; author reply 487 PMID: 21200260 **exclusion reason -** no original data.

1067. Olshansky, K. Rethinking our approach to pressure ulcers. Ostomy Wound Management; 2001. p. 6 PMID: 11889723 **exclusion reason -** no original data.

1068. Olshansky, K. Long-term outcomes of full-thickness pressure ulcers: Healing and mortality. Ostomy Wound Management; 2004. p. 12, 77; author reply 77 PMID: 15366146 **exclusion reason -** background.

1069. Olshansky, K. The 10 most important questions concerning pressure ulcers and quality of care. Advances in Skin & Wound Care; 2008. p. 505-8 PMID: 18981749 **exclusion reason -** background.

1070. Olshansky, K. "Kennedy terminal ulcer" and "skin failure," where are the data? Journal of Wound, Ostomy, & Continence Nursing; 2010. p. 466; author reply 466-7 PMID: 20838313 **exclusion reason -** background.

1071. Olson, A. The hard truth. PN; 2011. p. 14-16 **exclusion reason -** background.

1072. Olyaee Manesh, A., K. Flemming, N. A. Cullum and H. Ravaghi. Electromagnetic therapy for treating pressure ulcers. Cochrane Database of Systematic Reviews; 2006. p. CD002930 PMID: 16625564 **exclusion reason -** Systematic Review, not directly used.

1073. O'Meara, S., N. Cullum, M. Majid and T. Sheldon. Systematic reviews of wound care management: (3) antimicrobial agents for chronic wounds; (4) diabetic foot ulceration (structured abstract). Health Technology Assessment Database; 2012 **exclusion reason -** not relevant.

1074. O'Meara, S. M., N. Cullum, M. Majid and T. Sheldon. Systematic reviews of wound care management: (3) anitmicrobial agents for chronic wounds; (4) diabetic foot ulceration. Health Technology Assessment; 2000. p. 1-237 **exclusion reason -** background.

1075. O'Meara, S. M., N. A. Cullum, M. Majid and T. A. Sheldon. Systematic review of antimicrobial agents used for chronic wounds. British Journal of Surgery; 2001. p. 4-21 PMID: 11136304 **exclusion reason -** Systematic Review, not directly used.

1076. Omote, S., J. Sugama, H. Sanada, C. Konya, M. Okuwa and A. Kitagawa. Healing process of pressure ulcers after a change in the nutrition regimen of bedridden elderly: A case series. Japan Journal of Nursing Science; 2005. p. 85-93 **exclusion reason -** not relevant.

1077. O'Neil, C. K. Prevention and treatment of pressure ulcers. Journal of Pharmacy Practice; 2004. p. 137-148 **exclusion reason -** background.
1078. Onigbinde, A. T., R. A. Adedoyin, O. A. Ojoawo, O. E. Johnson, A. O. Obembe, F. K. Olafimihan, O. M. Omiyale and S. Oniyangi. Effects of ultraviolet radiation (type b) on wound exudates, appearance and depth description. Technology & Health Care; 2010. p. 297-302 PMID: 21209478 **exclusion reason -** wrong outcome.
1079. Onizuka, T., T. Jinnouchi, W. Haraguchi, R. Tanaka, K. Udagawa and H. Gyotoku. [treatment of decubitus ulcer]. Nippon Seikeigeka Gakkai Zasshi - Journal of the Japanese Orthopaedic Association; 1986. p. 1037-46 PMID: 3537167 **exclusion reason -** not relevant.
1080. Oot-Giromini, B., F. C. Bidwell, N. B. Heller, M. L. Parks, E. M. Prebish, P. Wicks and P. M. Williams. Pressure ulcer prevention versus treatment, comparative product cost study. Decubitus; 1989. p. 52-4 PMID: 2505808 **exclusion reason -** wrong intervention.
1081. Ooura, T. Treatment of deep pressure ulcers (stage iii iv). Japanese Journal of Plastic and Reconstructive Surgery; 1999. p. 1067-1078 **exclusion reason -** not relevant.
1082. Orgill, D. P., J. J. Pribaz and D. J. Morris. Local fasciocutaneous flaps for olecranon coverage. Annals of Plastic Surgery; 1994. p. 27-31 PMID: 8141533 **exclusion reason -** not relevant.
1083. Orkiszewski, M. [maggots of lucilia sericata in treatment of intractable wounds]. Wiadomosci Lekarskie; 2007. p. 381-5 PMID: 18175560 **exclusion reason -** not relevant.
1084. Orlando, P. L. Pressure ulcer management in the geriatric patient. Annals of Pharmacotherapy; 1998. p. 1221-7 PMID: 9825090 **exclusion reason -** Systematic Review, not directly used.
1085. Ormiston, M. C., M. T. Seymour, G. E. Venn, R. I. Cohen and J. A. Fox. Controlled trial of iodosorb in chronic venous ulcers. BMJ; 1985. p. 308-310 **exclusion reason -** wrong outcome.
1086. Orsted, H. L., R. Poulson, J. Baum, D. Christensen, M. Despatis, K. Goettl, D. Haligowski, C. Ho, K. Louis, D. O'Sullivan-Drombolis, V. Winberg and K. Y. Woo. Evidence-based practice standards for the use of topical pressurised oxygen therapy. International Wound Journal; 2012. p. 271-284 **exclusion reason -** no original data.
1087. Osterbrink, J., H. Mayer and G. Schroder. Clinical evaluation of the effectiveness of a multimodal statis pressure relieving device. Journal of Wound Healing European Wound Conference; 2005 **exclusion reason -** unable to find.
1088. Othman, T., G. Friese, T. Gierth, G. Ziegler and W. Scherbaum. [the treatment of heel pressure ulcer with the vacuum therapy (v.A.C. System)]. Zentralblatt fur Chirurgie; 2004. p. S116-8 PMID: 15168306 **exclusion reason -** not relevant.
1089. Ourabah, Z. and S. Meaume. Infected bed sores: New recommendations. Medecine et Maladies Infectieuses; 2003. p. 78-80 **exclusion reason -** background.
1090. Ovington, L. G. Dressings and ajunctive therapies: Ahcpr guidelines revisited. Ostomy Wound Management; 1999. p. 94S-106S; quiz 107S-108S PMID: 10085980 **exclusion reason -** background.
1091. Ovington, L. G. Evolution in the rainforest: The case for hydropolymer dressings. Advances in Skin & Wound Care; 2000. p. 4-8 **exclusion reason -** background.
1092. Ovington, L. G. Wound care products: How to choose. Advances in Skin & Wound Care; 2001. p. 259-64; quiz 265-6 PMID: 11905974 **exclusion reason -** background.
1093. Oyama, A., M. Murazumi, A. Tsutsumida, S. Fujii, S. Hata and T. Sugihara. The gluteal perforator-based island fasciocutaneous flap for sacral pressure sores. Japanese Journal of Plastic and Reconstructive Surgery; 1997. p. 963-968 **exclusion reason -** not relevant.
1094. Ozdemir, F., M. Rodoplu, F. Oymak and N. Sut. The effect of linear polarized polychromatic light therapies applied according to biochemical values on pressure ulcers. Turkiye Fiziksel Tip ve Rehabilitasyon Dergisi; 2007. p. 100-103 **exclusion reason -** not relevant.
1095. Pacifici, A., M. Cordellini, F. Duranti, V. Murgolo, B. Bovani, A. Coccaro and C. Dominici. Clinical use of the katomed dressing. Rivista Italiana di Chirurgia Plastica; 1992. p. 421-425 **exclusion reason -** not relevant.
1096. Page, J., B. Newswander and E. al. Retrospective analysis of negative pressure wound therapy in open foot wounds with significant soft tissue defects. Advances in Skin & Wound Care; 2004. p. 354-364 **exclusion reason -** wrong population.
1097. Paghetti, A., A. Bellingeri, G. Pomponio, J. Sansoni and D. Paladino. [topic efficacy of ialuronic acid associated with argentic sulphadiazine (connettivina plus) in the treatment of pressure sores: A prospective observational cohort study]. Professioni Infermieristiche; 2009. p. 67-77 PMID: 19664355 **exclusion reason -** not relevant.
1098. Pagnamenta, F. Is fluid filled mattress technology compatible with nice guidance? British Journal of Community Nursing; 2007. p. S35-8 PMID: 18361173 **exclusion reason -** background.
1099. Pai, C. H. and S. Toussaints. Surgical treatment of pressure sores in patients with traumatic spinal cord injury: With relative emphasis on multiple and recurrent sores. Formosan Journal of Surgery; 1999. p. 11-17 **exclusion reason -** not relevant.
1100. Paillaud, E., S. Herbaud, P. Caillet, J. L. Lejonc, B. Campillo and P. N. Bories. Relations between undernutrition and nosocomial infections in elderly patients. Age & Ageing; 2005. p. 619-625 **exclusion reason -** wrong population.
1101. Paletta, C., T. Bartell and S. Shehadi. Applications of the posterior thigh flap. Annals of Plastic Surgery; 1993. p. 41-7 PMID: 8101434 **exclusion reason -** not relevant.

1102. Palmieri, B. Heterologous collagen in wound healing: A clinical study. International Journal of Tissue Reactions; 1992. p. 21-5 **exclusion reason -** no original data.

1103. Panfil, E.-M. ["nursing patients with chronic wounds" expert standard: Qualification of needs]. Pflege Zeitschrift; 2008. p. 134-7 PMID: 18450257 **exclusion reason -** not relevant.

1104. Paris, A., R. Horvath, P. Basset, S. Thiery, P. Couturier, A. Franco and J. L. Bosson. Nitrous oxide-oxygen mixture during care of bedsores and painful ulcers in the elderly: A randomized, crossover, open-label pilot study. Journal of Pain and Symptom Management; 2008. p. 171-176 PMID: 18226725 **exclusion reason -** wrong intervention.

1105. Parish, L. C., M. Dryjski, S. Cadden and X. C. P. U. S. G. Versiva. Prospective clinical study of a new adhesive gelling foam dressing in pressure ulcers. International Wound Journal; 2008. p. 60-7 PMID: 18336380 **exclusion reason -** wrong outcome.

1106. Parish, L. C., P. T. Lowthian and J. A. Witkowski. The infected decubitus ulcer: Superman's kryptonite. SKINmed; 2005. p. 7-8 PMID: 15654157 **exclusion reason -** background.

1107. Parish, L. C., J. A. Witkowski and J. T. Crissey. Unusual aspects of the decubitus ulcer. Decubitus; 1988. p. 22-4 PMID: 3254235 **exclusion reason -** background.

1108. Park, C. and B. Y. Park. Fasciocutaneous v-y advancement flap for repair of sacral defects. Annals of Plastic Surgery; 1988. p. 23-6 PMID: 3048182 **exclusion reason -** not relevant.

1109. Park, S. Muscle-splitting approach to superior and inferior gluteal vessels: Versatile source of recipient vessels for free-tissue transfer to sacral, gluteal, and ischial regions. Plastic & Reconstructive Surgery; 2000. p. 81-6 PMID: 10883616 **exclusion reason -** not relevant.

1110. Park, S. and K. S. Koh. Superior gluteal vessel as recipient for free flap reconstruction of lumbosacral defect. Plastic & Reconstructive Surgery; 1998. p. 1842-9 PMID: 9623825 **exclusion reason -** not relevant.

1111. Parkash, S. and S. Banerjee. The total gluteus maximus rotation and other gluteus maximus musculocutaneous flaps in the treatment of pressure ulcers. British Journal of Plastic Surgery; 1986. p. 66-71 PMID: 3947796 **exclusion reason -** not relevant.

1112. Parpex, P. Local treatment of ulceration on white atrophy. Phlebologie; 1986. p. 603-604 PMID: 3786433 **exclusion reason -** not relevant.

1113. Partridge, C. J. Evaluation of the efficacy of ultrasound. Physiotherapy; 1987. p. 166-168 **exclusion reason -** no original data.

1114. Pasquini, G., C. Caglioni and P. Pandolfi. Surgical repair of decubitus ulcers. Rivista Italiana di Chirurgia Plastica; 1988. p. 178-185 **exclusion reason -** not relevant.

1115. Pasternak, N. S., L. A. L. Rau and B. J. Hensley. From chaos to consistency: The implementation of wound treatment tiers in home care. Home Health Care Management & Practice; 2003. p. 314-324 **exclusion reason -** background.

1116. Patrick, M. M. Specialty beds and wound care products: A new cost-saving role. Hospital Materiel Management Quarterly; 1994. p. 48-62 PMID: 10137782 **exclusion reason -** background.

1117. Patterson, J. A. and R. G. Bennett. Prevention and treatment of pressure sores. Journal of the American Geriatrics Society; 1995. p. 919-27 PMID: 7636103 **exclusion reason -** no original data.

1118. Paulson, R., P. Guthmiller and D. Rustvang. The latest in cutaneous ulcer care. Patient Care; 2005. p. 13-16 **exclusion reason -** background.

1119. Payne, W., D. Ochs, R. Wolcott, L. Morrow, G. Jameson, O. Alvarez, C. Kalinski, M. Brown-Etris, S. Hartwell and H. Dharma. A prospective, multi-center, randomized and comparative evaluation to assess the relative cost effectiveness of treatment of stage ii pressure ulcers with a self-adhesive polyurethane foam dressing* and saline soaked gauze. p. 50-5 PMID: 19246785 **exclusion reason -** no original data.

1120. Payne, W. G., R. Bhalla, D. P. Hill, Y. N. Pierpont and M. C. Robson. Wound healing trajectories to determine pressure ulcer treatment efficacy. Eplasty [Electronic Resource]; 2011. p. e1 PMID: 21245984 **exclusion reason -** background.

1121. Pearl, M. Ahcpr recommendations for assessment and treatment of pressure ulcers. Acute Care Perspectives; 1996. p. 6-7 **exclusion reason -** background.

1122. Pedrolli, C. and E. Cereda. Dramatic pressure ulcers. e-SPEN; 2010. p. e45-e46 **exclusion reason -** background.

1123. Peirce, B. and M. Gray. Radiant heat dressings for chronic wounds. Journal of Wound, Ostomy, & Continence Nursing; 2001. p. 263-6 PMID: 11707756 **exclusion reason -** background.

1124. Pelham, F. R., W. Minn, B. Wise, T. Morton, G. Powell and K. Egol. Staged surgical closure in combination with negative pressure wound therapy using open cell foam (npwt/ocf) increases closure success of stage iii and iv pressure ulcers (prus). **exclusion reason -** no original data.

1125. Pemberton, V., V. Turner and C. VanGilder. Early results of a pilot surface evaluation of a bariatric therapy support surface... 39th annual wound, ostomy and continence nurses annual conference. Journal of Wound, Ostomy & Continence Nursing; 2007. p. S75-S75 **exclusion reason -** not relevant.

1126. Pena, M. M., G. S. Drew, S. J. Smith and K. S. Given. The inferiorly based rectus abdominis myocutaneous flap for reconstruction of recurrent pressure sores. Plastic & Reconstructive Surgery; 1992. p. 90-5 PMID: 1727268 **exclusion reason -** not relevant.

1127. Peng, Y. H., C. T. Ye, H. Y. Zou and L. B. Dai. A new kind of material for curing bedsore: Acidic fibroblast growth factor-collagen sponge. Chinese Journal of Clinical Rehabilitation; 2005. p. 88-89 **exclusion reason -** not relevant.

1128. Perrero, L., D. Persico, A. Bellora, E. Laguzzi and M. C. Sacchi. Pressure ulcers in the elderly:

Advanced treatments and use of platelet gel (prp/gel). Giornale di Gerontologia; 2003. p. 12-17 **exclusion reason -** not relevant.

1129. Perrouin-Verbe, B., P. Poirier, S. Touchais, I. Richard, J. F. Mathe and J. V. Bainvel. Hip sepsis associated with pressure sore in paraplegic patients. Value of one-time surgical treatment. Annales de Readaptation et de Medecine Physique; 1994. p. 297-304 **exclusion reason -** not relevant.

1130. Pers, M. Plastic surgery for pressure sores. Paraplegia; 1987. p. 275-8 PMID: 2439973 **exclusion reason -** background.

1131. Pers, M., K. Snorrason and I. M. Nielsen. Primary results following surgical treatment of pressure sores. Scandinavian Journal of Plastic & Reconstructive Surgery; 1986. p. 123-4 PMID: 3490685 **exclusion reason -** not relevant.

1132. Peschardt, A., B. Alsbjorn and F. Gottrup. A comparative randomized study on performance characteristics of a new hydrogel versus saline gauze for the treatment of pressure sores. Proceedings of the 6th European Conference on Advances in Wound Management; 1995 **exclusion reason -** no original data.

1133. Peters, J. W. and G. E. Johnson. Proximal femurectomy for decubitus ulceration in the spinal cord injury patient. Paraplegia; 1990. p. 55-61 PMID: 2152395 **exclusion reason -** not relevant.

1134. Petrovici, V. [surgical treatment of decubitus ulcers]. Handchirurgie, Mikrochirurgie, Plastische Chirurgie; 1986. p. 242-8 PMID: 3527890 **exclusion reason -** not relevant.

1135. Pettit, K. L. and K. Wendt. Across the care continuum: Taking a pro-active approach to pressure ulcer care. Remington Report; 2007. p. 7-10 **exclusion reason -** background.

1136. Pfeffer, F., E. von Dobschuetz, H. Riediger, C. Moosmann and U. T. Hopt. [the non-healing wound]. MMW Fortschritte der Medizin; 2004. p. 45-8 PMID: 15566249 **exclusion reason -** not relevant.

1137. Pham, C., P. Middleton and G. Maddern. Vacuum-assisted closure for the management of wounds: An accelerated systematic review (structured abstract). Health Technology Assessment Database; 2011 **exclusion reason -** Systematic Review, not directly used.

1138. Phan, T. Q. V., G. Spilker, P. Theodorou, A. Gossmann, M. Heiss and C. Weinand. Combined latissimus dorsi and serratus anterior flaps for pelvic reconstruction. Microsurgery; 2011. p. 529-34 PMID: 21766332 **exclusion reason -** wrong intervention.

1139. Philbeck, T. E., Jr., K. T. Whittington, M. H. Millsap, R. B. Briones, D. G. Wight and W. J. Schroeder. The clinical and cost effectiveness of externally applied negative pressure wound therapy in the treatment of wounds in home healthcare medicare patients. Ostomy Wound Management; 1999. p. 41-50 PMID: 10687657 **exclusion reason -** background.

1140. Phillips, D. and C. Davey. Wound cleaning versus wound disinfection: A challenging dilemma. Perspectives; 1997. p. 15-6 PMID: 9460442 **exclusion reason -** background.

1141. Phillips, E. M. Evidence-based practice: Pressure ulcer management guidelines for spinal cord injury. Topics in Spinal Cord Injury Rehabilitation; 2003. p. 16-19 **exclusion reason -** background.

1142. Phillips, L. Pressure ulcers--prevention and treatment guidelines. Nursing Standard; 1999. p. 56-8, 60, 62 PMID: 11971342 **exclusion reason -** background.

1143. Phillips, L. Cost-effective strategy for managing pressure ulcers in critical care: A prospective, non-randomised, cohort study. Journal of Tissue Viability; 2000. p. 2-6 PMID: 11299575 **exclusion reason -** background.

1144. Phillips Tj, P. W. Clinial trial of cultured autologous keratinocyte grafts in the treatment of long-standing pressure ulcers. Wounds: A Compendium of Clinical Research and Practice; 1994. p. 113 **exclusion reason -** not relevant.

1145. Phipps, M., B. Bauman, D. Berner, M. Butler, A. Kalinoski, M. Looby, N. Malacaria, L. Pratt, P. Reiley and M. Sullivan. Staging care for pressure sores. American Journal of Nursing; 1984. p. 999-1003 PMID: 6565467 **exclusion reason -** background.

1146. Piatkowski, A., D. Ulrich, S. Seidel, M. Abel, N. Pallua and A. Andriessen. Randomized controlled pilot comparing collagen and foam dressings in pressure ulcer patients evaluating their influence on healing time, angiogenesis and proinflammatory cells. 15th Conference Nationale Des Plaies Et Cicatrisations Prevention Et Traitement; 2011 **exclusion reason -** no original data.

1147. Pieper, B., C. Mikols, W. Adams and B. Mance. Low and high air-loss beds in acute care hospitals. Journal of Enterostomal Therapy; 1990. p. 131-6 PMID: 2347992 **exclusion reason -** wrong outcome.

1148. Pierce, G. F., J. E. Tarpley, R. M. Allman, P. S. Goode, C. M. Serdar, B. Morris, T. A. Mustoe and J. V. Berg. Tissue repair processes in healing chronic pressure ulcers treated with recombinant platelet-derived growth factor bb. American Journal of Pathology; 1994. p. 1399-1410 PMID: 7992843 **exclusion reason -** duplicate.

1149. Pieroni, R. E. and E. S. Hanson. Use of galvanic stimulation in the treatment of decubitus ulcers in the elderly. **exclusion reason -** unable to find.

1150. Pilarski, D. [protocol of care and prevention of decubitus ulcers]. Soins; La Revue de Reference Infirmiere; 1986. p. 51-3 PMID: 3645791 **exclusion reason -** not relevant.

1151. Pinchcofsky-Devin, G. D. and M. V. Kaminski. Correlation of pressure sores and nutritional status. Journal of the American Geriatrics Society; 1986. p. 435-440 PMID: 3084610 **exclusion reason -** background.

1152. Pinter, L., J. Vosmik, L. Klein and Z. Talabova. [use of myocutaneous flaps in the treatment of decubitus ulcer]. Rozhledy V Chirurgii; 1988. p. 723-8 PMID: 3217839 **exclusion reason -** not relevant.

1153. Pistolesi, C. and E. Maffei. Pressure sores treatment: An update and some operative proposals. Giornale Italiano di Farmacia Clinica; 1998. p. 36-43 **exclusion reason -** background.

1154. Pohl, M., S. Ruckriem, H. Strik, B. Hortinger, D. Meissner, J. Mehrholz and M. Pause. Treatment of pressure ulcers by serial casting in patients with severe spasticity of cerebral origin. Archives of Physical Medicine & Rehabilitation; 2002. p. 35-9 PMID: 11782830 **exclusion reason -** wrong population.
1155. Poirier, P., P. Madezo, B. Perrouin-Verbe, D. Hepner-Lavergne, M. Pannier and J. V. Bainvel. Cover of trochanteric pressure sores by v-y tensor fascia latae musculocutaneous flap. Annales de Chirurgie Plastique et Esthetique; 1994. p. 464-468 PMID: 7755328 **exclusion reason -** not relevant.
1156. Popescu, L. and I. Petcu. [surgical treatment of decubitus eschars]. Revista Medico-Chirurgicala a Societatii de Medici Si Naturalisti Din Iasi; 1987. p. 685-8 PMID: 3452861 **exclusion reason -** not relevant.
1157. Posma, A. N. The innervated tensor fasciae latae flap in patients with meningomyelocele. Annals of Plastic Surgery; 1988. p. 594-6 PMID: 3239938 **exclusion reason -** not relevant.
1158. Posnett, J. and P. J. Franks. The burden of chronic wounds in the uk. Nursing Times; 2008. p. 44-5 PMID: 18293879 **exclusion reason -** no original data.
1159. Posthauer, M. E. Do patients with pressure ulcers benefit from oral zinc supplementation? Advances in Skin & Wound Care; 2005. p. 471-2 PMID: 16365542 **exclusion reason -** no original data.
1160. Posthauer, M. E. When is enteral nutrition support an effective strategy? Advances in Skin & Wound Care; 2006. p. 257-60 PMID: 16732071 **exclusion reason -** background.
1161. Posthauer, M. E. The role of nutrition in wound care. Adv Skin Wound Care; 2006. p. 43-52 **exclusion reason -** no original data.
1162. Posthauer, M. E. The role of nutrition in wound care. Advances in skin & wound care; 2012. p. 62-3 PMID: 22258214 **exclusion reason -** background.
1163. Postigo, S. [care of skin ulcers in hospital and outside]. Revista de Enfermeria; 1997. p. 40 PMID: 9233262 **exclusion reason -** background.
1164. Poteete, V. Case study: Eliminating odors from wounds. Decubitus; 1993. p. 43-6 PMID: 8297491 **exclusion reason -** not relevant.
1165. Priesack, W., K. H. Fuchs and E. Bauer. [primary immediate coverage of decubitus ulcers by musculocutaneous flaps and gentamicin pmma beads]. Handchirurgie, Mikrochirurgie, Plastische Chirurgie; 1987. p. 10-6 PMID: 3557201 **exclusion reason -** not relevant.
1166. Protz, K. [the agony of choice in wound management]. Pflege Zeitschrift; 2010. p. 206-9 PMID: 20426380 **exclusion reason -** not relevant.
1167. Pruss, S. [mis micro-stimulation system in general practice]. Krankenpflege Journal; 2005. p. 124-5 PMID: 16171068 **exclusion reason -** not relevant.
1168. Qian, X., H. Yuan and M. Zhang. Traditional chinese medicine to treat patients with pressure sore -- a meta analysis of randomized controlled trial [chinese]. Chinese Nursing Research; 2004. p. 568-570 **exclusion reason -** Systematic Review, not directly used.
1169. Quality, A. f. H. R. a. Air-fluidized beds used for treatment of pressure ulcers in the home environment - systematic review (brief record). Health Technology Assessment Database; 2011 **exclusion reason -** Systematic Review, not directly used.
1170. Queen, D. The emergence of a clinical specialty in wound care. International Wound Journal; 2010. p. 3-4 PMID: 20409244 **exclusion reason -** background.
1171. Quelard, B., M. E. Cordier, M. C. Regent and M. Tenette. Comparative study to determine the relative efficiency of two types of treatment of decubitus ulcers of sacro and ischial tuberosities: Topical ozone treatment versus the traditional methods. Annales Medicales de Nancy et de l'Est; 1985. p. 329-334 **exclusion reason -** not relevant.
1172. Quillot, M., J. P. Lodde, O. Pegorier, J. P. Reynaud and A. Cormerais. Variant of island flaps for cover of pressure sores: The hatchet flap. Report of a series of 31 cases. Annales de Chirurgie Plastique et Esthetique; 1994. p. 469-472 PMID: 7755329 **exclusion reason -** not relevant.
1173. Rabinovich, O. F. and E. L. Epel'dimova. [methods of diagnosis and local treatment of oral mucosa (lichen ruber planus, recurrent aphthous stomatitis, decubitus ulcers)]. Stomatologiia; 2005. p. 58-63 PMID: 16114139 **exclusion reason -** not relevant.
1174. Rabus, M. T., F. Dare, L. E. Le Mouel and S. Meaume. Sequential treatment using alginate-cmc and hydrocolloid dressing in pressure ulcers: Results of a controlled study (steps study). 2nd World Union of Wound Healing Societies Meeting; 2004 **exclusion reason -** no original data.
1175. Raffoul, W. Advances in wound care. Schweizerische Rundschau fur Medizin - Praxis; 2008. p. 257-260 **exclusion reason -** background.
1176. Rainfray, M., P. Dehail and N. Salles. [complications of immobility and bed rest. Prevention and management]. Revue du Praticien; 2007. p. 671-6 PMID: 17593793 **exclusion reason -** background.
1177. Rajacic, N., R. K. Gang, H. Dashti and A. Behbehani. Treatment of ischial pressure sores with an inferior gluteus maximus musculocutaneous island flap: An analysis of 31 flaps. British Journal of Plastic Surgery; 1994. p. 431-4 PMID: 7952811 **exclusion reason -** not relevant.
1178. Ramadan, A. An optimum current intensity for healing. Journal of Wound Care; 2012. p. 10-10 **exclusion reason -** wrong intervention.
1179. Ramirez, O. M., W. M. Swartz and J. W. Futrell. The gluteus maximus muscle: Experimental and clinical considerations relevant to reconstruction in ambulatory patients. British Journal of Plastic Surgery; 1987. p. 1-10 PMID: 3814892 **exclusion reason -** not relevant.
1180. Rasero, L., C. Fabbri, L. Cantasano, T. Lotti, T. Pucci, M. Veratti and M. Rossi. [prevention of pressure ulcers: Retrospective study regarding the effectiveness of an alternate pressure device].

Professioni Infermieristiche; 2007. p. 237-41 PMID: 18289496 **exclusion reason -** not relevant.
1181. Rath, E. [treatment of decubitus ulcers/wound management: A dry wound is a dead wound]. Pflege Zeitschrift; 1998. p. 510-2 PMID: 9752230 **exclusion reason -** not relevant.
1182. Ratliff, C. and N. Tomaselli. Wocn update on evidence-based guidelines for pressure ulcers. Journal of Wound, Ostomy & Continence Nursing; 2011. p. S8-S8 PMID: 20838310 **exclusion reason -** background.
1183. Ratliff, C. R. and G. T. Rodeheaver. Use of the push tool to measure venous ulcer healing. Ostomy Wound Management; 2005. p. 58-60, 62-3 PMID: 16014985 **exclusion reason -** background.
1184. Ratliff, C. R. and N. Tomaselli. Update on evidence-based guideline for pressure ulcers. Long-Term Living: For the Continuing Care Professional; 2010. p. 14 **exclusion reason -** background.
1185. Ratliff, C. R. and N. Tomaselli. Wocn update on evidence-based guideline for pressure ulcers. Journal of Wound, Ostomy, & Continence Nursing; 2010. p. 459-60 PMID: 20838310 **exclusion reason -** background.
1186. Ratliff, C. R. and Wocn. Wocn's evidence-based pressure ulcer guideline. Advances in Skin & Wound Care; 2005. p. 204-8 PMID: 15920372 **exclusion reason -** background.
1187. Rawat, S. S. and B. S. Mathur. Transverse lumbar flap for sacral bed sores. Plastic & Reconstructive Surgery; 1991. p. 154-8 PMID: 2052646 **exclusion reason -** not relevant.
1188. Reddy, M. Pressure ulcers. Clinical Evidence; 2011 PMID: 21524319 **exclusion reason -** background.
1189. Reddy, M., S. S. Gill, S. R. Kalkar, W. Wu, P. J. Anderson and P. A. Rochon. Treatment of pressure ulcers: A systematic review. JAMA; 2008. p. 2647-62 PMID: 19066385 **exclusion reason -** background.
1190. Redelings, M. D., N. E. Lee and F. Sorvillo. Pressure ulcers: More lethal than we thought? Advances in Skin & Wound Care; 2005. p. 367-72 PMID: 16160463 **exclusion reason -** background.
1191. Redelings, M. D., M. Wise and F. Sorvillo. Using multiple cause-of-death data to investigate associations and causality between conditions listed on the death certificate.[erratum appears in am j epidemiol. 2008 sep 15;168(6):666]. American Journal of Epidemiology; 2007. p. 104-8 PMID: 17426040 **exclusion reason -** background.
1192. Rees, R. S., A. F. Reilley, L. B. Nanney and J. B. Lynch. Sacral pressure sores: Treatment with island gluteus maximus musculocutaneous flaps. Southern Medical Journal; 1985. p. 1147-51 PMID: 3901280 **exclusion reason -** not relevant.
1193. Rees, R. S., M. C. Robson, J. M. Smiell and B. H. Perry. Becaplermin gel in the treatment of pressure ulcers: A randomized double-blind placebo-controlled study. Wound Repair and Regeneration; 1998. p. A478 PMID: 10417749 **exclusion reason -** not relevant.
1194. Rees, R. S., M. C. Robson, J. M. Smiell and B. H. Perry. A randomized, double-blind, placebo-controlled study of becaplermin (recombinant human platelet-derived growth factor-bb) gel in the treatment of pressure ulcers. Wound Repair and Regeneration; 1998. p. A246 **exclusion reason -** no original data.
1195. Reeves, I., M. Plourde, S. Authier and C. Doddridge. [combined effect of acticoat and vac on wound healing]. Perspective infirmiere: Revue Officielle de l'Ordre des Infirmieres et Infirmiers du Quebec; 2005. p. 10-5 PMID: 15962530 **exclusion reason -** not relevant.
1196. Regan, M. A., R. W. Teasell, D. L. Wolfe, D. Keast, W. B. Mortenson and J. A. L. Aubut. A systematic review of therapeutic interventions for pressure ulcers after spinal cord injury. Archives of Physical Medicine and Rehabilitation; 2009. p. 213-231 **exclusion reason -** Systematic Review, not directly used.
1197. Reger, S. I., S. Negami, E. T. Reyes, R. Navarro, N. Parikh and C. A. McDevitt. [610] use of direct current stimulation in pressure sore healing. Journal of Rehabilitation Research and Development; 1991. p. 478 **exclusion reason -** not relevant.
1198. Reichert, B., P. Brenner and A. Berger. [management of para-pelvic decubitus ulcers]. Zentralblatt fur Chirurgie; 1996. p. 83-4 PMID: 8967256 **exclusion reason -** not relevant.
1199. Reis, B. [doubts about modern treatment methods but: Moist wound treatment is cheaper]. Pflege Zeitschrift; 1999. p. 365-6 PMID: 10514739 **exclusion reason -** not relevant.
1200. Reis, J., J. Amarante, A. Costa-Ferreira, A. Silva and E. Malheiro. Surgical treatment of pressure sores. European Journal of Plastic Surgery; 1999. p. 318-321 **exclusion reason -** background.
1201. Relander, M. [conservative and surgical management of decubitus ulcer]. Duodecim; 1996. p. 1492-5 PMID: 10596137 **exclusion reason -** not relevant.
1202. Relander, M. and B. Palmer. Recurrence of surgically treated pressure sores. Scandinavian Journal of Plastic & Reconstructive Surgery & Hand Surgery; 1988. p. 89-92 PMID: 3387926 **exclusion reason -** not relevant.
1203. Remington, L. Wound care... Not an isolated problem. Remington Report; 2006. p. 5-5 **exclusion reason -** background.
1204. Remon, J. P. The magistral prescription on the basis of hypochlorite in the treatment of bedsores. Farmaceutisch Tijdschrift voor Belgie; 1995. p. 27-28 **exclusion reason -** not relevant.
1205. Rendo, M., C. Veneziani and S. Zappulla. [prevention and treatment of decubitus ulcers: An experience]. Professioni Infermieristiche; 1999. p. 48-53 PMID: 10455813 **exclusion reason -** not relevant.
1206. Rennert, R., M. Golinko, A. Yan, A. Flattau, M. Tomic-Canic and H. Brem. Developing and evaluating outcomes of an evidence-based protocol for the treatment of osteomyelitis in stage iv pressure ulcers: A literature and wound electronic medical record database review. Ostomy Wound Management; 2009.

p. 42-53 PMID: 19359709 **exclusion reason -** not relevant.

1207. Resch, C. S., E. Kerner, M. C. Robson, J. P. Heggers, M. Scherer, J. A. Boertman and R. Schileru. Pressure sore volume measurement. A technique to document and record wound healing. Journal of the American Geriatrics Society; 1988. p. 444-6 PMID: 3361046 **exclusion reason -** background.

1208. Ribinik, P., C. Yvon, B. Barrois, D. Colin and A. Megnigbeto. [decubitus ulcers and dressings. Nursing practices]. Soins; La Revue de Reference Infirmiere; 1997. p. 44-7 PMID: 9239098 **exclusion reason -** not relevant.

1209. Ricci, E. [treatment of skin lesions with katogel]. Minerva Chirurgica; 1996. p. 369-75 PMID: 9072749 **exclusion reason -** not relevant.

1210. Ricci, E., D. Bosio and M. Nano. Topical treatment of chronic pressure ulcers with ustiosan. Giornale Italiano di Dermatologia e Venereologia; 2003. p. 513-517 **exclusion reason -** not relevant.

1211. Rice, T. T. Metronidazole use in malodorous skin lesions. Rehabilitation Nursing; 1992. p. 244-5, 255 PMID: 1448604 **exclusion reason -** wrong population.

1212. Richards, J., K. Lowery and B. Atkinson. Installing electrically operated beds. Nursing Times; 2003. p. 71 PMID: 12715566 **exclusion reason -** background.

1213. Riebelova, V. The tensor fasciae latae musculocutaneous flap in operations for trochanteric decubitus ulcers. Acta Chirurgiae Plasticae; 1985. p. 17-25 PMID: 2581409 **exclusion reason -** not relevant.

1214. Rieger, U., O. Scheufler, D. Schmid, M. Zweifel-Schlatter, D. Kalbermatten and G. Pierer. [six treatment principles of the basle pressure sore concept]. Handchirurgie, Mikrochirurgie, Plastische Chirurgie; 2007. p. 206-14 PMID: 17602385 **exclusion reason -** not relevant.

1215. Rieger, U. M. and G. Pierer. Decubitus - six fundamental treatment principles. Haut; 2011. p. 13-16 **exclusion reason -** background.

1216. Riggs, R., V. Banks, S. Bale and K. Harding. Comparison of an absorbent semi-permeable polyurethane dressing (spyrosorb/mitraflex) and a hydrocolloid dressing (granuflex e) for the treatment of moderately exuding pressure sores in hospitalised patients. 3rd European Conference on Advances in Wound Management; 1993 **exclusion reason -** no original data.

1217. Rigotti, G., A. Bortolani, C. Cristofoli, P. L. Gibelli, A. Marchi and S. Furlan. Repair of loss of cutaneous tissue in the vertebral area. Rivista Italiana di Chirurgia Plastica; 1988. p. 277-281 **exclusion reason -** not relevant.

1218. Riihelainen, A. [care of pressure sores]. Sairaanhoitaja (Helsinki); 1991. p. 42-4 PMID: 1888910 **exclusion reason -** not relevant.

1219. Rimareix, F. and A. Lortat-Jacob. Surgical treatment of paraplegic patent's pressures sores. Retrospective study of 90 cases. Annales de Chirurgie Plastique et Esthetique; 2000. p. 589-596 **exclusion reason -** not relevant.

1220. Rindflesch, A. B. and N. E. Miller. The thoracic suspension orthosis - a seating option for patients with pressure ulcers. Journal of Spinal Cord Medicine; 2002. p. 306-309 PMID: 12482174 **exclusion reason -** not relevant.

1221. Rioufol, M. O. [care and prevention actions. 1/6. Prevention of decubitus ulcers]. Soins; La Revue de Reference Infirmiere; 2001. p. 51-2 PMID: 12008500 **exclusion reason -** not relevant.

1222. Rioufol, M. O. [5/6--prevention and treatment of effects of prolonged bedrest]. Soins; La Revue de Reference Infirmiere; 2001. p. 55-6 PMID: 12012690 **exclusion reason -** not relevant.

1223. Roales-Welsch, S., M. Antaszek, W. Hense, M. Pfeiffer, E. Freyenhagen and P. Engel. [study on quality assurance in the prevention and therapy of decubitus ulcer by measuring the overlay pressure with test subjects on different prophylaxis systems]. Pflege; 2000. p. 297-305 PMID: 11194333 **exclusion reason -** not relevant.

1224. Roberts, L. and B. Mello. Improving outcomes for pressure ulcer patients: Tying together financial and clinical quality for success. Remington Report; 2005. p. 35-36 **exclusion reason -** background.

1225. Robinson, B. J. The use of a hydrofibre dressing in wound management. Journal of Wound Care; 2000. p. 32-4 PMID: 10827666 **exclusion reason -** no original data.

1226. Robres, M. D. B., G. L. Ros and M. A. Melero Garcia. Starch paste as a treatment for pressure ulcers [spanish]. Enfermeria Clinica; 1994. p. 195-198 PMID: 1995008700 **exclusion reason -** not relevant.

1227. Robson, M. C. and A. Barbul. Guidelines for the best care of chronic wounds. Wound Repair & Regeneration; 2006. p. 647-648 PMID: 17199830 **exclusion reason -** background.

1228. Robson, M. C., S. P. Maggi, P. D. Smith, R. J. Wassermann, G. C. Mosiello, D. P. Hill and D. M. Cooper. Ease of wound closure as an endpoint of treatment efficacy. Wound Repair & Regeneration; 1999. p. 90-96 **exclusion reason -** wrong outcome.

1229. Robson, M. C., R. J. Mannari, P. D. Smith and W. G. Payne. Maintenance of wound bacterial balance. American Journal of Surgery; 1999. p. 399-402 PMID: 10612536 **exclusion reason -** wrong intervention.

1230. Rodier-Bruant, C., P. Keller, D. Herman, R. Stricher, D. Geiger, A. Manunta and A. Wilk. [the use of sorbsan in the treatment of the donor site of skin transplantations]. Minerva Chirurgica; 1992. p. 995-9 PMID: 1436580 **exclusion reason -** not relevant.

1231. Rodriguez Palma, M., R. Malia Gazquez and A. Barba Chacon. [immobilization and localization of pressure ulcers in aged patients under home care]. Revista de Enfermeria; 2000. p. 515-8 PMID: 10983158 **exclusion reason -** background.

1232. Rodriguez Rocha, C. [chronic ulcers. A protocol of care and treatment]. Revista de Enfermeria; 1993. p. 65-9 PMID: 8321990 **exclusion reason -** not relevant.

1233. Roeckl-Wiedmann, I., M. Bennett and P. Kranke. Systematic review of hyperbaric oxygen in the management of chronic wounds. British Journal of Surgery; 2005. p. 24-32 PMID: 15635604 **exclusion reason -** wrong population.
1234. Roghmann, M. C., A. Siddiqui, K. Plaisance and H. Standiford. Mrsa colonization and the risk of mrsa bacteraemia in hospitalized patients with chronic ulcers. Journal of Hospital Infection; 2001. p. 98-103 PMID: 11170772 **exclusion reason -** background.
1235. Rogissart, F., G. Malka and C. Guyenne. Gluteal decubitus ulcers: Our therapeutic approach over the last 10 years, base on a series of 32 cases. Annales de Chirurgie Plastique et Esthetique; 1997. p. 247-252 **exclusion reason -** not relevant.
1236. Roldan Valenzuela, A., P. Jaen Ferrer, F. Ferrer Cano and J. E. Torra i Bou. [decubitus ulcers in the sacrum. Evaluation of a specific hydrocolloid hydro-regulatory dressing]. Revista de Enfermeria; 1999. p. 223-30 PMID: 10437569 **exclusion reason -** not relevant.
1237. Romanelli, M., V. Dimi, M. S. Bertone, C. Mazzatenta and P. Martini. Efficacy and tolerability of "fitostimoline(registered trademark) antibiotico" soaked gauzes in the topical treatment of cutaneous sores, ulcers and burns, complicated with bacterial contamination. An open-label, controlled, randomised, multicentre, parallel group. Gazzetta Medica Italiana Archivio per le Scienze Mediche; 2008. p. 251-260 **exclusion reason -** not relevant.
1238. Romanelli, M., V. Dini, S. Barbanera and M. S. Bertone. Evaluation of the efficacy and tolerability of a solution containing propyl betaine and polihexanide for wound irrigation. Skin Pharmacology & Physiology; 2010. p. 41-4 PMID: 20829661 **exclusion reason -** wrong population.
1239. Romanelli, M., A. Magliaro, D. Mastronicola and S. Siani. Systemic antimicrobial therapies for pressure ulcers. Ostomy Wound Management; 2003. p. 25-9 PMID: 12883162 **exclusion reason -** no original data.
1240. Rooman, R. P. Ketanserin promotes wound healing: Clinical and preclinical results. Progress in Clinical & Biological Research; 1991. p. 115-28 PMID: 1862126 **exclusion reason -** wrong population.
1241. Roth, R. S., J. C. Lowery and J. B. Hamill. Assessing persistent pain and its relation to affective distress, depressive symptoms, and pain catastrophizing in patients with chronic wounds: A pilot study. American Journal of Physical Medicine & Rehabilitation; 2004. p. 827-34 PMID: 15502735 **exclusion reason -** wrong intervention.
1242. Rothenaicher, G. [possibilities of v.A.C. Therapy in outpatient surgical practices]. Zentralblatt fur Chirurgie; 2006. p. S182-4 PMID: 16575678 **exclusion reason -** not relevant.
1243. Rousseau, P. Management of pressure sores. Postgraduate Medicine; 1988. p. 51-2 PMID: 3357870 **exclusion reason -** background.
1244. Routkovsky, N. C., S. Meaume, J. M. Goldfarb, P. C. Le and A. Preauchat. Randomized comparative study of two hydrocolloid dressings in the treatment of decubitus ulcers. Revue de Geriatrie; 1996. p. 213-218 **exclusion reason -** wrong outcome.
1245. Routman, A., W. Van Manen and R. Haddad. Cefsulodin treatment for serious pseudomonas aeruginosa infections. Journal of International Medical Research; 1986. p. 242-253 PMID: 3770290 **exclusion reason -** wrong intervention.
1246. Rubayi, S., M. K. Ambe, D. E. Garland and D. Capen. Heterotopic ossification as a complication of the staged total thigh muscles flap in spinal cord injury patients. Annals of Plastic Surgery; 1992. p. 41-6 PMID: 1497295 **exclusion reason -** not relevant.
1247. Rubayi, S. and C. C. Burnett. The efficacy of single-stage surgical management of multiple pressure sores in spinal cord-injured patients. Annals of Plastic Surgery; 1999. p. 533-9 PMID: 10340863 **exclusion reason -** not relevant.
1248. Rubayi, S., S. Cousins and W. A. Valentine. Myocutaneous flaps. Surgical treatment of severe pressure ulcers. AORN Journal; 1990. p. 40-7, 50, 52-5 PMID: 2195991 **exclusion reason -** no original data.
1249. Rubayi, S. and B. S. Doyle. The gluteus maximus muscle-splitting myocutaneous flap for treatment of sacral and coccygeal pressure ulcers. Plastic & Reconstructive Surgery; 1995. p. 1366-71 PMID: 7480235 **exclusion reason -** not relevant.
1250. Rubayi, S. and Y. Kiyono. Flap surgery to cover olecranon pressure ulcers in spinal cord injury patients. Plastic & Reconstructive Surgery; 2001. p. 1473-81 PMID: 11335821 **exclusion reason -** not relevant.
1251. Rubayi, S., D. Pompan and D. Garland. Proximal femoral resection and myocutaneous flap for treatment of pressure ulcers in spinal injury patients. Annals of Plastic Surgery; 1991. p. 132-8 PMID: 1952736 **exclusion reason -** not relevant.
1252. Rubin, J. A., T. P. Whetzel and T. R. Stevenson. The posterior thigh fasciocutaneous flap: Vascular anatomy and clinical application. Plastic & Reconstructive Surgery; 1995. p. 1228-39 PMID: 7761510 **exclusion reason -** not relevant.
1253. Rumeau, P., P. Senet, G. Lefranc, C. Didailler and S. Meaume. [supports to aid in prevention and care]. Soins; La Revue de Reference Infirmiere; 2001. p. 22-3 PMID: 12008428 **exclusion reason -** not relevant.
1254. Russell, L. The sheepskin myth. Nursing Times; 2000. p. 4 PMID: 11963708 **exclusion reason -** background.
1255. Russell, L. Malnutrition and pressure ulcers: Nutritional assesment tools. British Journal of Nursing (BJN); 2000. p. 194-196 **exclusion reason -** wrong population.
1256. Russell, L. Overview of research to investigate pressure-relieving surfaces. British Journal of Nursing; 2001. p. 1421-6 PMID: 11865248 **exclusion reason -** background.
1257. Russell, L. What is the evidence for specific pressure-reducing mattresses? British Journal of Nursing; 2002. p. S5 PMID: 12476147 **exclusion reason -** no original data.

1258. Russell, L., T. M. Reynolds, J. Carr, A. Evans and M. Holmes. Randomised controlled trial of two pressure-relieving systems. Journal of Wound Care; 2000(a). p. 52-5 PMID: 11933280 **exclusion reason -** duplicate.
1259. Russell, L. J., T. M. Reynolds, C. Park, S. Rithalia, M. Gonsalkorale, J. Birch, D. Torgerson, C. Iglesias and P.-S. Group. Randomized clinical trial comparing 2 support surfaces: Results of the prevention of pressure ulcers study. Advances in Skin & Wound Care; 2003. p. 317-27 PMID: 14652518 **exclusion reason -** wrong outcome.
1260. Russell, T., A. L. Bsn and J. A. Lohman. A medical center's experience with managing specialty bed usage. Journal of Wound, Ostomy, & Continence Nursing; 2001. p. 274-8 PMID: 11707759 **exclusion reason -** background.
1261. Russell, T. and A. Logsdon. Pressure ulcers and lateral rotation beds: A case study. Journal of Wound, Ostomy, & Continence Nursing; 2003(b). p. 143-5 PMID: 12761485 **exclusion reason -** not relevant.
1262. Ryan, D. W. The fluidised bed i: Basic principles, bacteriology and wound care. Intensive Care World; 1990. p. 92-6 PMID: 10148102 **exclusion reason -** unable to find.
1263. Ryan, D. W. Cost effectiveness of specialised beds. Care of the Critically Ill; 1994. p. 10+12-13 **exclusion reason -** wrong outcome.
1264. Ryan, D. W. The fluidised bed. Intensive Care Medicine; 1995. p. 270-6 PMID: 7790620 **exclusion reason -** no original data.
1265. Ryan, J. M. Occupational therapists: A frontline approach to better managing pressure ulcers. Remington Report; 2008. p. 42 **exclusion reason -** background.
1266. Rycroft-Malone, J. and L. Duff. Developing clinical guidelines: Issues and challenges. Journal of Tissue Viability; 2000. p. 144-9, 152-3 PMID: 11949302 **exclusion reason -** background.
1267. Rycroft-Malone, J. and L. Duff. Pressure ulcer guidelines. Nursing Standard; 2000. p. 31 PMID: 11974175 **exclusion reason -** background.
1268. Ryden, M. B., M. Snyder, C. R. Gross, K. Savik, V. Pearson, K. Krichbaum and C. Mueller. Value-added outcomes: The use of advanced practice nurses in long-term care facilities. Gerontologist; 2000. p. 654-62 PMID: 11131082 **exclusion reason -** wrong intervention.
1269. Rygiel, R. Death from pressure ulcer. American Journal of Nursing; 2009. p. 13 PMID: 19411881 **exclusion reason -** not relevant.
1270. Sabharwal, S., P. Woods, A. M. Spungen, W. A. Bauman and J. F. Collins. Use of adjunctive therapies for pressure ulcer treatment in sci. Journal of Spinal Cord Medicine; 2009. p. 474 **exclusion reason -** wrong population.
1271. Sabree, M. Death from pressure ulcer. American Journal of Nursing; 2009. p. 13; author reply 14 PMID: 19411882 **exclusion reason -** no original data.
1272. Safaie, N. and N. Maghamipour. Management of deep bed sore with closed irrigation in cardiac surgery: Experience with the use of normal saline solution. Research Journal of Medical Sciences; 2009. p. 133-136 **exclusion reason -** not relevant.
1273. Saggini, R., A. Figus, A. Troccola, V. Cocco, A. Saggini and N. Scuderi. Extracorporeal shock wave therapy for management of chronic ulcers in the lower extremities. Ultrasound in Medicine & Biology; 2008. p. 1261-71 PMID: 18394777 **exclusion reason -** wrong outcome.
1274. Sahni, T., P. Singh and M. J. John. Hyperbaric oxygen therapy: Current trends and applications. Journal of the Association of Physicians of India; 2003. p. 280-4 PMID: 12839352 **exclusion reason -** background.
1275. Saint-Cyr, M. and A. Uflacker. Pedicled anterolateral thigh flap for complex trochanteric pressure sore reconstruction. Plastic & Reconstructive Surgery; 2012. p. 397e-399e PMID: 22286486 **exclusion reason -** not relevant.
1276. Saji, M., S. Taguchi, N. Hayama, E. Ohzono, Y. Kobayashi, K. Uchiyama, T. Kanekawa and H. Ohkuni. [effect of gentian violet on the elimination of methicillin-resistant staphylococcus aureus (mrsa) existing in the decubitus region]. Nippon Ronen Igakkai Zasshi - Japanese Journal of Geriatrics; 1993. p. 795-801 PMID: 8230793 **exclusion reason -** not relevant.
1277. Saji, M., S. Taguchi, K. Uchiyama, E. Osono, N. Hayama and H. Ohkuni. Efficacy of gentian violet in the eradication of methicillin-resistant staphylococcus aureus from skin lesions. Journal of Hospital Infection; 1995. p. 225-8 PMID: 8586792 **exclusion reason -** wrong outcome.
1278. Salas Campos, L., T. Pastor Amoros, R. Martin Campos, A. Martinez de la Chica and A. De Haro Barrios. [therapeutic uses for asian yellow-flowered crowfoot, genus ranunculus: The case of blastoestimulina]. Revista de Enfermeria; 2005. p. 59-62 PMID: 15768959 **exclusion reason -** background.
1279. Salawu, A., C. Middleton, A. Gilbertson, K. Kodavali and V. Neumann. Stump ulcers and continued prosthetic limb use. Prosthetics & Orthotics International; 2006. p. 279-85 PMID: 17162518 **exclusion reason -** not relevant.
1280. Salcido, R. Anabolic steroids and wound healing. Advances in Wound Care; 1999. p. 391-391 **exclusion reason -** no original data.
1281. Salcido, R. Anabolic steroids for pressure ulcers revisited. Advances in Skin & Wound Care; 2005. p. 344-6 PMID: 16160455 **exclusion reason -** no original data.
1282. Salcido, S. R. 2007 national patient safety goals: Pressure ulcers. Advances in Skin & Wound Care; 2007. p. 630, 632 PMID: 18091109 **exclusion reason -** background.
1283. Salles, N. and J. Jenn. Effect of nutritional support in prevention and treatment of pressure ulcers. Nutrition Clinique et Metabolisme; 2012 **exclusion reason -** background.
1284. Salzberg, C. A. Continuing the dialogue on healing... Proceedings of the national pressure ulcer advisory panel, fifth national conference, "monitoring pressure ulcer healing: An alternative to reverse

staging". Advances in Wound Care; 1997. p. 8-8 **exclusion reason -** background.
1285. Salzberg, C. A., S. A. Cooper-Vastola, F. Perez, M. G. Viehbeck and D. W. Byrne. The effects of non-thermal pulsed electromagnetic energy on wound healing of pressure ulcers in spinal cord-injured patients: A randomized, double-blind study. Ostomy Wound Management; 1995. p. 42-4, 46, 48 passim PMID: 7546114 **exclusion reason -** background.
1286. San Miguel, L., J. E. Torra i Bou and J. Verdu Soriano. Economics of pressure-ulcer care: Review of the literature on modern versus traditional dressings. Journal of Wound Care; 2007. p. 5-9 PMID: 17334139 **exclusion reason -** Systematic Review, not directly used.
1287. Sanada, H. [evaluation and management of pressure ulcers in the elderly]. Nippon Ronen Igakkai Zasshi - Japanese Journal of Geriatrics; 2006. p. 137-46 PMID: 16683635 **exclusion reason -** not relevant.
1288. Sanada, H. [updated pressure ulcer management]. Nippon Ronen Igakkai Zasshi - Japanese Journal of Geriatrics; 2007. p. 425-8 PMID: 17827794 **exclusion reason -** not relevant.
1289. Sanada, H., G. Nakagami, Y. Mizokami, Y. Minami, A. Yamamoto, M. Oe, T. Kaitani and S. Iizaka. Evaluating the effect of the new incentive system for high-risk pressure ulcer patients on wound healing and cost-effectiveness: A cohort study. International Journal of Nursing Studies; 2010. p. 279-86 PMID: 19748617 **exclusion reason -** not relevant.
1290. Santangelo, A., M. Testai, M. C. Ossino, P. Barbagallo, C. Crisafulli, G. Muscara, M. Tomarchio and D. Maugeri. Management and treatment of decubital ulcers of an elderly population in the assisted sanitary residence of futura-viagrande (catania, sicily, italy). Archives of Gerontology & Geriatrics; 2009. p. 332-4 PMID: 18456351 **exclusion reason -** wrong intervention.
1291. Santangelo, M. Alleviating bedsores can be done. Today's Caregiver; 2009. p. 26-27 **exclusion reason -** background.
1292. Santos, V. L. Selected abstracts from the 17th biennial congress of the wcet in slovenia: Wound care. World Council of Enterostomal Therapists Journal; 2010. p. 38-40 **exclusion reason -** background.
1293. Santos, V. L. and D. Rastinehad. Wcet: Advancing clinical practice and research-wound abstracts. World Council of Enterostomal Therapists Journal; 2007. p. 34-37 **exclusion reason -** background.
1294. Sapountzis, S., H. J. Park, J. H. Kim, A. Chantes, R. M. Beak and C. Y. Heo. The 'reading man flap' for pressure sore reconstruction. Indian Journal of Plastic Surgery; 2011. p. 448-52 PMID: 22279278 **exclusion reason -** not relevant.
1295. Sarabia Lavin, R. and E. Rojo Santos. [pressure ulcers - management of pressure injuries]. Enfermeria Clinica; 2010. p. 136-8 PMID: 20298952 **exclusion reason -** not relevant.
1296. Sari, A. A., K. Flemming, N. A. Cullum and U. Wollina. Therapeutic ultrasound for pressure ulcers. Cochrane Database of Systematic Reviews; 2009 **exclusion reason -** duplicate.
1297. Satoh, K., R. Aoyama, A. Yoshikawa, M. Iwanami and Y. Fukuya. Reconstruction of pressure sores of the buttocks using fasciocutaneous flaps. Japanese Journal of Plastic and Reconstructive Surgery; 1989. p. 371-377 **exclusion reason -** not relevant.
1298. Saydak, S. J. A pilot test of two methods for the treatment of pressure ulcers. Journal of Enterostomal Therapy; 1990. p. 139-42 PMID: 2347993 **exclusion reason -** not relevant.
1299. Scavron, C. Clinical investigation to determine an effective protocol for managing pressure on skin and soft tissue. Ostomy Wound Management; 1989. p. 70-9 PMID: 2730758 **exclusion reason -** wrong population.
1300. Schaefer, C. The treatment of wounds with collagen-containing ointments. Zeitschrift fur Allgemeinmedizin; 1990. p. 665 **exclusion reason -** no original data.
1301. Schaitel, C. Why use a hydrogel dressing? Advances in Wound Care; 1995. p. 12 **exclusion reason -** background.
1302. Schaum, K. D. A new medicare part b wound care policy. Advances in Skin & Wound Care; 2001. p. 238-40 PMID: 11905971 **exclusion reason -** background.
1303. Schaum, K. D. Medicare part b negative pressure wound therapy pump policy. A partner for medicare part a pps. Home Healthcare Nurse; 2002. p. 57-8 PMID: 11839966 **exclusion reason -** background.
1304. Schaum, K. D. New acute care inpatient hospital payment system affects wound care. Advances in Skin & Wound Care; 2008. p. 458-60 PMID: 18836323 **exclusion reason -** no original data.
1305. Scheffel, S. and E.-M. Panfil. [mattresses and co. For prevention of decubitus ulcer. What measures are effective]. Pflege Zeitschrift; 2011. p. 162-3 PMID: 21462468 **exclusion reason -** not relevant.
1306. Scherer, L. A., S. Shiver and E. al. The vacuum assisted closure device: A method of securing skin grafts and improving graft survival. Archives of Surgery; 2002. p. 930-934 PMID: 12146992 **exclusion reason -** wrong population.
1307. Schessel, E. S. and R. Ger. The management of pressure sores by constant-tension approximation. British Journal of Plastic Surgery; 2001. p. 439-46 PMID: 11428778 **exclusion reason -** not relevant.
1308. Scheufler, O., J. Farhadi, S. J. Kovach, S. Kukies, G. Pierer, L. S. Levin and D. Erdmann. Anatomical basis and clinical application of the infragluteal perforator flap. Plastic & Reconstructive Surgery; 2006. p. 1389-400 PMID: 17051110 **exclusion reason -** not relevant.
1309. Schiffman, J., M. S. Golinko, A. Yan, A. Flattau, M. Tomic-Canic and H. Brem. Operative debridement of pressure ulcers. World Journal of Surgery; 2009. p. 1396-402 PMID: 19424752 **exclusion reason -** not relevant.
1310. Schindler, S. and G. J. Motta. Study project: The use of a topical circulatory stimulant for the treatment

of pressure ulcers. Ostomy Wound Management; 1991. p. 50-2 PMID: 1998544 **exclusion reason -** not relevant.

1311. Schluer, A.-B., E. Cignacco and R. J. Halfens. [pressure ulcer prevention and therapy: Results of a descriptive study]. Pflege Zeitschrift; 2008. p. 158-61 PMID: 18450264 **exclusion reason -** not relevant.

1312. Schmid, P., D. Cox, G. Bilbe, G. McMaster, C. Morrison, H. Stahelin, N. Luscher and W. Seiler. Tgf-beta s and tgf-beta type ii receptor in human epidermis: Differential expression in acute and chronic skin wounds. Journal of Pathology; 1993. p. 191-7 PMID: 8277368 **exclusion reason -** background.

1313. Schmidt, A. B., G. Fromberg and M. H. Ruidisch. Applications of the pedicled vastus lateralis flap for patients with complicated pressure sores. Spinal Cord; 1997. p. 437-42 PMID: 9232748 **exclusion reason -** not relevant.

1314. Schmidtling, R. E., S. I. Gordon and B. B. Davenport. Treating pressure ulcers with a myocutaneous flap. Nursing; 1992. p. 56-9 PMID: 1407784 **exclusion reason -** not relevant.

1315. Schmuckler, J. Acoustic pressure wound therapy to facilitate granulation tissue in sacral pressure ulcers in patients with compromised mobility: A case series. Ostomy Wound Management; 2008. p. 50-3 PMID: 18716342 **exclusion reason -** not relevant.

1316. Schneider, S. M., P. Veyres, X. Pivot, A. M. Soummer, P. Jambou, J. Filippi, E. van Obberghen and X. HÃ©buterne. Malnutrition is an independent factor associated with nosocomial infections. Br J Nutr; 2004. p. 105-111 **exclusion reason -** wrong population.

1317. Schoeller, T., M. Shafighi, G. M. Huemer, G. Wechselberger and H. Piza-Katzer. [coverage of pressure sores with free flaps]. Chirurg; 2003. p. 671-6 PMID: 12883796 **exclusion reason -** not relevant.

1318. Schols, J. M. G. A. [dietary supplements are useful in the prevention and treatment of pressure sores]. Nederlands Tijdschrift voor Geneeskunde; 2007. p. 1014 PMID: 17508686 **exclusion reason -** not relevant.

1319. Schols, J. M. G. A. Protein leakage from pressure ulcers: Clinically relevant? Nutrition; 2010. p. 859-60 PMID: 20605697 **exclusion reason -** not relevant.

1320. Schols, J. M. G. A., H. Heyman and E. P. Meijer. Nutritional support in the treatment and prevention of pressure ulcers: An overview of studies with an arginine enriched oral nutritional supplement. Journal of Tissue Viability; 2009. p. 72-9 PMID: 19427218 **exclusion reason -** no original data.

1321. Schonfeld, M., I. Moll, K. Maier and E. G. Jung. [keratinocytes from cell culture for therapy of skin defects. Review and personal results]. Hautarzt; 1993. p. 281-9 PMID: 8320114 **exclusion reason -** not relevant.

1322. Schroder-Van Den Nieuwendijk Dl, D. J.-V. D. E. M. A. The effect of a pressure ulcer specific-versus a protein enriched-sip feed on pressure ulcer healing. 2nd World Union of Wound Healing Societies Meeting; 2004 **exclusion reason -** no original data.

1323. Schuz, W., H. G. Haas and K. Klemm. [closure of soft tissue defects in bone infections using free and pedicled muscle flaps]. Unfallchirurgie; 1987. p. 163-73 PMID: 3660502 **exclusion reason -** not relevant.

1324. Scopel, F., G. Mazzon, P. Zanettin, F. Filippi, C. Cattoni and G. Pinato. The use of cadexomer iodine in the treatment of decubitus ulcers. A preliminary note. Giornale Italiano di Ricerche Cliniche e Terapeutiche; 1991. p. 37-44 **exclusion reason -** not relevant.

1325. Seaborne, D., C. Quirion-DeGirardi, M. Rousseau, M. Rivest and J. Lambert. The treatment of pressure sores using pulsed electromagnetic energy (peme). Physiotherapy Canada; 1996. p. 131-137 **exclusion reason -** wrong outcome.

1326. Seal, D. V. and K. Middleton. Healing of cavity wounds with sugar. Lancet; 1991. p. 571-2 PMID: 1678823 **exclusion reason -** no original data.

1327. Seaman, S. Evaluation & management of lower extremity ulcers. Adherence to prescribed therapy can save limbs. Advance for Nurse Practitioners; 2002. p. 32-6, 39-42, 44 passim PMID: 12418335 **exclusion reason -** not relevant.

1328. Seaman, S., S. Herbster, J. Muglia, M. Murray and C. Rick. Simplifying modern wound management for nonprofessional caregivers. Ostomy Wound Management; 2000. p. 18-27 PMID: 11189544 **exclusion reason -** wrong outcome.

1329. Sebern, M. Home-team strategies for treating pressure sores. Nursing; 1987. p. 50-3 PMID: 3645405 **exclusion reason -** no original data.

1330. Secretariat, M. A. Management of chronic pressure ulcers - evidence-based analysis (structured abstract). Health Technology Assessment Database; 2011 **exclusion reason -** not relevant.

1331. Sedigh, M., E. Polykandriotis, M. Jost, M. G. Kees, F. Kees and R. E. Horch. Penetration of moxifloxacin into wound tissue and wound exudate obtained during topical negative pressure therapy. Clinical Microbiology and Infection; 2011. p. S196-S197 **exclusion reason -** wrong outcome.

1332. Segovia Gomez, T., M. Bermejo Martinez, R. Molina Silva, J. Rueda Lopez and J. E. Torra i Bou. [skin care and pressure ulcer. Hyperoxygenated fatty acids in the prevention of pressure ulcers and treatment of stage i lesions]. Revista de Enfermeria; 2001. p. 18-22 PMID: 12150123 **exclusion reason -** not relevant.

1333. Segovia Gomez, T., J. Verdu Soriano, A. Nolasco Bonmati and J. Rueda Lopez. The effectiveness of a hyperoxygenated fatty acid compound in preventing pressure ulcers. EWMA Journal; 2005. p. 27-31 **exclusion reason -** not relevant.

1334. Seiler, W. O. [home treatment of decubitus]. Deutsche Medizinische Wochenschrift; 1989. p. 1137 PMID: 2743879 **exclusion reason -** not relevant.

1335. Seiler, W. O. [prevention of decubitus ulcers and their treatment]. Krankenpflege Journal; 1989. p. 15-20 PMID: 2601292 **exclusion reason -** not relevant.

1336. Seiler, W. O. and H. B. Stahelin. Pressure sores in geriatrics - pathogenesis, prophylaxis and therapy. Therapeutische Umschau; 1991. p. 329-340 **exclusion reason -** not relevant.

1337. Seiler, W. O. and H. B. Stahelin. [therapy of decubitus ulcers. 3]. Krankenpflege - Soins Infirmiers; 1994. p. 53-9 PMID: 8015266 **exclusion reason -** not relevant.

1338. Seiler, W. O. and H. B. Stahelin. [a little known element of modern ulcer therapy: Moist therapy of chronic skin ulcers]. Krankenpflege - Soins Infirmiers; 1998. p. 35-8 PMID: 9748959 **exclusion reason -** not relevant.

1339. Seiler, W. O. and H. B. Stahelin. [malnutrition prevents healing of decubitus ulcers]. Krankenpflege Journal; 1998. p. 333-41 PMID: 9807378 **exclusion reason -** not relevant.

1340. Seiler, W. O. and H. B. Stahelin. [search for factors preventing wound healing. A motivating therapy concept in chronic decubitus ulcers]. Krankenpflege Journal; 1999. p. 317-23 PMID: 10542559 **exclusion reason -** not relevant.

1341. Seki, M., H. Takahashi and N. Chino. [treatment of pressure sores accompanied by infection in outpatients with spinal cord injury]. Gan to Kagaku Ryoho [Japanese Journal of Cancer & Chemotherapy]; 2000. p. 756-9 PMID: 11190341 **exclusion reason -** not relevant.

1342. Semo, A. H. Relationship-based care: A model for wocn and woca practice... 41st annual wound, ostomy and continence nurses annual conference, st. Louis, missouri, june 6-10, 2009...Wound, ostomy, continence nurse...Wound, ostomy, continence associate. Journal of Wound, Ostomy & Continence Nursing; 2009. p. S25-S25 **exclusion reason -** background.

1343. Senet, P. and S. Meaume. Local and general treatment of pressure sores in the elderly. Presse Medicale; 1999. p. 1840-1845 PMID: 10584120 **exclusion reason -** not relevant.

1344. Senet, P. and S. Meaume. Decubitus ulcers. Revue du Praticien; 2000. p. 1965-1969 PMID: 11151341 **exclusion reason -** not relevant.

1345. Serena, T., R. Wolcott, M. DiSalvo and D. Hurley. Bilayered living cell-based treatment for pressure ulcers:Reuslts of a prospective, randomized, multi-center, open-label clinical trial. The Symposium on Advanced Wounds Care and the Wound Healing Society; 2010 **exclusion reason -** unable to find.

1346. Severens, J. L., J. M. Habraken, S. Duivenvoorden and C. M. A. Frederiks. The cost of illness of pressure ulcers in the netherlands. Advances in Skin & Wound Care; 2002. p. 72-7 PMID: 11984050 **exclusion reason -** background.

1347. Seyhan, T., N. M. Ertas, T. Bahar and H. Borman. Simplified and versatile use of gluteal perforator flaps for pressure sores. Annals of Plastic Surgery; 2008. p. 673-8 PMID: 18520206 **exclusion reason -** not relevant.

1348. Sha, L. Clinical observation on w-s analogous mankind frequency spectrum apparatus for treatment of bed sore [chinese]. Shanxi Journal of Nursing; 1995. p. 80-1 PMID: 1997050695 **exclusion reason -** not relevant.

1349. Shahin, E. S. M., T. Dassen and R. J. G. Halfens. Incidence, prevention and treatment of pressure ulcers in intensive care patients: A longitudinal study. International Journal of Nursing Studies; 2009. p. 413-21 PMID: 18394626 **exclusion reason -** wrong outcome.

1350. Sham, E., W.-T. Choi and S. J. Flood. Lateral supramalleolar flap in reconstruction of pressure ulcers in patients with spinal cord injury. ANZ Journal of Surgery; 2008. p. 167-71 PMID: 18269481 **exclusion reason -** not relevant.

1351. Shamimi Nouri, K., R. Heshmat, R. Karimian, E. Nasli, B. Larijani, Y. A. Novitsky, M. Farhadi and F. Gharibdoust. Intravenous semelil (angipars(trademark)) as a novel therapy for pressure ulcers: A randomized clinical trial. Daru; 2008. p. 49-53 **exclusion reason -** wrong intervention.

1352. Shannon, M. L. and B. Miller. Evaluation of hydrocolloid dressings on healing of pressure ulcers in spinal cord injury patients. Decubitus; 1988. p. 42-6 PMID: 3254702 **exclusion reason -** not relevant.

1353. Shapiro, P. An investigation into the prevention and management of pressure ulcers in ventilator assisted patients using an alternating mattress replacement with advanced features. 2008 **exclusion reason -** no original data.

1354. Sharp, A. Pilot study to compare the incidence of pressure ulceration on two therapeutic support surfaces in elderly care. 17th Conference of the European Wound Management Association; 2007 **exclusion reason -** wrong population.

1355. Sharp, C., G. Burr, M. Broadbent, M. Cummins, H. Casey and A. Merriman. Pressure ulcer prevention and care: A survey of current practice. Journal of Quality in Clinical Practice; 2000. p. 150-7 PMID: 11207953 **exclusion reason -** background.

1356. Sheffet, A., A. S. Cytryn and D. B. Louria. Applying electric and electromagnetic energy as adjuvant treatment for pressure ulcers: A critical review. Ostomy Wound Management; 2000. p. 28-33, 36-40, 42-4 PMID: 10745854 **exclusion reason -** background.

1357. Shekhterman, T., A. Targonski and M. L. Mulhall. Evaluation and treatment of pressure ulcers. Combined Sections Meeting of the Specialty Sections of the American Physical Therapy Association. San Diego, California; 2006 **exclusion reason -** unable to find.

1358. Sherman, R. A. Maggot therapy for treating diabetic foot ulcers unresponsive to conventional therapy. Diabetes Care; 2003. p. 446-451 **exclusion reason -** wrong population.

1359. Shigeyama, M. [preparation of a gel-forming ointment base applicable to the recovery stage of bedsore and clinical evaluation of a treatment method with different ointment bases suitable to each stage of bedsore]. Yakugaku Zasshi - Journal of the Pharmaceutical Society of Japan; 2004. p. 55-67 PMID: 14978948 **exclusion reason -** not relevant.

1360. Shigeyama, M., T. Oogaya, T. Yoneyama, M. Futamura, T. Murakawa, H. Shibata, H. Takeuchi and Y. Kawashima. [preparation of a gel-forming ointment base applicable to the recovery stage of bedsore and clinical evaluation of a treatment method with

different ointment bases suitable to each stage of bedsore]. Yakugaku Zasshi - Journal of the Pharmaceutical Society of Japan; 2001. p. 441-50 PMID: 11433778 **exclusion reason -** not relevant.

1361. Shimada, S., T. Ogawa and Y. Fukuya. The method of keeping complete rest for postoperative patients of pressure sore. Japanese Journal of Plastic and Reconstructive Surgery; 2004. p. 1234-1236 **exclusion reason -** not relevant.

1362. Shimamoto, Y., H. Shimamoto, H. Fujihata, H. Nakamura and Y. Matsuura. Topical application of sugar and povidone-iodine in the management of decubitus ulcers in aged patients. Hiroshima Journal of Medical Sciences; 1986. p. 167-9 PMID: 3771275 **exclusion reason -** not relevant.

1363. Shindo, K. Clinical report on effects of skin barrier containing sodium carboxymethyl cellulose on decubitus. Japanese Pharmacology and Therapeutics; 1990. p. 277-288 **exclusion reason -** not relevant.

1364. Shioda, K., K. Nisijima, T. Kobayashi and S. Kato. Iodoform poisoning: An unrecognized cause of consciousness disturbance. General Hospital Psychiatry; 2004. p. 83-4 PMID: 14757308 **exclusion reason -** not relevant.

1365. Shipkov, C., B. Hadjiev, P. Stefanova, A. Mojallal and A. Uchikov. The posterior thigh flap for ischial pressure sores. Journal of Reconstructive Microsurgery; 2011. p. 141-2 PMID: 20945278 **exclusion reason -** no original data.

1366. Shipperley, T. Guidelines for pressure sore prevention and management. Journal of Wound Care; 1998. p. 309-11 PMID: 9697467 **exclusion reason -** background.

1367. Shipperley, T. Guidelines for pressure ulcer prevention and management. Nursing Times; 2000. p. 11-2 PMID: 10827728 **exclusion reason -** background.

1368. Shojaei, H., Y. Sokhangoei and M. R. Soroush. Low level laser therapy in the treatment of pressure ulcers in spinal cord handicapped veterans living in tehran. Iranian Journal of Medical Sciences; 2008. p. 44-48 **exclusion reason -** wrong population.

1369. Sholar, A. D., L. K. Wong, J. W. Culpepper and L. A. Sargent. The specialized wound care center: A 7-year experience at a tertiary care hospital. Annals of Plastic Surgery; 2007. p. 279-84 PMID: 17471132 **exclusion reason -** wrong intervention.

1370. Shutler, S., J. Stock, S. Bale, K. G. Harding, D. Squires, I. Wilson and et al. A multi-centre comparison of a hydrocellular adhesive dressing (allevyn adhesive) and a hydrocolloid dressing (granuflex) in the management of stage 2 and 3 pressure sores. Proceedings of the 5th European Conference on Advances in Wound Management; 1995 **exclusion reason -** no original data.

1371. Sibbald, R. G., P. Coutts and K. Y. Woo. Reduction of bacterial burden and pain in chronic wounds using a new polyhexamethylene biguanide antimicrobial foam dressing-clinical trial results. Advances in Skin & Wound Care; 2011. p. 78-84 PMID: 21242737 **exclusion reason -** wrong outcome.

1372. Sibbald, R. G., K. Y. Woo and E. A. Ayello. Healing chronic wounds: Dim before dime can help... Debridement, infection/inflammation, moisture balance, edge effect. Ostomy Wound Management; 2009. p. 12-12 **exclusion reason -** not relevant.

1373. Siddiqui, A., T. Wiedrich and V. L. Lewis, Jr. Tensor fascia lata v-y retroposition myocutaneous flap: Clinical experience. Annals of Plastic Surgery; 1993. p. 313-7 PMID: 8239429 **exclusion reason -** not relevant.

1374. Siddiqui, F. and J. Steinberg. Essential treatment tips for decubitus ulcers. Podiatry Today; 2011. p. 44 **exclusion reason -** background.

1375. Sideranko, S., A. Quinn, K. Burns and R. D. Froman. Effects of position and mattress overlay on sacral and heel pressures in a clinical population. Research in Nursing & Health: Wiley Subscription Services, Inc., A Wiley Company; 1992. p. 245-251 PMID: 1496149 **exclusion reason -** wrong outcome.

1376. Siegel, T. J. Death from pressure ulcer. American Journal of Nursing; 2009. p. 13-4; author reply 14 PMID: 19411880 **exclusion reason -** not relevant.

1377. Silvetti, A. N., J. C. Hagen, J. Gaffud, J. Sankoorikal, S. Neerukonda and E. Pettke. Topical use of d - glucose polysaccaharide (dgp) and other nutrients as an effective method to treat and prevent pressure ulcers in the elderly. San Antonio, TX **exclusion reason -** no original data.

1378. Singh, R., R. K. Rohilla, R. Siwach, V. Verma and K. Kaur. Surgery for pressure ulcers improves general health and quality of life in patients with spinal cord injury. Journal of Spinal Cord Medicine; 2010. p. 396-400 PMID: 21061899 **exclusion reason -** not relevant.

1379. Singh, R. and V. Verma. Does surgery for pressure ulcers alter rehabilitation outcome? Journal of Spinal Cord Medicine; 2009. p. 459 **exclusion reason -** not relevant.

1380. Sinha, S. N. and I. Amarasena. Does phenytoin have a role in the treatment of pressure ulcers? Wound Practice & Research; 2008. p. 37-41 **exclusion reason -** not relevant.

1381. Sipponen, A., J. J. Jokinen and J. Lohi. Resin salve from the norwegian spruce tree: A 'novel' method for the treatment of chronic wounds. Journal of Wound Care; 2007. p. 72-4 PMID: 17319621 **exclusion reason -** not relevant.

1382. Sipponen, A., J. J. L. J. Jokinene and P. Sipponen. Efficiency of resin salve from norway spruce in treatment of pressure ulcers and chronic surgical and traumatic wounds. EWMA Journal. p. 41 **exclusion reason -** not relevant.

1383. Skipper, A. Challenges in nutrition, pressure ulcers, and wound healing. Nutrition in Clinical Practice; 2010. p. 13-5 PMID: 20130153 **exclusion reason -** background.

1384. Skorkowska-Telichowska, K., A. Kulma, M. Zk, T. Czuj and J. Szopa. The effects of newly developed linen dressings on decubitus ulcers. Journal of Palliative Medicine; 2012. p. 146-148 **exclusion reason -** no original data.

1385. Smith, D. M. Pressure ulcers in the nursing home. Annals of Internal Medicine; 1995. p. 433-42 PMID: 7639444 **exclusion reason -** Systematic Review, not directly used.
1386. Smith, D. M., D. E. Snow, E. Rees, A. M. Zischkau, J. D. Hanson, R. D. Wolcott, Y. Sun, J. White, S. Kumar and S. E. Dowd. Evaluation of the bacterial diversity of pressure ulcers using btefap pyrosequencing. BMC Medical Genomics; 2010 PMID: 20854691 **exclusion reason -** background.
1387. Smith, N. The benefits of vac therapy in the management of pressure ulcers. British Journal of Nursing; 2004. p. 1359-65 PMID: 15687905 **exclusion reason -** no original data.
1388. Smith, R. A. and J. F. Powell. Pressure sores. Prevention and treatment. Current Therapeutics; 1986. p. 49-62 **exclusion reason -** no original data.
1389. Smith-Temple, J. and J. Y. Johnson. Hospital extra. Clinical procedures. Decubitus care... Adapted with permission from nurses' guide to clinical procedures, 2nd edition, by jean smith-temple, msn, rn, and joyce young johnson, phd, ccrn, copyright 1994 by j.B. Lippincott company, phildelaphia. American Journal of Nursing; 1997. p. 16D-e **exclusion reason -** background.
1390. Smith-Temple, J. and J. Y. Johnson. Hospital extra. Clinical procedures. Pressure ulcer management... Adapted with permission from nurses' guide to clinical procedures, 3rd edition, by jean smith-temple, msn, rn, and joyce young johnson, phd, ccrn, copyright 1998 by lippincott-raven publishers, philadelphia, pa. American Journal of Nursing; 1998. p. 16D **exclusion reason -** background.
1391. Smoot, E. C. Beware of the low-pressure bed substitute [18]. Plastic and Reconstructive Surgery; 2000. p. 1908 **exclusion reason -** background.
1392. Smy, J. Making the beds better. Nursing Times; 2004. p. 24-5 PMID: 15630966 **exclusion reason -** background.
1393. Snyder, R. J. Wound management. Nutrition and its role in wound healing. Podiatry Management; 2006. p. 175-176 **exclusion reason -** background.
1394. Soares, M. O., J. C. Dumville, R. L. Ashby, C. Iglesias, L. Bojke, U. Adderley, E. McGinnis, N. Stubbs, D. J. Torgerson, K. Claxton and N. Cullum. Negative pressure wound therapy for severe pressure ulcers: Evidence synthesis and the value of further research. Wound Repair and Regeneration; 2011. p. A52 **exclusion reason -** no original data.
1395. Sobotka, L. and M. M. Meguid. Healing of wounds and pressure ulcers. Nutrition; 2010. p. 856-7 PMID: 20598854 **exclusion reason -** background.
1396. Sociedad Espanola de, Q., I. Sociedad Espanola de Medicina and C. Asociacion Espanola de. [treatment guide for skin and soft tissue infections. Spanish chemotherapy society, spanish internal medicine society, spanish association of surgeons]. Revista Espanola de Quimioterapia; 2006. p. 378-94 PMID: 17235409 **exclusion reason -** background.
1397. Soldevilla Agreda, J. and F. Martinez Cuervo. [society and chronic wounds. Thoughts to stop invisibility]. Revista de Enfermeria; 2005. p. 35-8 PMID: 15768956 **exclusion reason -** background.
1398. Soldevilla Agreda, J. J. [research on chronic wounds]. Revista de Enfermeria; 2007. p. 4-6 PMID: 17380629 **exclusion reason -** background.
1399. Soldevilla Agreda, J. J., Je, J. Posnett, J. Verdu Soriano, L. San Miguel and M. Mayan Santos. The burden of pressure ulcers in spain. Wounds: A Compendium of Clinical Research & Practice; 2007. p. 201-206 **exclusion reason -** background.
1400. Solomon, M., P. Davis, N. V. Tran and M. Rock. Use of bioabsorbable bone graft in osteomyelitis associated with ischial pressure sores. Plastic & Reconstructive Surgery; 2010. p. 102e-4e PMID: 20679810 **exclusion reason -** wrong population.
1401. Soloway, D. N. Civil claims relating to pressure ulcers: A claimants' lawyer's perspective. Ostomy Wound Management; 1998. p. 20-4, 26 PMID: 9526418 **exclusion reason -** background.
1402. Song, K. Y. [effects of immobility: Pressure sores and their management]. Taehan Kanho - Korean Nurse; 1991. p. 32-40 PMID: 1921267 **exclusion reason -** not relevant.
1403. Sopata, M. Advances in treatment of pressure ulcers and chronic wounds. Onkologia Polska; 2008. p. 153-156 **exclusion reason -** no original data.
1404. Sopata, M. and J. Luczak. The new dressing aquacel -- advances in the treatment of heavily exuding pressure sores [polish]. Przeglad Flebologiczny; 2003. p. 139-142 **exclusion reason -** not relevant.
1405. Sopata, M., J. Luczak and M. Ciupinska. Effect of bacteriological status on pressure ulcer healing in patients with advanced cancer. Journal of Wound Care; 2002. p. 107-10 PMID: 11933727 **exclusion reason -** not relevant.
1406. Soppi E, T. J. Novel carital specialty mattress in the management of pressure sores. 2nd World Union of Wound Healing Societies Meeting; 2004 **exclusion reason -** no original data.
1407. Sorensen, J. L., B. Jorgensen and F. Gottrup. Surgical treatment of pressure ulcers. American Journal of Surgery; 2004. p. 42-51 PMID: 15223502 **exclusion reason -** background.
1408. Sorensen, J. L., M. K. Lassen, B. F. Alsbjorn and F. Gottrup. [pressure sores. Background and therapeutic strategy]. Ugeskrift for Laeger; 1997. p. 275-9 PMID: 9054068 **exclusion reason -** background.
1409. Sorrentino, E. A. and H. N. Mayrovitz. Microcirculation: An open area for nursing research. Critical Care Nursing Quarterly; 1991. p. 1-7 PMID: 1933540 **exclusion reason -** background.
1410. Spadafora, A., A. S. Durand, E. De los Rios and J. M. Vinas. Rocking shoes for beds: Prevention and treatment of pressure sores. Prensa Medica Argentina; 1985. p. 324-328 **exclusion reason -** not relevant.
1411. Spahn, J. G. Develop a seamless individualized pressure ulcer care plan: Recognize-understand-solve. Home Health Care Management & Practice; 2007. p. 285-293 **exclusion reason -** background.

1412. Spahn, J. G. Rethinking treatment for pressure sores. Advance for Physical Therapy & Rehab Medicine; 2010. p. 55-55 **exclusion reason -** background.

1413. Sparholt, S. H. Cost-effectiveness of wound management protocols debated. British Journal of Nursing; 2001. p. 216-7; author reply 216-7 PMID: 12170644 **exclusion reason -** background.

1414. Spauwen, P. H. M., P. H. Robinson, H. P. De Bruijn and D. Mulder. Surgical treatment of pressure sore in paraplegic patients: An evaluation. Netherlands Journal of Surgery; 1989. p. 68-70 PMID: 2747967 **exclusion reason -** not relevant.

1415. Specht, J. P., S. Bergquist and R. A. Frantz. Adoption of a research-based practice for treatment of pressure ulcers. Nursing Clinics of North America; 1995. p. 553-63 PMID: 7567579 **exclusion reason -** background.

1416. Speed, C. A. C. Therapeutic ultrasound in soft tissue lesions. Rheumatology (Oxford); 2001. p. 1331-1336 PMID: 11752501 **exclusion reason -** background.

1417. Spetalnick, B. M. and J. S. Powers. Decubitus ulcer treatment with the water flotation mattress. Journal of the Tennessee Medical Association; 1989. p. 471-2 PMID: 2796333 **exclusion reason -** wrong outcome.

1418. Spillo, N. M. Managing stage iv pressure ulcers in the home. Ostomy Wound Management; 2009. p. 6 PMID: 19673057 **exclusion reason -** no original data.

1419. Splete, H. International pressure ulcer guidelines released in draft. Caring for the Ages; 2009. p. 2p **exclusion reason -** background.

1420. Spoelhof, G. D. and K. Ide. Pressure ulcers in nursing home patients. American Family Physician; 1993. p. 1207-15 PMID: 8465716 **exclusion reason -** background.

1421. Sposato, G., P. Ziccardi, G. Di Caprio, M. Scioli, T. Palma and N. Scuderi. Gluteus myocutaneous flap repairs ischial pressure sores. Rivista Italiana di Chirurgia Plastica; 2001. p. 99-102 **exclusion reason -** not relevant.

1422. Sprigle, S. Prescribing pressure ulcer treatment. Rehab Management; 2000. p. 72-7 PMID: 11702387 **exclusion reason -** no original data.

1423. Spungen, A. M. Vacuum assisted therapy for pressure ulcers in patients with spinal cord injury. **exclusion reason -** no original data.

1424. Spungen, A. M. Healing rate of chronic stage 3 and 4 pressure ulcers. 52nd Annual Conference of American Paraplegia Society **exclusion reason -** Systematic Review, not directly used.

1425. Spungen, A. M., K. M. Koehler, R. Modeste-Duncan, M. Rasul, A. S. Cytryn and W. A. Bauman. 9 clinical cases of nonhealing pressure ulcers in patients with spinal cord injury treated with an anabolic agent: A therapeutic trial. Advances in Skin & Wound Care; 2001. p. 139-44 PMID: 11905979 **exclusion reason -** not relevant.

1426. Spurgin, S. and K. Clinch. Journal of wound care nursing. A new dressing for pressure sores. Nursing Times; 1991. p. 82, 84 PMID: 1886821 **exclusion reason -** wrong outcome.

1427. Srivastava, A., A. Gupta, A. B. Taly and T. Murali. Surgical management of pressure ulcers during inpatient neurologic rehabilitation: Outcomes for patients with spinal cord disease. Journal of Spinal Cord Medicine; 2009. p. 125-31 PMID: 19569459 **exclusion reason -** not relevant.

1428. St Clair, M. Descriptive study of the use of a specialty bed in the united kingdom. Decubitus; 1992. p. 28-30, 32, 36 passim PMID: 1558690 **exclusion reason -** no original data.

1429. Staas, W. E., Jr. and H. M. Cioschi. Pressure sores--a multifaceted approach to prevention and treatment. Western Journal of Medicine; 1991. p. 539-44 PMID: 1830985 **exclusion reason -** background.

1430. Stacey, M., V. Falanga, W. Marston, C. Moffat, T. Phillips, R. G. Sibbald, W. Vanscheidt and C. Lindholm. Compression therapy in the treatment of venous leg ulcers. Nursing Times; 2002. p. 39-43 PMID: 12244668 **exclusion reason -** wrong population.

1431. Staiano, J., B. Richard and K. Graham. Pressure sore of the helical rim: A new problem, a novel treatment. Plastic & Reconstructive Surgery; 2004. p. 1655-7 PMID: 15509972 **exclusion reason -** background.

1432. Stair, J. M. and P. M. Petty. Clinical uses of the tensor fascia lata myocutaneous flap. Journal of the Arkansas Medical Society; 1985. p. 475-7 PMID: 3156119 **exclusion reason -** no original data.

1433. Stamate, T. and A. R. Budurca. The treatment of the sacral pressure sores in patients with spinal lesions. Acta Neurochirurgica - Supplement; 2005. p. 183-7 PMID: 15986752 **exclusion reason -** not relevant.

1434. Stapleton, M. Preventing pressure sores--an evaluation of three products. Geriatric nursing (London, England); 1986. p. 23-5 PMID: 3635484 **exclusion reason -** wrong population.

1435. Starritt, T. and E. Ewing. Implementing good practice in the prevention and management of pressure sores. British Journal of Theatre Nursing; 1999. p. 60-3 PMID: 10232135 **exclusion reason -** background.

1436. Stechmiller, J. K., L. Cowan, J. D. Whitney, L. Phillips, R. Aslam, A. Barbul, F. Gottrup, L. Gould, M. C. Robson, G. Rodeheaver, D. Thomas and N. Stotts. Guidelines for the prevention of pressure ulcers. Wound Repair & Regeneration; 2008. p. 151-168 PMID: 18318801 **exclusion reason -** background.

1437. Steele, K., G. Irwin and N. Dowds. Cadexomer iodine in the management of venous leg ulcers in general practice. Practitioner; 1986. p. 63-68 PMID: 3513150 **exclusion reason -** wrong population.

1438. Steenfos, H. H. and M. S. Agren. A fibre-free alginate dressing in the treatment of split thickness skin graft donor sites. Journal of the European Academy of Dermatology and Venereology; 1998. p. 252-256 PMID: 9883438 **exclusion reason -** wrong population.

1439. Stenberg, M. Air support therapy. Journal of ET Nursing; 1993. p. 132-3 PMID: 8347760 **exclusion reason -** not relevant.

1440. Stephen-Haynes, J. Achieving effective outcomes: Monitoring the effectiveness of the softform premier active[™] mattress. British Journal of Community Nursing; 2010. p. S48-54 **exclusion reason -** no original data.

1441. Stephen-Haynes, J. Managing exudate and the key requirements of absorbent dressings. British Journal of Cardiac Nursing; 2011. p. S44-9 **exclusion reason -** not relevant.

1442. Stephen-Haynes, J. and R. Callaghan. Clinical outcomes using a low friction and shear garment in the care home setting. Wounds UK; 2011. p. 76-84 **exclusion reason -** wrong population.

1443. Stevenson, T. R., R. A. Pollock, R. J. Rohrich and C. A. VanderKolk. The gluteus maximus musculocutaneous island flap: Refinements in design and application. Plastic & Reconstructive Surgery; 1987. p. 761-8 PMID: 3575521 **exclusion reason -** not relevant.

1444. Stockarova, D., J. Pilnacek and J. Rubin. Gluteus maximus musculocutaneous island flaps and their use in sacral decubitus ulcers. Acta Chirurgiae Plasticae; 1985. p. 176-84 PMID: 4060966 **exclusion reason -** not relevant.

1445. Stockarova, D., J. Pilnacek and J. Rubin. [treatment of sacral decubiti using musculocutaneous flaps]. Rozhledy V Chirurgii; 1986. p. 85-92 PMID: 3961603 **exclusion reason -** not relevant.

1446. Stone, A. Pilot study of pressure ulcer mitigation using a unique pressure-redistributing support surface. **exclusion reason -** Scientific Information Packets, not directly used.

1447. Stone, J. M., V. A. Wolfe, M. Nino-Murcia and I. Perkash. Colostomy as treatment for complications of spinal cord injury. Archives of Physical Medicine & Rehabilitation; 1990. p. 514-8 PMID: 2350223 **exclusion reason -** not relevant.

1448. Stone, P., J. Prigozen, M. Hofeldt and E. al. Bolster versus negative pressure wound therapy for securing split-thickness skin grafts in trauma patients. Wounds UK; 2004 **exclusion reason -** wrong population.

1449. Stoneberg, C., N. Pitcock and C. Myton. Pressure sores in the homebound: One solution. American Journal of Nursing; 1986. p. 426-8 PMID: 3633697 **exclusion reason -** wrong population.

1450. Stranadko, E. P., P. I. Tolstykh and I. Y. Kuleshov. Antibacterial photodynamic therapy for treating non-healing purulent wounds and trophic ulcers. Photodiagnosis and Photodynamic Therapy; 2010. p. S18 **exclusion reason -** no original data.

1451. Stratton, R. J., A.-C. Ek, M. Engfer, Z. Moore, P. Rigby, R. Wolfe and M. Elia. Enteral nutritional support in prevention and treatment of pressure ulcers: A systematic review and meta-analysis. Ageing Research Reviews; 2005. p. 422-50 PMID: 16081325 **exclusion reason -** Systematic Review, not directly used.

1452. Strauss, M. J., J. Gong, B. D. Gary, W. D. Kalsbeek and S. Spear. The cost of home air-fluidized therapy for pressure sores. A randomized controlled trial. Journal of Family Practice; 1991. p. 52-9 PMID: 2056290 **exclusion reason -** duplicate.

1453. Suissa, D., A. Danino and A. Nikolis. Negative-pressure therapy versus standard wound care: A meta-analysis of randomized trials. Plastic & Reconstructive Surgery; 2011. p. 498e-503e PMID: 22030509 **exclusion reason -** background.

1454. Suit, H. and I. J. Spiro. Soft tissue sarcomas: Radiation as a therapeutic option. Ann Acad Med Singapore; 1996. p. 855-861 PMID: 9055016 **exclusion reason -** wrong population.

1455. Sullivan, N., D. L. Snyder, K. Tipton, S. Uhl and K. M. Schoelles. Negative pressure wound therapy devices. Technology Assessment Report. Rockville, Maryland: AHRQ 2009. p. 494 **exclusion reason -** Systematic Review, not directly used.

1456. Summer, W. R., P. Curry, E. F. Haponik, S. Nelson and R. Elston. Continuous mechanical turning of intensive care unit patients shortens length of stay in some diagnostic-related groups. Journal of Critical Care; 1989. p. 45-53 **exclusion reason -** wrong population.

1457. Summers, J. B. and J. M. Kaminski. Management of pressure ulcers. JAMA; 2003. p. 2210; author reply 2210-1 PMID: 12734127 **exclusion reason -** no original data.

1458. Sung, Y. H. and K. H. Park. Factors affecting the healing of pressure ulcers in a korean acute care hospital. Journal of Wound, Ostomy, & Continence Nursing; 2011. p. 38-45 PMID: 21178788 **exclusion reason -** background.

1459. Surratt, S. C. Help for managing pressure ulcers. Nursing Management; 2000. p. 6-6 **exclusion reason -** no original data.

1460. Suzuki, S. Conservative treatment using various dressings. Japanese Journal of Plastic and Reconstructive Surgery; 2003. p. 471-475 **exclusion reason -** not relevant.

1461. Suzuki, T., R. Yamashita, M. Tanaka, N. Yamada, E. Uchinuma and Y. Kuroyanagi. Development of new hydrocolloid-type wound dressing containing silver sulfadiazine - multi-centre's clinical reports. Japanese Pharmacology and Therapeutics; 2000. p. 621-633 **exclusion reason -** not relevant.

1462. Szabo, E. and J. Bujdoso. Calendula officinalis in wound treatment [hungarian]. Nover; 1994. p. 20-22 **exclusion reason -** not relevant.

1463. Szor, J. K. and C. Bourguignon. Description of pressure ulcer pain at rest and at dressing change. Journal of Wound, Ostomy, & Continence Nursing; 1999. p. 115-20 PMID: 10711120 **exclusion reason -** wrong intervention.

1464. Tachi, M. and S. Hirabayashi. Adjuvant therapy for pressure ulcer management. Japanese Journal of Plastic and Reconstructive Surgery; 2003. p. 477-483 **exclusion reason -** wrong population.

1465. Tachi, M., S. Hirabayashi, Y. Yonehara, G. Uchida, T. Tohyama and H. Ishii. Topical negative

pressure using a drainage pouch without foam dressing for the treatment of undermined pressure ulcers. Annals of Plastic Surgery; 2004. p. 338-42 PMID: 15385767 **exclusion reason -** not relevant.

1466. Tachibana, S. Clinical evaluation of ulcer dressing for burns, pressure sores, donor sites of skin grafts and similar applications. Japanese Journal of Plastic and Reconstructive Surgery; 1990. p. 321-326 **exclusion reason -** not relevant.

1467. Tada, H., M. Hatoko, A. Tanaka, M. Kuwahara, K. Mashiba and S. Yurugi. Experiences of the reconstruction of sacral pressure sores with the parasacral perforator-based island flap. European Journal of Plastic Surgery; 2002. p. 17-20 **exclusion reason -** not relevant.

1468. Takahashi, C., H. Nemoto and Y. Shibagaki. Management of pressure ulcers using design. World Council of Enterostomal Therapists Journal; 2010. p. 40 **exclusion reason -** wrong intervention.

1469. Takahashi, P. Y., S. S. Cha and L. J. Kiemele. Six-month mortality risks in long-term care residents with chronic ulcers. International Wound Journal; 2008. p. 625-31 PMID: 19134063 **exclusion reason -** wrong intervention.

1470. Takahashi, P. Y., L. J. Kiemele, A. Chandra, S. S. Cha and P. V. Targonski. A retrospective cohort study of factors that affect healing in long-term care residents with chronic wounds. Ostomy Wound Management; 2009. p. 32-7 PMID: 19174587 **exclusion reason -** wrong intervention.

1471. Takahashi, P. Y., L. J. Kiemele and J. P. Jones. Wound care for elderly patients: Advances and clinical applications for practicing physicians. Mayo Clinic Proceedings; 2004. p. 260-7 PMID: 14959923 **exclusion reason -** wrong population.

1472. Takala, J., S. Varmavuo and E. Soppi. Prevention of pressure sores in acute respiratory failure: A randomised controlled trial. Clin Intensive Care; 1996. p. 228-235 **exclusion reason -** wrong outcome.

1473. Takeuchi, A., Y. Yamamoto, H. Minakawa, I. Kokubu, T. Sugihara and T. Yoshida. The use of a rectus abdominis myocutaneous flap for repair of defects of the inguinal and ischial regions. Japanese Journal of Plastic and Reconstructive Surgery; 1996. p. 21-25 **exclusion reason -** not relevant.

1474. Takeuchi, K. [treatment of decubitus and leg ulcer in small cohort hospital without plastic surgeon--a view point of community cooperation and home-based care]. Gan to Kagaku Ryoho [Japanese Journal of Cancer & Chemotherapy]; 2009. p. 63-5 PMID: 20443404 **exclusion reason -** not relevant.

1475. Taniguchi, S. and S. Urakawa. A follow-up study of recurred decubites ulcer cases. Japanese Journal of Plastic and Reconstructive Surgery; 1990. p. 547-554 **exclusion reason -** not relevant.

1476. Tarantola, P., G. Lombardi, M. R. Inzoli, C. Malgeri and G. Magnolfi. The effect of local application of hyaluronic acid associated with lasertherapy in the treatment of decubitus ulcers. An open control clinical study. Giornale di Gerontologia; 1990. p. 151-155 **exclusion reason -** not relevant.

1477. Tarvainen. Cadexomer iodine (iodosorb) compared with dextranomer (debrisan) in the treatment of chronic leg ulcers. Acta Chir Scand Suppl; 1988. p. 57-59 PMID: 2459870 **exclusion reason -** wrong population.

1478. Tate, P. A holistic approach to pressure area care. Nursing Times; 1998. p. 69-72 PMID: 9625971 **exclusion reason -** no original data.

1479. Tavakoli, K., S. Rutkowski, C. Cope, M. Hassall, R. Barnett, M. Richards and J. Vandervord. Recurrence rates of ischial sores in para- and tetraplegics treated with hamstring flaps: An 8-year study. British Journal of Plastic Surgery; 1999. p. 476-9 PMID: 10673925 **exclusion reason -** not relevant.

1480. Taylor, A. Managing pressure ulcers: The need for pain assessment. Community Nurse; 2000. p. 45-6 PMID: 12778508 **exclusion reason -** no original data.

1481. Taylor, B. B. Duoderm wafers: A report on product evaluation. New Zealand Nursing Journal; 1985. p. 10-1 PMID: 3858747 **exclusion reason -** no original data.

1482. Taylor, T. V., S. Rimmer, B. Day, J. Butcher and I. W. Dymock. Ascorbic acid supplementation in the treatment of pressure-sores. Lancet; 1974. p. 544-546 PMID: 4140267 **exclusion reason -** background.

1483. Tazawa, K., T. Kasagi, S. Takemori, H. Arai, K. Yamamoto and M. Fujimaki. Clinical evaluation of a new hydrocolloid dressing in pressure sores. Therapeutic Research; 1990. p. 231-245 **exclusion reason -** not relevant.

1484. Tebbe, B. and C. E. Orfanos. Therapy of leg ulcers and decubitus ulcers with a xerodressing: Modern wound dressing with anti-bacterial activity. H+G Zeitschrift fur Hautkrankheiten; 1996. p. 697-702 **exclusion reason -** not relevant.

1485. Teichs, T. and J. Purfield. Keeping current: Electrical stimulation can augment standard pressure ulcer management. Advance for Physical Therapy & Rehab MedicineAdv Phys Ther Rehab Med.; 2010. p. 28 **exclusion reason -** wrong intervention.

1486. Tellioglu, A. T., B. T. Bilen, G. Ulusoy, M. Akan, S. Celebioglu, U. Kocer and C. Baran. Ideal treatment modality for trochanteric pressure sores. European Journal of Plastic Surgery; 1998. p. 184-185 **exclusion reason -** not relevant.

1487. Tellioglu, A. T., I. Tekdemir, M. Akyuz, K. Arifoglu, B. T. Bilen, G. Ulusoy and O. Sensoz. Ischial pressure sores treated with a sensate gracilis myocutaneous flap. European Journal of Plastic Surgery; 2000. p. 132-134 **exclusion reason -** not relevant.

1488. Teng, B. T., E. W. Tam, I. F. Benzie and P. M. Siu. Protective effect of caspase inhibition on compression-induced muscle damage. Journal of Physiology; 2011. p. 3349-69 PMID: 21540338 **exclusion reason -** wrong population.

1489. Teno, J., P. Gozalo, S. Mitchell, S. Kuo, A. Fulton and V. Mor. Does percutaneous gastrostomy tubes prevent or heal decubitus ulcers in advanced cognitive impairment? Journal of Pain and Symptom

Management; 2012. p. 335 **exclusion reason -** not relevant.
1490. Teno, J. M., P. Gozalo, S. L. Mitchell, S. Kuo, A. T. Fulton and V. Mor. Feeding tubes and the prevention or healing of pressure ulcers. Archives of Internal Medicine; 2012. p. 697-701 PMID: 22782196 **exclusion reason -** not relevant.
1491. Teot, L. [the "surgical moment" in the care of chronic wounds]. Soins; La Revue de Reference Infirmiere; 2000. p. 9-11 PMID: 11040819 **exclusion reason -** not relevant.
1492. Teot, L. [decubitus ulcers]. Revue de L'Infirmiere; 2003. p. 55-8 PMID: 12677911 **exclusion reason -** not relevant.
1493. Teot, L. [decubitus ulcers in paraplegics]. Soins; La Revue de Reference Infirmiere; 2005. p. 20-1 PMID: 15997483 **exclusion reason -** not relevant.
1494. Ter Riet, G. Correction: Randomised clinical trial of ultrasound treatment for pressure ulcers (british medical journal (22nd april) (1040-1041)). British Medical Journal; 1995. p. 1300 **exclusion reason -** no original data.
1495. ter Riet, G., A. G. Kessels and P. Knipschild. Problems in the conduct of a randomised clinical trial. Journal of Wound Care; 1998. p. 259-62 PMID: 9677998 **exclusion reason -** background.
1496. ter Riet, G., A. G. H. Kessels and P. Knipschild. Vitamin c and ultrasound in the treatment of pressure ulcers. PhD Thesis; 1994 **exclusion reason -** not relevant.
1497. Terashi, H., S. Sakakibara, M. Noguchi, K. Matsumoto, M. Sugimoto, S. Sakurai, Y. Shibaoka and S. Tahara. Sugical treatment and perioperative management for pressure ulcers on ischial region. Wound Repair and Regeneration; 2012. p. A3 **exclusion reason -** wrong outcome.
1498. Theilla, M., B. Schwartz, Y. Zimra, H. Shapiro, R. Anbar, E. Rabizadeh, J. Cohen and P. Singer. Enteral n-3 fatty acids and micronutrients enhance percentage of positive neutrophil and lymphocyte adhesion molecules: A potential mediator of pressure ulcer healing in critically ill patients. British Journal of Nutrition; 2011. p. 1-6 **exclusion reason -** wrong outcome.
1499. Thomas, D. R., P. S. Goode, P. H. Tarquine and R. M. Allman. Hospital-acquired pressure ulcers and risk of death. Journal of the American Geriatrics Society; 1996. p. 1435-40 PMID: 8951312 **exclusion reason -** wrong outcome.
1500. Thomas, D. R., G. T. Rodeheaver, A. A. Bartolucci, R. A. Franz, C. Sussman, B. A. Ferrell, J. Cuddigan, N. A. Stotts and J. Maklebust. Pressure ulcer scale for healing: Derivation and validation of the push tool. The push task force. Advances in Wound Care; 1997. p. 96-101 PMID: 9362591 **exclusion reason -** background.
1501. Thomas, R. Acoustic pressure wound therapy in the treatment of stage ii pressure ulcers. Ostomy Wound Management; 2008. p. 56-8 PMID: 19037138 **exclusion reason -** not relevant.
1502. Thomas, S. Alginate dressings in surgery and wound management: Part 2. Journal of Wound Care; 2000. p. 115-9 PMID: 11933292 **exclusion reason -** Systematic Review, not directly used.
1503. Thompson, P., J. Anderson, D. Langemo, D. Hanson and S. Hunter. Support surfaces: Definitions and utilization for patient care. Advances in Skin & Wound Care; 2008. p. 264-266 PMID: 18525248 **exclusion reason -** background.
1504. Thornhill-Joynes, M., F. Gonzales and C. A. Stewart. Osteomyelitis associated with pressure ulcers. Archives of Physical Medicine and Rehabilitation; 1986. p. 314-318 PMID: 3707316 **exclusion reason -** wrong outcome.
1505. Tintle, T. E. and K. F. Jeter. Early experience with a calcium alginate dressing. Ostomy Wound Management; 1990. p. 74-81 PMID: 2363804 **exclusion reason -** wrong outcome.
1506. Tizian, C. and P. Brenner. Coverage of sacral pressure sores by myocutaneous gluteus maximums island flap. Handchirurgie Mikrochirurgie Plastische Chirurgie; 1985. p. 156-160 PMID: 3891544 **exclusion reason -** not relevant.
1507. Toba, K., N. Sudoh, K. Nagano, M. Eto, Y. Mizuno, H. Nakagawa, Y. Kawabata, N. Yamami, M. Hara, Y. Fukushima and Y. Ouchi. [randomized prospective trial of gentian violet with dibutyryl camp and povidone-iodine with sugar as treatment for pressure sores infected with methicillin-resistant staphylococcus aureus in elderly patients]. Nippon Ronen Igakkai Zasshi - Japanese Journal of Geriatrics; 1997. p. 577-82 PMID: 9388378 **exclusion reason -** not relevant.
1508. Toriyabe, S. A film-dressing therapy for pressure ulcers at npuap stages lll/lv. 2nd World Union of Wound Healing Societies Meeting; 2004 **exclusion reason -** no original data.
1509. Torra i Bou, J. E. [treatment of pressure ulcers at home. Multicenter study of a dressing made of a combination of carboxymethyl-cellulose and calcium alginate with hydro-regulatory activity]. Revista de Enfermeria; 1995. p. 23-30 PMID: 8539517 **exclusion reason -** not relevant.
1510. Torra i Bou, J. E., J. Rueda Lopez, G. Camanes, E. Herrero Narvaez, J. Blanco Blanco, E. H. Martinez-Esparza, J. Aneas Alcantara and J. Verdu Soriano. [heel pressure ulcers. Comparative study between heel protective bandage and hydrocellular dressing with special form for the heel]. Revista de enfermeria (Barcelona, Spain); 2002. p. 50-6 **exclusion reason -** not relevant.
1511. Torres de Castro, O. G., A. Galindo Carlos and J. E. Torra i Bou. [pure calcium-sodium alginate dressing. Multicenter evaluation of chronic cutaneous lesions]. Revista de Enfermeria; 1997. p. 23-30 PMID: 9385189 **exclusion reason -** not relevant.
1512. Tymec, A. C., B. Pieper and K. Vollman. A comparison of two pressure-relieving devices on the prevention of heel pressure ulcers. Advances in Skin & Wound Care; 1997. p. 39 PMID: 9204803 **exclusion reason -** wrong population.
1513. Tzeng, Y.-S., C.-C. Yu, T.-D. Chou, T.-M. Chen and S.-G. Chen. Proximal pedicled anterolateral thigh flap for reconstruction of trochanteric defect. Annals

of Plastic Surgery; 2008. p. 79-82 PMID: 18580155 **exclusion reason -** not relevant.

1514. U.S. Food and Drug Administration. Medical devices; general and plastic surgery devices; classification of non-powered suction apparatus device intended for negative pressure wound therapy. Final rule. Federal Register. 2010/11/26 ed; 2010. p. 70112-4 PMID: 21090144 **exclusion reason -** background.

1515. Ubbink, D. T., H. Vermeulen and D. A. Legemate. Comment on: "Negative pressure wound therapy: A systematic review of effectiveness and safety", p. Vikatmaa, v. Juutilainen, p. Kuukasjarvi, a. Malmivaara, eur j vasc endovasc surg 2008;36(4):438-48. European Journal of Vascular & Endovascular Surgery; 2009. p. 740-1; author reply 741-2 PMID: 19328731 **exclusion reason -** Systematic Review, not directly used.

1516. Ubbink, D. T., S. J. Westerbos, E. A. Nelson and H. Vermeulen. A systematic review of topical negative pressure therapy for acute and chronic wounds. British Journal of Surgery; 2008. p. 685-92 PMID: 18446777 **exclusion reason -** Systematic Review, not directly used.

1517. Ueda, Y., S. Mizumoto, Y. Nakagawa, A. Fukui and S. Tamai. Clinical study on the distal vastus lateralis musculocutaneous island flap - a method of elevating this musculocutaneous flap and the clinical results obtained. Japanese Journal of Plastic and Reconstructive Surgery; 1999. p. 543-550 **exclusion reason -** not relevant.

1518. Ullah, N. and I. Alam. Nutritional care of patients with pressure ulcers: Some evidence based guidelines. Pakistan Journal of Medical Sciences; 2012. p. 196-200 **exclusion reason -** no original data.

1519. Ulusoy, M. G., A. M. Akan, O. Esoz and R. Ozdemir. Bilateral, extended v-y advancement flap. Annals of Plastic Surgery; 2001. p. 5-8 PMID: 11192035 **exclusion reason -** not relevant.

1520. Upton, Z., H. J. Wallace, G. K. Shooter, D. R. van Lonkhuyzen, S. Yeoh-Ellerton, E. A. Rayment, J. M. Fleming, D. Broszczak, D. Queen, R. G. Sibbald, D. I. Leavesley and M. C. Stacey. Human pilot studies reveal the potential of a vitronectin: Growth factor complex as a treatment for chronic wounds. International Wound Journal; 2011. p. 522-32 PMID: 21914133 **exclusion reason -** wrong population.

1521. USPSTF. U.S. Preventive services task force procedures manual. United States PreventiveServices Task Force; 2008. p. Section 4: Evidence Report Development **exclusion reason -** background.

1522. Valenzuela, A. R. and N. S. Perucho. [the effectiveness of a 0.1% polyhexanide gel]. Revista de Enfermeria; 2008. p. 7-12 PMID: 18564781 **exclusion reason -** not relevant.

1523. van Anholt, R. D., L. Sobotka, E. P. Meijer, H. Heyman, H. W. Groen, E. Topinkova, M. van Leen and J. M. G. A. Schols. Specific nutritional support accelerates pressure ulcer healing and reduces wound care intensity in non-malnourished patients. Nutrition; 2010. p. 867-72 PMID: 20598855 **exclusion reason -** duplicate.

1524. Van Den Boogaard, M., E. De Laat, P. Spauwen and L. Schoonhoven. The effectiveness of topical negative pressure in the treatment of pressure ulcers: A literature review. European Journal of Plastic Surgery; 2008. p. 1-7 **exclusion reason -** Systematic Review, not directly used.

1525. Van den Plas, D. L., A. Lambrecht, D. Jacobs, J. Liekens and M. Van Hoey. Treatment of recalcitrant wounds of diverse etiology with a new hydoactive gel. Wounds: A Compendium of Clinical Research & Practice; 2009. p. 243-248 **exclusion reason -** not relevant.

1526. van Leen, M. Randomised study on the efficacy of collagenase - containing ointment versus hydrocolloid dressing in wound repair after surgical/enzymatic debridement of necrotic tissue. In: Springer-Verlag, editor The Clinical Relevance of Debridement New York; 1999. p. 71-78 **exclusion reason -** not relevant.

1527. van Leen, M., S. Hovius, J. Neyens, R. Halfens and J. Schols. Pressure relief, cold foam or static air? A single center, prospective, controlled randomized clinical trial in a dutch nursing home. Journal of Tissue Viability; 2011. p. 30-4 PMID: 20510611 **exclusion reason -** wrong intervention.

1528. Van Leen, M. W. F. Collagenase therapy in decubitus ulcers. TGO - Tijdschrift voor Therapie Geneesmiddel en Onderzoek; 1994. p. 2-7 **exclusion reason -** not relevant.

1529. Van Rijswijk, L. and M. Gray. Evidence, research, and clinical practice: A patient-centered framework for progress in wound care. Journal of Wound, Ostomy, and Continence Nursing; 2012. p. 1-10 PMID: 22124460 **exclusion reason -** Scientific Information Packets, not directly used.

1530. van Twisk, R. and J. M. Borghouts. [surgical treatment of decubitus ulcers in the area of the ischium, sacrum and trochanter major]. Handchirurgie, Mikrochirurgie, Plastische Chirurgie; 1987. p. 277-80 PMID: 3666597 **exclusion reason -** not relevant.

1531. Vangilder, C., G. D. Macfarlane and S. Meyer. Results of nine international pressure ulcer prevalence surveys: 1989 to 2005. Ostomy Wound Management; 2008. p. 40-54 PMID: 18382042 **exclusion reason -** background.

1532. Vannini, M. A., F. Carpanelli, C. Puglisi and M. Biraghi. Clinical and iconographical assessment of cadexomer iodine efficacy in the treatment of decubitus wounds. Gazzetta Medica Italiana Archivio per le Scienze Mediche; 1993. p. 25-30 **exclusion reason -** not relevant.

1533. Varea, S., C. Oro, J. Bronchales, M. J. Sapena, C. Poveda, F. Maranchon, J. Fornes and J. M. Oro. [occlusive dressings in the management of decubitus ulcers]. Revista de Enfermeria; 1988. p. 39-42 PMID: 3231977 **exclusion reason -** not relevant.

1534. Vega, A. A review of the efficacy of zinc, selenium, and vitamin c in the treatment of pressure ulcers. Topics in Clinical Nutrition; 2011. p. 115-125 **exclusion reason -** Systematic Review, not directly used.

1535. Veit, N., B. L. Bailey and L. Swoager. Clinical evaluation of dermagran spray and ointment in the treatment of pressure ulcers in spinal cord injury. Sci Nursing; 1993. p. 135-6 PMID: 7863307 **exclusion reason -** not relevant.
1536. Venezia, L., F. Velardo, R. A. Tisci, G. Baldassarre, V. Forino, V. Aloia and M. Biraghi. Efficacy and tolerability of cadexomer iodine ointment in the treatment of decubitus ulcers. Results of an open study performed in elderly patients. Gazzetta Medica Italiana Archivio per le Scienze Mediche; 1990. p. 213-219 **exclusion reason -** not relevant.
1537. Venkataramakrishnan, V., D. Mohan, A. Krishna and S. Chowdhary. The longest pedicle for a gastrocnemius flap! Annals of Plastic Surgery; 1997. p. 106-8 PMID: 9229107 **exclusion reason -** not relevant.
1538. Verdote-Robertson, R., M. M. Munchua and J. R. Reddon. The use of low intensity laser therapy (lilt) for the treatment of open wounds in psychogeriatric patients: A pilot study. Physical & Occupational Therapy in Geriatrics; 2000. p. 1-19 **exclusion reason -** wrong population.
1539. Verdu Soriano, J., A. Nolasco Bonmati, P. Lopez Casanova and J.-E. Torra i Bou. ["auriga-04" study on the use of a range of allevyn hydro-cellular dressings in the treatment of bed sores and leg ulcers by primary health care professionals]. Revista de Enfermeria; 2006. p. 43-9 PMID: 16724499 **exclusion reason -** not relevant.
1540. Viau, F., D. Mangenot, C. Boval and J. Perron. Crystallized sugar for the treatment of wounds, pressure sores and leg ulcers. Semaine des Hopitaux; 1986. p. 2431-2435 **exclusion reason -** not relevant.
1541. Vig, S., C. Dowsett, L. Berg, C. Caravaggi, P. Rome, H. Birke-Sorensen, A. Bruhin, M. Chariker, M. Depoorter, R. Dunn, F. Duteille, F. Ferreira, J. M. Francos Martinez, G. Grudzien, D. Hudson, S. Ichioka, R. Ingemansson, S. Jeffery, E. Krug, C. Lee, M. Malmsjo, N. Runkel, R. Martin and J. Smith. Evidence-based recommendations for the use of negative pressure wound therapy in chronic wounds: Steps towards an international consensus. Journal of tissue viability; 2011. p. S1-S18 **exclusion reason -** Systematic Review, not directly used.
1542. Vigil-Escalera Quintanal, L. J. Treatment of heel pressure sores. Clinical performance of a new adhesive dressing [spanish]. Metas de Enfermería; 2003. p. 19-26 **exclusion reason -** not relevant.
1543. Vikatmaa, P., V. Juutilainen, P. Kuukasjarvi and A. Malmivaara. Negative pressure wound therapy: A systematic review on effectiveness and safety. European Journal of Vascular & Endovascular Surgery; 2008. p. 438-48 PMID: 18675559 **exclusion reason -** Systematic Review, not directly used.
1544. Vink, L., C. S. Blok, R. J. Scheper, C. Van Montfrans, E. M. De Boer and S. Gibbs. Retrospective analysis of patients with ulcers of (arterio-)venous, traumatic or decubitus origin treated with autologous skin substitute. Wound Repair and Regeneration; 2011. p. A96 **exclusion reason -** wrong population.
1545. Vlastou, C. Alternatives in soft tissue reconstruction of the ankle and foot. Acta Orthopaedica Scandinavica. Supplementum; 1995. p. 27-30 PMID: 7604725 **exclusion reason -** not relevant.
1546. Vodovnik, L., A. Stefanovska and R. Turk. [611] therapeutic intervention for healing pressure sores with electrical stimulation on persons with spinal discontinuities. Journal of Rehabilitation Research and Development; 1991. p. 479 **exclusion reason -** wrong intervention.
1547. Vogelpohl, T. Description and critique of the guidelines for pressure ulcers. Decubitus; 1991. p. 32-4 PMID: 2036166 **exclusion reason -** background.
1548. Voigt, D. W. and C. N. Paul. The use of acticoat as silver impregnated telfa dressings in a regional burn and wound care center: The clinicians view. Wounds: A Compendium of Clinical Research & Practice; 2001. p. 11-22 **exclusion reason -** wrong population.
1549. Voigt, H., U. R. Kleeberg and R. Naquin. Pathogenesis, prevention, and therapy for decubitus in cancer patients. Medizinische Klinik; 1987. p. 191-195 **exclusion reason -** not relevant.
1550. Volker, H. U. Decubitus ulcers. Pressure relief is of the essence. MMW-Fortschritte der Medizin; 1999. p. 30-33 **exclusion reason -** background.
1551. Vu, T., A. Harris, G. Duncan and G. Sussman. Cost-effectiveness of multidisciplinary wound care in nursing homes: A pseudo-randomized pragmatic cluster trial. Family Practice; 2007. p. 372-9 PMID: 17602174 **exclusion reason -** not relevant.
1552. Vuerstaek, J. D. D., T. Vainas, J. Wuite, P. Nelemans, M. H. A. Neumann and J. C. J. M. Veraart. State-of-the-art treatment of chronic leg ulcers: A randomized controlled trial comparing vacuum-assisted closure (v.A.C.) with modern wound dressings. Journal of Vascular Surgery; 2006. p. 1029-1037 PMID: 17000077 **exclusion reason -** wrong population.
1553. Vyhlidal, S. K., D. Moxness, K. S. Bosak, F. G. Van Meter and N. Bergstrom. Mattress replacement or foam overlay? A prospective study on the incidence of pressure ulcers. Applied Nursing Research; 1997. p. 111-120 PMID: 9274063 **exclusion reason -** wrong population.
1554. Wahrburg, U. Nutrition and decubital ulcers. Tägliche Praxis; 2004. p. 381 **exclusion reason -** not relevant.
1555. Walding, M. Wound care. Skin treatment. Nursing Times; 1994. p. 78-82 PMID: 8127765 **exclusion reason -** no original data.
1556. Walker, A. The cost-effectiveness of home health: A case presentation. Geriatric Nursing; 1996. p. 37-40 PMID: 8707142 **exclusion reason -** not relevant.
1557. Walker, P. Management of pressure ulcers. Oncology (Williston Park); 2001. p. 1499-508, 1511; discussion1511,1515-6 PMID: 11758876 **exclusion reason -** background.
1558. Wallenstein, S., M. Carasa, N. Kapil-Pair, E. P, C. M, J. Zoller, L. Hollier and H. Brem. Defining the rate of healing of pressure ulcers (poster presentation).

EPUAP. Budapest, Hungary; 2002 **exclusion reason -** not relevant.
1559. Wallin, A.-M., L. Bostrom, J. Ulfvarson and C. Ottosson. Negative pressure wound therapy - a descriptive study. Ostomy Wound Management; 2011. p. 22-9 PMID: 21701045 **exclusion reason -** wrong outcome.
1560. Walsh, N. S., A. W. Blanck and K. L. Barrett. Pressure ulcer management in the acute care setting: A response to regulatory mandates. Journal of Wound, Ostomy, & Continence Nursing; 2009. p. 385-8 PMID: 19609158 **exclusion reason -** wrong intervention.
1561. Wang, C.-H., S.-Y. Chen, J.-P. Fu, N.-T. Dai, S.-L. Chen, T.-M. Chen and S.-G. Chen. Reconstruction of trochanteric pressure sores with pedicled anterolateral thigh myocutaneous flaps. Journal of Plastic, Reconstructive & Aesthetic Surgery: JPRAS; 2011. p. 671-6 PMID: 20884307 **exclusion reason -** not relevant.
1562. Wang, Z., J. Ren and J. Song. Clinical and experimental study on the use of chuangling solution to treat the ulcer [chinese]. Shanxi Nursing Journal; 1997. p. 200-203 **exclusion reason -** not relevant.
1563. Warbanow, K., A. Krause-Bergmann, P. Brenner, B. Reichert and A. Berger. [myocutaneous flap as reliable defect coverage in high grade pelvic decubitus ulcers. Classification, therapeutic concept and presentation of personal patient sample of 16 years]. Langenbecks Archiv fur Chirurgie; 1997. p. 359-66 PMID: 9498209 **exclusion reason -** not relevant.
1564. Ward, C. The value of systematic evaluation in determining the effectiveness and practical utility of a pressure-redistributing support surface. Journal of Tissue Viability; 2010. p. 22-7 PMID: 20106665 **exclusion reason -** wrong intervention.
1565. Warnet, S. and L. Bandelier. [prevention and management of decubitus ulcers]. Revue de L'Infirmiere; 2007. p. 24-5 PMID: 17566501 **exclusion reason -** not relevant.
1566. Warren, S., M. Neto and M. H. E. Hermans. Better pressure relief and a reduction of the environmental impact of mattress technology. **exclusion reason -** Scientific Information Packets, not directly used.
1567. Warren, S., M. Neto and M. H. E. Hermans. A reduction in the environmental impact of mattress production **exclusion reason -** Scientific Information Packets, not directly used.
1568. Warren, S., M. Neto and M. H. E. Hermans. Reduction of average and peak pressures with a hybrid gel/smt support surface: Pressure mapping results in volunteers. **exclusion reason -** Scientific Information Packets, not directly used.
1569. Waterlow, J. Wound care. Recording risk factors. Nursing Times; 1995. p. 64-6 PMID: 7716024 **exclusion reason -** no original data.
1570. Waterlow, J. From costly treatment to cost-effective prevention: Using waterlow. British Journal of Community Nursing; 2005. p. S25-6, S28, S30 PMID: 16245392 **exclusion reason -** not relevant.
1571. Watier, E., S. Chevrier, N. Georgieu, A. Pardo, S. Schuck and J. P. Pailheret. Our experience with ischial pressure sores in a series of 34 patients. European Journal of Plastic Surgery; 2000. p. 32-35 **exclusion reason -** background.
1572. Watkoskey, C. "Pressure ulcers: Collaboration in wound care. Is there a reasonable approach?". Ostomy Wound Management; 1997. p. 6 PMID: 9282042 **exclusion reason -** no original data.
1573. Watret, L. Not easily used by all. Nursing Times; 1994. p. 25 PMID: 8058508 **exclusion reason -** no original data.
1574. Watson, R. Sore point. Geriatric Nursing & Home Care; 1989. p. 26-7 PMID: 2721956 **exclusion reason -** no original data.
1575. Watson, R. Pressure sores: A rational approach to treatment. Nursing Standard; 1989. p. 22-5 PMID: 2503730 **exclusion reason -** not relevant.
1576. Watson, R. The benefits of excellence. A cost-effective treatment programme for pressure sores. Professional Nurse; 1990. p. 356-62 PMID: 2111550 **exclusion reason -** not relevant.
1577. Webb, M. Selection of a cost-effective debriding alternative to a pharmaceutical enzymatic agent at one county long-term care facility... 41st annual wound, ostomy and continence nurses annual conference, st. Louis, missouri, june 6-10, 2009. Journal of Wound, Ostomy & Continence Nursing; 2009. p. S17-8 **exclusion reason -** not relevant.
1578. Webster, R. M. Pressure ulcers [5]. Journal of the American Medical Directors Association; 2002. p. 210-211 **exclusion reason -** background.
1579. Wechselberger, G., T. Schoeller and A. Otto. Principles in the operative treatment of pressure sores. Archives of Surgery; 1998. p. 465 PMID: 9565131 **exclusion reason -** background.
1580. Wechselberger, G., T. Schoeller, A. Schwabegger, M. Ninkovic, C. Papp and H. Anderl. [plastic surgery treatment of extensive decubitus ulcers of the pelvic area]. Chirurg; 1996. p. 1147-51 PMID: 9035951 **exclusion reason -** not relevant.
1581. Weeks, S. K. Save our skin (sos). Rehabilitation Nursing; 1996. p. 267-8 PMID: 8868759 **exclusion reason -** no original data.
1582. Weheida, S. M., H. H. Nagubib, H. M. El-Banna and S. Marzouk. Comparing the effects of two dressing techniques on healing of low grade pressure ulcers. Journal of the Medical Research Institute; 1991. p. 259-78 **exclusion reason -** wrong population.
1583. Weiler, P. G., C. Franzi and D. Kecskes. Pressure sores in nursing home patients. Aging-Clinical & Experimental Research; 1990. p. 267-75 PMID: 2094365 **exclusion reason -** background.
1584. Welber, A. The pressure is on! Med-Surg Matters; 2005. p. 3-4 **exclusion reason -** background.
1585. Wells, J. A. and D. Karr. Interface pressure, wound healing, and satisfaction in the evaluation of a non-powered fluid mattress. Ostomy Wound Management; 1998. p. 38-42, 44-6, 48 passim PMID: 9526420 **exclusion reason -** wrong population.
1586. Welton, J. M. Implications of medicare reimbursement changes related to inpatient nursing

care quality. Journal of Nursing Administration; 2008. p. 325-30 PMID: 18690122 **exclusion reason -** not relevant.

1587. Werdin, F., M. Tennenhaus, H.-E. Schaller and H.-O. Rennekampff. Evidence-based management strategies for treatment of chronic wounds. Eplasty [Electronic Resource]; 2009. p. e19 PMID: 19578487 **exclusion reason -** background.

1588. Werner, G. T., M. Gadomski and F. Wehle. Immersion into co2-water in the treatment of chronic ulcers with delayed healing. Zeitschrift fur Physikalische Medizin Balneologie Med. Klimatologie; 1990. p. 52-56 **exclusion reason -** not relevant.

1589. West, B. J., S. J. Brockman and A. Scott. Action research and standards of care. The prevention and treatment of pressure sores in elderly patients. Health Bulletin; 1991. p. 356-61 PMID: 1765486 **exclusion reason -** background.

1590. Westerhof, W., F. C. Jansen, F. S. de Wit and R. H. Cormane. Controlled double-blind trial of fibrinolysin-desoxyribonuclease (elase) solution in patients with chronic leg ulcers who are treated before autologous skin grafting. Journal of the American Academy of Dermatology; 1987. p. 32-39 PMID: 2956297 **exclusion reason -** wrong population.

1591. Weum, S. and L. De Weerd. The butterfly design as an alternative to the "double-a" bilateral flaps for the treatment of large sacral defects. Plastic and Reconstructive Surgery; 2008. p. 1513-1514 PMID: 18349687 **exclusion reason -** no original data.

1592. White-Chu, E. F., P. Flock, B. Struck and L. Aronson. Pressure ulcers in long-term care. Clinics in Geriatric Medicine; 2011. p. 241-58 PMID: 21641509 **exclusion reason -** background.

1593. Whitehead, S. J. and P. Trueman. To what extent can pressure relieving surfaces help reduce the costs of pressure ulcers? Nursing Times; 2010. p. 10-2 PMID: 20836473 **exclusion reason -** not relevant.

1594. Whitney, J., L. Higa, G. Savadalena and M. Mich. Effect of radiant heat treatment on pressure ulcer healing: Preliminary findings. 31st Annual Wound, Ostomy and Continence Conference; 1999 **exclusion reason -** not relevant.

1595. Whitney, J., L. Phillips, R. Aslam, A. Barbul, F. Gottrup, L. Gould, M. C. Robson, G. Rodeheaver, D. Thomas and N. Stotts. Guidelines for the treatment of pressure ulcers. Wound Repair & Regeneration; 2006. p. 663-79 PMID: 17199832 **exclusion reason -** background.

1596. Whittemore, R. Pressure-reduction support surfaces: A review of the literature. Journal of Wound, Ostomy, & Continence Nursing; 1998. p. 6-25 PMID: 9481284 **exclusion reason -** Systematic Review, not directly used.

1597. WHO. Uv raditation. World Health Organization; 2012 **exclusion reason -** background.

1598. Wiechula, R., E. Paillaud, S. Herbaud, P. Caillet, J. L. Lejonc, B. Campillo, P. N. Bories, J. J. Hutchinson and M. McGuckin. The use of moist wound-healing dressings in the management of split-thickness skin graft donor sites: A systematic review relations between undernutrition and nosocomial infections in elderly patients occlusive dressings: A microbiologic and clinical review. International Journal of Nursing Practice; 2003. p. S9-17 **exclusion reason -** wrong population.

1599. Wikipedia. Laser. Wikipedia: Wikipedia; 2012 **exclusion reason -** background.

1600. Wild, T., S. Stremitzer, A. Budzanowski, T. Hoelzenbein, C. Ludwig and G. Ohrenberger. Definition of efficiency in vacuum therapy--a randomised controlled trial comparing with v.A.C. Therapy. International Wound Journal; 2008. p. 641-7 PMID: 19134065 **exclusion reason -** no original data.

1601. Wilk, A. [decubitus ulcer]. Revue du Praticien; 1994. p. 1769-75 PMID: 7939261 **exclusion reason -** background.

1602. Wilk, A., C. Rodier, C. Beau, F. Stricher, F. Lesage, J. Lecocq, B. Wilhelm and J. Bougrelle. [sacral bedsore: An evaluation of 10 years' treatment with the gluteus maximus muscle]. Annales de Chirurgie Plastique et Esthetique; 1991. p. 132-137 PMID: 1718202 **exclusion reason -** not relevant.

1603. Wilm, S. and D. Geisler. Care for patients with decubitus by general practitioners in germany. Zeitschrift fur Allgemeinmedizin; 1999. p. 257-264 **exclusion reason -** background.

1604. Wilson, D. Silver polymeric membrane dressings promote healing of multiple small stalled pressure ulcers... 39th annual wound, ostomy and continence nurses annual conference. Journal of Wound, Ostomy & Continence Nursing; 2007. p. S13-S13 **exclusion reason -** wrong population.

1605. Wilson, G. and H. Logan. The role of education, technique and equipment in pressure area care. British Journal of Nursing; 2005. p. 990-4 PMID: 16237357 **exclusion reason -** background.

1606. Wind, S., E. Happ and M. D. Kerstein. Pressure ulcers: Collaboration in wound care. Is there a reasonable approach? Ostomy Wound Management; 1997. p. 40-4, 46, 48-50 passim PMID: 9205397 **exclusion reason -** background.

1607. Winter, E., J. E. Muller, H. Bilow, A. Eggstein, D. Hontzsch and S. Weller. [indications, technique and results of muscle flaps in decubitus ulcers of the pelvic region in paraplegic patients]. Aktuelle Traumatologie; 1994. p. 222-7 PMID: 7801819 **exclusion reason -** not relevant.

1608. Wiseman, L. A. Sugar as an aid to wound healing and the treatment of ulcers in leprosy. Leprosy Review; 1989. p. 67-8 PMID: 2634986 **exclusion reason -** not relevant.

1609. Wisniewska-Wrona, M., M. Kucharska, A. Niekraszewicz, I. Kardas, D. Ciechaniska and K. H. Bodek. [chitosan-alginate biocomposites in the form of films used in bedsores treatment]. Polimery W Medycynie; 2010. p. 57-64 PMID: 20649090 **exclusion reason -** not relevant.

1610. Witkowski, J. A. and L. C. Parish. Topical metronidazole gel. The bacteriology of decubitus ulcers. International Journal of Dermatology; 1991. p. 660-1 PMID: 1938084 **exclusion reason -** wrong intervention.

1611. Witkowski, J. A. and L. C. Parish. The decubitus ulcer: Skin failure and destructive behavior. International Journal of Dermatology; 2000. p. 894-6 PMID: 11168655 **exclusion reason -** background.
1612. Witkowski, W., M. Baranski, A. Broma and M. Olszowska-Golec. [the operative management of sacral pressure sores with a bilateral modificated myocutaneous v-y plasty]. Polski Merkuriusz Lekarski; 2005. p. 192-5 PMID: 17877129 **exclusion reason -** not relevant.
1613. Witkowski, W., A. Jawien, W. Witkiewicz and B. Zon. Initial multi-centre observations upon the effect of a new topical negative pressure device upon patient and clinician experience and the treatment of wounds. International Wound Journal; 2009. p. 167-74 PMID: 19432667 **exclusion reason -** wrong population.
1614. Wollina, U. [lower leg ulcers and decubitus ulcer. Optimal wound management improves relative quality of life]. MMW Fortschritte der Medizin; 1999. p. 50-2, 54 PMID: 10904642 **exclusion reason -** background.
1615. Wong, C.-H., B.-K. Tan and C. Song. The perforator-sparing buttock rotation flap for coverage of pressure sores. Plastic & Reconstructive Surgery; 2007. p. 1259-66 PMID: 17496599 **exclusion reason -** not relevant.
1616. Wong, T. C. and F. K. Ip. Comparison of gluteal fasciocutaneous rotational flaps and myocutaneous flaps for the treatment of sacral sores. International Orthopaedics; 2006. p. 64-7 PMID: 16333656 **exclusion reason -** not relevant.
1617. Wong, V. Skin blood flow response to 2-hour repositioning in long-term care residents: A pilot study. Journal of Wound, Ostomy, & Continence Nursing; 2011. p. 529-37 PMID: 21860333 **exclusion reason -** wrong population.
1618. Wong, V. K., N. A. Stotts, H. W. Hopf, E. S. Froelicher and G. A. Dowling. How heel oxygenation changes under pressure. Wound Repair and Regeneration; 2007. p. 786-794 PMID: 18028125 **exclusion reason -** background.
1619. Woo, K. Y. and R. G. Sibbald. Topical treatment of pain in pressure ulcers: A systematic review... 41st annual wound, ostomy and continence nurses annual conference, st. Louis, missouri, june 6-10, 2009. Journal of Wound, Ostomy & Continence Nursing; 2009. p. S58-S58 **exclusion reason -** Systematic Review, not directly used.
1620. Woo, K. Y., R. G. Sibbald and E. A. Ayello. Wound edge effect. Ostomy Wound Management; 2009. p. 21-22 **exclusion reason -** background.
1621. Wood, J. M., W. F. Jacobson, K. U. Schallreuter, P. Evans, M. Jacobson, R. Suffer, J. Newman and C. White. Pulsed low-intensity direct current (plidc) is effective in healing chronic decubitus ulcers in stages ii and iii. Abstract 136. Journal of Investigative Dermatology; 1992. p. 574 PMID: CN-00321001 **exclusion reason -** not relevant.
1622. Woolsey, R. M. and J. D. McGarry. The cause, prevention, and treatment of pressure sores. Neurologic Clinics; 1991. p. 797-808 PMID: 1921959 **exclusion reason -** background.
1623. Worsley, M. Comparing efficacies... Treatment of leg ulcers and pressure sores. Nursing Standard; 1991. p. 5-6 **exclusion reason -** no original data.
1624. Wright, R. D. and C. O'Brien. Technological advances in wound care. DNA Reporter; 1999. p. 18-20 **exclusion reason -** no original data.
1625. Wu, F. X. [repair of bedsores and ulcers with gluteus maximus musculocutaneous flap]. Chung-Hua Cheng Hsing Shao Shang Wai Ko Tsa Chih - Chinese Journal of Plastic Surgery & Burns; 1992. p. 293-4, 330 PMID: 1304963 **exclusion reason -** not relevant.
1626. Wu, J. X. [axial skin flap and musculocutaneous flap in the treatment of bedsores--report of 8 cases]. Chung-Hua Cheng Hsing Shao Shang Wai Ko Tsa Chih - Chinese Journal of Plastic Surgery & Burns; 1988. p. 112-3, 158 PMID: 3151451 **exclusion reason -** not relevant.
1627. Wyndaele, J. J. Medical honey for chronic pressure ulcers in sci individuals. Spinal Cord; 2012. p. 87 **exclusion reason -** no original data.
1628. Xie, X., M. McGregor and N. Dendukuri. The clinical effectiveness of negative pressure wound therapy: A systematic review. Journal of Wound Care; 2010. p. 490-5 PMID: 21135797 **exclusion reason -** background.
1629. Xin, S. F. [guangzhou yuchuangjia in the treatment of bedsore]. Chung-Hua Hu Li Tsa Chih Chinese Journal of Nursing; 1993. p. 714-6 PMID: 8156610 **exclusion reason -** not relevant.
1630. Xu, X. W., Y. Qing, Z. Y. Li and Y. Cen. Treatment of sacrococcygeal decubitus ulcers by two period operations of myocutaneous flap transposition: Reports of 19 cases. Journal of Clinical Rehabilitative Tissue Engineering Research; 2008. p. 364-367 **exclusion reason -** not relevant.
1631. Xu, Y., H. Hai, Z. Liang, S. Feng and C. Wang. Pedicled fasciocutaneous flap of multi-island design for large sacral defects. Clinical Orthopaedics & Related Research; 2009. p. 2135-41 PMID: 19048353 **exclusion reason -** not relevant.
1632. Xu, Y., Z. Liang and S. Feng. [an effect of multi-island flap with shallow branch of gluteus upper artery on repair of sacrum soft tissue defect]. Chung-Kuo Hsiu Fu Chung Chien Wai Ko Tsa Chih/Chinese Journal of Reparative & Reconstructive Surgery; 2007. p. 850-3 PMID: 17882883 **exclusion reason -** not relevant.
1633. Yamamoto, Y., A. Oyama, A. Tsutsumida, M. Murazumi, K. Honda and T. Sugihara. Reconstructive surgery with the fasciocutaneous flap for the treatment of pressure sores. Japanese Journal of Plastic and Reconstructive Surgery; 1998. p. 1113-1119 **exclusion reason -** not relevant.
1634. Yamashita, R., Y. Kuroyanagi, N. Nakakita, E. Uchinuma and N. Shioya. Allogeneic cultured dermal substitute composed of spongy collagen containing fibroblasts: Preliminary clinical trials. Wounds: A Compendium of Clinical Research & Practice; 1999. p. 34-44 **exclusion reason -** not relevant.
1635. Yamashita, R., E. Uchinuma and Y. Kuroyanagi. Treatment of skin ulcers and pressure sores using allogeneic cultured dermal substitute composed of

fibroblasts combined within spongy collagen matrix. Japanese Journal of Plastic and Reconstructive Surgery; 1998. p. 917-923 PMID: 10450570 **exclusion reason -** not relevant.

1636. Yan, C.-L., Q.-J. Liu, P. Yang, A.-J. Fu, J. Zhu and H.-H. Wang. [clinical research on bedsores treated with fire needle therapy]. Zhongguo Zhenjiu; 2010. p. 819-21 PMID: 21058478 **exclusion reason -** not relevant.

1637. Yanai, A., Y. Kosaka, A. Teraoka and C. Papp. Several types of gluteus maximus musculocutaneous flaps for closure of sacral decubitus ulcer - refinements in design. European Journal of Plastic Surgery; 1991. p. 157-163 **exclusion reason -** not relevant.

1638. Yang, C.-H., Y.-R. Kuo, S.-F. Jeng and P.-Y. Lin. An ideal method for pressure sore reconstruction: A freestyle perforator-based flap. Annals of Plastic Surgery; 2011. p. 179-84 PMID: 21200313 **exclusion reason -** not relevant.

1639. Yelken, B. and A. Ay. Comparison of hydropolymer dressing and hydrocolloid dressing in management of pressure ulcers. 19th Annual Congress of the European Society of Intensive Care Medicine. Barcelona (Spain): Springer; 2006 **exclusion reason -** no original data.

1640. Zelenkova, H. Enzymatic debridement in dermatology. Cesko-Slovenska Dermatologie; 2000. p. 18-21 **exclusion reason -** not relevant.

1641. Zeleznik, J. Review: Specially designed products to prevent or heal pressure ulcers are more effective than standard mattresses... Commentary on cullum n, deeks j, sheldon ta, song f, fletcher aw. Beds, mattresses and cushions for pressure sore prevention and treatment. Cochrane review, latest version 26 may 1999. In: The cochrane library. Oxford: Update software. ACP Journal Club; 2000. p. 59-59 **exclusion reason -** not relevant.

1642. Zeppetella, G., J. Paul and M. D. C. Ribeiro. Analgesic efficacy of morphine applied topically to painful ulcers. Journal of Pain and Symptom Management; 2003. p. 555-558 PMID: 12782436 **exclusion reason -** wrong population.

1643. Zhang, J. Clinical effects f moist burn adhesive plaster on bed sore. Chinese Journal of Clinical Rehabilitation; 2003. p. 345 **exclusion reason -** not relevant.

1644. Zhang, Q. H., Z. R. Sun, J. H. Yue, X. Ren, L. B. Qiu, X. L. Lv and W. Du. Traditional chinese medicine for pressure ulcer: A meta-analysis. International Wound Journal; 2012 PMID: 22512889 **exclusion reason -** background.

1645. Zhao, J. Application of iodophor for nursing care of patients with pressure sore [chinese]. Chinese Nursing Research; 2009. p. 1090-1090 **exclusion reason -** not relevant.

1646. Zhou, D. P., L. Q. Lu and X. L. Mao. [insulin and hyperosmotic glucose solution external used for treating pressure sore]. Bulletin of Hunan Medical University; 2001. p. 475-6 PMID: 12536508 **exclusion reason -** not relevant.

1647. Zhou, G., Q. Qiao, G. Y. Chen, Y. C. Ling and R. Swift. Clinical experience and surgical anatomy of 32 free anterolateral thigh flap transplantations. British Journal of Plastic Surgery; 1991. p. 91-6 PMID: 2018912 **exclusion reason -** not relevant.

1648. Zhou Sh, J. X. Y. Observation of the effects of physical therapy in the treatment of decubitus ulcer. Stroke and Nervous Diseases; 1996. p. 156-7 **exclusion reason -** unable to find.

1649. Ziegler, U. E., K. Schmidt, H. P. Keller and A. Thiede. [treatment of chronic wounds with an alginate dressing containing calcium zinc and manganese]. Fortschritte der Medizin. Originalien: Erganzungsband ... der MMW, Fortschritte der Medizin; 2003. p. 19-26 PMID: 15117065 **exclusion reason -** not relevant.

1650. Zogovska, E., L. Novevski, L. Agai, V. Mircevski, I. Peev and G. Dzokic. Our experience in treatment of pressure ulcers by using local cutaneous flaps. Makedonska Akademija na Naukite i Umetnostite Oddelenie Za Bioloshki i Meditsinski Nauki Prilozi; 2008. p. 199-210 PMID: 18709010 **exclusion reason -** not relevant.

1651. Zolghadrasli, A. A. Ciclosporin for pressure ulcers. Journal of Wound Care; 2008. p. 208 PMID: 18546994 **exclusion reason -** no original data.

1652. Zuccarelli, G. C., D. Berna and A. E. Tammaro. Collagenase in the treatment of decubitus ulcers in elderly high-risk patients. Giornale di Gerontologia; 1990. p. 237-241 **exclusion reason -** not relevant.

1653. Zuloff-Shani, A., E. Kachel, O. Frenkel, A. Orenstein, E. Shinar and D. Danon. Macrophage suspensions prepared from a blood unit for treatment of refractory human ulcers. Transfusion & Apheresis Science; 2004. p. 163-7 PMID: 15062757 **exclusion reason -** wrong population.

1654. Zur Nieden, H. C., R. Pullen and I. Fusgen. Treatment of decubital ulcers in geriatric patients with ornithine- oxoglutarate - a randomized, double-blind pilot study. European Journal of Geriatrics; 1999. p. 144-147 **exclusion reason -** not relevant.

Appendix F. Quality Assessment Methods

Individual studies were rated as "good," "fair" or "poor" as defined below[1]:

For Controlled Trials:
Each criterion was give an assessment of yes, no, or unclear.

1. Was the assignment to the treatment groups really random?

Adequate approaches to sequence generation:

- Computer-generated random numbers
- Random numbers tables

Inferior approaches to sequence generation:

- Use of alternation, case record numbers, birth dates or week days
- Randomization reported, but method not stated
- Not clear or not reported
- Not randomized

2. Was the treatment allocation concealed?

Adequate approaches to concealment of randomization:

- Centralized or pharmacy-controlled randomization (randomization performed without knowledge of patient characteristics).
- Serially-numbered identical containers
- On-site computer based system with a randomization sequence that is not readable until allocation
- Sealed opaque envelopes

Inferior approaches to concealment of randomization:

- Use of alternation, case record numbers, birth dates or week days
- Open random numbers lists
- Serially numbered non- opaque envelopes
- Not clear or not reported

3. Were the groups similar at baseline in terms of prognostic factors?
4. Were the eligibility criteria specified?
5. Were outcome assessors and/or data analysts blinded to the treatment allocation?
6. Was the care provider blinded?
7. Was the patient kept unaware of the treatment received?
8. Did the article include an intention-to-treat analysis, or provide the data needed to calculate it (i.e., number assigned to each group, number of subjects who finished in each group, and their results)?
9. Did the study maintain comparable groups?
10. Did the article report attrition, crossovers, adherence, and contamination?
11. Is there important differential loss to followup or overall high loss to followup?

For Cohort Studies:
Each criterion was give an assessment of yes, no, or unclear.

1. Did the study attempt to enroll all (or a random sample of) patients meeting inclusion criteria, or a random sample (inception cohort)?
2. Were the groups comparable at baseline on key prognostic factors (e.g., by restriction or matching)?
3. Did the study use accurate methods for ascertaining exposures, potential confounders, and outcomes?
4. Were outcome assessors and/or data analysts blinded to treatment?
5. Did the article report attrition?
6. Did the study perform appropriate statistical analyses on potential confounders?
7. Is there important differential loss to followup or overall high loss to followup?
8. Were outcomes pre-specified and defined, and ascertained using accurate methods?

For Case-Control Studies:
Each criterion was given an assessment of yes, no, or unclear.

1. Did the study attempt to enroll all (or a random sample of) cases using pre-defined criteria?
2. Were the controls derived from the same population as the cases, and would they have been selected as cases if the outcome was present?
3. Were the groups comparable at baseline on key prognostic factors (e.g., by restriction or matching)?
4. Did the study report the proportion of cases and controls who met inclusion criteria that were analyzed?
5. Did the study use accurate methods for identifying outcomes?
6. Did the study use accurate methods for ascertaining exposures and potential confounders?
7. Did the study perform appropriate statistical analyses on potential confounders?

Appendix G. Overall Strength of Evidence

Table G-1. Overall strength of evidence

Key Question	Number of Studies	Number of Subjects	Quality (Good, Fair, Poor)	Consistency (High, Moderate, Low)	Directness (Direct or indirect)	Precision (High, Moderate, Low)	Strength of Evidence (High, Moderate, Low, or Insufficient)
1. In adults with pressure ulcers, what is the comparative effectiveness of treatment strategies for improved health outcomes including but not limited to: complete wound healing, healing time, reduced wound surface area, pain, and prevention of serious complications of infection?							
Support Surfaces							
Air-fluidized beds superior to other surfaces	4 randomized trials, 1 observational	908	Fair	High	Direct	Low	Moderate
Alternating pressure surfaces similar to each other	4 randomized trials	369	Fair	High	Direct	Low	Moderate
AP beds versus other surfaces	2 randomized trials, 1 trial, allocation unclear, 1 retrospective cohort	368	Poor	Moderate	Direct	Low	Low
AP cushions versus other cushions	2 randomized trials	77	Fair	Low	Direct	Low	Insufficient
LAL beds similar to other surfaces	4 randomized trials; 1 observational	329	Poor	Low	Direct	Low	Low
Nutrition							
Protein-containing nutritional supplements superior to standard diets or placebo	10 randomized trials 2 observational	562	Fair	High	Direct	Imprecise	Moderate

Key Question	Number of Studies	Number of Subjects	Quality (Good, Fair, Poor)	Consistency (High, Moderate, Low)	Directness (Direct or indirect)	Precision (High, Moderate, Low)	Strength of Evidence (High, Moderate, Low, or Insufficient)
Vitamin C similar to placebo	1 randomized trial	88	Good	NA (one study)	Direct	Imprecise	Low
Zinc supplementation versus no zinc supplementation	1 randomized trial	70	Fair	NA (one study)	Direct	Imprecise	Insufficient
Local Wound Applications							
Hydrocolloid superior to standard care	10 randomized trials	560	Poor	Moderate	Direct	Low	Low
Hydrogel versus standard care	4 randomized trials	156	Poor	Low	Direct	Low	Insufficient
Foam versus standard care	3 randomized trials	118	Poor	Low	Direct	Low	Insufficient
Transparent film versus standard care	3 randomized trials	106	Poor	Low	Direct	Low	Insufficient
Hydrocolloid versus hydrogel	3 randomized trials	167	Poor	Low	Direct	Low	Insufficient
Hydrocolloid equivalent to foam	8 randomized trials	508	Fair	Moderate	Direct	Moderate	Moderate
Radiant heat similar to other dressings (complete wound healing)	4 randomized trials	160	Good	Moderate	Direct	Moderate	Moderate
Radiant heat superior to other dressings	4 randomized trials	160	Good	Moderate	Direct	Moderate	Moderate
Debriding enzymes versus hydrocolloid/standard care	5 randomized trials	218	Fair	Low	Direct	Low	Insufficient
Phenytoin versus hydrocolloid/standard care	3 randomized trials	154	Fair	Low	Direct	Low	Insufficient
Dextranomer paste inferior to hydrogel/alginate dressings	2 randomized trials	227	Fair	Moderate	Direct	Low	Low
Collagen applications similar to hydrocolloid/standard care	3 randomized trials	169	Fair	Low	Direct	Low	Low
Maggot therapy versus standard care	3 observational	129	Poor	Moderate	Direct	Low	Insufficient
Platelet-derived growth factor superior to placebo	3 randomized trials	196	Fair	Moderate	Direct	Low	Low

Key Question	Number of Studies	Number of Subjects	Quality (Good, Fair, Poor)	Consistency (High, Moderate, Low)	Directness (Direct or indirect)	Precision (High, Moderate, Low)	Strength of Evidence (High, Moderate, Low, or Insufficient)
Fibroblast growth factor versus placebo	2 randomized trials	60	Poor	Low	Direct	Low	Insufficient
Nerve growth factor versus placebo	1 randomized trial	36	Good	NA	Direct	Low	Insufficient
Macrophage suspension versus standard care	2 observational	299	Poor	Low	Direct	Low	Insufficient
Surgery							
Cutaneous versus fasciocutaneous versus myocutaneous flaps	4 observational	560	Fair	Low	Indirect	Low	Insufficient
Adjunctive Therapies							
Electrical stimulation superior to sham	9 randomized trials	397	Fair	Moderate	Direct	Moderate	Moderate
Electromagnetic therapy equivalent to sham	4 randomized trials	112	Fair	Moderate	Direct	Low	Low
Ultrasound similar to sham or standard care	3 randomized trials	148	Fair	Moderate	Direct	Low	Low
NPWT similar to standard care or topical gel	2 randomized trials 1 observational	52 86	Fair	High	Direct	Low	Low
Light Therapy similar to sham or standard care (complete wound healing)	1 randomized trials 1 observational	489	Fair	Low	Direct	Low	Low
Light Therapy superior to sham or standard care in (wound surface area reduction)	4 randomized trials 1 observatonal	489	Fair	Low	Direct	Low	Low
Laser Therapy similar to sham or standard care	4 randomized trials	157	Fair	Moderate	Direct	Low	Low
Hydrotherapy superior versus sham or standard care	2 randomized trials	128	Fair	Moderate	Direct	Low	Insufficient

Key Question	Number of Studies	Number of Subjects	Quality (Good, Fair, Poor)	Consistency (High, Moderate, Low)	Directness (Direct or indirect)	Precision (High, Moderate, Low)	Strength of Evidence (High, Moderate, Low, or Insufficient)
1a. Does the comparative effectiveness of treatment strategies differ according to features of the pressure ulcers, such as anatomic site or severity at baseline?*							
Surgery							
Ulcer recurrence rate after surgery lower for sacral versus. ischial ulcers	4 observational	560	Fair	Moderate	Indirect	Low	Low
Adjunctive Therapies							
Electrical stimulation vs. sham, by ulcer stage	5 randomized trials	197	Fair	Moderate	Direct	Moderate	Insufficient
Electromagnetic therapy versus sham, by ulcer stage	1 randomized trial	30	Fair	NA	Direct	Low	Insufficient
1b. Does the comparative effectiveness of treatment strategies differ according to patient characteristics, including but not limited to: age; race/ethnicity; body weight; specific medical comorbidities; and known risk factors for pressure ulcers, such as functional ability, nutritional status, or incontinence? *							
Surgery							
Ulcer recurrence rate greater after surgery for patients with spinal cord injury versus others	1 observational	158	Fair	NA	Indirect	Low	Low
Adjunctive Therapies							
Electrical stimulation versus sham in spinal cord injured patients versus others	4 randomized trials	138	Fair	Moderate	Indirect	Low	Low
Electromagnetic therapy versus sham	2 randomized trials	60	Fair	Moderate	Direct	Low	Insufficient

Key Question	Number of Studies	Number of Subjects	Quality (Good, Fair, Poor)	Consistency (High, Moderate, Low)	Directness (Direct or indirect)	Precision (High, Moderate, Low)	Strength of Evidence (High, Moderate, Low, or Insufficient)
1c. Does the comparative effectiveness of treatment strategies differ according to patient care settings such as home, nursing facility, or hospital, or according to features of patient care settings, including but not limited to nurse/patient staffing ratio, staff education and training in wound care, the use of wound care teams, and home caregiver support and training? *							
Key Outcomes: Adjunctive							
Electrical stimulation versus sham	9 randomized trials	397	Fair	Moderate	Direct	Low	Low
Electromagnetic therapy versus sham	3 randomized trials	72	Fair	High	Direct	Low	Insufficient
2. What are the harms of treatments for pressure ulcers? *							
Support Surfaces							
Unclear harms of support surfaces	6 randomized trials; 1 observational	2,399	Fair	Low	Direct	Low	Insufficient
Nutrition							
Unclear harms of nutritional supplementation	5 randomized trials 2 observational studies	448	Fair	Low	Direct	Low	Insufficient
Local Wound Applications							
Dressings and topical therapies associated with skin complications	25 randomized trials 5 observational studies	3,728	Fair	Moderate	Direct	Low	Moderate

Key Question	Number of Studies	Number of Subjects	Quality (Good, Fair, Poor)	Consistency (High, Moderate, Low)	Directness (Direct or indirect)	Precision (High, Moderate, Low)	Strength of Evidence (High, Moderate, Low, or Insufficient)
Dressings/topical therapies vs. other dressings/topical therapies	6 randomized trials 1 observational	2276	Poor	Low	Direct	Low	Insufficient
Biological agents not associated with significant harms	4 randomized trials 1 observational	332	Fair	Low	Direct	Low	Insufficient
Surgery							
Ulcer recurrence from flap failure 12 to 24 percent	2 observational	3	Fair	Moderate	Indirect	Low	Low
Adjunctive Therapies							
Local skin irritation with electrical stimulation	3 randomized trials	146	Fair	Low	Direct	Low	Low
Unclear harms of electromagnetic therapy	1 randomized trial	30	Fair	NA	Direct	Low	Insufficient
Unclear harms of therapeutic ultrasound	3 randomized trials	101	Fair	Low	Direct	Low	Insufficient
Unclear harms of negative pressure wound therapy	2 observational	77	Fair	Low	Indirect	Low	Insufficient
Light therapy not associated with significant harm	4 randomized trials	327	Fair	Moderate	Direct	Low	Low
Short-term laser therapy not associated with significant harm	4 randomized trials	137	Fair	Moderate	Direct	Moderate	Low
2a. Do the harms of treatment strategies differ according to features of the pressure ulcers, such as anatomic site or severity at baseline? *							

Key Question	Number of Studies	Number of Subjects	Quality (Good, Fair, Poor)	Consistency (High, Moderate, Low)	Directness (Direct or indirect)	Precision (High, Moderate, Low)	Strength of Evidence (High, Moderate, Low, or Insufficient)
Surgery							
More harms with ischial versus sacral and trochanteric surgical repairs	2 observational	376	Fair	Low	Indirect	Low	Low
Wound dehiscence more common when bone removed at time of surgery	1 observational	148	Fair	NA (one study)	Direct	Low	Low
Adjunctive Therapies							
Harms of electrical stimulation, by ulcer stage	3 randomized trials	146	Fair	Low	Direct	Low	Insufficient
2b. Do the harms of treatment strategies differ according to patient characteristics, including: age, race/ethnicity; body weight; specific medical comorbidities; and knows risk factors for pressure ulcers, such as functional ability, nutritional status, or incontinence? *							
Adjunctive Therapies							
More adverse events with electrical stimulation versus sham in frail elderly vs. younger (mostly spinal cord injured- patients	3 randomized trials	146	Fair	Moderate	Direct	Low	Low
2c. Do the harms of treatment strategies differ according to patient care settings such as home, nursing facility, or hospital, or according to features of patient care settings, including but not limited to nurse/patient staffing ratio, staff education and training in wound care, the use of wound care teams, and home caregiver support and training? *	No studies	-	-	-	-	-	-

Abbreviations: NA+ not applicable.

* Overall strength of evidence ratings are displayed for key questions and comparisons for which our review included a body of evidence that could be rated. Key questions and comparisons for which there were no studies, or single poor-quality studies, were not rated for strength of evidence. Strength of evidence domains were adapted from Owens et al.

Appendix H. Evidence Tables and Overall Quality Ratings

Evidence Table H-1: Support

Evidence Table H-1a. Support trials

Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type
Allman, 1987[1] US Good	18 years or older Presence of a PU on sacrum, buttocks, trochanters, or back Activity expected to be limited to bed or chair in hospital for at least one week Patient expected to live at least one week	Previous inclusion in trial Skin graft or flap planned for pressure sore within one week	NR/140/72/65	Age (Mean): 67 years Female: 58% Race: Black: 62%	Support: AF Beds
Branom, 2001[2] US Poor	Admitted as inpatient to one of the two test sites Stage III or IV PUs on trunk or pelvis Bedridden	NR	NR/NR/20/20	Age (Mean):74 years Female: NR Race: NR	Support: Support: Air Bed with Foam Overlay
Caley, 1994[3] US Poor	Existing PU LAL recommended for treatment by MD or enterostomal therapy nurse	NR	NR/NR/93/55 (106 PUs. Results presented for PUs)	Age (Mean): 76 years Female: 60% Race: Caucasian: 87% African American: 13%	Support: LAL Beds
Clark, 1997 [4] UK Fair	Over 65 years old Stage II, III, or IV PU greater than 2 cm^2 in surface area PU located on the sacrum or ischial tuberosities At moderate to high risk of developing further sores Able to sit for at least 2 hours Serum albumin level of greater than 2.5 mg/dl Expected to remain in study for more than 7 days	PU greater than 15 cm^2	NR/33/33/25	Age (Mean): 83 years Female: 72% Race: NR	Support: AP Cushions
Day, 1993 [5] US Poor	Hospitalized 18 years or older Stage II, III or IV PU Life expectancy of at least one week Activity limited to bed or chair during hospitalization	Previous study enrollment Expected hospitalization less than 7 days Skin graft or flap within 7 days of enrollment.	118/83/83/83	Age (Mean):76 years Female: 58% Race: NR	Support: Air suspension

Evidence Table 1a. Support Trials, continued					
Author, year Country Overall Quality Rating	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type**
Devine, 1995[6] Scotland Fair	Patients admitted to Geriatric Unit PU of Stage II or above (on a five grade scale)	NR	NR/NR/41/30	Age (Mean): 83 years Female: 59% Race: NR	Support: AP Beds
Evans, 2000 [7] Land, 2000[8] UK Good	65 years or older Stage III PU or stage II PU and one or more of the following: difficulty repositioning in bed and unable to tolerate at 30 degree tilt; unable to move in bed; in bed for more than 20 hours in 24 hours; weight greater than 108 kg and bed bound; or undergone spinal anesthetic	Spinal metastases Exudating wounds that may lead to hygiene or infection control problems Weight greater than 250 kg	NR/NR/32/32	Age (Mean):81 years Female: 78% Race: NR	Support: AP Beds
Ferrell, 1993[9] US Good	Stage II or higher PU (Shea scale) on trunk, buttocks or trochanters	Expected survival of less than one month Previous participation in study Previous or planned surgical excision of PU.	NR/NR/84/84	Age (Mean):85 years Female: 50% Race: NR	Support: LAL Beds
Groen, 1999[10] Holland Fair	60 years or older PU on truck classified as grade III or IV (article did describe grading system)	Severe or terminal illness	NR/NR/120/101	Age (Mean): 83 years Female: NR Race: NR	Support: Foam and Water Mattresses
Izutsu, 1998[11] Japan Poor	Bedridden patients with decubitus	Immunocompromised and patients with mycobacterial infections	NR/NR/31/31	Age (Mean): 78 years Female: 58% Race: NR	Support: Automatic Rolling Air Cushioned Bed
Jackson, 1988[12] US Poor	18 years or older Stage III, IV, or V PU Required some form of pressure-relieving device	Renal disease; fluid restriction, dehydration, congestive heart failure/pulmonary edema; urinary incontinence (in which indwelling catheters were contraindicated) and severe diarrhea; daily treatments that required getting the patient into and out of the air-fluidized bed; patient inability to get into and out of bed without assistance; sensory deprivation; and poor ventilatory excursion.	NR/NR/35/35	Age (Mean):77 years Female: 64% Race: NR	Support: AF Beds
Keogh, 2001[13] UK Poor	Patient over 18 years old Patients had to give consent Likely to stay in bed for at least 12 hours a day Tissue damage no greater than stage I PU	Patient with terminal illness Weighing more than 120 kg Patients posing a manual handling risk who required an electric bed.	NR/100/100/70 (14 had PU on admission and were analyzed for treatment)	Age (Mean): 70 years Female: 45% Race: NR	Support: Profiling Bed
Makhsous, 2009[14] US Fair	Wheelchair user with SCI Stage II or III PUs in sacral and/or ischial area Able to independently use manual or powered wheelchair Sitting tolerance of at least 4 hours per day	Degenerative disorders of the spine History of injury or surgery of the pelvis, hip joint and the thigh; hip contractures Severe pain, spasm, and psychological concerns preventing proper cooperation	NR/NR/44/44	Age (Mean):43 years Female: 7% Race: NR	Support: Cyclic Pressure Relief Seats

Evidence Table 1a. Support Trials, continued					
Author, year Country Overall Quality Rating	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type**
Malbrain, 2010[15] Belgium Fair	ICU patients with high PU risk (Norton Score ≤to 8) or a PU who were going to require mechanical ventilation for an estimated duration of at least 5 days.	If consent was not obtained from closest relative or at least one of each of the two mattresses studied were not available when the patient was admitted.	NR/NR/16/16	Age (Mean): 64 years Female: 50% Race: NR	Support: Reactive Air and Active Alternating Pressure
Mulder, 1994[16] US Poor	PU Stage III or IV (Int'l Assoc. of Enterostomal Therapies) PU area between 1.5 cm x 1.5 cm and 10.0 cm x 20.0 cm	Carcinomatosis Osteomyelitis affecting the target PU Uncontrolled target PU infection Immune deficiency disorders Inadequate nutritional status	NR/NR/49/39	Age (Mean): NR Female: NR Race: NR	Support: LAL Beds
Munro, 1989[17] US Fair	Stage II or III PU Expected to remain in hospital at least 15 days	Stage IV PU Weight over 250 pounds Extremely malnourished (<70% of ideal body weight) or with serum albumin <2.1g /100 ml	NR/NR/40/40	Age (Mean): 67 Female: 0% Race: NR	Support: AF Bed
Nixon, 2006[18] UK Good	Sub group of large study of PU prevention and treatment 55 years old or older Admitted to participating vascular, orthopaedic, medical or geriatric ward in previous 24 hours Expected length of stay 7 or more days Consented to participate Restricted mobility or Stage II PU	Stage III or higher existing PU Prior participation in trial Elective surgery patients with planned post-op in ICU or admitted more than 4 days pre surgery Slept in chair at night Weight more than 140 kg or less than 45 kg	6155/1972/1972/1971 Full trial including prevention. NR/NR/113/113 for patients with PUs	Age (Mean): 75 years Female: 64% Race: NR	Support: AP Overlay and Mattresses
Rosenthal, 2003[19] US Poor	Stage III or IV PU on coccyx, trochanter, or ischial tuberosities Able to sit up during previous 6 months with assistance Alert	Previously enrolled in a trial to treat their current pressure PU; already using LAL or transfer to LAL was planned, skin grafting was planned within 1 week; they had an active sinus tract or fistula, nutrition was poor, as indicated by albumin levels below 3.0 g/dL; antibiotics were required to treat methicillin-resistant Staphylococcus aureus, vancomycin-resistant enterococci, or active skin infection; osteomyelitis was diagnosed; body weight was below 60 kg; patients were unable to flex both hip and knee past 90 degrees. Further, persons with sacral PU were excluded from the study because the sacral area is suspended above the generic total contact seat and hence is not in contact with the seat.	NR/NR/207/203	Age (Mean): 70 years Female: NR Race: NR	Support: Generic Total Contact Seat
Russell, 2000(a)[20] Russell, 2000(b)[21] UK Fair	Stage II or higher PU (Torrance grading scale)	Unwilling to participate Randomized equipment not available Previous inclusion in trial and readmitted Weighed more than 25 stone	NR/NR/183/112	Age (Mean): 84 years Female: NR Race: NR	Support: AP Beds
Russell, 2003[22] UK Fair	Admitted between April 2001 and April 2002 Stage I PU or above on EPUAP	Unwilling to participate Previously in trial Obese	NR/NR/199/158	Age (Mean): 80 years Female: 54% Race: NR	Support: AP vs. Fluid Overlay

Evidence Table 1a. Support Trials, continued					
Author, year **Country** **Overall Quality Rating**	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age** **Sex** **Race**	**Intervention Type**
Strauss, 1991[23] US Fair	16 years or older Stage 3 or 4 PU Future PU-related hospitalization expected Severely limited mobility Adequate social support to use home AF therapy Likely to live one year or more; Out of hospital at least 3 weeks; Medical provider willing to closely manage care in home	Febrile or septic or otherwise required immediate hospitalization PU on radiated skin	NR/112/97/69	Age (mean): 64 years Female: 49% Race: NR	Support: AF Beds

Evidence Table 1a. Support Trials, continued								
Author, year Country Overall Quality Rating	**Intervention: Ulcer Type/Severity at Baseline (Intervention Onset)**	**Treatment A**	**Treatment B**	**Treatment C**	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Pain**
Allman, 1987[1] US Good	Stage I, II, III, IV, and unstageable Treatment A: Superficial-Epidermis: 13% (4) Superficial- Dermis: 39% (12) Deep-Subcutis: 29% (9) Deep-Bone/Muscle: 6% (2) Deep-Eschar: 13% (4) Treatment B: Superficial-Epidermis: 12% (4) Superficial- Dermis: 47% (16) Deep-Subcutis: 32% (11) Deep-Bone/Muscle: 3% (1) Deep-Eschar: 6% (2)	AF bed with positioning every 4 hours from 0700 hours to 2300 hours.	Alternating air mattress covered by a foam pad with repositioning every 2 hours and elbow or heel pads as needed.	NA	Patients with one or more healed sores during study Treatment A: 65% (20) Treatment B: 44% (15) p=0.10	Change in total surface area, cm^2 Median (Range) Treatment A: -1.2 (-38.0 to +15.5) Treatment B: + 0.5 (-55.1 to +94.7) p=0.01 50% reduction in total surface area Treatment A: 29% (9) Treatment B: 24% (8) p=0.64	NR	Change in pain intensity from baseline Treatment A: Decreased: 62% (8) No change: 38% (5) Increased: 0 Treatment B: Decreased: 29% (4) No change: 50 (7) Increased: 21% (3) p=0.01 Change in comfort from baseline Treatment A Increased: 62% (8) No change: 31% (4) Decreased: 8% (1) Treatment B: Increased: 23% (3) No change: 31% (4) Decreased: 46% (6) p=0.04

Evidence Table 1a. Support Trials, continued								
Author, year Country Overall Quality Rating	**Intervention: Ulcer Type/Severity at Baseline (Intervention Onset)**	**Treatment A**	**Treatment B**	**Treatment C**	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Pain**
Branom, 2001[2] US Poor	Treatment A: Stage III: 30% (3) Stage IV: 70% (7) Treatment B: Stage III: 25% (2) Stage IV: 75% (6) Staging system not cited	Non-powered air mattress with foam overlay	LAL mattress	NA	NR	At 3 Weeks Treatment A: Mean Amount Closed (cm^2): 17.0, Mean % Closed: 43% Treatment B: Mean Amount Closed (cm^2): 17.1, Mean % Closed: 22% At 8 Weeks Treatment A: Mean Amount Closed (cm^2): 25.8 Mean % Closed: 60% Treatment B: Mean Amount Closed (cm^2): 22.2 Mean % Closed: 40%	At 3 Weeks Treatment A: Rate of Closure per Week (cm^2): 5.7 % Closed per Week: 14.4% Treatment B: Rate of Closure per Week (cm^2): 5.7 % Closed per Week: 7.2% At 8 Weeks Treatment A: Rate of Closure per Week (cm^2): 3.5 % Closed per Week: 9.0% Treatment B: Rate of Closure per Week (cm^2): 2.8 % Closed per Week: 5.0%	NR

Evidence Table 1a. Support Trials, continued								
Author, year Country Overall Quality Rating	**Intervention: Ulcer Type/Severity at Baseline (Intervention Onset)**	**Treatment A**	**Treatment B**	**Treatment C**	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Pain**
Caley, 1994[3] US Poor	NR	LAL Bed	LAL overlay	NA	NR	Change in Surface Area Mean, cm^2 Treatment A: 3.8 Treatment B: 10.2 p=0.06 Perimeter average of initial and final, cm Mean (Range) Treatment A: 20.0 Treatment B: 23.7 p=0.06	NR	NR
Clark, 1997[4] UK Fair	Treatment A: Stage II: 50% (7) Stage III: 14% (2) Stage IV: 36% (5) Sacrum: 93% (13) Ischial: 7% (1) Treatment B: Stage II: 64% (7) Stage III: 9% (1) Stage IV: 27% (3) Sacrum: 91% (10) Ischial: 9% (1)	AP cushion with 4 cells	Static air filled cushion	NA	Treatment A: 21% (3) Treatment B: 45% (5) p=NS	Mean Reduction in Area per Day(Stage II only) absolute change: mean Treatment A: 0.13 Treatment B: 0.27	NR	NR
Day, 1993[5] US Poor	Treatment A: Stage II: 57% (25) Stage III: 14% (6) Stage IV: 25% (11) Unstageable: 5% (2) Treatment B: Stage II: 59% (23) Stage III: 21% (8) Stage IV: 10% (4) Unstageable: 10% (4)	Air-suspension bed	Foam overlay	NA	NR	Initial/ Ending Mean Area in cm^2 by Stage Stage II Treatment A: 12.7 /7.3 Treatment B: 10.0/5.3 Stage III and IV Treatment A: 51.8/37.1 Treatment B: 13.7/12.4 p>0.05	NR	NR

Evidence Table 1a. Support Trials, continued								
Author, year Country Overall Quality Rating	**Intervention: Ulcer Type/Severity at Baseline (Intervention Onset)**	**Treatment A**	**Treatment B**	**Treatment C**	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Pain**
Devine, 1995[6] Scotland Fair	Median Initial Stage, range Treatment A: 3 (2-5) Treatment B: 3 (2-5) Location (total population): Sacrum/buttocks: 59% Heels: 20% Trochanter: 17% Others: 5%	AP bed	Airwave bed	NA	Treatment A: 64% (10) Treatment B: 36% (5) p=NS	Median Reduction per Day cm^2 Treatment A: 0.089 Treatment B: 0.107 p=0.92	NR	NR
Evans, 2000[7] Land, 2000[8] UK Good	Hospital Treatment A: Stage II: 43% (3) Stage III: 57% (4) Sacrum: 47% (4) Buttock: 0 Heel: 53% (3) Treatment B: Stage II: 40% (2) Stage III: 60% (3) Sacrum: 40% (2) Buttock: 20% (1) Heel: 40% (2) Nursing Home Treatment A: Stage II: 10% (1) Stage III: 70% (7) Stage IV: 20% (2) Sacrum: 20% (2) Buttock: 10% (1) Heel: 60% (6) Malleolus: 10% (1) Treatment B: Stage II: 20% (2) Stage III: 40% (4) Stage IV: 40% (4) Sacrum: 50% (5) Buttock: 0 Heel: 40% (4) Malleolus: 10% (1)	AP mattress	Other brands of AP mattresses	NA	NR	Median Reduction per Day (range) Hospital, Treatment A: 0.12 cm^2 (0-0.21cm^2) Treatment B: 0.08cm^2 (0.04-0.33cm^2) p=NS Nursing Home Treatment A: 0.11 cm^2 (0.04-0.41cm^2) Treatment B: 0.05cm^2 (0-0.48cm^2) p=NS Median Relative % reduction per Day (range) Hospital Treatment A: 2.44% (0-7.14%) Treatment B: 1.34% (1.11-2.88%) p=NS Nursing Home Treatment A: 1.57% (0.45-5.00%) Treatment B: 0.99% (0-2.54%) p=NS	NR	NR

Evidence Table 1a. Support Trials, continued								
Author, year Country Overall Quality Rating	**Intervention: Ulcer Type/Severity at Baseline (Intervention Onset)**	**Treatment A**	**Treatment B**	**Treatment C**	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Pain**
Ferrell, 1993[9] US Good	Stage (Shea scale) Treatment A: Stage II: 58% (25) Stage III/IV: 42% (18) Treatment B: Stage 2: 66% (27) Stage III/IV: 34% (14) Deep Ulcers	LAL Bed	Foam convoluted mattress (10 cm) overlying a hospital mattress.	NA	Treatment A: 60% (26) Treatment B: 46% (19) p=0.19	Decrease in Size, mm^2 per Day Median (25th, 75th percentile) All PUs Treatment A: 9.0 (4.0, 19.8) Treatment B: 2.5 (0.5, 6.5) p=0.0002	NR	NR
Groen, 1999[10] Holland Fair	Stage III or IV was an inclusion criteria	High Quality Foam Replacement Mattress	Water mattress	NA	Percent completely healed at four weeks A. Treatment A: 45% B. Treatment B: 48% p=NS	NR	NR	Reported as complicating factor: see harms
Izutsu, 1998[11] Japan Poor	Average Grade: Treatment A: II Treatment B: III	Rolling air cushion bed	Conventional bed with their positions being changed every 2 hours	NA	NR	Wound Area Reduction: No significant difference (p=NR)	NR	NR
Jackson, 1988[12] US Poor	NR	Air-Fluidized mattress	A variety of non air-fluidized devices were used, including a non alternating air mattress	NA	NR	Patients Experiencing Decrease in Ulcer Area: Treatment A: 60% (9) Treatment B 45% (9). p=NR	NR	NR
Keogh, 2001[13] UK Poor	Treatment A: Stage I: 11.4% (4) Treatment B: Stage I: 28.5% (10)	Profiling Bed	Conventional Bed	NA	Treatment A: 100% (4) Treatment B: 20% (2) p=NR	NR	NR	NR
Makhsous, 2009[14] US Fair	Treatment A: Stage II: 55% (12) Stage III: 45% (10) Treatment B: Stage II: 43% (9) Stage III: 57% (13)	Wheelchairs with a cyclic pressure-relief seating system	Regular wheelchairs	NA	NR	Reduction in Wound Area: Treatment A: 45% Treatment B: 10% p<0.001 Probability to achieve 30% wound closure at 30 days: Treatment A: 0.727 Treatment B: 0.364 p=0.007	Median Time 30% Wound Reduction in Days Treatment A: 25 Treatment B: >30 p=0.007	NR

Evidence Table 1a. Support Trials, continued								
Author, year Country Overall Quality Rating	**Intervention: Ulcer Type/Severity at Baseline (Intervention Onset)**	**Treatment A**	**Treatment B**	**Treatment C**	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Pain**
Malbrain, 2010[15] Belgium Fair	PU at admission. Treatment A: Category I: 50% (5) Category II: 30% (3) Category III: 20% (2) Treatment B: Category I: 20% (2) Category II: 20% (2) Category III: 0	AP mattress (Nimbus 3)	Reactive low-pressure mattress	NA	NR	Change in surface area (cm^2) Treatment A:-2.1 Treatment B: 25.8 p=0.05	NR	NR
Mulder, 1994[16] US Poor	Treatment A: Stage III: 77% (24)Stage IV: 23% (7) Sacral: 48% (15) Trochanter: 29% (9) Ischial: 16% (5) Heel: 3% (1) Ankle: 3% (1) Treatment B: Stage III: 72% (13) Stage IV: 28% (5) Sacral: 50% (9) Trochanter: 28% (5) Ischial: 22% (4) Heel: 0 Ankle: 0 (International Association of Enterostomal Therapists staging system)	LAL Bed	Foam Overlay	NA	Treatment A: 16% (5) in treatment B: 17% (3) p=NR	Decrease in ulcer area was 77% greater in treatment A vs. treatment B p=0.042	NR	NR
Munro, 1989[17] US Fair	Total Population: Stage II: 52% (21) Stage III: 48% (19)	Air fluidized bed	Standard hospital bed	NA	NR	Mean ulcer size shrank in treatment A and expanded in treatment B. p=0.05	NR	Pain scores fell over time in treatment A and Treatment B: p=0.359

Evidence Table 1a. Support Trials, continued								
Author, year Country Overall Quality Rating	**Intervention: Ulcer Type/Severity at Baseline (Intervention Onset)**	**Treatment A**	**Treatment B**	**Treatment C**	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Pain**
Nixon, 2006[18] UK Good	Stage II Only	AP Mattress Overlay	AP Mattress Replacement	NA	Treatment A: 34% (20) Treatment B: 35% (19)	Mean Absolute change Treatment A: 1.0 Treatment B: 2.0 Mean Percentage change Treatment A: -35 Treatment B: 34.4	Median Time to Healing: Treatment A: 20 days Treatment B: 20 days p=0.86	NR
Rosenthal, 2003[19] US Poor	Stage III and IV	Generic Total Contact Seat	LAL Bed	Bed Overlay	NR	NR	Median Time to Total Healing: Treatment A: 3.33 months Treatment B: 4.38 months Treatment C: 4.55 months	NR
Russell 2000(a)[20] Russell 2000(b)[21] UK Fair	Average Ulcer Severity Treatment A: 2.46 Treatment B: 2.57	AP Bed and Cushion (Nimbus 3 and Aura Cushion)	AP Bed and Cushion (Pegasus Cairewave and Proactive Seating cushion)	NA	NR	Mean Linear Growth Rate of Wound Edge (area change/ circumference/ time increment) (mm/24 hours): Treatment A: Stage IIa: 1.50 Stage IIb: 0.04 Stage III +: excluded due to insufficient data Treatment B: Stage IIa 0.17 Stage IIb -0.84 Stage III +: excluded due to insufficient data p=NS	NR	NR
Russell, 2003[22] UK Fair	NR	AP mattress	Fluid overlay system	NA	NR	NR	NR	NR

Evidence Table 1a. Support Trials, continued								
Author, year Country Overall Quality Rating	**Intervention: Ulcer Type/Severity at Baseline (Intervention Onset)**	**Treatment A**	**Treatment B**	**Treatment C**	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Pain**
Strauss, 1991[23] US Fair	Stage III and IV	AF Bed	Conventional treatment. Included AP beds, air, water and high density foam.	NA	Treatment A: 62% (29) healed to Stage 2 or better and were removed from treatment Treatment B: NR	NR	Mean Days to Heal to Stage II or Better: Treatment A: 93 Treatment B: NR	NR

Evidence Table 1a. Support Trials, continued						
Author, year Country Overall Quality Rating	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis**	**Outcomes: Recurrence Rate**	**Other Outcomes: Specify**	**Timing: Duration of Followup**	**Setting**
Allman, 1987[1] US Good	NR	NR	NR	Patients who Improved: Treatment A: 62% Treatment B: 29% p=0.05 Odds of improvement on Treatment A compared to Treatment B: 5.6	Weekly from enrollment until death or discharge from hospital Median: 13 days Range: 4 to 77 days	Hospital
Branom, 2001[2] US Poor	NR	NR	NR	Goals for Treatment vs. Results (at admission goal was classified as progressive closure, prepare for flap or maintenance) Treatment A vs. LAL Achieved: 70% (7) Exceeded: 30% (3) Not achieved: 0% Treatment B: Achieved: 50% (4) Exceeded: 13% (1) Not achieved: 37% (3)	8 weeks	Acute care with specialty in ventilator and sub-acute center
Caley, 1994[3] US Poor	NR	NR	NR	NR	1 month or until hospital discharge.	Hospital
Clark, 1997[4] UK Fair	NR	NR	NR	Stage III and IV only Mean Change in Volume (cm^3): Treatment A: 0.56 Treatment B: 0.49 % Change in Volume per Day: Treatment A: 1% Treatment B: 0.7%	Mean Days of Followup Treatment A: 58.64 Treatment B: 43.73 p=NS	Hospital and nursing homes

Evidence Table 1a. Support Trials, continued						
Author, year Country Overall Quality Rating	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis**	**Outcomes: Recurrence Rate**	**Other Outcomes: Specify**	**Timing: Duration of Followup**	**Setting**
Day, 1993[5] US Poor	NR	NR	NR	Mean of Weekly Patient Assessments of Comfort Treatment A: 4.1 Treatment B: 3.7 p>0.05 Note: most patients unable to report	Assessed weekly until discharge.	Hospital
Devine, 1995[6] Scotland Fair	NR	NR	NR	Median, range (10 point scale) How comfortable was the mattress? Treatment A: 8 (5-10) Treatment B: 8 (3-10) How well did you sleep? Treatment A: 8 (4-10) Treatment B: 8(7-10) Many patients unable to report	Followed for 4 weeks after enrollment.	Nursing home/Long-term care
Evans, 2000[7] Land, 2000[8] UK Good	NR	NR	NR	Median weekly comfort rating (5 point scale) Hospital: Treatment A: 5 Treatment B: 4 p=0.006 Nursing Home: Treatment A: 5 Treatment B: 4 p=0.002	Hospital: Until death, discharge, or healing Nursing Home: Until death, hospitalization, healing, or completion of study period.	Hospital and nursing home

Evidence Table 1a. Support Trials, continued						
Author, year Country Overall Quality Rating	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis**	**Outcomes: Recurrence Rate**	**Other Outcomes: Specify**	**Timing: Duration of Followup**	**Setting**
Ferrell, 1993[9] US Good	NR	NR	NR	Improvement Change in Stages Median (25th, 75th percentile) Shea scale Treatment A: 2.0 (0, 2) Treatment B: 1.0 (0,2) p<0.05 Sessing scale Median (25th, 75th percentile) Treatment A: 3.0 (1,3) Treatment B: 1.0 (0,3) p<0.01 Cure Probability ratio= Cox hazard ratio (probability of cure with Low-Air Loss divided by the probability of cure with foam for subjects under each condition for the same period of time. Ratio (95% confidence level) p value All PU 2.66 (1.34-5.17) p=0.004 Superficial 2.60 (1.24-5.41) p=0.01 Deep 2.97 (0.61-14.5 p=0.18	Until healing, death, transfer, withdrawal, or protocol deviation Number of Followup Days, Median (25th, 75th percentile): Treatment A: 33 (15, 60) Treatment B: 40 (21.5, 90.5) p=0.56	Nursing home/LTC
Groen, 1999[10] Holland Fair	NR	NR	NR	NR	Four weeks from initial assessment and assignment	Nursing home/LTC
Izutsu, 1998[11] Japan Poor	NR	NR	NR	Improvement in Stage Treatment A: Stage improved from 2.8 to 2.0 p<0.01 after three months Treatment B: Stage changed from 3.0 to 3.2 p>0.5 after three months.	3 months	Nursing home/LTC

Evidence Table 1a. Support Trials, continued						
Author, year Country Overall Quality Rating	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis**	**Outcomes: Recurrence Rate**	**Other Outcomes: Specify**	**Timing: Duration of Followup**	**Setting**
Jackson, 1988[12] US Poor	NR	NR	NR	NR	Until discharge Median Days in Study: Treatment A: 20 days Treatment B: 37.5 days	Hospital
Keogh, 2001[13] UK Poor	NR	NR	NR	NR	5 to 10 days.	Hospital
Makhsous, 2009[14] US Fair	NR	NR	NR	Percentage Improvement in PUSH score (mean): Treatment A: 21.9 Treatment B: 5.8 (9.2) p=0.003	30 days	Community
Malbrain, 2010[15] Belgium Fair	NR	NR	NR	Change in PUSH score – Treatment A: 1 Treatment B; 3.4 p=0.01 Change in Category (EPUAP) Treatment A: 0 Treatment B: 0.8 p=0.03	Followed until discharge. Mean was 11days	Hospital
Mulder, 1994[16] US Poor	NR	NR	NR	NR	12 weeks or until ulcer healed	Nursing home/Long-term care
Munro, 1989[17] US Fair	NR	NR	NR	NR	15 days	Hospital
Nixon, 2006[18] UK Good	NR	NR	NR	NR	Until healing, discharge, or end of trial.	Hospital
Rosenthal, 2003[19] US Poor	NR	NR	NR	NR	6 months	Nursing home/Long-term care
Russell, 2000(a)[20] Russell, 2000(b)[21] UK Fair	NR	NR	NR	NR	Until discharge or healing	Hospital

Evidence Table 1a. Support Trials, continued						
Author, year Country Overall Quality Rating	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis**	**Outcomes: Recurrence Rate**	**Other Outcomes: Specify**	**Timing: Duration of Followup**	**Setting**
Russell, 2003[22] UK Fair	NR	NR	NR	Overall Ulcer Progress: Treatment A: Improved: 71% (60) No Change: 1% (1) Worse: 27% (22) Treatment B: Improved: 75% (56) No change: 4% (3) Worse: 21% (16) p=0.67 Worst Ulcer Progress: Treatment A: Improved: 76% (63) No Change: 1% (1) Worse: 23% (19) Treatment B: Improved: 84% (63) No change: 5% (4) Worse: 11% (8) p=0.053	Until discharge Average Length of Stay: Treatment A: 22.17 days Treatment B: 20.05 days. p=0.23	Hospital
Strauss, 1991[23] US Fair	NR	NR	11% (5) returned to AF bed after recurrence of stage 3 or 4 PU	Improved Reviewer 1 % (#)/ Reviewer 2 %/(#) Treatment A:91% (20) /82% (18) Treatment B: 62% (8)/77% (10) AF had 55% fewer hospital days and used fewer inpatient resources.	36 weeks	Other

Evidence Table 1a. Support Trials, continued								
Author, year Country Overall Quality Rating	**Harms: Pain**	**Harms: Dermatologic Complication**	**Harms: Bleeding**	**Harms: Infection**	**Severe Adverse Events**	**Withdrawal due to Adverse Events**	**Overall Adverse Events Rate**	**Funding Source**
Allman, 1987[1] US Good	NR	New skin breakdown Treatment A 29%:(9) Treatment B: 44% (15) p=0.24	Treatment A: Epitaxis: 3% (1)	NR	NR	4 withdrew due to difficulty in transferring from AF beds	3%	Support Systems International, Inc. American Pharmaceutical Company (provided supplies), Henry J. Kaiser Family Foundation, Burroughs-Wellcome Scholar in Pharmacoepidemiology.
Branom, 2001[2] US Poor	NR	NR	NR	NR	NR	NR	NR	Mattress supplied by Span-America Medical System
Caley, 1994[3] US Poor	NR	NR	NR	NR	NR	NR	NR	NR
Clark, 1997[4] UK. Fair	NR	NR	NR	NR	NR	2 (1 from each group) withdrew due to malfunction of the cushion	NR	Raymor Ltd. supplied Quadtro cushions. Funding by Pegasus Airwave Ltd.
Day, 1993[5] US Poor	NR	NR	NR	NR	NR	NR	NR	Supported in part by funding from KCI
Devine, 1995[6] Scotland Fair	NR	NR	NR	NR	NR	NR	NR	Supported by HNE healthcare grant for a part-time research nurse and provision of 3 Nimbus 1 mattresses
Evans, 2000[7] Land, 2000[8] UK Good	NR	NR	NR	NR	NR	NR	NR	Huntleigh Healthcare
Ferrell, 1993[9] US Good	NR	NR	NR	NR	NR	Treatment B: 9 subjects were deviated from the protocol because their ulcers became substantially worse or failed to heal.	NR	Jewish Home for the Aged of Greater Los Angeles Sepulveda VA Geriatric Research and Education Clinical Center West Los Angeles VA Geriatric Research and Education Clinical Center; Kinetic Concepts International

Evidence Table 1a. Support Trials, continued								
Author, year Country Overall Quality Rating	**Harms: Pain**	**Harms: Dermatologic Complication**	**Harms: Bleeding**	**Harms: Infection**	**Severe Adverse Events**	**Withdrawal due to Adverse Events**	**Overall Adverse Events Rate**	**Funding Source**
Groen, 1999[10] Holland Fair	Patients with Pain Treatment A: Week 0: 40% Week 1: 27% Week 2: 22% Week 3: 10% Week 4: 4% Treatment B: Week 0: 20% Week 1: 17% Week 2: 12% Week 3: 5% Week 4: 4%	Patients with Eczema Treatment A: Week 0: 10% Week 1: 0% Week 2: 2% Week 3: 4% Week 4: 0% Treatment B: Week 0: 2% Week 1: 0% Week 2: 0% Week 3: 0% Week 4: 0% p=NS Maceration Treatment A: Week 0: 17% Week 1: 15%.0 Week 2: 7% Week 3: 6% Week 4: 4% Treatment B: Week 0: 13% Week 1: 8% Week 2: 2% Week 3: 4% Week 4: 4% p=NS	NR	NR	NR	NR	NR	NR
Izutsu, 1998[11] Japan Poor	NR	NR	NR	NR	NR	None	NR	NR

Evidence Table 1a. Support Trials, continued								
Author, year Country Overall Quality Rating	**Harms: Pain**	**Harms: Dermatologic Complication**	**Harms: Bleeding**	**Harms: Infection**	**Severe Adverse Events**	**Withdrawal due to Adverse Events**	**Overall Adverse Events Rate**	**Funding Source**
Jackson, 1988[12] US Poor	NR	NR	Among the 15 patients in the treatment group, all had some granulation or bleeding at both entry and endpoint. Among 17 patients in the comparator group with evolutions at both entry and endpoint, 14 continued to have granulation or bleeding. In one subject, granulation or bleeding ceased; in two subjects, granulation or bleeding developed. These findings were not statistically significant.	NR	NR	NR	NR	Support Systems International
Keogh, 2001[13] UK Poor	NR	NR	NR	NR	NR	NR	NR	Huntleigh Healthcare Ltd
Makhsous, 2009[14] US Fair	NR	NR	NR	NR	NR	NR	NR	National Institutes of Health and Falk Medical Research Trust
Malbrain, 2010[15] Belgium Fair	NR	NR	NR	NR	NR	None	NR	Beds, but no other support provided by manufacturers. No other funding source reported.
Mulder, 1994[16] US Poor	NR	NR	NR	NR	NR	NR	NR	Kinetic Concepts, Inc.
Munro, 1989[17] US Fair	NR	NR	NR	NR	NR	NR	NR	Support Systems International

Evidence Table 1a. Support Trials, continued								
Author, year Country Overall Quality Rating	**Harms: Pain**	**Harms: Dermatologic Complication**	**Harms: Bleeding**	**Harms: Infection**	**Severe Adverse Events**	**Withdrawal due to Adverse Events**	**Overall Adverse Events Rate**	**Funding Source**
Nixon, 2006[18] UK Good	NR	NR	NR	NR	NR	NR	Nine reported for the full trial, but not separated for the cohort with existing PU. These included 4 falls, 3 cot-side incidents, one contact dermatitis and one patient who caught back on bed rail when mattress deflated during transfer.	National Health Service, Health Technology Assessment
Rosenthal, 2003[19] US. Poor	NR	NR	NR	NR	NR	3 patients worsened on bed overlay and were withdrawn.	NR	Equipment loaned to hospital by manufacturers.
Russell, 2000(a)[20] Russell, 2000(b)[21] US Fair	NR	NR	NR	NR	NR	NR	NR	Equipment loaned to hospital by manufacturers
Russell, 2003[22] UK Fair	NR	NR	NR	NR	NR	NR	NR	KCI Medical
Strauss, 1991[23] US Fair	NR	Treatment A: Dry skin: "several"; number NR Dehydration: 1	NR	NR	NR	NR	NR	Support Systems International

Note: AF=air fluidized, AP=alternating pressure, LAL= low air loss.

Evidence Table H-1b. Support observational studies

Author, year Country Overall Quality Rating	Population: Eligibility Criteria	Population: Exclusion Criteria	Population Data: Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention: Type	Intervention Ulcer Type/Severity at Baseline (Intervention Onset)
Ochs, 2005[24] US Fair	Enrolled in National Pressure Ulcer Long-Term Care Study (NPULS) 18 years old or older Length of stay of 14 days or longer One or more documented PUs in medical record; Treated with one of the three groups of support surfaces	Treated on support surface for less than 5 days	2,486/664/664/664	Age (Mean): 78 Female: 63% Race (available for 28% of sample): Caucasian: 66.5% African American: 28.6% Other: 4.9%	Support Surface	Stage: Treatment A: Not Staged: 2% (10) Stage I:10% (47) Stage II: 62% (288) Stage III: 13% (59) Stage IV: 7% (32) Eschar: 6% (27) Treatment B: Not Staged: 3% (3) Stage I: 8% (9) Stage II: 38% (45) Stage III:19% (23) Stage IV: 24% (29) Eschar: 8% (10) Treatment C: Not Staged: 0 Stage I: 4% (3) Stage II: 18% (15) Stage III: 17% (14) Stage IV: 54% (44) Eschar: 7% (6)
Valente, 2012[25] US Poor	All patients admitted to a geriatric center between 7/1/2001 and 6/30/2002 A Brandon score of 16 or higher (high risk) Existing PU requiring institution of pressure reduction product	Length of stay less than 10 days Development of a stage III or IV PU and moved to a low-air loss bed	NR/122/122/122	Age (Mean): 68 years Female: 65% Race: Caucasian 77% African American 23%	Support: Improved Gel and AP	Stage I and II only
Warner, 1992[26] US Poor	21 years or older Presence of a PU less than 12 cm in diameter Use of LAL or Foam mattress	Lesions due to peripheral vascular disease Multiple system failure Septicemia Planned graft or flap surgery of PU Restrictive immobility	NR/NR/20/20	Age (Mean): 64 years Female: 45% Race: White 80% Black: 10% Hispanic 10%	Support: LAL beds	Treatment A: Stage 1: 6% (1) Stage II: 29% (5) Stage III: 41% (7) Stage IV: 0 Eschar/Slough: 24% (4) Treatment B: Stage 1: 7% (1) Stage II: 29% (4) Stage III: 19% (4) Stage IV: 0 Eschar/Slough: 35% (5)

Evidence Table H-1b: Support Observational Studies, continued									
Author, year Country Overall Quality Rating	**Treatment A**	**Treatment B**	**Treatment C**	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Pain**	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis**
Ochs, 2005[24] US Fair	Static overlays and replacement mattresses Air fluidized beds	Static overlays and replacement mattresses	LAL beds, powered, and non-powered overlays and mattresses.	NR	Mean change in cm^2/per week All ulcers Treatment A: 5.2 Treatment B: 1.5 Treatment C: 1.8 p=0.0071 Stage I/II: Treatment A: 8.8 Treatment B: 1.6 Treatment C: 2.4 p=0.0229 Stage III/IV/eschar: Treatment A: 4.1 Treatment B: 1.1 Treatment C: 1.4 ANOVA p=0.0259 Group 3 statistically significantly better Subset stage III/IV with baseline size 20-75 cm^2 Group 1: 2.5 Group 2: -2.1 (Group 3: 2.3 Groups 1 and 3 significantly better than 2 (p=0.0399)	NR	NR	NR	NR

Evidence Table H-1b: Support Observational Studies, continued									
Author, year Country Overall Quality Rating	**Treatment A**	**Treatment B**	**Treatment C**	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Pain**	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis**
Valente, 2012[25] US Poor	AP overlay	Gel Overlay	NA	Complete Wound Healing for PUs Present on Admission Treatment A: 27% (13/48) Treatment B: 17% (5/30) Complete Wound Healing PU Developed During Stay Treatment A: 22% (15/67)Treatment B: 11% (6/55) Not significantly different p<0.05	Treatment A: 31.3 cm^2 per week Treatment B: 31.9 cm^2 per week p=NS	NR	NR	NR	NR
Warner, 1992[26] US Poor	LAL Bed	Foam Mattress with loose-fitting cover	NA	NR	Mean Progress Toward Wound Closure: Treatment A: 0.16 cm Treatment B: 0.27 cm p>0.05	NR	NR	NR	NR

Evidence Table H-1b: Support Observational Studies, continued													
Author, year Country Overall Quality Rating	**Outcomes: Recurrence Rate**	**Other Outcomes: Specify**	**Timing: Duration of Followup**	**Setting**	**Setting Comment**	**Harms: Pain**	**Harms: Dermatologic Complication**	**Harms: Bleeding**	**Harms: Infection**	**Severe Adverse Events**	**Withdrawal Due to Adverse Events**	**Overall Adverse Events Rate**	**Funding Source**
Ochs, 2005[24] US Fair	Hospitalizations and ER visits Number (%) of patients with 1 or more Treatment A: 7% (47) Treatment B: 10% (23) Treatment C: 19% (6) Probability of difference B vs. C p=0.0080 A vs. C p=0.0195 A vs. B p=0.4184	NR	3 months	Hospital - Nursing home/Long-term care	NR	NR	NR	NR	NR	NR	NR	Analyses were done on person level and episode level, where episode is each ulcer for a 7-10 day period. As conclusion are the same, person level is included here.	Hill-Rom
Valente, 2012[25] US Poor	NR	NR	Mean Length of Stay Treatment A: 133 days Treatment B: 83 days	Chronic Care Beds/Long-term care	NR	NR	NR	NR	NR	NR	NR	NR	John A. Hartford Foundation/ American Federation for Aging and Research
Warner, 1992[26] US Poor	NR	NR	4 weeks	Hospital	NR	NR	NR	NR	NR	NR	NR	NR	Sigma Theta Tau International

Evidence Table H-2: Support Quality Rating

Evidence Table H-2a. Support trials quality rating

Author, Year Country	(1) Appropriate Randomization Technique	(2) Allocation concealment adequate?	(3) Groups (intervention and comparator) similar at baseline?	(4) Eligibility criteria specified?	(5) Outcome assessors masked?	Reporting of: a) Attrition b) Crossovers, c) Adherence d) Contamination	(7) Dropout rate percent	(8) Intention-to-treat analysis	(9) Appropriate statistical analyses	Overall Quality Rating	Funding Source
Allman,1987[1] US	Yes	Yes	Yes	Yes	Yes	a) Yes b) No c) Yes d) Yes	Yes	Yes	Yes	Good	Support Systems International, Inc. American Pharmaceutical Company (provided supplies), Henry J. Kaiser Family Foundation, Burroughs-Wellcome Scholar in Pharmacoepidemiology.
Branom, 2001[2] US	No	No	Yes	Yes	No	a) NA b) No c) No d) Yes	Yes	No	No	Poor	Mattress supplied by Span-America Medical System
Caley, 1994[3] US	Unclear	No	Yes	Yes	No	a) Yes b) No c) No d) No	No	Unclear	Yes	Poor	NR
Clark, 1997[4] UK	Yes	Yes	Yes	Yes	No	a) Yes b) No c) No d) No	Yes	No	Unclear	Fair	Raymor Ltd. supplied Quadtro cushions. Funding by Pegasus Airwave Ltd.
Day, 1993[5] US	Yes	Yes	No	Yes	No	a) No b) No c) No d) No	Unclear	Unclear	Yes	Poor	Kinetic Concepts, Inc.
Devine, 1995[6] Scotland	Yes	Yes	Yes	Yes	No	a) Yes b) No c) Yes d) No	Yes	Yes	Yes	Fair	HNE Healthcare
Evans, 2000[7] Land, 2000[8] UK	Yes	Yes	Yes	Yes	Yes	a) Yes b) No c) No d) No	Yes	Yes	Yes	Good	Huntleigh Healthcare

Evidence Table H-2a: Support Trial Studies Quality Rating, continued											
Author, Year Country	**(1) Appropriate Randomization Technique**	**(2) Allocation concealment adequate?**	**(3) Groups (intervention and comparator) similar at baseline?**	**(4) Eligibility criteria specified?**	**(5) Outcome assessors masked?**	**Reporting of: a) Attrition b) Crossovers, c) Adherence d) Contamination**	**(7) Dropout rate percent**	**(8) Intention-to-treat analysis**	**(9) Appropriate Statistical Analyses**	**Overall Quality Rating**	**Funding Source**
Ferrell, 1993[9] US	Unclear	Yes	Yes	Yes	No	a) Yes b) Yes c) Yes d) Yes	No	Yes	Yes	Good	Jewish Home for the Aged of Greater Los Angeles Sepulveda VA Geriatric Research and Education Clinical Center West Los Angeles VA Geriatric Research and Education Clinical Center; Kinetic Concepts International
Groen, 1999[10] Holland	Yes	Yes	Yes	Yes	No	a) Yes b) No c) Yes d) No	Yes	Unclear	Unclear	Fair	NR
Izutsu, 1998[11] Japan	No	No	Yes	Yes	No	a) Yes b) No c) No d) No	Yes	Unclear	Yes	Poor	NR
Jackson, 1988[12] US	Unclear	No	Yes	Yes	No	a) No b) No c) No d) No	Yes	No	Yes	Poor	Support Systems International
Keogh, 2001[13] UK	Yes	Yes	Yes	Yes	Unclear	a) Yes b) No c) No d) No	No	No	Unclear	Poor	Huntleigh Healthcare Ltd
Makhsous, 2009[14] US	Unclear	Unclear	Yes	Yes	No	a) Yes b) No c) Yes d) No	Yes	Yes	Yes	Fair	National Institutes of Health and Falk Medical Research Trust

Evidence Table H-2a: Support Trial Studies Quality Rating, continued

Author, Year Country	(1) Appropriate Randomization Technique	(2) Allocation concealment adequate?	(3) Groups (intervention and comparator) similar at baseline?	(4) Eligibility criteria specified?	(5) Outcome assessors masked?	Reporting of: a) Attrition b) Crossovers, c) Adherence d) Contamination	(7) Dropout rate percent	(8) Intention-to-treat analysis	(9) Appropriate Statistical Analyses	Overall Quality Rating	Funding Source
Malbrain, 2010[15] Belgium	Yes	Yes	Yes	Yes	No	a) No b) No c) No d) No	Yes	Unclear	Yes	Fair	Beds, but No other support provided by manufacturers. No other funding source reported.
Mulder, 1994[16] US	No	No	Yes	Yes	No	a) Yes b) No c) No d) No	No	Yes	Yes	Poor	Kinetic Concepts, Inc.
Munro, 1989[17] US	Unclear	Unclear	Yes	Yes	Unclear	a) Yes b) No c) No d) No	No	No	Yes	Fair	Support Systems International
Nixon, 2006[18] UK	Yes	Yes	Yes	Yes	No	a) Yes b) No c) Yes d) Yes	No	Yes	Yes	Good	National Health Service, Health Technology Assessment
Rosenthal, 2003[19] US	No	Yes	Yes	Yes	No	a) Yes b) No c) Yes d) No	Yes	No	Yes	Poor	General statement that author has No financial interest in the results
Russell, 2000(a0[20] Russell, 2000(b)[21] UK	No	No	Yes	Yes	Yes	a) Yes b) No c) No d) No	No	No	Yes	Fair	Equipment loaned to hospital by manufacturers.
Russell, 2003[22] UK	Yes	Yes	Yes	Yes	No	a) Yes b) No c) No d) Yes	Yes	No	Yes	Fair	NR
Strauss, 1991[23] US	Yes	Unclear	Yes	Yes	Yes	a) Yes b) No c) No d) No	No	Yes	Unclear	Fair	Support Systems International

Evidence Table H-2b. Support observational studies quality rating

Author, year Country	Study Type	(1) Did the study attempt to enroll all (or a random sample of) patients meeting inclusion criteria, or a random sample (inception cohort)?	(2) Were the groups comparable at baseline on key prognostic factors (e.g., by restriction or matching)?	(3) Did the study maintain comparable groups through the study period?	(4)Did the study use accurate methods for ascertaining exposures and potential confounders?	(5) Were outcome assessors and/or data analysts blinded to the exposure being studied?	(6) Did the article report attrition?	(7) Did the study perform appropriate statistical analyses on potential confounders?	(8) Is there important differential loss to followup or overall high loss to followup?	Overall Quality Rating	Funding Source
Ochs, 2005[24] US	Cohort	Yes	No	No	Yes	No	Yes	Yes	No	Fair	Hill-Rom
Valente, 2012[25] US	Cohort	Unclear	Yes	Yes	Yes	No	No	Unclear	No	Poor	Sigma Theta Tau International
Warner, 1992[26] US	Retrospective Cohort	Yes	No	No	Yes	No	No	No	No	Poor	John A. Hartford Foundation/ American Federation for Aging and Research

Evidence Table H-3: Nutrition

Evidence Table H-3a. Nutrition trials

Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type: Specify	Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Duration of Followup	Study Setting
Benati, 2001[27] Italy Poor	Patients with severe cognitive impairment and pressure ulcers	Unlikely to benefit from nutritional supplement-ation	NR/NR/36/16	Age range: 72-91 44% female Race NR	Nutrition: protein and arginine enriched supplements	NR	n=5 standard hospital diet	n=5 standard diet plus 2 x 200 ml aliquots/day of a high protein calorie supplementary feeding, providing an extra 500 kcal and approximately 37 g of proteins	n=6 standard diet and treatment B enriched with arginine (7.5g/day), zinc (25 mg) and antioxidants	2 weeks	Health institution
Cereda, 2009[28] Italy Good	Residents of long-term care, age 65+; recent stage II, III and IV PU (NPUAP)	Presence of acute illness or chronic disease possibly affecting the nutritional intervention and healing process	371/39/30/28	Treatment A: mean age 82 69% female p=0.71 race NR Treatment B: mean age 81 60% female race NR	Nutrition: 30 kcal/kg per day plus 400 mL oral supplement vs. 30 kcal/kg per day plus standard nutrition	Treatment A: PU n=13 15% stage II 31% stage III 54% stage IV Treatment B: PU n=15 20% stage II 27% stage III 53% stage IV	30 kcal/kg per day plus 400 mL oral supplement with 20% of calories from protein	30 kcal/kg per day plus standard nutrition with 16% of calories from protein	NA	12 weeks	4 long-term care facilities
Chernoff, 1990[29] USA Poor	Institutionalized tube feeding dependent with decubitus ulcer	NR	NR/NR/NR/12	Mean age: 72 58% female Race NR	Nutrition: high protein formula	NR	n=6 High protein (16% of calories) HP	n=6 Very high protein (25% of calories) VHP	NA	8 weeks	Health institution

Evidence Table H-3a: Nutrition Trials, continued											
Author, year Country Overall Quality Rating	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type: Specify**	**Ulcer Type/Severity at Baseline (Intervention Onset)**	**Treatment A**	**Treatment B**	**Treatment C**	**Duration of Followup**	**Study Setting**
Desneves, 2005[30] Australia Poor	Bedridden elderly patients with stage II, III and IV PU. Comparator groups did not have PU, half were at high risk for developing PU and the other half were not bedridden nor were they at high risk for developing PU	Clinical suspicion or diagnosis of osteomyelitis; diabetes mellitus; receiving enteral or parenteral nutrition support; prescribed hydroxyurea or greater than 10 mg of steroids/day	NR/NR/16/16	Treatment A: mean age 63 33% female race NR Treatment B: mean age 76 40% female race NR Treatment C: mean age 83 40% female race NR	Nutrition; protein, arginine, vitamin C, zinc.	75% with stage II PU 19% with stage III PU 6% with stage IV PU (Stages according to Australian Wound Management Association Clinical Practice Guidelines which are compatible with NPUAP)	Standard hospital diet	Standard hospital diet plus two TetraPaks of a high-protein, high-energy supplement providing an additional 500 kcal: 18g protein, 0g fat, 72mg vitamin C and 7.5mg zinc (brand name Resource Fruit Beverage)	Standard hospital diet plus two TetraPaks of a defined arginine-containing supplement supplying an additional 500 kcal: 21 g protein, 0g fat, 500mg vitamin C, 30 mg zinc and 9g arginine (brand name Resource Arginaid Extra)	3 weeks	Hospital
Lee, 2006[31] US Poor	Residents of long-term care facilities with stage II, III or IV PU	Terminal diagnosis; hospice care; protein-restricted diet due to renal insufficiency; active metabolic or gastrointestinal diseases; food allergies; use of corticosteroids or antibiotics for wound infection; failure to provide informed consent	295/89/89/71	NR	Nutrition: collagen protein hydrolysate supplement vs. placebo	Treatment A: n=44 PU n=75 65% stage II 17.8% stage III 17.2% stage IV (NPUAP) Treatment B: n=27 PU n= 33 51% stage II 26.2% stage III 22.8% stage IV	Standard care plus concentrated, fortified, collagen protein hydrolysate supplement (Pro-Stat) 15g in a 45mL dose	Standard care plus placebo: noncaloric liquid indistinguishable from study product	NA	8 weeks	Long-term care facilities

Evidence Table H-3a: Nutrition Trials, continued											
Author, year Country Overall Quality Rating	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type: Specify**	**Ulcer Type/Severity at Baseline (Intervention Onset)**	**Treatment A**	**Treatment B**	**Treatment C**	**Duration of Followup**	**Study Setting**
Leigh, 2012[32] Australia Good	Stage II, III or IV PU not showing healing signs; oral diet without arginine-containing supplement	Evidence of sepsis; acute gastrointestinal surgery; receiving dialysis; receiving hydroxyurea or >10mg of prednisolone or 1.5mg dexamethasone/day	29/29/29/23	Treatment A: n=12 mean age 70 33% female race NR Treatment B: n=11 mean age 68 45% female race NR	Nutrition: arginine supplement	Treatment A: PU n=17 76% stage II 18% stage III 6% stage IV Location: sacrum 24% heel 35% ischium 29% knee 12% Treatment B: PU n=14 71% stage II 21% stage III 7% stage IV Location: sacrum 43% heel 21% ischium 14% ankle/elbow 14% trochanter 7%	Standard hospital diet plus 4.5 g arginine (one sachet of Arginaid, Nestle Medical Nutrition)	Standard hospital diet plus 9g arginine (two sachets of Arginaid)	NA	3 weeks	Tertiary care facilities
Meaume, 2009[33] Bulgaria France Germany Italy Romania Spain Fair	Over 60 years; written informed consent; heel PU stage II or III in process of recovery with early signs of granulation tissue, after accidental immobilization (NPUAP)	Confined to bed 24 hours/day before development of PU; PU entirely covered by necrosis or fibrin, infected ulcer; poorly controlled type I or II diabetes; dialyses patient; active neoplastic disease; parenteral nutrition serum albumin <22g/I advanced peripheral arterial occlusive disease	194/165/165/ 160	Treatment A: n=85 mean age 81 p=0.760 66% female p=0.017 race NR Treatment B: n=75 mean age 81 47% female race NR	Nutrition: ornithine alpha-ketoglutarate vs. placebo	Treatment A: 38.8% stage II 47.1% stage II or III p=0.656 14.1% stage III Treatment B: 32.0% stage II 53.3% stage II or III 14.7% stage III	10g of ornithine alpha-ketoglutarate per day with 200ml of water or with food at lunch	Placebo of similar aspect and taste administered in the same way	NA	6 weeks	Hospital

Evidence Table H-3a: Nutrition Trials, continued											
Author, year Country Overall Quality Rating	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type: Specify**	**Ulcer Type/Severity at Baseline (Intervention Onset)**	**Treatment A**	**Treatment B**	**Treatment C**	**Duration of Followup**	**Study Setting**
Myers, 1990[34] US Poor	Patients with non-surgically debrided PU, admitted to medical center over 2 year period	NR	80/80/80/80	Mean age 70 43% female Race NR	Nutrition: oral supplements vs. wound care	7.5% stage I 41.2% stage II 20% stage III 31.2% stage IV (stage criteria not specified whether it is NPUAP or otherwise; criteria is compatible with NPUAP)	Treatment A: wound care	Treatment B: Prescribed nutritional support including oral supplements, tube feedings, parenteral nutrition, vitamins and trace elements	Treatment C: wound care and nutritional support Treatment D: Standard hospital care	7 days	Hospital
Ohura, 2011[35] Japan Poor	Tube-fed patients; NPUAP stage III-IV PU in the sacral, coccygeal, trochanteric, or calcaneal region; Albumin (Alb) 2.5-3.5 g/dL, Braden scale 9-17	Current condition or history of serious liver or renal disorder; severe diabetes mellitus; arteriosclerosis obliterans; or a malignant tumor (within the past 5 years); unmanageable severe general condition; unevaluable pressure ulcer wounds	NR/NR/60/50	Treatment A: n=21 age: 81 p=0.738 sex: 71% female p=0.658 race: NR Treatment B: n=29 age: 81 sex: 66% female race: NR	Nutrition: calorie supplementation	Stage III and IV PU (NPUAP)	Administered calories accordingly. Standard tube-feeding formula (Brand name Racol) at mean of 1384kcal/day	Standard tube-feeding formula (Brand name Racol) at mean of 1092kcal/day	NA	12 weeks	Hospital

Evidence Table H-3a: Nutrition Trials, continued											
Author, year Country Overall Quality Rating	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type: Specify**	**Ulcer Type/Severity at Baseline (Intervention Onset)**	**Treatment A**	**Treatment B**	**Treatment C**	**Duration of Followup**	**Study Setting**
ter Riet, 1995[36] The Netherlands Good	Residence in a nursing home or hospital; at least 1 existing pressure ulcer. Patients with stage II ulcers could only participate if de-epithelization had persisted for at least 7 days without interruption	Difficulties swallowing; frequent vomiting; osteomyelitis in the ulcer area; idiopathic hemochromatosis; thalassemia major; sideroblastic anemia; Cushing's syndrome or disease; pregnancy; radiotherapy in the ulcer area; use of antineoplastic agents or systemic glucocorticosteroids and a high probability to drop out and already taking vitamin C supplements in excess of 50mg/day	NR/NR/88/79	NR	Nutrition: vitamin C supplementation	Treatment A: n=43 stages II and III: 86% Treatment B: n=45 stages II and III: 78 % (Study uses grade criteria to categorize PU)	Ascorbic acid, 500 mg twice daily	Ascorbic acid, 10 mg twice daily	NA	12 weeks	Nursing home and Hospital
van Anholt, 2010[37] Czech Republic, Belgium, The Netherlands, Curacao Fair	18 to 90 years; one or more stage III to IV PU; receiving standard care and standard diet without nutritional supplements for at least 2 weeks before the study	Malnourished; severe medical conditions; non-pressure-related ulcers; life expectancy less than 6 months; receiving palliative care; use of corticosteroids; dietary restrictions	NR/NR/47/43	Treatment A: n=22 mean age 76 64% female race: NR Treatment B: n=21 mean age 73 48% female race: NR	Nutrition: calorie and vitamin/mineral supplementation	Treatment A: stage III: 77% stage IV: 23% Treatment B: stage III: 67% stage IV: 33% (PU stages are in accordance with EPUAP, which are compatible with NPUAP)	Nutritional Supplement 750 kcal/day 85.2g carbohydrate 60g protein (includes 9g arginine) 21g fat, several vitamins and minerals	Non-caloric flavored placebo	NA	8 weeks	Health care centers Hospitals Long-term care facilities

Evidence Table
H-3a: Nutrition
Trials, continued

Author, year Country Overall Quality Rating	Outcomes: Complete Wound Healing	Outcomes: Wound Surface Area	Outcomes: Healing Time	Outcomes: Infection Rate	Outcomes: Osteomyelitis Rate	Outcomes: Recurrence Rate	Outcomes: Pain	Other Outcomes: Specify
Benati, 2001[27] Italy Poor	NR	Treatment A did not seem to have any considerable improving effect Treatment B and C had a more rapid improvement	NR	NR	NR	NR	NR	NR
Cereda, 2009[28] Italy Good	Treatment A: 8% (n=1) Treatment B: NR	Treatment A: Pressure Ulcers decreased from 2,151mm^2 to 701mm^2 at 12 weeks. 68% improvement in wound surface area Treatment B: Pressure Ulcers decreased from 2,069mm^2 to 1228mm^2 at 12 weeks 41% improvement in wound surface area	Treatment A: Area was reduced 40% at 6 weeks and 70% at 12 weeks Treatment B Area was reduced 30% at 6 weeks and 40% at 12 weeks	Treatment A: 23% (n=3) Treatment B: 60% (n=9) p=0.07, Fisher exact test	NR	NR	NR	NR
Chernoff, 1990[29] USA Poor	Treatment A: 0% Treatment B: 67% (n=4)	Treatment A: 42% average decrease Treatment B: 73% average decrease	NR	NR	NR	NR	NR	NR
Desneves, 2005[30] Australia Poor	NR	PUSH score at 3 weeks (lower is better) A; 7 B: 6 C: 2.6 P<0.05	Estimate Treatment A: 16 weeks to completely heal Treatment B: 15 weeks to completely heal Treatment C: 5 weeks to completely heal	NR	NR	NR	NR	NR
Lee, 2006[31] US Poor	NR	Treatment A: 60% decrease in PUSH score Treatment B: 48% decrease in PUSH score p<0.05	Treatment A showed approximately twice the rate of healing compared with Treatment B	NR	NR	NR	NR	NR
Leigh, 2012[32] Australia Good	Treatment A: 0% Treatment B: 0%	Treatment A: PUSH score decreased from 8.9 to 5.0 Treatment B: PUSH score decreased from 9.0 to 5.9	Treatment A: Estimated time to complete wound healing 9 weeks Treatment B: Estimated time to complete wound healing 8 weeks	NR	NR	NR	NR	NR

Evidence Table H-3a: Nutrition Trials, continued								
Author, year Country Overall Quality Rating	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis Rate**	**Outcomes: Recurrence Rate**	**Outcomes: Pain**	**Other Outcomes: Specify**
Meaume, 2009[33] Bulgaria France Germany Italy Romania Spain Fair	Treatment A: 2% (n=2) Treatment B: 4% (n=3)	Treatment A: Mean decrease in area for PU (equal or less than 8cm^2) was 2.3cm^2 Treatment B: Mean decrease in area for PU (equal or less than 8cm^2) was 1.7cm^2 p=0.006	Treatment A: Mean closure rate for PU (equal or less than 8cm^2) was 0.07 cm^2/day Treatment B: Mean closure rate for PU (equal or less than 8cm^2) was 0.04cm^2/day p=0.007	NR	NR	NR	NR	NR
Myers, 1990[34] US Poor	NR	Treatment A: ulcer size mean change 2.76mm 70% improvement Treatment B: ulcer size mean change 2.60mm 70% improvement Treatment C: ulcer size mean change 2.34 mm 65% improvement Treatment D: ulcer size mean change 2.70 mm 50% improvement	NR	NR	NR	NR	NR	NR
Ohura, 2011[35] Japan Poor	Treatment A: 24% (n=7) Treatment B: 19% (n=4)	Treatment A: Mean wound size decreased from 30 cm² to 0.5 cm² Wound surface improved 83% Treatment B: Mean wound size decreased from 40 cm² to 7 cm² Wound surface improved 82%	Treatment A: Mean wound size decreased to 2cm² at 6 weeks and 0.5cm² at 12 weeks Treatment B: Mean wound size decreased to 9cm² at 6 weeks and 7cm² at 12 weeks	NR	NR	NR	NR	NR
ter Riet, 1995[36] The Netherlands Good	Treatment A: 40% (n=17) healed at 11 weeks Treatment B: 55% (n=25) healed at 12 weeks	Treatment A: Mean surface reduction: 0.21cm²/week 13.88%/week Treatment B: Mean surface reduction: 0.27cm²/week 22.85%/week	Treatment A: 30% (n=13) of ulcers healed at 6 weeks and 40% (n=17) at 11 weeks Treatment B: 30% (n=14) of ulcers healed at 6 weeks and 55% (n=25) at 12 weeks	NR	NR	NR	NR	NR

Evidence Table H-3a: Nutrition Trials, continued								
Author, year Country Overall Quality Rating	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis Rate**	**Outcomes: Recurrence Rate**	**Outcomes: Pain**	**Other Outcomes: Specify**
van Anholt, 2010[37] Czech Republic, Belgium, The Netherlands, Curacao. Fair	Treatment A: 27% (n=6) Treatment B: 24% (n=5)	Treatment A: Mean ulcer size decreased from 10.5 to 2cm² Wound area improved 81% Treatment B: Mean ulcer size decreased from 11.5 to 3cm² Wound area improved 74%	Treatment A: 9% (n=2) healed at 4 weeks and 27% (n=6) at 8 weeks Treatment B: 0% healed at 4 weeks, and 24% (n=5) at 8 weeks	NR	NR	NR	NR	NR

Evidence Table H-3a: Nutrition Trials, continued								
Author, Year Country Overall Quality Rating	**Harms: Dermatologic Complications**	**Harms: Bleeding**	**Harms: Infection**	**Other Harms: Specify**	**Severe Adverse Events**	**Withdrawal due to Adverse Events**	**Overall Adverse Events Rate**	**Funding Source**
Benati, 2001[27] Italy Poor	NR	NR	NR	NR	NR	NR	NR	NR
Cereda, 2009[28] Italy Good	NR	NR	NR	NR	NR	NR	NR	Nutricia
Chernoff, 1990[29] USA Poor	NR	NR	NR	NR	No adverse effects	NR	NR	NR
Desneves, 2005[30] Australia Poor	NR	NR	NR	NR	NR	NR	NR	Windermere Foundation Ltd.
Lee, 2006[31] US Poor	NR	NR	NR	Discontinuations: hip fracture due to fall (2); changes in renal lab values (3); nausea or distention (4); death (2). No difference between groups in rate of events. p>0.05	NR	NR	NR	Medical Nutrition, US, Inc
Leigh, 2012[32] Australia Good	NR	NR	NR	NR	Side effects	4% (n=1)	NR	NR
Meaume, 2009[33] Bulgaria France Germany Italy Romania Spain Fair	NR	NR	NR	No serious adverse events related to treatment	Diarrhea, vomiting and nausea	NR	2% of AE related to treatment	CHIESI France and Italy
Myers, 1990[34] US Poor	NR	NR	NR	NR	NR	NR	NR	Ross Laboratories
Ohura, 2011[35] Japan Poor	NR	NR	NR	NR	Treatment A: 38% (n=8) Treatment B: 17% (n=5)	Treatment A: 5% (n=1) Treatment B: NR	Treatment A: 38% (n=8) Treatment B: 17% (n=5)	Health and Labor Sciences Research Grants (Comprehensive Research on Aging and Health)
ter Riet, 1995[36] The Netherlands Good	NR	NR	NR	NR	NR	Unclear if AE related to treatment	Unclear	The Netherlands Organization for Scientific Research

Evidence Table H-3a: Nutrition Trials, continued								
Author, Year Country Overall Quality Rating	**Harms: Dermatologic Complications**	**Harms: Bleeding**	**Harms: Infection**	**Other Harms: Specify**	**Severe Adverse Events**	**Withdrawal due to Adverse Events**	**Overall Adverse Events Rate**	**Funding Source**
van Anholt, 2010[37] Czech Republic, Belgium, The Netherlands, Curacao. Fair	NR	NR	NR	Higher rate of gastrointestinal symptoms in nutritional support group	Diarrhea, nausea, vomiting, constipation and dyspepsia	Treatment A: 9% (n=2) Treatment B: 0	5% (n=2)	Nutricia

Evidence Table H-3b. Nutrition observational studies

Author year Country Overall Quality Rating	Study Type	Confounders assessed in analysis	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Ulcer Type/ Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Duration of Followup	Study Setting
Barnes, 2007[38] US Poor	Observational	Hypertension Cardiovascular disease Paraplegia/ quadriplegia organic brain syndrome	Stage III-IV PU; chronically malnourished patients	Extremity decubital	NR/28/28/28	Age (Mean): NR Female: NR Race: NR	Stages III and IV	Prealbumin levels of 18.0 to 45.0 mg/dL	NA	NA	≥30 days	Hospital
Breslow, 1993[39] US Fair	Observational: non-randomized trial	Malnourished; dementia; cerebrovascular accident; anozic encephalopathy; spinal cord injury; Parkinson's disease	NPUAP Stage III-IV PU; malnourished; nutritional risk (Article reports Shea stage II-IV PU criteria)	Insulin dependent diabetes, renal failure, liver dysfunction, hematocrit <25%, chronic use of steroids; cancer; significant gastrointestinal dysfunction	NR/48/48/28	Age (Mean): 72 years Female: 58% Race: NR	Total PU n=33 Treatment A n=13 38% stage III 62% stage IV Treatment B n=15 47% stage III 53% stage IV	14% of total calories as protein (brand name Ensure, 1000 calories and 37 g protein/L) tube fed or as meal supplements	24% of total calories as protein (brand name Sustacal, 1060 calories and 61g protein/L) tube fed or as meal supplements	NA	8 weeks	Nursing home/long-term care facility
Brewer, 2010[40] Australia Fair	Observational: prospective	Spinal cord injury Paraplegic Quadriplegic	Spinal cord injury, 18+ years of age, residing in Melbourne metropolitan area and category II, III or IV PU	Phenylketonuria, Sepsis, Chronic renal failure, metabolic disease, diabetic foot ulcers and clinical suspicion of osteomyelitis, receiving hydroxyurea or greater than 10 mg prednisolone or 1.5 mg dexamethasone/ day	68/35/35/35	Age (Mean): 51 years, Female: 3% Race: NR	Treatment A PU n=30 Treatment B PU n=26	Two sachets of commercially available argine-containing powder per day until full wound healing had been confirmed	Participants were compared to a historical comparator group.	NA	10 months	Community

Evidence Table H-3b: Nutrition Observational Studies, continued												
Author year Country Overall Quality Rating	**Study Type**	**Confounders assessed in analysis**	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Ulcer Type/ Severity at Baseline (Intervention Onset)**	**Treatment A**	**Treatment B**	**Treatment C**	**Duration of Followup**	**Study Setting**
Houston, 2001[41] US Fair	Observational	Older population	Older; institutionalized; under current PU treatment	NR	NR/NR/70/68	Age (Mean): NR Female: NR Race: NR	Treatment A 84% stage II 16% stage III-IV Treatment B 91% stage II 9% stage III-IV	Zinc sulfate (440mg/d, similar to 100mg elemental zinc/day)	Similar care, no oral supplements	NA	30 days	Nursing home/long-term-care facility
Yamamoto, 2009[42] Japan Fair	Observational: retrospective	Malignant neoplasm Cerebral disease Orthopedic disease Cardiovascular disease Gastrointestinal disease Renal disease Respiratory disease	Medical Center patients with either improved or worsened PU wounds	Discharged prior to PU healing or died within 1 month	NR/40/40/40	Age (Mean): 69 years Female: NR Race: NR	Treatment A: 38% stage I 62% stage II Treatment B: 26% stage I 74% stage II	More than 30k cal/kg per day	Less than 20 kcal/kg per day	NA	6 weeks	Hospital

Evidence Table H-3b: Nutrition Observational Studies, continued								
Author, year Country Overall Quality Rating	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis Rate**	**Outcomes: Recurrence Rate**	**Outcomes: Pain**	**Other Outcomes: Specify**
Barnes, 2007[38] US Poor	NR	Mean improvement of 0.82 cc reduction of wound volume per day	NR	NR	NR	NR	NR	NR
Breslow, 1993[39] US Fair	NR	Treatment A -2.1 cm^2change from baseline to final 15% improvement Treatment B- 4.2cm^2 change from baseline to final (p<0.02) 15% improvement	Treatment A PU decreased by 2.1cm^2 in 8 weeks Treatment B PU decreased by 4.2 cm^2 in 8 weeks	NR	NR	NR	NR	NR
Brewer, 2010[40] Australia Fair	Treatment A: 100% (n=30) Treatment B: 100% (n=26)	NR	Treatment A: 11 weeks, mean healing time Treatment B: 21 weeks mean healing time p=0.006	NR	NR	NR	NR	NR
Houston, 2001[41] US Fair	NR	Improvement in volume of PU stages III or IV of intervention patients but not in stage II PU	NR	NR	NR	NR	NR	NR
Yamamoto, 2009[42] Japan Fair	53% (n=21) of patients healed or improved	NR	52% (n=21) of patients healed or improved in 6 weeks	NR	NR	NR	NR	NR

Evidence Table H-3b: Nutrition Observational Studies, continued									
Author, year Country Overall Quality Rating	**Harms: Pain**	**Harms: Dermatologic Complications**	**Harms: Bleeding**	**Harms: Infection**	**Other Harms: Specify**	**Serve Adverse Events**	**Withdrawal due to Adverse Events**	**Overall Adverse Events Rate**	**Funding Source**
Barnes, 2007[38] US Poor	NR	NR	NR	NR	NR	NR	NR	NR	NR
Breslow, 1993[39] US Fair	NR	NR	NR	NR	NR	NR	NR	NR	Mean Johnson Nutritional Group, Francis Scott Key Medical Center General Clinical Research Center, Johns Hopkins Academic Teaching Nursing Home Award
Brewer, 2010[40] Australia Fair	NR	NR	NR	NR	NR	NR	NR	NR	The Eirene Lucas Foundation
Houston, 2001[41] US Fair	NR	NR	NR	Infection requiring antibiotics: Treatment A 28% (n=7) Treatment B 5% (n=2)	NR	Nausea/vomiting Treatment A: 20% (n=5) Treatment B: 2% (n=1)	NR	22% (n=15)	NR
Yamamoto, 2009[42] Japan Fair	NR	NR	NR	NR	NR	NR	NR	NR	NR

Evidence Table H-4: Nutrition Quality Rating

Evidence Table H-4a. Nutrition trial quality rating

Author Year Country	Appropriate randomization technique?	Allocation concealment adequate?	Groups (intervention and comparator) similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Reporting of: a) Attrition b) Crossovers, c) Adherence d) Contamination	Dropout rate <20 percent?	Intention-to-treat analysis?	Appropriate statistical analyses?	Overall Quality Rating	Funding Source
Benati, 2001[27] Italy	No	No	Unclear	Yes	No	a) No b) No c) No d) No	No	Yes	No	Poor	NR
Cereda, 2009[28] Italy	Yes	No	Yes	Yes	Yes	a) Yes b) No c) Yes d) Yes	Yes	No	Yes	Good	Nutricia
Chernoff, 1990[29] USA	No	No	No	No	No	a) No b) No c) No d) No	Yes	Yes	No	Poor	NR
Desneves, 2005[30] Australia	No	No	No; quite big age differences (20 year difference between A and C)	Yes	Yes	a) No b) No c) Yes d) No	Unclear	Yes	Yes	Poor	Windermere Foundation Ltd.
Lee, 2006[31] US	No	No	Yes	Yes	Yes	a) Yes b) No c) No d) No	Yes	Yes	Yes	Poor	Medical Nutrition, US, Inc
Leigh, 2012[32] Australia	Yes	Yes	Yes	Yes	Yes	a) Yes b) Yes c) No d) No	Yes	Yes	Yes	Good	None
Meaume, 2009[33] Bulgaria France Germany Italy Romania Spain	Yes	No	Yes	Yes	Yes	a) Yes b) No c) No d) No	No	Yes	Yes	Fair	CHIESI France and Italy
Myers, 1990[34] US	No	No	No	Yes	Yes	a) Yes b) No c) No d) No	Yes	Yes	Yes	Poor	Ross Laboratories

Evidence Table
H-4a: Nutrition
Trial Quality Rating, continued

Author Year Country	Appropriate randomization technique?	Allocation concealment adequate?	Groups (intervention and comparator) similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Reporting of: a) Attrition b) Crossovers, c) Adherence d) Contamination	Dropout rate <20 percent?	Intention-to-treat analysis?	Appropriate statistical analyses?	Overall Quality Rating	Funding Source
Ohura, 2011[35] Japan	Yes	Yes	Yes	Yes	No	a) Yes b) No c) Yes d) No	Yes	No	Yes	Poor	Health and Labor Sciences Research Grants (Comprehensive Research on Aging and Health)
ter Riet, 1995[36] The Netherlands	Yes	No	Yes	Yes	Yes	a) Yes b)No c)Yes d)No	Yes	Yes	Yes	Good	The Netherlands Organization for Scientific Research
Van Anholt, 2010[37] Czech Republic Belgium The Netherlands Curacao	No	No	Yes	Yes	Unclear	a)Yes b)No c)Yes d)No	No	Yes	Yes	Fair	Nutricia

Evidence Table H-4b. Nutrition cohort study quality rating

Author, Year Country	(1) Did the study attempt to enroll all (or a random sample of) patients meeting inclusion criteria, or a random sample (inception cohort)?	(2) Were the groups comparable at baseline on key prognostic factors (e.g., by restriction or matching)?	(3) Did the study maintain comparable groups through the study period?	(4) Did the study use accurate methods for ascertaining exposures and potential confounders?	(5) Were outcome assessors and/or data analysts blinded to the exposure being studied?	(6) Did the article report attrition?	(7) Did the study perform appropriate statistical analyses on potential confounders?	(8) Is there important differential loss to followup or overall high loss to followup?	(9) Were outcomes pre specified and defined, and ascertained using accurate methods?	Overall Quality Rating	Funding Source
Barnes, 2007[38] US	Yes	Unclear	Unclear	Yes	No	No	Yes	Unclear	Yes	Poor	NR
Breslow, 1993[39] US	No	Yes	Yes	Yes	No	No	No	Yes	Yes	Fair	Mean Johnson Nutritional Group, Francis Scott Key Medical Center General Clinical Research Center, Johns Hopkins Academic Teaching Nursing Home Award
Brewer, 2010[40] Australia	Yes	Yes	Yes	Yes	No	No	Yes	No	Yes	Fair	The Eirene Lucas Foundation
Houston, 2001[41] US	Yes	Yes	Yes	Yes	No	No	Yes	Unclear	Yes	Fair	NR
Yamamoto, 2009[42] Japan	Unclear	Yes	No	Yes	Unclear	No	No	Unclear	Yes	Fair	NR

Evidence Table H-5: Local Wound Applications (Dressings, Topical Applications, and Biological Therapies)

Evidence Table H-5a. Dressings trials

Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset)
Alm, 1989[43] Sweden Fair	Long-term ward patients with pressure ulcers whose condition was evaluated with the Norton scale less than or equal to 9 and greater than or equal to 7	Pressure ulcers evaluated at less than 7 on the Norton scale at screening	NR/NR/50/50 PU N=56	Age (Mean): 83 years Female: 75% Race: NR	Local Wound Application: Dressing	Mean Norton Score: 12 vs. 13 Location: Heel: 33.9% vs. 33.3% Sacrum: 27.4% vs. 37.5% Malleolus: 11.3% vs. 12.5% Gluteal region: 8.1%^ vs. 12.5% Hip: 12.9% vs. 4.2% Other: 6.4% vs. 4.2%
Bale, 1997[44] UK Fair	Patients 18 and older who were able to give consent. Stage II or III PU	Those with no history of poor compliance or previous involvement in the study.	NR/NR/51/50	Age (Mean): 74 years Female: 55% Race: NR	Local Wound Application: Dressing	Stage: II: 79% (N=23) vs. 71% (N=22) III: 21% (N=6) vs. 29% (N=9)
Bale, 1998(b)[45] UK Poor	Leg ulcers except venous leg ulcers that were able to tolerate high compression therapy, and stage II or III PU or other granulating wounds with moderate to high levels of exudates	Pregnant and lactating women, patients with stage I or IV PU, wounds that were too large to be covered by one dressing, Wounds expected to heal within one week, wounds with sloughy or necrotic tissue or grossly infected wounds	NR/100/100/96 PU N=32	Age (Mean): 76 years Female: 77% Race: NR	Local Wound Application: Dressing	Stage II: 65% (N=11) vs. (40%) N=6 Stage III: 35%(N=6) vs. 60%(N=9) Note: Mean area at baseline available for aggregate data only which includes venous leg ulcers and PU
Bale, 1998(a)[46] UK Poor	Patients with necrotic PU who could give written informed consent	Wound greater than 8cm in diameter; immunosuppression related disease; pregnant or nursing; in any other clinical trial less than one month prior; had already participated in this study	NR/53/50/42	Age (Mean): 77 years Female: 61% Race: NR	Local Wound Application: Dressing	Stage II: N=2 vs N=0 Stage III: N=20 vs. N=21 Stage IV: N=2 vs. N=1 Location: Sacrum: N=5 vs. N=4 Ischium: N=2 vs. N=0 Heel: N=14 vs. N=19 Foot: N=2 vs N=0 Gaiter Area: N=1 vs. N=0 Elbow: N=1 vs N=0 Lateral malleolus: N=0 vs. N=1 Buttock: N=1 vs. N=0

Evidence Table H-5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type**	**Ulcer Type/Severity at Baseline (Intervention Onset)**
Banks, 1994(a)[47] UK Poor	Written, informed consent; older than 16 years old, both sexes, with shallow, moist PU, stage II and III; PU that could be covered by a single 10 x 10 cm dressing; subjects who could be managed to prevent further lesions developing	Lesions involving tissues other than skin and subcutaneous fat; stage I, IV and V PU; dry or necrotic lesions; taking systemic corticosteroids; PU that had been dressed with either of the study dressings in the preceding two weeks; sensitivity reaction to either dressing; infected PU; incapable of giving opinion of the dressing; incontinent of urine or feces with PU on the sacrum or a site likely to be soiled repeatedly	NR/NR/40/40	Age (Mean): 72 years Female: 47% Race: NR	Local Wound Application: Dressing	Stages II and III: 100% vs. 100% Location: Buttock 50% vs. 45% Sacrum 20% vs. 5% Other 30% vs. 50%
Banks, 1994(b)[48] UK (Wales) Poor	Written, informed consent; over 16 years old; shallow, moist pressure sores stage II or III; could be managed to prevent further lesions developing	Lesions involving tissues other than skin or subcutaneous fat; stage I, IV or V PU; dry or necrotic lesions (could be included after debriding); taking systemic corticosteroids; PU that had been dressed with either of the study dressings in preceding two weeks; previous sensitivity to either dressing; infected PU; incapable of giving opinion of dressing; incontinent of urine or feces with PU on sacrum or any other site likely to be soiled	NR/NR/29/29	Age (Mean): 75 years Female: 64% Race: NR	Local Wound Application: Dressing	Location: Buttock: 62% vs. 56% Sacrum: 31% vs. 38% Other: 7% vs. 6%
Belmin, 2002[49] France Fair	Patients with ulcers located on the sacrum, elsewhere on the pelvic girdle, or on the heel; surface area of less than 50 cm2, as measured by planimetry; granulation tissue area not covering more than 50% of ulcer surface, as visually estimated by the investigator; and no clinical evidence of active infection	Serum albumin concentration below 25 g/L; being treated with radiotherapy, cytotoxic drugs, or corticosteroids; surgical or palliative care needed	NR/NR/110/ 110	Age (Mean): 83 years Female: 71% Race: NR	Local Wound Application: Dressing	Stage III: 71.4%(N=40) vs. 82.7%(N=43) Stage IV: 28.6%(N=16) vs. 17.3%(N=9)

Evidence Table H-5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type**	**Ulcer Type/Severity at Baseline (Intervention Onset)**
Bito, 2012[50] Japan Good	50 years or older, 1+ NPAUP stage II or III pressure ulcer on torso or trochanter, body temp of 35.5 C-37.5C, 600kcal+ daily intake, no critical nutritional impairment, renal failure, cirrhosis, immunosuppresion, uncontrollable diabetes, or cancer. Written consent from patient or family member	Patients with <3 months life expectancy	67/66/66/64	Age: 81 years Female: 51% Race: NR	Local Wound Application: Dressing	Wrap therapy: Stage II- 11% Stage III- 89% Conventional treatment: Stage II: 28% Stage III: 72% Location: Sacrum, trochanter, gluteus, coccyx
Brod, 1990[51] US Poor	Estimated life expectancy >/= 6 months and normal marrow, hepatic, and renal function; elderly with stage II or III PU	NR	NR/NR/43/43	Age (Mean): 84 years Female: NR Race: NR	Local Wound Application: Dressing	All Stage II or III
Brown-Etris, 2008[52] US Fair	One or more stage II or shallow stage III, minimally to moderately draining PU or any anatomical location that could have been treated with a hydrocolloid dressing	Skin disease or abnormal conditions on or near t application site. Insulin-dependent diabetes that had inadequately controlled blood sugar; Receiving steroid, immunosuppressive therapy, or radiation to the area where the PU was located. Participating in another clinical research study Wounds with more than 50% necrotic tissue should have undergone debridement before application of a dressing. Greater than 1cm undermining or tunneling, required use of a filling or packing material, required the dressing to be cut to a smaller size or to a specialty shape, exhibited clinical infection as, or required treatment with a concomitant medication or product	NR/NR/72/72	Age (Mean): 75 years Female: 56% Race: NR	Local Wound Application: Dressing	Stage II: 65.7% vs. 59.5% Stage III: 34.3% vs. 40.5% Location: sacrum, buttock, ischium, heel, other

Evidence Table H-5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type**	**Ulcer Type/Severity at Baseline (Intervention Onset)**
Chang, 1998[53] Malaysia Poor	Stage II or III PU; at least 18 years old; written informed consent	Immunocompromised; infected PU; known sensitivity to study dressings	NR/NR/34/34	Age (Mean): 58 years Female: NR Race: NR	Local Wound Application: Dressing	Stage II N=11 vs. 7 Stage III N=6 vs. 7 Note: 3 cases are missing from the gauze group, N is reported at 17, however only 14 PU are reported Location (both groups): Sacral: N=30 Iliac: N=3 Greater Trochanter: N=1
Chuangsuwanich, 2011[54] Thailand Fair	Out and in patients with PU	NR	NR/NR/40/40	Age (Mean): 65 years Female: 54% Race: NR	Local Wound Application: Dressing	NUPAP III-IV Localization: Sacrum, greater trochanteric, ischium
Colin, 1996[55] Multinational Poor	NR	NR	NR/NR/135/135	Age (Mean): 79 years Female: 54% Race: NR	Local Wound Application: Dressing	Stage I: 0% vs. 1.4% Stage II: 23.8% vs. 14.7% Stage III: 56.7% vs. 66.1% Stage IV: 19.4% vs. 17.6%
Colwell, 1993[56] US Poor	Non-infected stage II or III PU	Uncontrolled diabetes mellitus or radiation therapy; signs and symptoms of infection; stage I or IV PU; PU unstageable. Did not remain in study for a minimum of 8 days or receiving any other kind of treatment that could confound the results of the treatment.	NR/NR/94/70 PU N=97	Age (Mean): 68 years Female: 47% Race: NR	Local Wound Application: Dressing	Stage II: 69% vs. 44% Stage III: 31% vs. 56% Location: Sacrum/coccyx: 60% vs. 55% Other: 40% vs. 45%
Darkovich, 1990[57] US Poor	Stage I and II PU, 2-30 cm^2 on sacrum, trochanters, lower extremities, buttocks, scapula, and heel; blood sugar levels less than 180mg/dl; improved nutritional status	Known infection, sinus tracts, or fistulae in the wound; radiation therapy	NR/NR/90/90 PU N=129	Age (Mean): 75 years Female: 61% Race: NR	Local Wound Application: Dressing	Stage I: 43.5% vs. 46.2% Stage II: 56.4% vs. 53.7% (Enis and Sarmienti pressure ulcer grades)

Evidence Table H-5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type**	**Ulcer Type/Severity at Baseline (Intervention Onset)**
Day, 1995[58] US, UK, Canada Fair	Legal consenting age; stage II or III PU in the sacral area which required treatment	Infection; treatment with systemic steroid medication; a condition known to impair healing; receiving concomitant topical or local treatment of their PU which could not be interrupted; chronic skin disorders, hypersensitivity to skin adhesives; participation in a similar study within one month of treatment	NR/NR/103/96 PU N=96	Age (Mean): 75 years Female: 49% Race: Caucasian 94%; Black, Hispanic, American Indian, Asian 6%	Local Wound Application: Dressing	Stage II: 81% vs. 84% Stage III: 19% vs. 16% Location: Sacrum
Gorse, 1987[59] US Poor	Stage II and III PU. Stage IV PU that only extended into muscle	Osteomyelitis or extension of PU into fascia, bone, and or joints; Venous stasis and ischemic ulcers of the extremities; Rapidly fatal underlying disease; Planned hospital discharge within 7 days of treatment initiation	NR/NR/52/52 PU N=128	Age (Mean): 70 years Female: 0% Race: NR	Local Wound Application: Dressing	Stage II: 86.8% vs. 78.8% Stage III: NR StageIV:NR Location: Femoral trochanteric: 19.7% vs. 26.9% Sacral/Coccygeal: 47.45% vs. 38.5% Ischiatic: 15.8% vs. 19.2% Other: 17.1% vs. 15.4% Article used Shea scale for stages
Honde, 1994[60] Japan Fair	Hospitalized patients; aged >65 years; stage II to IV pressure (Shea) at any site and <10 cm in diameter	Infection, necrotic PU with black crust; PU on irradiated skin; PU requiring surgery; deep PU in bone with risk of osteitis, patients on air-fluidized beds	NR/NR/168/ 167	Age (Mean): 82 years Female: 72% Race: NR	Local Wound Application: Dressing	Stage II: 63.7% vs. 54.0% Stage III: 30.0% vs. 40.2% Stage IV: 6.2% vs. 5.7%. Location (both): foot 54.1%, sacrum 36.3%, trochanter 29.7%, shoulder 0.59%, elbow 0.59%, knee 2.3% thigh 0.59%, back 1.78%
Kaya, 2005[61] Turkey Poor	Hospitalized patients with spinal cord injury and with PU	NR	NR/NR/27/27	Age (Mean): 19 years Female: 11% Race: NR	Local Wound Application: Dressing	Stage I: 24% vs. 25% Stage II: 68% vs. 70.8% Stage III 8% vs. 4.2%
Kerihuel, 2010[62] France Good	PUs 5 - 100 cm^2 in area. PUs of < 3 month's duration. PUs stage II or IV. PUs with abundant necrotic tissue and slough	Inability to give written consent, severe illness; PUs totally covered with necrotic tissue or requiring surgical debridement; infected ulcers requiring systemic antibiotics; allergy to study dressing; previous use of Actisorb	NR/NR/60/59	Age (Mean): 81 years Female: 76% Race: NR	Local Wound Application: Dressing	Location: Heel 75.9% vs. 66.7% Sacrum 3.8% vs. 20% Other 10.3% vs. 13.3%

Evidence Table H-5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type**	**Ulcer Type/Severity at Baseline (Intervention Onset)**
Kim, 1996[63] Korea Poor	Admitted to the Department of Rehabilitation Medicine presenting stage I or II decubitus ulcers	Stage III or IV PU, systemic infections, endocrinologic disorders, difficulty keeping pressure relieving positions, or with aggravated conditions due to other factors	NR/NR/44/44	Age (Mean): 49 Female: 13% Race: NR	Local Wound Application: Dressing	Stage I: 23% vs. 33.3% Stage II: 76.9% vs. 66.6% Location: Sacral ulcer: 26.9% vs. 22.2% Other pelvic girdle ulcer: 26.9% vs. 38.8% Other regions: 46.1% vs. 38.8
Kloth, 2002[64] US Fair	NR	Poorly controlled diabetes; terminally ill; undermining greater than 1cm; >50% of wound bed covered with necrotic tissue after debridement; allergy to adhesives	NR/53/43/40 PU N=56	Age (Mean): 78 years Female: 39% Race: NR	Local Wound Application: Dressing	NR
Kraft, 1993[65] US Poor	Stage II and III ulcers; Specific eligibility criteria not reported	Stage I and IV PUs. Infected PUs. Patients on special beds. Uncontrolled diabetes. Serum albumin < 2g. Hemoglobin < 12 g. Class IV congestive heart failure. Chronic renal insufficiency. Severe peripheral vascular disease. Severe COPD	NR/NR/38/38	Age (Mean): 56 years Female: NR Race: 37% African-American; 63% Caucasian	Local Wound Application: Dressing	Stage II: 57.8% Stage III: 42.1%
Kurzuk-Howard, 1985[66] US Poor	All patients who were admitted with decubitus ulcers	NR	NR/NR/43/43	Age (Mean): 77 years Female: 70% Race: NR	Local Wound Application: Dressing	Stage I: 16.2% Stage II: 41.8% Stage III: 32.5% Stage IV: 9.3%
Matzen, 1999[67] Denmark Poor	Patients with stage III or IV non-infected PUs located in the sacral or trochanteric areas	Patients with diseases or taking drugs known to impair healing.	NR/NR/32/32	Age (Mean): 83 years Female: 84% Race: NR	Local Wound Application: Dressing	All patients had stage III and IV wounds

Evidence Table H-5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type**	**Ulcer Type/Severity at Baseline (Intervention Onset)**
Meaume, 2005[68] France Fair	Hospitalized adult patients who could be seen for 14 days and who had one of the following: leg ulcer >2cm in one dimension but no larger than 20cm; APBI >0.7 within the previous six months; stage III-IV PU on the ischium, sacrum, trochanter or heel. No signs of infection and at least two of the following criteria: continuous pain; erythema; edema; heat; moderate to high levels of serous exudate;> 50% of the wound has yellow slough, discolored, or friable granulation tissue, pocketing or undermining at the base of the wound, or foul odor	Received systemic antibiotics during the previous five days; a very poor life expectancy or with a clinical condition that might interfere with wound healing within the past 30 days; patients who had received a topical chemical debriding agent within the previous 7 days	NR/NR/101/99	Age (Mean): 77 years Female: 64% Race: NR	Local Wound Application: Dressing	NR
Meaume, 2003[69] France Fair	65 years or older; stage II PU; a Modified Norton scale of 11 or above; a red/yellow wound according to the Red-Yellow Brick System	Underlying disease that might interfere with the treatment of the PU; food and/or intake score of 2 or below on the Modified Norton Scale; allergic/hypersensitivity problem with any material in the two dressings; wound larger than 11 cm x 11 cm; or a wound with black necrotic tissue or clinical signs of local infection at baseline	NR/NR/38/38	Age NR Female: NR Race: 100% Caucasian	Local Wound Application: Dressing	Stage II ulcer Mostly located on heels and the sacral area
Motta, 1999[70] US Poor	Stage II or III PU; No underlying medical condition such as long term steroid use or uncontrolled diabetes Understood and executed informed consent agreement	NR	NR/NR/10/10	Age (Mean):60 years Female: 50% Race: NR	Local Wound Application: Dressing	Stage II: 30% Stage III: 70% Location: Foot/Ankle: 20%; coccyx: 40%; buttock: 10%; sacrum: 10%; elbow: 20%
Mulder, 1993[71] US Poor	Stage II or III PU no smaller than 10 cm x 10 cm. At least 18 years of age, signed an informed consent, and a life expectancy of at least 2 months	Stage IV wounds or those with tendon, bone capsule, of fascia exposure; pregnant women, receiving chemotherapy, documented wound infection extensive undermining (>1.0 cm)of the ulcer, testing positive for HIV, or receiving more than 10 mg of corticosteroids per day	NR/NR/67/53	Age (Mean):59 years Female: 15% Race: Caucasian - 52.4% Black - 21% Hispanic - 3%	Local Wound Application: Dressing	Stage II: 8 vs. 9 vs. 5 Stage III: 14 vs. 13 vs. 18

Evidence Table H-5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type**	**Ulcer Type/Severity at Baseline (Intervention Onset)**
Neill, 1989[72] US Poor	18 years or older, written consent obtained, stage II or III PU	Patient: Inability to give written consent. Insulin dependent diabetes; Skin problems. Radiation treatment of PU area ;Medical condition that would interfere with study PU: Stage I or IV, 1.5 cm in depth, undermining, or 5.6 cm x 10 cm in area, skin disease, infected Peripheral vascular ulcers, contusions, abrasions, or open skin in immediate PU area	NR/NR/65/65 PU N=87 Subject N=65	Age (Mean):NR Female: NR Race: NR	Local Wound Application: Dressing	Stage II: 59.5% vs. 75.5% Stage III: 40.4% vs. 24.4%
Oleske, 1986[73] US Poor	Patient: 21 years or older; Diagnosed with a PU; Afebrile (less than 100f orally or less than 101f rectally) Expected to be hospitalized for at least two weeks. Able to communicate in English or must have next of kin who is capable of communicating in English PU: Involves a skin break caused by pressure; Skin break is a minimum, but does not extend into muscle (stage I or II only); Not in an area that is currently being irradiated; No evidence of infection.	NR	59/22/16/15	Age (Mean):69 years Female: NR Race: NR	Local Wound Application: Dressing	Stage: I: 22.2% vs. 50% II: 77.7% vs. 50% Location: Gluteal or coccyx
Payne, 2009[74] US Poor	At least 18 years of age; either gender; not pregnant or using contraception; Stage II PU with slight to moderate levels of exudate. If more than one eligible wound, the largest wound was selected	Known history of poor compliance; presence of infection in the; Stage I, Stage III, or Stage IV PU; and previous participation in the evaluation	NR/NR/36/36	Age (Mean):73 years Female: 39% Race: NR	Local Wound Application: Dressing	Stage II: 100% Location: Hip/buttocks: 35% vs. 43.8% Sacrum: 40% vs. 43.8% Upper leg: 5% vs. 0% Ankle/foot: 20% vs. 6.3% Lower leg: 0% vs. 6.3%
Price, 2000[75] UK Good	Adults with stage III and IV non infected PU	Existing dermatitis, a history of sensitivity to adhesive products, taking oral corticosteroids	NR/NR/58/50 PU N=21	Age (Mean):71 years Female: 64% Race: NR	Local Wound Application: Dressing	Stage III: 80% vs. 92% Stage IV:20% vs. 8%
Sebern, 1986[76] Sebern, 1989[77] US Poor	Stage II or III PU Receiving VNA (Visiting Nursing Association) service	Stage I or IV PU; ulcer containing eschar; terminal patient; white count below 4,000	NR/NR/100/48 PU N=77	Age (Mean):74 years Female: NR Race: NR	Local Wound Application: Dressing	Stage II:59.4% vs. 30% Stage III: 40.5% vs. 70% (Article used Shea ulcer stages: II, III)

Evidence Table H-5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type**	**Ulcer Type/Severity at Baseline (Intervention Onset)**
Seeley, 1999[78] US Fair	Either sex,>18 years; one or more stage II or III (AHCPR system) PU	PU smaller than 1cm^2 or larger than 50cm^2; Clinically infected ulcer; Uncontrolled diabetes. Known history of poor compliance with medical treatment	NR/NR/40/39 PU N=40	Age (Mean):76 years Female: 54% Race: NR	Local Wound Application: Dressing	Stage II:15%(N=3) vs. N=2 (11%) Stage III: 85%(N=17) vs. 89%(N=17) Location: Sacrum or Coccyx: N=4 vs. N=5 Heel: N=7 vs. N=3 Foot: N=3 vs. N=4 Trochanter: N=1 vs. N=1 Ischium: N=1 vs. N=1 Thigh: N=2 vs. N=1 Buttocks: N=1 vs. N=2 Other: N=1 vs. N=2
Small, 2002[79] South Africa Fair	Patients in the Bloemfontein community 18 years or older with a clinically uninfected stage 2,3, or 4 PU (Stirling scale); Patients with their guardians, who gave informed consent and were willing and able to comply	NR	60/58/58/58	Age (Mean):77 years Female: 61% Race: NR	Local Wound Application: Dressing	Location: Sacrum: N=11 vs. N=15 Trochanter: N=6 vs. N=6 Malleolus: N=3 vs. N=0 Iliac crest: N=2 vs. N=2 Ischium: N=2 vs. N=1 Heel: N=2 vs. N=3 Wrist: N=1 vs. N=0 Lat. Side of foot: N=1 vs. N=0 Elbow: N=0 vs. N=2 Scapula: N=0 vs. N=1
Thomas, 1997[80] UK Poor	Stage II or III PU; Any wound less than 10mm deep and maximum diameter of 8cm	<16 years of age; History of poor compliance with treatment; Insulin dependent diabetes; Unlikely to survive study period; Previous adverse reaction to test materials; Infected wounds	NR/NR/NR/99 (total N=199 including those with venous leg ulcers, which were separated in analysis)	Age (Mean):79 years Female: 69% Race: NR	Local Wound Application: Dressing	Stage II: N=30 vs. N=27 Stage III: N=19 vs. N=23 Location: Heel: N=25 vs. N=23 Buttock: N=2 vs. N=6 Sacrum: N=6 vs. N=10 Hip: N=4 vs. N=2 Other: N=12 vs. N=9

Evidence Table H-5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type**	**Ulcer Type/Severity at Baseline (Intervention Onset)**
Thomas, 1998[81] US Poor	>18 years old Stage II, III, IV PU area >/= to 1.0cm^2	Ulcers resulting from venous or arterial insufficiency or other nonpressure etiology Wounds with sinus tracts and or undermining greater than 1cm; Infected wounds; Concomitant use of other topical medications; Severe generalized medical conditions and estimated survival of less than 6 mo;HIV positive, currently abusing drugs, pregnant, breast feeding, non on acceptable means of contraception, cancer diagnosis or chemotherapy	NR/NR/41/30 PU N=30	Age (Mean): 77 years Female: 54% Race: 53% Caucasian	Local Wound Application: Dressing	Stage: Stage II: N=8 (50%) vs. N=6 (43%) Stage III: 6 (38%) vs. 7 (50%) Stage IV: 2 (13%) vs. 1 (7%)
Thomas, 2005[82] US Good	Male or female subjects, > 18 years old with a diagnosis of a non-infected stage 3 or stage 4 PU with an area greater than or equal to 1.0 cm^2	History of sensitivity to adhesive products; wound with a sinus tract and/or extensive undermining (greater than 1 cm); nonpressure ulcer; infected ulcer; concomitant use of other topical medication to study ulcer; HIV positive; pregnant, breast-feeding or not on contraception in premenopausal women, current diagnosis of cancer, severe generalized medical condition with estimated survival of <6 months, concomitant systemic steroid therapy at a dose equivalent to greater than 10 mg prednisone daily, or current alcohol or drug abuse	NR/NR/41/41	Age (Mean): 75 years Female: 32% Race: 51% Caucasian	Local Wound Application: Dressing	Stage III: N=11 vs. N=11 Stage IV: N=10 vs. N=9
Whitney, 2001[83] US Fair	Male or female; 18 years or older; Stage III or IV PU (NPAUP); English speaking	Documented wound infection; Dermatitis; Recurrent ulcer; Sensitivity to adhesives; Corticosteroid medication; End-stage disease with <3 mo life expectancy	NR/NR/40/29 PU N=30	Age (Mean): 58 years Female: 38% Race: 79% Caucasian	Local Wound Application: Dressing	Ulcer Stage: III: N=7 vs. 11 IV: N=8 vs. 3 Ulcer locations: Ischium: 5 vs. 3 Sacrum: 3 vs. 3 Coccyx: 2 vs. 1 Heel: 1 vs. 4 Malleolus: 2 vs. 2 Plantar: 0 vs. 1 Trochanter: 1 vs. 0 Thoracic: 1 vs. 0
Winter, 1990[84] UK Poor	Chronic leg ulcers or PU	Terminally ill; Wounds <1cm^2	NR/NR/114/51	Age (Mean): 74 years Female: 67% Race: NR	Local Wound Application: Dressing	NR

Evidence Table H-5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type**	**Ulcer Type/Severity at Baseline (Intervention Onset)**
Xakellis, 1992[85] US Fair	PU with a break in the skin	Stage I and IV PU; Anticipated discharge within 1 week; PU caused by other causes	NR/NR/39/39 PU N=39	Age (Mean): 80 years Female: 92% Race: NR	Local Wound Application: Dressing	Stage II: N=18 vs. 19 Stage III: N=0 vs. 2 Location: Sacrum: N=6 vs. 8 Pelvic girdle: N=8 vs. 6 Other: N=4 vs. 7 (Article used Shea Ulcer rating: II and III)
Yapucu Gunes, 2007[86] Turkey Fair	Stage II or III PU; 18 years or older	Diabetes mellitus; Terminal illness	NR/36/27/26	Age (Mean):66 years Female: 39% Race: NR	Local Wound Application: Dressing	Mean stage of PU, 2.96 vs. 2.96
Yastrub 2004[87] US Poor	> 65 years old, location of the PU, limitations in ADLs, and the Agency for Health Care Policy and Research (AHCPR, 1994) definition of a stage II PU	NR	NR/NR/50/44	Age (Mean):NR Female: NR Race: NR	Local Wound Application: Dressing	NR

Evidence Table H-5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	**Treatment A**	**Treatment B**	**Treatment C**	**Duration of Treatment/Followup**	**Study Setting**	**Funding Source**
Alm, 1989[43] Sweden Fair	Hydrocolloid Dressing (Comfeel Ulcus dressing system: Comfeel Ulcus sheet, Comfeel paste, Comfeel powder) Changed when necessary N=31	Wet Saline Gauze Changed 2x daily N=25	NA	6 Weeks	Hospitals	NR
Bale, 1997[44] UK Fair	Polyurethane foam dressing N=29	Hydrocolloid Dressing N=31	NA	30 days	NR	Smith and Nephew
Bale, 1998(b)[45] UK Poor	Hydrocellular dressing (Allevyn): 10cm by 10cm with specifications to allow a 2cm border over healthy tissue. Dressings were changed only if there was leakage or imminent leakage or if a clinical reason such as wound pain required investigation N = 17	Hydrocolloid dressing (Granuflex): 10cm by 10cm with specifications to allow a 2cm border over healthy tissue. Dressings were changed only if there was leakage or imminent leakage or if a clinical reason such as wound pain required investigation N =15	NA	8 weeks	Community	Smith and Nephew Ltd
Bale, 1998(a)[46] UK Poor	Hydrocellular dressing (Allevyn): 10cm by 10cm with specifications to allow a 2cm border over healthy tissue. Dressings were changed only if there was leakage or imminent leakage or if a clinical reason such as wound pain required investigation N = 17	Hydrocolloid dressing (Granuflex): 10cm by 10cm with specifications to allow a 2cm border over healthy tissue. Dressings were changed only if there was leakage or imminent leakage or if a clinical reason such as wound pain required investigation N =15	NA	8 weeks	Community	Smith and Nephew Ltd

Evidence Table H-5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	**Treatment A**	**Treatment B**	**Treatment C**	**Duration of Treatment/Followup**	**Study Setting**	**Funding Source**
Banks, 1994(a)[50] UK Poor	Polyurethane (Spyrosorb): dressings were changed when area discolored by exudates was less than 1cm from the edge of the dressing. Removal of the dressing solely for inspection of the wound was discouraged. Cleansing with warmed sterile saline was undertaken only if necessary and no topical applications were allowed, no limit was placed on the time a dressing could remain in situ.\ N=20	Hydrocolloid (Granuflex): dressings were changed when area discolored by exudates was less than 1cm from the edge of the dressing. Removal of the dressing solely for inspection of the wound was discouraged. Cleansing with warmed sterile saline was undertaken only if necessary and no topical applications were allowed, no limit was placed on the time a dressing could remain in situ. N=20	NA	6 weeks	Community	C.V. Laboratories Ltd and Calgon Vestal Laboratories
Banks, 1994(b)[48] UK Fair	Semi-permeable polyurethane: dressings were changed when the area discolored by exudates was less than 1cm from the edge of the dressing and before exudates had leaked. Dressings were left in situ for a maximum of seven days. Removal of dressing for inspection of the wound was avoided and wounds were cleansed only if necessary with warmed sterile normal saline; no other topical applications were permitted. N=13	Hydrocolloid: dressings were changed when the area discolored by exudates was less than 1cm from the edge of the dressing and before exudates had leaked. Dressings were left in situ for a maximum of seven days. Removal of dressing for inspection of the wound was avoided and wounds were cleansed only if necessary with warmed sterile normal saline; no other topical applications were permitted. N=16	NA	6 weeks	Hospital	C.V. Laboratories Ltd and Calgon Vestal Laboratories
Belmin, 2002[49] France Fair	Alginate for 4 weeks and hydrocolloid for 4 weeks. Calcium alginate dressings were removed every other day or more often if they were saturated, especially when exudates appeared through the secondary dressing. Hydrocolloid dressings were removed every third day or more often if the area discolored by exudates was less than 1cm from the edge of the dressing or if a leakage was apparent. N=57	Hydrocolloid dressings alone for 8 weeks. Dressings were removed every third day or more often if the area discolored by exudates was less than 1cm from the edge of the dressing or if a leakage was apparent. N=53	NA	8 weeks	Hospital	Laboratories Urgo

Evidence Table H-5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	**Treatment A**	**Treatment B**	**Treatment C**	**Duration of Treatment/Followup**	**Study Setting**	**Funding Source**
Bito, 2012[50] Japan Good	Wrap therapy using food wraps and perforated polyethylene changed everyday N=35	Standard care according to Evidence-Based Localized Pressure Ulcer Treatment Guidelines" N=29	NA	3 months	15 hospitals	Division of Health for the Elderly at Japanese Ministry of Health, Labour and Welfare
Brod, 1990[51] US Poor	Poly-hema paste changed twice weekly N=27	Hydrocolloid dressing changed twice weekly N=16	NA	16 weeks	Long-term care	Acme/Chaston Division, National Patent Development Corp.
Brown-Etris, 2008[52] US Fair	Transparent absorbent acrylic dressing (TAAD) N=35	Hydrocolloid dressing (HD) N=37	NA	56 days	Community	3M Company
Chang, 1998[53] Malaysia Poor	Gauze dressings soaked in normal sterile saline changed daily or when secondary dressing was soaked through N=17	DuoDERM CGF Hydrocolloid dressing changed every seven days or when leakage occurred N=17	NA	8 weeks	University Hospital, Kuala Lumpur	ConvaTec (Bristol-Myers Squibb)
Chuangsuwanich, 2011[54] Thailand Fair	Silver mesh dressing with cotton gauze as outer dressing, changed every three days	Silver sulfadiazine with cotton gauze as outer dressing, changed twice daily	NA	8 weeks	Siriraj Hospital	NR
Colin, 1996[55] Multinational Poor	Hydrogel (IntraSite) N=67	Dextranomer paste (Debrisan), N=68	NA	3 weeks	"Multicenter investigation"	NR
Colwell, 1993[56] US Poor	Hydrocolloid (DuoDerm), changed every 4 days or as needed N=48	Saline gauze, changed every 6 hours or as needed. N=49	NA	14 months	Long-term care	ConvaTec
Darkovich, 1990[57] US Poor	Hydrogel (BioFilm), changed every three or four days N=41	Hydrocolloid, changed every three or four days N=49	NA	8.6 weeks (60 days)	Acute and long-term care	NR
Day, 1995[58] US, UK, Canada Fair	Hydrocolloid triangle N=52	Hydrocolloid oval N=51	NA	10 treatment days (mean)	Hospital (acute care)	NR
Gorse, 1987[59] US Poor	Hydrocolloid (DuoDerm), changed every four days or more frequently N=76	Saline gauze + chramine-T (Dakin's solution), changed every 8 hours N=52	NA	5-40 days	Hospital	NR
Honde, 1994[60] France Fair	Amino acid copolymer (Inerpan) N=80	Hydrocolloid dressing (Comfeel) N=88	NA	8 weeks	Hospital	Synthélabo Recherche

Evidence Table H-5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	**Treatment A**	**Treatment B**	**Treatment C**	**Duration of Treatment/Followup**	**Study Setting**	**Funding Source**
Kaya, 2005[61] Turkey Poor	Hydrogel-type dressing (Elasto-gel), changed every four days, or more frequently if the membrane became contaminated or non-occlusive. N=15 patients, 25 PU	Povidone-iodine-soaked gauze, changed daily to prevent contamination N=12 patients, 24 PU	NA	NR	Hospital	NR
Kerihuel, 2010[62] France Good	Actisorb, changed two to three times per week or more frequently in cases of abundant exudation N=29	Hydrocolloid dressing (DuoDerm), changed two to three times per week or more frequently in cases of abundant exudation N=30	NA	4 weeks in study period.	Hospital	Systagenix Wound Management
Kim, 1996[63] Korea Poor	Hydrocolloid occlusive dressing: dressing change every 4 to 5 days or more if leakage occurred N=26	Wet-to-dry gauze dressing: povidone soaked wet gauze and then covered with a layer of dry gauze changed three times per day N=18	NA	NR	Hospital	NR
Kloth, 2002[64] US Fair	Normothermic Noncontact Wound Therapy: 3 separate 1-hour periods per day, N=22	Standard care: removing moisture-retentive dressing daily, irrigating the wound with normal saline, and applying a fresh dressing, N=21	NA	12 weeks	Hospital and Long-term care	Augustine Medical Inc
Kraft, 1993[65] US Poor	Epi-Lock: can be left on for up to 7 days or until there is leakage of exudates N=24	Saline Dressings: changed once every 8 hours N=14	NA	24 weeks	Hospital	Calgon Vestal Laboratories
Kurzuk-Howard, 1985[66] US Poor	Moist Wound Healing (Op Site treatment): applied to dry, clean wound area and removed after healing or it may slough off naturally.	Dry Wound Healing (Alternative treatment); depending on ulcer stage this can vary from egg crate mattresses and turning the patient every two hours to cleaning and dressing the ulcer followed by a heat lamp for 15-20 minutes.	NA	20 days	Hospital	Partially funded by Acme United Corporation, Bridgeport, Connecticut
Matzen, 1999[67] Denmark Poor	Hydrogel: wounds were changed and dressing changed daily N=17	Saline gauze compress: wounds were changed and dressing changed daily N=15	NA	12 weeks	Hospital	NR

Evidence Table H-5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	**Treatment A**	**Treatment B**	**Treatment C**	**Duration of Treatment/Followup**	**Study Setting**	**Funding Source**
Meaume, 2005[68] France Fair	Silvercel- A sterile non-woven pad composed of a high-G alginate, carboxymethylcellulose and silver-coated fibres. For the first 2 weeks dressings were changed at least 5 times/week, afterwards dressings were changed every 2-3 days as needed. N=13	Algosteril- A sterile non-woven pad composed of 100% calcium alginate. For the first 2 weeks dressings were changed at least 5 times/week, afterwards dressings were changed every 2-3 days as needed. N= 15	NA	4 weeks	Hospital	Johnson and Johnson Wound Management
Meaume, 2003[69] Finland Fair	Silicone, polyurethane foam, and polyacrylate fibers; dressings changed at least once a week or more frequently as needed. If the PU was highly exudating in the initial period, the dressing was changed more frequently to avoid leakage. N=18	Hydropolymer containing polyurethane foam, a nonwoven layer, and polyurethane backing: dressings changed at least once a week or more frequently as needed. If the PU was highly exudating in the initial period, the dressing was changed more frequently to avoid leakage. N=20	NA	8 weeks	Nursing home/LONG-TERM CARE	NR
Motta, 1999[70] US Poor	Polymer hydrogel dressing (AcryDerm Sheet Wound Dressing) changed as needed, at least once a week. N=5	Hydrocolloid dressing (DuoDERM), changed as needed, at least once a week N=5	NA	8 weeks	Home healthcare	AcryMed, Portland, OR
Mulder, 1993[71] US Poor	Clearsite: changed twice a week by the patient or caregiver N=22	DuoDERM: changed twice a week by the patient or caregiver N=22	Standard wet-to-moist saline gauze dressing: changed three times a day by the patient or caregiver N=23	8 weeks	Hospital	NR
Neill, 1989[72] US Poor	Hydrocolloid (Tegasorb): changed every 3 – 7 days N=42	Saline gauze (wet-to-dry): changed every 8 hours N=42	NA	15 months	Tertiary care facility and nursing home	3M Company, Medical-Surgical Division
Oleske, 1986[73] US Poor	Saline: Normal saline dressings custom cut to the size of the ulcer and covered with a plastic pad. Changed every 4 hours N=8	Polyurethane dressing that was self adhesive. Changed only if it dislodged from the ulcer site, usually remained in place for 2 days N=7	NA	10 days	Hospital	Department of Medical Neurnign, Rush-Presbyterian-St. Luke's Medical Center and the Chicago Community Trust

Evidence Table H-5a: Dressings Trials, continued						
Author, year Country Overall Quality Rating	**Treatment A**	**Treatment B**	**Treatment C**	**Duration of Treatment/Followup**	**Study Setting**	**Funding Source**
Payne, 2009[74] US Poor	Self adhesive polyurethane foam: dressing change frequency determined at the discretion of the clinical investigator N=20	Saline-soaked gauze dressings: dressing change frequency determined at the discretion of the clinical investigator N=16	NA	4 weeks	Hospital inpatient wards, outpatient clinics, long-term residential center, and a community based wound clinic	NR
Price, 2000[75] UK Good	Radiant heat dressing: warming element inserted into dressing pocket for 1 hour, twice daily (morning and evening) N=25	Standard care (alginate absorbent dressings): cleaned as clinically indicated N=25	NA	6 weeks	Multiple: Hospital, long-term care, community	NR
Sebern, 1986[76] Sebern, 1989[77] US Poor	Transparent Moisture vapor permeable dressing (MVP): changed daily to three times a week, N=37	Saline gauze: changed every 24 hours, wounds were irrigated at each change with half strength hydrogen peroxide and rinsed with physiologic saline, N=40	NA	8 weeks	Community	NR
Seeley, 1999[78] US Fair	Hydrocellular dressing N=20	Hydrocolloid dressing N=19	NA	8 weeks	Long term care facilities and Outpatient wound clinic	NR
Small, 2002[79] South Africa Good	Advanced wound care: Hydrogel dressing Foam dressing Transparent film dressing, N=28	Standard wound care: Cotton, alginates, gauze, hydrocolloids, N=30	NA	6 weeks	Community	NR
Thomas, 1997[80] UK Poor	Hydrocolloid dressing N= 49	Hydropolymer dressing N = 50	NA	6 weeks	community	NR
Thomas, 1998[81] US Poor	Topical hydrogel dressing N=16	Saline gauze n=14	NA	10 weeks	Skilled nursing facilities and Community	Carrington Laboratories
Thomas, 2005[82] US Good	Radiant heat dressing, N=21	Hydrocolloid, N=20	NA	12 weeks	Outpatient clinics, Long-term care, and rehabilitation center	NR
Whitney, 2001[83] US Fair	Noncontact normothermic wound therapy (heated dressing) N=15	Standard care (moisture retentive dressings including alginates with saline gauze, foam, hydrocolloids, or hydrogels) N=14	NA	8 Weeks	Multiple: Acute care, community, and long-term care	Augustine Medical Inc and Small Business Innovation Grant No. NIH
Winter, 1990[84] UK Poor	Hydrocolloid N=58	Paraffin Gauze N=56	NA	12 Weeks	Hospital and community	Coloplast Ltd

Evidence Table H-5a: Dressings Trials, continued						
Author, year **Country** **Overall Quality Rating**	**Treatment A**	**Treatment B**	**Treatment C**	**Duration of Treatment/Followup**	**Study Setting**	**Funding Source**
Xakellis, 1992[85] US Fair	Hydrocolloid N=18	Saline gauze N=21	NA	6 Months	Long-term care	Family Health Foundation of America and ConvaTec
Yapucu Gunes, 2007[86] Turkey Fair	Honey dressing, N=15	Exthoxy-diaminoacridine + nitrofurazone dressing, N=11	NA	5 weeks	Hospital	NR
Yastrub, 2004[87] US Poor	Polymer membrane dressing, N=21	Dry clean dressing (gauze and antibiotic ointment), N=23	NA	4 weeks	LONG-TERM CARE	Partially funded by NPUAP

Evidence Table H-5a: Dressings Trials, continued								
Author, year Country Overall Quality Rating	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis Rate**	**Outcomes: Recurrence Rate**	**Outcomes: Pain**	**Other Outcomes: Specify**
Alm, 1989[43] Sweden Fair	Treatment A: 50-60% had healed Treatment B: Saline Gauze: 10-20% had healed	Treatment A: At 6 weeks median value: 0% Treatment B: At 6 weeks median value: 31% (p=0.016)	" Healing was faster in ulcers dressed with the hydrocolloid dressing"	NR	NR	NR	Treatment A: Authors report that neither the patients nor the staff believed that the dressing change was ever painful. Treatment B: NR	NR
Bale, 1997[44] UK Fair	Treatment A: N=7 Treatment B: N=5	NR	NR	NR	NR	NR	NR	NR
Bale, 1998(b)[45] UK Fair	Treatment A: N=10 (59%) Treatment B: N=4 (27%)	NR	NR	NR	NR	NR	NR	NR
Bale, 1998(a)[46] UK Poor	NR	NR	NR	NR	NR	NR	NR	NR
Banks, 1994(a)[50] UK Poor	Treatment A: 60% complete wound healing Treatment B: 50% complete wound healing	Treatment A: 30% showed improvement. Treatment B: 0% showed improvement	NR	NR	NR	NR	Treatment A: NR Treatment B: Authors report Two patients were withdrawn at their own request because discomfort they experienced with the dressing.	NR
Banks, 1994(b)[48] UK Fair	Treatment A: 77% complete wound healing Treatment B: 62.5% complete wound healing	Treatment A: No data Treatment B: 6.1% greatly improved	Treatment A: 13.36 days Treatment B: 12.69 days	NR	NR	NR	NR	

Evidence Table H-5a: Dressings Trials, continued								
Author, year Country Overall Quality Rating	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis Rate**	**Outcomes: Recurrence Rate**	**Outcomes: Pain**	**Other Outcomes: Specify**
Belmin, 2002[49] France Fair	Treatment A: 5.1% complete wound healing Treatment B: 15.1% complete wound healing (p=0.162)	Wound surface area mean: Treatment A: 5.0cm^2, 66% improvement Treatment B: 7.4cm^2, 42% improvement (p<0.0001)	NR	NR	NR	NR	NR	NR
Bito, 2012[50] Japan Good	Treatment A: 52% Treatment B: 46%	NR	Treatment A: 60 days Treatment B: 58 days	NR	NR	NR	NR	NR
Brod, 1990[51] US Poor	Treatment A: 52% Treatment B: 62% (p=0.54)	NR	Treatment A: 0.18cm^2/week Median time to complete healing: 32 days Treatment B: Hydrocolloid: 0.10cm^2/week (p=0.005) Median time to complete healing: 42 days (p=0.56)	NR	NR	NR	NR	NR
Brown-Etris, 2008[52] US Fair	Treatment A: 21, 60% Treatment B: 22, 59.5%, (p=0.963)	Treatment A: 1.1 cm^2 Treatment B: HD: 1.6 cm^2 (p=0.598)	Treatment A: Linear healing rate, mean: 0.10cm^2 Treatment B: Linear healing rate, mean: 0.12cm^2 (p=0.6520)	NR	NR	NR	NR	NR

Evidence Table H-5a: Dressings Trials, continued								
Author, year Country Overall Quality Rating	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis Rate**	**Outcomes: Recurrence Rate**	**Outcomes: Pain**	**Other Outcomes: Specify**
Chang, 1998[53] Malaysia Poor	NR	Treatment A: mean reduction of 34% from baseline surface area Treatment B: mean 9% increase to baseline surface area p=0.2318	NR	Treatment A: NR Treatment B: One subject developed infection	NR	NR	Overall comfort Treatment A: 0% uncomfortable Treatment B: 50% uncomfortable (p<0.01)	Exudate handling good/excellent: Treatment A: 69% Treatment B: 44% (p<0.019)
Chuangsuwanich, 2011[54] Thailand Fair	NR	Treatment A: Mean surface area at 8th week 7.96 cm^2 Treatment B: Mean surface area at 8th week 18.22 cm^2 (p=0.093)	Treatment A: Mean healing rate, 36.95% Treatment B: Mean healing rate, 25.06% (p=0.507)	Treatment A: 3 patients had microbiologic growth rated as "numerous" Treatment B: 9 patients had microbiologic growth rated "numerous"	NR	NR	NR	NR
Colin, 1996[55] Multinational Poor	NR	Treatment A: – 35% Treatment B: 7% (p=0.03)	NR	NR	NR	NR	NR	NR
Colwell, 1993[56] US Poor	Treatment A: 22% Treatment B: 2%	Treatment A: 0.73 cm reduction Treatment B: 0.67 cm increase	NR	NR	NR	NR	NR	NR
Darkovich, 1990[57] US Poor	Treatment A: 43% Treatment B: 24%	Treatment A: 68% (7.5cm^2) wound area difference from baseline Treatment B: 40% (3.7cm^2) difference from baseline	Treatment A: 8.1% wound area/day Treatment B: 3.1% wound area/day	NR	NR	NR	NR	NR

Evidence Table H-5a: Dressings Trials, continued								
Author, year Country Overall Quality Rating	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis Rate**	**Outcomes: Recurrence Rate**	**Outcomes: Pain**	**Other Outcomes: Specify**
Day, 1995[58] US, UK, Canada Fair	Treatment A: 36% Treatment B: 22% (p=0.17)	Treatment A: Mean width reduction: 32% Mean length reduction: 28% Treatment B: Mean width reduction: 17% (p=0.034) Mean length reduction: 24% (NS)	Treatment A: Hydrocolloid triangle: 13.5 days Treatment B: Hydrocolloid oval: 11.0 days	NR	NR	NR	Treatment A: (baseline vs. final): 47% vs. 18% Treatment B: 29% vs. 32% Pain higher at final assessment in treatment B group (p=0.04)	NR
Gorse, 1987[59] US Poor	Treatment A: 87% healed Treatment B: 69% healed	Treatment A: 15.7% healing Treatment B; 19.2% healing	Treatment A: 0.72cm^2/day Mean healing days: 10 Treatment B: 0.55cm^2/day Mean healing days: 8.7	NR	NR	NR	NR	NR
Honde, 1994[60] France Fair	Treatment A: 38.7% achieved healing (chi-square test; (p=0.089) Treatment B: 26.1% achieved healing (p=0.089)	Treatment B: The authors report that progress toward healing tended to be higher (p=0.090).	Treatment A: 32 days Treatment B: 38 days (p=0.44)	NR	NR	NR	NR	Authors report that Shea grade distributions in each group were compared, and on day 14, there were more patients healed or nearing healing (Grade I) in treatment A (25.8%) than treatment B (8.3%), (p=0.029)
Kaya, 2005[61] Turkey Poor	Treatment A: 84% of wounds became epithelialized Treatment B: 54.2% of wounds became epithelialized (p=0.04)	NR	Treatment A: 0.12cm^2/days Healing time was 48 days Treatment B: 0.08cm^2/days Healing time was 45.23 days (p=0.06)	NR	NR	NR	NR	NR

Evidence Table H-5a: Dressings Trials, continued								
Author, year Country Overall Quality Rating	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis Rate**	**Outcomes: Recurrence Rate**	**Outcomes: Pain**	**Other Outcomes: Specify**
Kerihuel, 2010[62] France Good	NR	Treatment A: 26.9% wound reduction Treatment B: 18.5% wound reduction	NR	NR	NR	NR	NR	NR
Kim, 1996[63] Korea Poor	Treatment A: 80% complete wound healing Treatment B: 77.8% complete wound healing	NR	Treatment A: 9.1mm2/day Treatment B: 7.9mm2/day	NR	NR	NR	NR	NR
Kloth, 2002[64] US Fair	Treatment A: 48% wound closure Treatment B: 36% wound closure	Treatment A: 69% decrease in mean surface area Treatment B: 50% decrease in mean surface area	Treatment A: 0.52cm^2 per week Treatment B: 0.23cm^2 per week (p=0.02)	NR	NR	NR	NR	NR
Kraft, 1993[65] US Poor	Treatment A: 42% healed Treatment B: 21% healed	NR	NR	NR	NR	NR	NR	NR
Kurzuk-Howard, 1985[66] US Poor	32.5% total healing (Treatment A and B combined)	No significant difference between treatment A and treatment B was found in the average rate of improvement in the size (p<0.66)	The rate of improvement over time was greater for the treatment A than for the treatment B.	Treatment A: 1 patient experienced an infection Treatment B: NR	NR	NR	Many patients reported being more comfortable after an application of Treatment A to the ulcers. Treatment B: NR	No significant difference was found for the average overall rate of improvement in size, depth, and redness for the two treatment groups (p<0.61)
Matzen, 1999[67] Denmark Poor	Treatment A: 29% complete wound healing Treatment B: 0% complete wound healing	NR	NR	Treatment A: NR Treatment B: 40% developed necrotic tissue with infection	NR	NR	Treatment A: Median of 2 patients reported pain Treatment B: Median of 2 patients reported pain	NR

Evidence Table H-5a: Dressings Trials, continued								
Author, year Country Overall Quality Rating	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis Rate**	**Outcomes: Recurrence Rate**	**Outcomes: Pain**	**Other Outcomes: Specify**
Meaume, 2005[68] France Fair	NR	Treatment A: Absolute decrease: 7.2cm^2 wound reduction: 31.6% Treatment B: Absolute decrease: 0.8cm^2 wound reduction: 13.9%	Treatment A: 0.26cm^2/day Treatment B: 0.03cm^2/day	NR	NR	NR	Treatment A: NR Treatment B: Pain during dressing and erythema, pain reported	NR
Meaume, 2003[69] Finland Fair	Treatment A: 44.4% healed Treatment B: 50% healed	Treatment A: 38.8% showed improvement Treatment B: NR	NR	NR	NR	Treatment A: 0% developed new ulcers Treatment B: 10% developed new ulcers	NR	NR
Motta, 1999[70] US Poor	Treatment A: 40% healed Treatment B: 40% healed	Treatment A: 79.2% wound improvement Treatment B: 88.6% wound improvement	Treatment A: 0.15cm/day Treatment B: 0.35cm/day	NR	NR	NR	NR	NR
Mulder, 1993[71] US Poor	NR	NR	Treatment A vs. Treatment B vs. Treatment C: Mean reduction/week 8% vs. 3.3% vs. 5.1% (p=0.89)	Treatment A: 1 case of inflammation Treatment B: NR	NR	NR	NR	NR
Neill, 1989[72] US Poor	Treatment A: 31% healed Treatment B: 22% healed	50% or more reduction in size: Treatment A: 50% Treatment B: 46%	NR	Treatment A: No infection occurred Treatment B: NR	NR	NR	NR	NR

Evidence Table H-5a: Dressings Trials, continued								
Author, year Country Overall Quality Rating	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis Rate**	**Outcomes: Recurrence Rate**	**Outcomes: Pain**	**Other Outcomes: Specify**
Oleske, 1986[73] US Poor	Treatment A: 1 ulcer healed Treatment B: 0 healed	Treatment A: Mean 7.7 cm^2 SD (pre and post change not significant) Treatment B: Mean 2.0 cm^2 (pre and post change significant at p=0.01)	NR	Treatment A: One patient developed an infection in the treated ulcer and died the next day from pulmonary embolism and sepsis. It is not clear what (the underlying disease, or the dressing) contributed to the infection Treatment B: NR	NR	NR	NR	Authors note that in one instance a patient in the treatment B with two ulcers within 1 cm of one another, the two ulcers merged into a single ulcer with greater depth.
Payne, 2009[74] US Poor	Treatment A: 55.5% healed Treatment B: 37.5% healed	NR	NR	Treatment A: 5.56% showed signs of infection Treatment B: No infections reported	NR	NR	NR	NR
Price, 2000[75] UK Good	Treatment A: 12% complete wound healing Treatment B: 8% complete wound healing	Reduction of initial wound area: Treatment A: 75% Treatment B: 40%	Treatment A: 66.7cm^2/week Treatment B: 63.3cm^2/week	NR	NR	NR	Treatment A: No difference in pain scores from baseline to end of study Treatment B: No difference in pain scores from baseline to end of study.	NR
Sebern, 1986[76] Sebern, 1989[77] US Poor	Grade II Treatment A: 64% Treatment B: 0% (p<0.01)	Grade II Median improvement: Treatment A: 100% Treatment B: 52% (p<0.05)	NR	Treatment A: No sepsis reported Treatment B: No sepsis reported	NR	NR	NR	NR

Evidence Table H-5a: Dressings Trials, continued								
Author, year Country Overall Quality Rating	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis Rate**	**Outcomes: Recurrence Rate**	**Outcomes: Pain**	**Other Outcomes: Specify**
Seeley, 1999[78] US Fair	Treatment A: 40% of all PU healed Treatment B: 40% of all ulcers healed	Treatment A: Stage II median improvement: 100% Stage III median improvement: 67% Treatment B: Stage II median improvement: 52% (p<0.01) Stage III median improvement: 44%	NR	NR	NR	NR	Treatment A: Mean wound pain 0.15 Treatment B: mean wound pain 0.47	NR
Small, 2002[79] South Africa Good	Treatment A: 53.6% Treatment B: 30%	NR	NR	Treatment A: 1 infection Treatment B: 1 infection	NR	NR	NR	NR
Thomas, 1997[80] UK Poor	Treatment A: 33% Treatment B: 20%	Treatment A: 47% Treatment B: 10%	NR	NR	NR	NR	NR	NR
Thomas, 1998[81] US Poor	Treatment A: 63% Treatment B: 64%	NR	Treatment A: 5.3 weeks Treatment B: 5.2 weeks (p=0.87)	NR	NR	NR	NR	NR
Thomas, 2005[82] US Good	Treatment A: 57% Treatment B: 44% (p=0.46)	NR	NR	NR	NR	NR	NR	NR
Whitney, 2001[83] US Fair	Treatment A: 53% Treatment B: 43%	NR	Mean linear rate of healing: Treatment A: 0.012cm^2 per day Treatment B: 0.004 cm^2 per day (p=0.01)	NR	NR	NR	NR	NR
Winter, 1990[84] UK Poor	Treatment A: 63% (n=12) Treatment B: 19% (n=3)	NR	NR	NR	NR	NR	NR	NR

Evidence Table H-5a: Dressings Trials, continued								
Author, year Country Overall Quality Rating	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis Rate**	**Outcomes: Recurrence Rate**	**Outcomes: Pain**	**Other Outcomes: Specify**
Xakellis, 1992[85] US Fair	Treatment A: 89% Treatment B: 86%	NR	Treatment A: 9 days (median) Treatment B: 11 days (median) (p=0.12)	NR	NR	NR	NR	NR
Yapucu Gunes, 2007[86] Turkey Fair	Treatment A: 20% Treatment B: 0% (p<0.05)	Decrease in ulcer size: (mean) Treatment A: 56% reduction Treatment B: 13% (p<0.001)	NR	NR	NR	NR	NR	Improved PUSH tool scores: Treatment A:6.55 Treatment B:12.62 (p<0.001)
Yastrub, 2004[87] US Poor	NR	improvement in wound healing: Treatment A: 87% Treatment B: 65.2%	NR	NR	NR	NR	NR	NR

Evidence Table H-5a: Dressings Trials, continued								
Author, year Country Overall Quality Rating	**Harms: Pain**	**Harms: Dermatologic Complications**	**Harms: Bleeding**	**Harms: Infection**	**Other Harms: Specify**	**Severe Adverse Events**	**Withdrawal Due to Adverse Events**	**Overall Adverse Events Rate**
Alm, 1989[43] Sweden Fair	Treatment A: No pain reported on dressing removal (Although, it later says one patient withdrew due to pain.) Treatment B: No pain reported on dressing removal	NR	NR	NR	NR	NR	1 patient withdrawn from hydrocolloid due to pain from changing the dressings	Hydrocolloid dressing: N=1 Wet saline gauze: N=0
Bale, 1997[44] UK Fair	NR	Treatment A: Skin rash, N=1 Treatment B: Skin rash, N=0	NR	NR	NR	NR	NR	NR
Bale, 1998(b)[45] UK Poor	Patients who found the dressing "uncomfortable" are reported, but only in aggregate with the other types of wounds	NR	NR	NR	NR	NR	NR	NR
Bale, 1998(a)[46] UK Poor	Patients who found the dressing "uncomfortable" are reported, but only in aggregate with the other types of wounds	NR	NR	NR	NR	NR	NR	NR
Banks, 1994(a)[50] UK Poor	Treatment A: NR Treatment B: Two patients were withdrawn at their own request because of the discomfort they experienced using the dressing.	NR	NR	NR	NR	NR	NR	NR
Banks, 1994(b)[48] UK (Wales) Poor	NR	NR	NR	NR	Treatment A: Wound deterioration, n=1 Wound/dressing-related problems n=1 Treatment B: Wound deterioration, n=3 Wound/dressing related problems, n=1	NR	Treatment A: 3 Treatment B: 4	20.6%

Evidence Table H-5a: Dressings Trials, continued								
Author, year Country Overall Quality Rating	**Harms: Pain**	**Harms: Dermatologic Complications**	**Harms: Bleeding**	**Harms: Infection**	**Other Harms: Specify**	**Severe Adverse Events**	**Withdrawal Due to Adverse Events**	**Overall Adverse Events Rate**
Belmin, 2002[49] France Fair	Treatment A: 31.3% reported pain during the removal of the dressings. Treatment B: 35.6% reported pain during the removal of the dressings. p=.03	Treatment A: Erythema of surrounding skin 3.5%, Maceration 1.8% Treatment B: Erythema of surrounding skin 0%, Maceration 0%	Treatment A: N=1 Treatment B: N=0	Treatment A: n=1 Treatment B: n=0	Hypergranulation: Treatment A: n=1, Treatment B: n=5	NR	Treatment A: n=1 Treatment B: n=3	Treatment A: local adverse events n=6 Treatment B: local adverse events n=5
Bito, 2012[50] Japan Good	NR	Treatment A: 6 cases of eczema, maceration, or rash with the covered skin Treatment B: Cases of eczema, maceration, and rash reported N not given	NR	NR	NR	None related to treatment	NR	NR
Brod, 1990[51] US Poor	NR	NR	NR	NR	NR	NR	Treatment A: NR Treatment B: n=1	2.3%
Brown-Etris, 2008[52] US Fair	NR	NR	NR	NR	NR	NR	NR	NR
Chang, 1998[53] Malaysia Poor	Treatment A: Pain during dressing removal moderate/severe 0% Treatment B: Pain during dressing removal moderate/severe, 44% p<0.01	Treatment A: Adherence to surrounding skin, non-adherent 44% Treatment B: Adherence to surrounding skin non adherent, 94% p<0.01	NR	Treatment A: No infection reported Treatment B: 1 infection reported	Adherence to wound bed: Treatment A: 100% Treatment B: 44% (p<0.01)	NR	Treatment A: NR Treatment B: 1 subject in gauze group developed wound infection and withdrew	NR
Chuangsuwanich, 2011[54] Thailand Fair	NR	NR	NR	NR	NR	NR	NR	NR
Colin, 1996[55] Multinational Poor	Treatment A: No pain reported Treatment B: One patient reported pain when dressing was removed	NR	NR	NR	Treatment A: Only dressing related adverse event was pain upon application of dressing, n=1 Treatment B: NR	NR	NR	NR

Evidence Table
H-5a: Dressings
Trials, continued

Author, year Country Overall Quality Rating	Harms: Pain	Harms: Dermatologic Complications	Harms: Bleeding	Harms: Infection	Other Harms: Specify	Severe Adverse Events	Withdrawal Due to Adverse Events	Overall Adverse Events Rate
Colwell, 1993[56] US Poor	NR	NR	NR	NR	NR	NR	NR	NR
Darkovich, 1990 [57] US Poor	NR	NR	NR	NR	Wound deterioration: Treatment A: 1.5% Treatment B: 10%	NR	NR	NR
Day, 1995[58] US, UK, Canada Fair	Treatment A: Mean pain score at dressing change 3.8 (range 1-10) Treatment B: Mean pain score at dressing changes 4.3 (range 2-9)	Hydrocolloid triangle Wound Deterioration Treatment A: 4% Treatment B: 31%	Treatment A: NR Treatment B: Minor bleeding reported	NR	Erythema, severe pain, increase in necrotic tissue, wound size, and depth: Treatment A: 4% Treatment B: 31%	Treatment A: NR Treatment B: Deteriorating wound appearance, inflammation of surrounding skin, severe pain upon dressing removal/redness of the surrounding skin, minor bleeding at the wound site	Treatment A: NR Treatment B: n=7 patients	10%
Gorse, 1987[59] US Poor	NR	NR	NR	Treatment A: Rate of wound increase: 2.89cm^2/day Treatment B: Rate of wound increase: 0.75cm^2/day	NR	NR	NR	NR
Honde, 1994[60] France Fair	NR	Ten withdrew from the study for emergent reasons (4 Treatment A and 6 Treatment B) because of local complication (mainly necrosis)	NR	NR	NR	Local complications (mainly necrosis)	10	5.9%
Kaya, 2005[61] Turkey Poor	NR	NR	NR	NR	NR	NR	NR	NR

Evidence Table H-5a: Dressings Trials, continued								
Author, year Country Overall Quality Rating	**Harms: Pain**	**Harms: Dermatologic Complications**	**Harms: Bleeding**	**Harms: Infection**	**Other Harms: Specify**	**Severe Adverse Events**	**Withdrawal Due to Adverse Events**	**Overall Adverse Events Rate**
Kerihuel, 2010[62] France Good	Harms: A: 7% (infection, pruritus) B: 16% (maceration/exudation, infection, wound aggravation, overgranulation, eczema)	None	None	Treatment A: 1 patient Treatment B: 2 patients	NR	Maceration/high exudation; wound infection; wound aggravation; overgranulation; eczema; pruritus	1 from hydrocolloid group	16.9%
Kim, 1996[63] Korea Poor	NR	NR	NR	NR	NR	NR	NR	NR
Kloth, 2002[64] US Fair	NR	NR	NR	NR	NR	NR	NR	NR
Kraft, 1993[65] US Poor	NR	NR	NR	NR	NR	NR	NR	NR
Kurzuk-Howard, 1985[66] US Poor	NR	NR	NR	Treatment A: 1 patient Treatment B: NR	NR	NR	NR	NR
Matzen, 1999[67] Denmark Poor	NR	NR	NR	NR	NR	NR	9	28.1%
Meaume, 2005[68] France Fair	NR	NR	NR	NR	Poor local acceptability and/or tolerability was noted in 1 PU case in the treatment A group	Dry wound; pain; peri-wound eczema	19 withdrawals: 10 vs. 9	19.2%
Meaume, 2003[69] Finland Fair	NR	In most patients, the sign/symptom reported as damage to the surrounding skin was redness. Two patients in Treatment B developed blisters on the surrounding skin. This was not observed in Treatment A.	NR	NR	NR	None	None	NR
Motta, 1999[70] US Poor	NR	NR	NR	NR	NR	NR	NR	NR
Mulder, 1993[71] US Poor	NR	NR	NR	NR	NR	NR	NR	NR

Evidence Table H-5a: Dressings Trials, continued								
Author, year Country Overall Quality Rating	**Harms: Pain**	**Harms: Dermatologic Complications**	**Harms: Bleeding**	**Harms: Infection**	**Other Harms: Specify**	**Severe Adverse Events**	**Withdrawal Due to Adverse Events**	**Overall Adverse Events Rate**
Neill, 1989[72] US Poor	NR	Treatment A: mild skin irritation, perilesional erythema, and eczema reported Treatment B: NR	NR	NR	Treatment A: NR Treatment B: One sore enlarged by 216%	NR	Treatment A: 9 Treatment B: 1	18% vs. 2%
Oleske, 1986[73] US Poor	NR	NR	NR	Treatment A: One patient developed an infection in the treated ulcer and died the next day from pulmonary embolism and sepsis. It is not clear what (the underlying disease, or the dressing) contributed to the infection Treatment B: NR	Treatment A: One a patient with two ulcers within 1 cm of one another, the two ulcers merged into a single ulcer with greater depth.	NR	NR	NR
Payne, 2009[74] US Poor	NR	NR	NR	Treatment A: One patient (5%) in the foam group showed clinical signs of infection in the reference wound and was withdrawn from the study. Treatment B: No infection was reported in the saline group	NR	NR	0	NR
Price, 2000[75] UK Good	Treatment A: No pain reported due to dressing Treatment B: No pain reported due to treatment	NR	NR	NR	Undermining, no difference reported in the occurrence of undermining	NR	NR	NR

Evidence Table H-5a: Dressings Trials, continued								
Author, year Country Overall Quality Rating	**Harms: Pain**	**Harms: Dermatologic Complications**	**Harms: Bleeding**	**Harms: Infection**	**Other Harms: Specify**	**Severe Adverse Events**	**Withdrawal Due to Adverse Events**	**Overall Adverse Events Rate**
Sebern, 1986[76] Sebern, 1989[77] US Poor	NR	Treatment A: Wound deterioration: 14% Stage II skin maceration: 50% Stage III skin maceration: 40% Treatment B: Wound deterioration: 58% Stage II skin maceration: 25% Stage III skin maceration: 25% (p<0.01)	NR	Treatment A: 0 Treatment B: 0	11 ulcers developed necrosis and eschar after being randomly assigned treatment	NR	NR	NR
Seeley, 1999[78] US Fair	Treatment A: mean wound pain 0.15 Treatment B: mean wound pain 0.47 (wound pain rated on a scale of non, mild, moderate, or severe)	Treatment A: Blisters beneath adhesive border 5% (1) Treatment B: Maceration of ulcer 5% (1); Rash beneath dressing 5% (1)	NR	NR	Adverse incidents (blisters, rash or maceration) Treatment A: 5% Treatment B: 10%	NR	Treatment A: 1 patients Treatment B: 2 patients	8% (n=3)
Small, 2002[79] South Africa Good	NR	NR	NR	NR	NR	NR	NR	NR
Thomas, 1997[80] UK Poor	NR	NR	NR	NR	Minor trauma or erythema removal during dressing change, maceration, bleeding, and wound dehydration Treatment A: n=7 Treatment B: n=10 Note: leg ulcer group and PU group data combined.	Five patients died during the study for reasons unrelated to the treatments	NR	NR

Evidence Table H-5a: Dressings Trials, continued								
Author, year Country Overall Quality Rating	**Harms: Pain**	**Harms: Dermatologic Complications**	**Harms: Bleeding**	**Harms: Infection**	**Other Harms: Specify**	**Severe Adverse Events**	**Withdrawal Due to Adverse Events**	**Overall Adverse Events Rate**
Thomas, 1998[81] US Poor	NR	NR	NR	NR	Worsening of Ulcer: Treatment A: 6% (n=1) Treatment B: 7% (n=1)	NR	2	7% (n=2)
Thomas, 2005[82] US Good	NR	NR	NR	NR	NR	NR	NR	NR
Whitney, 2001[83] US Fair	NR	Treatment A: 1 patient had maceration of wound due to treatment Treatment B: NR	NR	NR	Treatment A: NR Treatment B: periwound maceration related to treatment 7% (N=1)	NR	Treatment B: 1 patient withdrawn due to periwound maceration related to treatment	3% (1 out of 30)
Winter, 1990[84] UK Poor	NR	Treatment A: Rash, inflammation, or allergic reaction to dressing 1 Treatment B: Rash, inflammation, allergic reaction to dressing, 1	NR	Treatment A: N=5 Treatment B: N=4	Wound deterioration: Treatment A: N=3 Treatment B: N1	NR	15 patients did not proceed beyond the first week of the study owing to non-compliance, allergic reaction to the dressing or invasive infection.	NR
Xakellis, 1992[85] US Fair	NR	NR	NR	NR	NR	NR	NR	NR
Yapucu Gunes, 2007[86] Turkey Fair	NR	NR	NR	NR	NR	NR	NR	NR
Yastrub, 2004[87] US Poor	NR	NR	NR	NR	NR	NR	NR	NR

Abbreviations: LONG-TERM CARE, long-term care; NR, not reported; PU, pressure ulcer.

Evidence Table H-5b. Dressings observational studies

Author, year Country Overall Quality Rating	Study Type	Confounders Assessed in Analysis	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Ulcer Type/Severity at Baseline (Intervention Onset)
Meaume, 2007[88] France Fair	Observational	NR	Hospitalized in geriatric institutions; Acute or chronic wounds in the granulation phase; <100 cm^2; and not presenting clinical infection	Any progressive neoplastic lesion; Known hypersensitivity to carboxymethylcellulose Receiving radiotherapy or chemotherapy Taking immunosuppressive drugs	NR/NR/43/43 PU N=7	PU group only Age (Mean): 80 years Female: 57.1% Race: NR	Location: Upper Limb: N=1 Lower Limb: N=5 Thorax: N=0 Others: N=1
Moody, 1991[89] US Poor	Non comparative, single-treatment study	NR	Informed consent; Grade II or III PU or venous leg ulcer or other wound; male or female; 16 years or older	Lesion dry or crusted over; PU more than 1cm deep; insulin dependent diabetes; incontinent without a catheter; infection of lesion; fragile or excessively dry skin.	NR/NR/10/7 (Includes other types of wounds, PU N=9)	Age (Mean): 78 years Female: 10% Race: NR	Location: Sacrum: N=8 Buttocks: N=1
Parnell, 2005[90] Country Not Reported Poor	Observational	NR	At least one Stage II or Stage III; PU >1.0 cm^2; Have used a low-air-loss support surface (Dyna Medics Corporation; Keller, Tex.) for at least the previous 14 days. PU with a treatment history that included enzymatic debridement had to be at least 7 days post-treatment.	Severe medical condition that could lead to death within the study period; current use of systemic steroids, chemotherapeutic agents, or other immunosuppressives; HIV-positive; hypersensitivity to fruit and vegetables or enzymes from fruits and vegetables; history of alcohol or drug abuse. Exclusion criteria for the study ulcer: Undermining or serious sinus tracts ≥1.0 cm; clinical or laboratory signs of infection; required topical medications; required debridement; ulcer present for more than 3 months before study enrollment.	NR/NR/10/10	Age (Mean): NR Female: NR Race: NR	Stage II: N=3, Stage III: N=7,
Stoker, 1990[91] UK Poor	Observational	NR	NR	NR	NR/NR/42/29 (PU N=36)	Age (Mean): 70 years Female: NR Race: NR	Stage I: N=1 Stage II: N=16 Stage III: N=15 Stage IV: N=4 Location: Left Heel: N= 3 Right Heel: N=3 Left Buttock: N=6 Right Buttock: N=5 Buttock: N=6 Sacrum: N=10 Left Ankle: N=1 Right Foot: N=1

Evidence Table H-5b: Dressings Observational Studies, continued							
Author, year Country Overall Quality Rating	**Treatment A**	**Treatment B**	**Treatment C**	**Duration of Treatment/Followup**	**Study setting**	**Author, year Country Overall Quality Rating**	**Treatment A**
Viamontes, 2003[92] US Poor	Observational	Patients in the database who had a PU, venous ulcer, diabetic ulcer, or traumatic wound that was treated with either the hydrocellular or soft-silicone dressing or both dressings on at least one occasion	NR	NR/NR/1,891/1,891 (PU N=4,200)	Local Wound Application: Dressing	Age (Mean):82 years Female: NR Race: NR	Of 4,200 wounds included in the study 3,969 were PU (94%)

Evidence Table H-5b: Dressings Observational Studies, continued					
Author, year **Country** **Overall Quality Rating**	**Treatment A**	**Treatment B**	**Treatment C**	**Duration of Treatment/Followup**	**Study setting**
Meaume, 2007[88] France Fair	Dressing, Urgotul Duo a new dressing composed of an Urgotul interface (polyester textile support impregnated with hydrocolloid particles and Vaseline in contact with the wound bed) and a 100% viscose, gas permeable and neutral absorbent.	NA	NA	4 weeks	11 Hospitals
Moody, 1991[89] US Poor	Dressing, Kaltoclude- a pad of calcium sodium alginate fiber	NA	NA	8-15 days	Hospital
Parnell, 2005[90] Country Not Reported Poor	Dressing: Hydrovase- a greaseless, glycerin hydrogel that contains a combination of endopeptidase enzymes and is designed to maintain a moist wound environment for a minimum of 24 hours.	NA	NA	12 weeks	Nursing homes
Stoker, 1990[91] UK Poor	Dressing: Comfeel Pressure Relieving Dressing	NA	NA	Until wound healing was complete	Hospital
Viamontes, 2003[92] US Poor	Hydrocellular dressing N (wounds)= 3,795	Soft silicone dressing N (wounds)=352	Both dressings N (wounds)=53	Data was gathered retroactively for a 5 year period	Nursing home

Evidence Table H-5b: Dressings Observational Studies, continued								
Author, year Country Overall Quality Rating	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis Rate**	**Outcomes: Recurrence Rate**	**Outcomes: Pain**	**Other Outcomes: Specify**
Meaume, 2007[88] France Fair	Treatment A: 14.2% healed	Treatment A: Mean PU surface area reduced by 74.8%	Treatment A: 1 PU healed after 21 days of treatment	NR	NR	NR	NR	Treatment A: In 100% of PU cases, perilesional skin was considered to be healthy" vs. 55% "healthy" at the start of the trial
Moody, 1991[89] US Poor	N=4 PU healed	NR	NR	NR	NR	NR	All patients reported the dressing was comfortable	NR
Parnell, 2005[90] Country Not Reported Poor	Treatment a:50% (n=5)	Treatment A: NR, though authors report four Stage III ulcers "improved"	Treatment A: Average healing time: Stage II: 3.3 weeks (range 1-7 weeks) Stage III: 6.5 weeks	NR	NR	NR	NR	NR
Stoker, 1990[91] UK Poor	NR	Treatment A:Mean percent change per day in trial: Buttock: 3.1091 cm^2 SD 9.5641 Sacrum: -.0346 cm^2 SD 2.0187 Heel: -1.8405 cm^2 SD 4.8918	Treatment A: Mean % change (excluding two patients who healed within the first two weeks of the trial): 1.66% per day	NR	NR	NR	NR	NR
Viamontes, 2003[92] US Poor	Treatment A: 1,996 of 3,792 (53%) wound closed completely. Treatment B: 152 out of 351 (50%) wounds closed completely. Note: Authors do not present data for the subgroups of wounds (Pressure vs. traumatic vs. diabetic ulcers)	NR	Average treatment time (for all groups) 71.3 days (range 5-1386 days)	NR	NR	NR	NR	NR

Evidence Table H-5b: Dressings Observational Studies, continued									
Author, year Country Overall Quality Rating	**Harms: Pain**	**Harms: Dermatologic Complications**	**Harms: Bleeding**	**Harms: Infection**	**Other Harms: Specify**	**Serve Adverse Events**	**Withdrawal due to Adverse Events**	**Overall Adverse Events Rate**	**Funding Source**
Meaume, 2007[88] France Fair	NR	NR	NR	NR	NR	NR	NR	NR	NR
Moody, 1991[89] US Poor	NR	NR	NR	NR	NR	NR	NR	NR	NR
Parnell, 2005[90] Country Not Reported Poor	NR	NR	NR	NR	NR	NR	NR	NR	NR
Stoker, 1990[91] UK Poor	Treatment A: Found the dressing uncomfortable n=1	Treatment A: Rash related to dressing, n=1	NR	NR	NR	NR	2 patients (dressing uncomfortable and rash)	NR	Coloplast Ltd.
Viamontes, 2003[92] US Poor	NR	Treatment A: 12 PU experienced skin stripping Treatment B: 4 PU experienced skin stripping	NR	Treatment A:35 (n=76) Treatment B: 9% (n=23)23 out of 265 (9%) Note: Authors do not present data for the subgroups of wounds (Pressure vs. traumatic vs. diabetic ulcers)	Skin stripping: Treatment A: <1% (n=13) Treatment B: 2% (n=4)	NR	NA	3% (n=116)	NR

Abbreviations: LONG-TERM CARE, long-term care; NR, not reported; PU, pressure ulcer.

Evidence Table H-5c. Topical application trials

Author, year Country Overall Quality	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/ Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Duration of Treatment/ Followup	Study Setting
Agren, 1985[93] Sweden Poor	Geriatric patients with one or more necrotic PU	NR	NR/NR/28/28	Age (Median): 84 vs. 86 years Female: 64% vs. 78% Population: elderly	Local Wound Application: Topical	Stage III Location: Trochanter, ischial, knee, foot, lower leg, other	Topical streptokinase-streptodor-nase (Varidase) – 100,000 IU streptokinase + 25,000 IU streptodor-nase dissolved into 20 ml sterile isotonic saline solution and applied on a sterile gauze compress Dressings changed 2x/day for 8 weeks	Zinc oxide – premedicated compresses with 400 mcg ZnO/cm^2 Dressings changed 1x/day for 8 weeks	NA	8 weeks/NR	(Mixed) Hospitals/ outpatient

Evidence Table H-5c: Topical Application Trials, continued											
Author, year Country Overall Quality	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type**	**Ulcer Type/ Severity at Baseline (Intervention Onset)**	**Treatment A**	**Treatment B**	**Treatment C**	**Duration of Treatment/ Followup**	**Study Setting**
Alvarez, 2000[94] US Fair	>18 years of age; completed two week screening period to stabilize the wound and institute physical and supportive therapies. PU must require debridement and must have nonviable tissue attached to the base of the wound.	Infection, cellulitis, osteomyelitis, inadequate nutrition, uncontrolled diabetes and other significant medical conditions that would impair wound healing including renal, hepatic, hematologic, neurological or immunological disease. Receiving corticosteroids, immunosuppressive agents, radiation or chemotherapy within one month prior to entry into the study.	NR/ NR/ 22/ 21	Age (Mean): 82 years Female: 50% vs. 36.4% Race: NR	Local Wound Application: Topical	Depth-stage Partial thickness-II: 1 vs. 2 Full thickness-III-IV: 9 vs. 9	Collagenase debriding ointment - 250 bacterial collagenase units/g applied over surface of nonviable tissue 1x/day and covered with dry gauze dressing	Papain/urea debriding ointment containing papain $1.1x10^6$ units of activity per gram and urea 100 mg per gram	NA	4 weeks	Nursing home
Burgos, 2000(a)[95] Spain Good	Hospitalized or institutionalized patients of either gender aged 55 years or over; APAUP Stage III PU for <1 year.	End-stage diseases, localized or systemic signs and/or symptoms of infection or hypersensitivity to collagenase.	NR/NR/102/86	Age (Mean) 78.8 years Female 64.7% Race: NR	Local Wound Application: Topical	All stage III Location: Sacrum: 44% (N=8) vs. 37% (N=7) Trochanter: 22% (N=4) vs. 21% (N=4) Heel: 17% (N=3) vs. 32% (N=6) Other: 14% (N=5) vs. 11% (N=2)	Collagenase ointment application - at 24-hour intervals for a maximum of 8 weeks (or until complete healing of the ulcer, whatever occurred first).	Collagenase ointment application - at 48-hour intervals for a maximum of 8 weeks (or until complete healing of the ulcer, whatever occurred first).	NA	8 weeks/NR	Hospital or institution

Evidence Table H-5c: Topical Application Trials, continued											
Author, year Country Overall Quality	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type**	**Ulcer Type/ Severity at Baseline (Intervention Onset)**	**Treatment A**	**Treatment B**	**Treatment C**	**Duration of Treatment/ Followup**	**Study Setting**
Burgos, 2000(b)[96] Spain Fair	Either gender 55 years old or over Presenting stage III PU for <1 year.	End-stage organ disease Localised or systemic signs and/or symptoms of infection (fever, local erythema, regional lymph node swelling) Hypersensitivity to collagenase.	NR/43/37/37	Age (Mean): 80 (range 55-96) Female: 54% female Race: NR	Local Wound Application: Dressing	Stage III only Location:: Sacrum: 41% (N=15) Trochaner: 22% (N=8) Heel: 24% (N=9) Other: 14% (N=5)	Collagenase ointment (Iruxol® Mono, Laboratorios Knoll, SA) applied once daily in a 1 to 2mm thick layer to the ulcer bed	Application of a hydrocolloid dressing (Varihesive®, Convatec, SA) that was changed every 3 days.	NA	12 weeks or complete healing of PU	Hospitals
Chuangsuwanich, 2011[54] Thailand Fair	In and out patients with PU staged II or IV (NPAUP scale)	NR	NR/NR/40/40	Age (Mean): 66 years Female: 58% Race: NR	Local Wound Application: Topical	Location: Sacrum: N=14 vs. N=16 Rt. Greater Trochanteric: N= 3 vs. N=1 Lt. Greater Trochanteric: N=2 vs. N=2 Rt. Ischium: N=1 vs. N=2	Silver sulfide cream covering wound, changed twice daily N=20	Silver mesh covering wound changed every three days N=20	NA	8 weeks	Siriraj Hospital
Felzani, 2011[97] Italy Poor	Hospitalized patients of both sexes, aged >18 years, with foreseen hospitalization period of >15 days, with stage I-III decubitus ulcers	Patients unable to co-operate with hygienic measures to be adopted for treatment of sores, those with history of intolerance to hyaluronic acid, those in need of concomitant local and/or general antibiotic therapy for skin lesions or for systemic disease	NR/59/ 50/ 50	Age (Mean): 56 years Female: 58% Race: NR	Local Wound Application: Topical	Grouped by stages; Stage I, Stage II, Stage III	Sodium hyaluronate acid plus standard of care (nutrition supplements, patient mobilization) Stage 1: n=10 Stage 2: n=10 Stage 3: n=7	Lysine hyaluronate acid plus standard of care Stage 1: n=10 Stage 2: n=10 Stage 3: n=7	NA	15 days of treatment	Hospital

Evidence Table H-5c: Topical Application Trials, continued											
Author, year Country Overall Quality	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type**	**Ulcer Type/ Severity at Baseline (Intervention Onset)**	**Treatment A**	**Treatment B**	**Treatment C**	**Duration of Treatment/ Followup**	**Study Setting**
Gerding, 1992[98] US Poor	Newly diagnosed stage I or II skin lesion and treatment with an emollient ordered by the attending physician. Patients with one or more lesions were included.	NR	NR/NR/74/74 patients(137 ulcers)	Age (Mean): NR Female: NR Race: NR	Local Wound Application: Topical	Stage I: N=69 Stage II: N=68 (Shea stage)	Oxyquinoline-containing ointment (DermaMend) Stage I: n=29 residents, 41 lesions Stage II: n=26 residents, 45 lesions	A&D ointment Stage I: n=14 residents, 28 lesions Stage II: n=13 residents, 23 lesions	NA	28 days after initial treatment or until wound resolution	Long term care facilities
Graumlich, 2003[99] US Good	18 years and older; at least one PU, stage II or III	Hypersensitivity to collagen or bovine products; concomitant investigational therapy; osteomyelitis; cellulites; malnutrition; ulcers covered by eschar or necrotic material; ulcers covered by orthopedic casts or devices; burn ulcers; diabetic ulcers.	NR/NR/NR/65	Age (Mean): 81 years Female: 80% Race: NR	Local Wound Application: Topical	Stage II, III	Topical collagen applied 1x/day for 8 weeks	Hydrocolloid applied 2x/week for 8 weeks	NA	8 weeks/Median Follow-up 35 days	Nursing Home
Guthrie, 1989[100] US Fair	Patients with Shea stage 1 – 4 ulcers who resided at nursing homes in Lackawanna and Luzerne counties (Pennsylvania, USA)	Patients with known sensitivity to ingredients in the test product or who suffered chronic renal disease.	NR/NR/128/58	78 years Female: 81% Race: NR	Local Wound Application: Dressing	Stage I-IV	Combination - Dermagran Spray and Dermagran ointment applied and wound evaluated 1x/ week for 42 days	Demagran spray only	Dermagran ointment only	Placebo	Nursing home

Evidence Table H-5c: Topical Application Trials, continued											
Author, year Country Overall Quality	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type**	**Ulcer Type/ Severity at Baseline (Intervention Onset)**	**Treatment A**	**Treatment B**	**Treatment C**	**Duration of Treatment/ Followup**	**Study Setting**
Hollisaz, 2004[101] Iran Good	Paraplegia caused by spinal cord injury; PU stage I and II (Shea classification or NPUAP); informed consent; smoothness of ulcer area to establish whether adhesive could be used at the site.	(Addiction; heavy smoking (more than 20 cigarettes a day or more than 10 packs per year); concomitant chronic disease (e.g. diabetes mellitus or frank vascular disease such as Buerger's disease).	2015/151/83/ 83	Age (Mean): 37 years Female;' 0% Race NR	Local Wound Application: Topical	Stage I: N=13 vs. N=9 vs. N=11 Stage II: N=18 vs. N=21 vs. N=19	Hydrocolloid	Phenytoin cream	Simple dressing	4 months after completion of 8 week trial	Other
Hsu, 2000[102] Japan Poor	In patients with "the largest and deepest" ulcers	NR	NR/NR/32/32	Age (Mean): 71 years Female: 59% Race: NR	Local Wound Application: Topical	NR	Sheng-Ji-San formula plus routine medical care	Routine medical care	NA	3 weeks of treatment	Hospital
Kuflik, 2001[103] US Poor	Elderly, immobile patients with Stage I or Stage II ulcers	Patients with PU who also had complex underlying etiologies like venous stasis, severe diabetes	NR/NR/20/15 patients (16 ulcers)	Age (Mean): Elderly, no further details reported Female: Males and females, no further details reported Race: European back-ground, no further details reported	Local Wound Application: Topical	Stage I: N=6 vs. N=6Stage II: N=4 vs. N=2	Resurfix ointment plus nutrition, n=10 patients, 11 ulcers at start; n=8 patients, 9 ulcers at end of study	Petrolatum ointment plus nutrition, n=9 patients, 9 ulcers at start; n=7 patients, 7 ulcers at end of study	NA	6 weeks	Rehabilitation Center and Nursing Center (two sites)

Evidence Table H-5c: Topical Application Trials, continued											
Author, year Country Overall Quality	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type**	**Ulcer Type/ Severity at Baseline (Intervention Onset)**	**Treatment A**	**Treatment B**	**Treatment C**	**Duration of Treatment/ Followup**	**Study Setting**
Levasseur, 1991[104] Australia Poor	NR	NR	NR/NR/34/21 patients (21 ulcers)	Age (Mean): 82 Female: 52% Race: NR Population: elderly	Local Wound Application: Topical	Stage 1,11 (Shea) Location: Iliac crest: N=1 vs. N=0 Greater Trochanter: N=1 vs. N=0 Ischium: N=4 vs. N=4 Lateral Malleolus: N=2 vs. N=2 Sacrum: N=0 vs. N=5 Foot: N=0 vs. N=2 Lower leg: N=0 vs. N=1	F14001 (active based cream)	Placebo (non active based cream)	NA	6 weeks	Hospital and Long-term care
Muller, 2001[105] Germany and The Netherlands Poor	Inpatients with stage IV pressure sores on the heel following orthopaedic surgery	Patients with a life expectancy of less than 6 months	NR/NR/24/23	Age (Mean): 73 years Female: 100% Race: NR	Local Wound Application: Topical	All patients had stage IV pressure sores on the heel	Collagenase ointment - treated once a day with a collagenase-containing ointment (Novuxol®), paraffin gauze (Jelonet®) and absorbent bandages after the wound had been cleaned with saline 0.9%. N= 12	Hydrocolloid dressing (DuoDerm ®) twice a week. N=11	NA	treatment continued until total epithelialization was achieved	Hospital

Evidence Table H-5c: Topical Application Trials, continued											
Author, year Country Overall Quality	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type**	**Ulcer Type/ Severity at Baseline (Intervention Onset)**	**Treatment A**	**Treatment B**	**Treatment C**	**Duration of Treatment/ Followup**	**Study Setting**
Nisi, 2005[106] Italy Poor	NR	Decompensating diabetes, hypertension, severe hypoalbuminosis(<3.00 g/100ml), clinical evidence of arterial or venous insufficiency, hematocrit values <41% for males and 36% for females, treatments with steroids or immunosuppressive drugs	NR/NR/80/80	Age (Mean): 45 years Female: 34% Race: NR	Local Wound Application: Topical	NR	Protease-modulating matrix BID or TID (consisting of 55% freeze-dried collagen and 45% oxidized regenerated cellulose Promogran) according to wound exudation + covering with hydropolymer patch	50% povidone iodine solution, saline wash, positioning of viscose-rayon gauze soaked in white Vaseline and covering with a hydropolymer patch.	NA	NR	Hospital
Pullen, 2002[107] Germany Fair	Patients with Seiler stage 2,3, or 4 PU with fibrinous and/or necrotic slough	History of alcohol or drug dependency, hypersensitivity to collagenase or fibrinolysin/DNAse, planned co-medication with local antiseptics, antibiotics, occlusive wound dressings, hydrogels, or hydrocolloids PU covered with black eschar only or whose localization did not permit parallel positioning of the reference scale	NR/NR/135/121	Age (Mean): 79 years Female: 51% vs. 47% Population: Elderly	Local Wound Application: Topical	Stage I, II, IV (Seiler stage 2, 3, or 4)	Collagenase, N= 60	Fibrinolysin and deoxyribonuclease (DNAse), N=61	NA	4 weeks	Hospital

Evidence Table H-5c: Topical Application Trials, continued											
Author, year Country Overall Quality	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type**	**Ulcer Type/ Severity at Baseline (Intervention Onset)**	**Treatment A**	**Treatment B**	**Treatment C**	**Duration of Treatment/ Followup**	**Study Setting**
Rhodes, 2001[108] US Poor	>60 years old Stage II PU	Wound infection, anemia, malnutrition, folate deficiency, chronic use of immunosuppressant medications, receiving or having a history of adverse effect caused by oral phenytoin	NR/NR/47/39 PU N=47	Age (Mean): 78 years Female: 8% Population: elderly	Local Wound Application: Topical	Stage II	Topical Phenytoin	Collagen Dressing (DuoDerm)	Triple antibiotic ointment	8 weeks or complete wound healing	Long-term care
Sayag, 1996[109] France Good	>60 and had been hospitalized for at least 8 weeks with a stage II or IV PU (Yarkony classification)	More than half the ulcer area comprised of granulated tissue, if the PU was covered with necrotic plaque, or if there was active infection. Renal failure requiring dialysis or heel ulcers combined with end stage arteriopathy of the lower limbs.	NR/NR/92/92 PU N=92	Age (Mean): 81 years Female: 74% Race: NR Population: elderly, limited mobility	Local Wound Application: Topical	Yarkony's classification: Stage III: 70% (N=33) vs. 67% (N=30) Stage IV: 30% (N=14) vs. 33% (N=15) Location: Pelvis area: 30%(N=14) vs. 51% (N=23) Heel: 64%)N=30) vs. 49% (N=22) Other: N=3 (6%)	Calcium alginate, N=47	Dextranomer, N=45	NA	8 weeks	Long-term care and dermatology centers
Shamimi Nouri, 2008(a)[110] Iran Poor	18 years and older with PU; PU size must be at least 1cm² with occurrence within the last 2 weeks.	Acute infection or bone exposure; presence of disease or situation that would impair ulcer improvement; alcohol and drug abuse, dialysis and renal failure, corticosteroid consumption, use of immune suppressive agents, radiotherapy, chemotherapy and drug hypersensitivity.	NR/18/18/18	Age (Mean): 47 Female: 22% Race: NR	Local Wound Application: Topical	NR	Herbal extract, topical Semelil (Brand name ANGIPARS) 3% gel daily	Conventional treatment	NA	1 year	Hospital

Evidence Table H-5c: Topical Application Trials, continued											
Author, year Country Overall Quality	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type**	**Ulcer Type/ Severity at Baseline (Intervention Onset)**	**Treatment A**	**Treatment B**	**Treatment C**	**Duration of Treatment/ Followup**	**Study Setting**
Sipponen, 2008[111] Finland Poor	Patients with one or several severe PU (stage II-IV) with or without infection, not considered suitable for surgical treatment	NR (dropouts were not included in any data at baseline or end of study)	NR/ NR/37/ 22	Age (Mean): 77 years Female: 59% Race: NR	Local Wound Application: Topical	Stage II: 39% (N=7)vs. 45%(N=5) Stage III: 50% (N=9) vs. 45%(N=5) Stage IV: 11%(N=2) vs. 9%(N=1)	Norway spruce resin mixed with butter for 6 months Dressing changed daily if ulcer was infected or producing discharge and changed every third day otherwise n=21 patients, 27 ulcers at baseline; n=13 patients, 18 ulcers at end of study	Sodium carboxymethylcellulose hydrocolloid polymer without or with ionic silver (Aquacel+/-Ag); silver used when ulcer found to be infected on bacterial culture for 6 months Dressing changed daily if ulcer was infected or producing discharge and changed every third day otherwise for 6 months n=16 patients, 18 ulcers at baseline; n=9 patients, 11 ulcers at end of study	NA	6 months	Primary care hospitals

Evidence Table H-5c: Topical Application Trials, continued											
Author, year Country Overall Quality	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type**	**Ulcer Type/ Severity at Baseline (Intervention Onset)**	**Treatment A**	**Treatment B**	**Treatment C**	**Duration of Treatment/ Followup**	**Study Setting**
Subbanna, 2007[112] India Good	Paraplegic patients aged 10 to 55 years with stage 2 PU without necrotic tissue	Anemia, hypoalbuminemia, elevated serum creatinine, abnormal liver function tests, history of smoking, peripheral vascular disease, diabetes mellitus, malignancy, connective tissue disorders, psychiatric illness	43/28/28/26	Age (Mean):33 Female: 12% Race: NR	Local Wound Application: Topical	PUSH 3.0 mean rating: 13.5+/-1.16 vs. 13.21+/-1.42	Treatment: Phenytoin solution daily for 15 days n=14 enrolled, 12 analyzed	Comparator: Normal saline solution daily for 15 days n=14 enrolled and analyzed	NA	15 days of treatment, measures on Day 1 before treatment and Day 16	Hospital
Tytgat, 1988[113] Belgium Poor	Multiple sclerosis patients with decubitus ulcers	NR	NR/NR/16/16	Age (Mean): 59 years Female: 50% Race: NR	Local Wound Application: Topical	NR	Ketanserin 2%	Placebo	NA	3 weeks	NR
Zeron, 2007[114] Mexico and Spain Poor	65 years and older with stage II or III pressure ulcer	Prior surgical treatment of PU, septic state; mechanical breathing support; state of coma or brain death; ingestion of steroids; abandonment of the patient by their family.	NR/NR/NR/24	Age (Mean): 79 Female: 79% Race: NR Population: general	Local Wound Application: Topical	NR	Zinc oxide paste + collagen-polyvinylpyrrolidone (clg-pvp) - a total of 1.5 ml of medication was injected intradermally into the patient, equally applied at four points equidistant from the edges of the wound applied 1x week for 3 weeks	Zinc oxide paste + placebo (not described) - a total of 1.5 ml of placebo was injected intradermally into the patient, equally applied at four points equidistant from the edges of the wound applied 1x week for 3 weeks	NA	3 weeks/3 weeks	Hospital

Evidence Table H-5c: Topical Application Trials, continued								
Author, year Country Overall Quality	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis Rate**	**Outcomes: Recurrence Rate**	**Other Outcomes: Specify**	**Harms: Pain**
Agren, 1985[93] Sweden Poor	NR	Disappearance of necrotic tissue: Treatment A: 43% Treatment B: 50% Wound area reduction: Treatment A: 18.7% Treatment B: 2.4%	NR	NR	NR	NR	NR	NR

Evidence Table H-5c: Topical Application Trials, continued								
Author, year Country Overall Quality	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis Rate**	**Outcomes: Recurrence Rate**	**Other Outcomes: Specify**	**Harms: Pain**
Alvarez, 2000[94] US Fair	NR	% reduction in wound area from baseline with (SD) Treatment A: Week 1: 1.9 (7.6) Week 2: 23.7 (25.8) Week 3: 34.8 (25.2) Week 4: 55.4 (33.5) Treatment B: Week 1: 5.8 (17.4) Week 2: 19.9 (29.2) Week 3: 27.3 (28.5) Week 4: 33.9(26.17)	Mean time to 50% granulation (time in days for 50% of the wounds to be covered by granulation tissue): Treatment A: 6.8 Treatment B: 28 No significant difference in healing rates between 2 groups	Treatment A: Bacterial count at baseline 5.6 CFU/mL Bacterial count at 4 weeks 4.6CFU/mL Treatment B: Bacterial count at baseline 5.4CFU/mL Bacterial count at 4 weeks: 5.0 CFU/mL	NR	NR	Treatment A vs. B: Reduction in non-viable tissue: 2 weeks: 68.3% vs. 22.3% 3 weeks: 86.5% vs. 37.3%, ($p<0.05$) 4 weeks: 95.4% vs. 35.8%, ($p<0.01$) % reduction in area of necrotic tissue (slough) from baseline: Week 3: 73.4 vs. vs. 32.7, Week 4: 93.3 vs. 34.0 % reduction in area of necrotic tissue (eschar) from baseline: Week 3: 90.8 vs. 46.7 Week 4: 98.5 vs. 43.1 % reduction of necrotic tissue by planimetry from baseline: Week 1: 13.5 vs. 7.5 Week 2: 68.3 vs. 22.3 Week 3: 86.5 vs. 37.3 ($p<0.05$)Week 4: 95.4 vs. 35.8 ($p<0.01$) Debridement of necrotic tissue by clinical evaluation: Week 1: 3.9 vs. 2.0 Week 2 4.5 vs. 2.0 Week 34.9 vs. 2.2, Week 4 5.5 vs. 1.3 (Relative score 1=76-100%, covered with necrotic tissue, 2=51-75%, 3=26-50%, 4=11-25%, 5=1-10%, 6=none) Overall wound response 4.5 vs. 1.1 9$p<0.01$, (0=wound deteriorated, 1=no change, 2=minimal change, 3=average improvement, 4=significant improvement, 5=necrotic tissue resolved.	NR

Evidence Table H-5c: Topical Application Trials, continued								
Author, year Country Overall Quality	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis Rate**	**Outcomes: Recurrence Rate**	**Other Outcomes: Specify**	**Harms: Pain**
Burgos, 2000(a)[95] Spain Good	Closure and epithelialization: Treatment A: n=12 Treatment B: n=9 : (p=0.451)	ITT analysis: Change from baseline in wound area at 8 weeks (24 hour interval): - Treatment A: 5.1 cm^2 Treatment B: 6 cm^2 Change from baseline in both groups (p<0.0005) Difference between 2 groups: (p=0.641) Per Protocol analysis: Change from baseline in wound area at 8 weeks (24 hour interval): - Treatment A: 5.4 Treatment B: 7cm^2 Change from baseline in both groups (p<0.0005) Difference between 2 groups: (p=0.595)	NR	NR	NR	NR	Granulation tissue formation increased p<0.0005 and exudate production decreased in both groups (Treatment A, p=0.012, Treatment B, p=0.04)	Treatment A: ITT analysis: Pain intensity decrease from baseline (p=0.001) Difference between Treatment A and B favored 24 hour interval group: (p=0.004) Per protocol analysis: pain intensity decrease from baseline (p=0.001) Difference between treatment A vs. B=NS Treatment B: Pain intensity decrease from baseline, NS ITT and Per protocol analysis

Evidence Table H-5c: Topical Application Trials, continued								
Author, year Country Overall Quality	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis Rate**	**Outcomes: Recurrence Rate**	**Other Outcomes: Specify**	**Harms: Pain**
Burgos, 2000(b)[96] Spain Fair	Treatment A: N=3 Treatment B: N=3 (p=0.451)	Collagenase group: Mean reduction in PU size: Treatment A: 9.1 cm2 Treatment B: 6.2 cm2 Total ulcer area reduction: Treatment A: 44% Treatment B: 28% (p=0.369)	NR	NR	NR	NR	Decrease in pain in treatment A compared with treatment B (p=0.001)	NR
Chuangsuwanich, 2011[54] Thailand Fair	NR	Treatment A: 18.22 cm^2 at week 8 Treatment B: 7.96 cm^2 at week 8 (p=0.09)	Treatment A: Healing rate 25% Treatment B: Healing rate 37% p=value 0.51	NR	NR	NR	PUSH Score reduction: Treatment A: 34.51% Treatment B: 28.15% (p=0.473)	NR

Evidence Table H-5c: **Topical Application** **Trials, continued**								
Author, year **Country** **Overall Quality**	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis Rate**	**Outcomes: Recurrence Rate**	**Other Outcomes: Specify**	**Harms: Pain**
Felzani, 2011[97] Italy Poor	–Treatment A: 15 days of treatment: Group 1 (stage 1 ulcers): Healing of 90% of the lesion 100% (n=10) Group 2 (stage 2 ulcers): Healing of 70% of the lesion 100% (n=10) Group 3 (stage 3 ulcers): healing of 100%(n=5) Treatment B: 15 days of treatment: Group 1 (stage 1 ulcers): Healing of 70% of the lesion in 50%(n=10) Group 2 (stage 2 ulcers): Healing of 40% of the lesion in 100%(n=10) Group 3 (stage 3 ulcers):100% (n=2)	NR	Treatment A: treatment period necessary to reach 50% Regression Group 1 - 9 days Group 2 - 9.5 days Group 3 - 12.9 days Treatment B: treatment period necessary to reach 50% Regression Group 1 - 15 days, $p<0.05$ Group 2 - 15 days, $p<0.05$ Group 3 - 19.2 days, $p<0.05$	NR	NR	NR	NR	NR
Gerding, 1992[98] US Poor	<u>Treatment A:</u> <u>Resolved lesions (%)</u> Stage I: 58.5% Stage II: 44.5% Treatment B: <u>Resolved lesions (%)</u> Stage I: 57.1% Stage II: 21.8%, ($p<0.03$)	NR	<u>Treatment A:</u> <u>Day to resolve</u> Stage I: 6.2 Stage II: 7.8 Treatment B: <u>Days to resolve</u> Stage I: 7.3 Stage II: 13.0, ($p<0.05$)	NR	NR	NR	Treatment A vs. B: <u>No change lesions (%)</u> Stage I: 9.8 vs. 14.3 Stage II: 11.1 vs. 30.4 <u>Worse lesions (%)</u> Stage I: 0 vs. 7.2 Stage II: 2.2 vs. 13.0 <u>No change/worse (%)</u> Stage I: 9.8 vs. 21.5 Stage II 13.3 vs. 43.4	NR

Evidence Table H-5c: Topical Application Trials, continued								
Author, year Country Overall Quality	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis Rate**	**Outcomes: Recurrence Rate**	**Other Outcomes: Specify**	**Harms: Pain**
Graumlich, 2003[99] US Good	Treatment A: 51% Treatment B: 50% (p=0.89)	NR	Area healed per day: (mm2/day, mean, SD) Treatment A: -6 Treatment B: 6 (p=0.94)	NR	NR	NR	NR	NR
Guthrie, 1989[100] US Fair	NR	Decrease in size: Treatment A: 90.7% Treatment B: 6.7% Treatment C: 25.9%	NR	NR	NR	NR	NR	NR
Hollisaz, 2004[101] Iran Good	All stages: Treatment A compared to Treatment B. [74.19% (n=23) vs. 12/30 (40%); difference 34.19% (p < 0.01)]. Stage I: Treatment A [11/13 (85%)] was also better than Treatment C [5/11 (45%); difference 40%, 95% (p < 0.05)] or Treatment B [2/9 (22%); difference 63%, 95%, (p < 0.005)]. Stage II: Treatment A [12/18 (67%)] than in the Treatment C [3/19 (16%); difference 51%, 95% (p<0.005], but there was no significant difference from Treatment B [10/21 (48%); difference 19%; 95% CI, -11.47 to 49.47 (p >0.05).	NR	NR	NR	NR	NR	NR	NR

Evidence Table H-5c: Topical Application Trials, continued								
Author, year Country Overall Quality	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis Rate**	**Outcomes: Recurrence Rate**	**Other Outcomes: Specify**	**Harms: Pain**
Hsu, 2000[102] Taiwan Poor	Effective treatment=complete or incomplete healing: Treatment A: Effective treatment- 83 % (n=20), Complete healing- 5% (n=1) Treatment B: Effective treatment - 37% (n=3) Complete healing- 0% (n=0)	Treatment A: Decreased surface area from 26.71+/-29.37 cm^2 to 18.33+/-28.28 cm^2, ($p<0.005$) Reduction ratio of surface area (RSA) = (initial area - final area) / initial area x 100% RSA = 33.83%=/-33.32% Treatment B: Increased surface area from 35.09+/-40.35 cm^2 to 41.59+/-53.11 cm^2, not significant RSA = -2.85%+/-47.54%, ($p<0.05$) compared to Treatment A	NR	NR	NR	NR	Effective ratio (ER) = Number effectively treated / Number treated x 100% Treatment A: 83% Treatment B: 38% ($p<0.05$) Multivariate analysis performed to account for age, gender, disease type and SJS as independent variables; only SJS had significant correlation with RSA, p=0.03 and ER, OR 9.5, 95% CI, 1.41 to 64.6	NR
Kuflik, 2001[103] US Poor	Treatment A: 50% (n=10) 5/10 (4 Stage I, 1 Stage II) Treatment B: 22% (n=2)(both Stage I)	Mean size after treatment, cm/diam: Treatment A: 0.9 (those who terminated treatment not included, n=2) Treatment B: 1.8 (those who terminated treatment not included, n=2)	NR	NR	NR	NR	Erythema noted in tables by ulcer, but no collapsed data available	NR
Levasseur, 1991[104] Australia Poor	NR	Based on repeated measures over six weeks there was reduction in both groups (size not specified) ($p <.001$)	Treatment A: 18 days Treatment B: 29 days ($p=0.08$)	NR	NR	NR	NR	NR

Evidence Table H-5c: Topical Application Trials, continued								
Author, year Country Overall Quality	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis Rate**	**Outcomes: Recurrence Rate**	**Other Outcomes: Specify**	**Harms: Pain**
Muller, 2001[105] Germany and The Netherlands Poor	Treatment A: 91.7%(N=11) Treatment B: 63.6%(N=7)	NR	Treatment A: wound healing ranged from 6 to 12 weeks, mean 10 weeks Treatment B: wound healing ranged from 11-16 weeks, mean 14 weeks	NR	NR	NR	NR	NR
Nisi, 2005[106] Italy Poor	Treatment A: 90% Treatment B: 70% (p=0.59)	NR	Time to wound healing (2nd phase results) Treatment A: 2-6 weeks Treatment B: 2-8 weeks	NR	NR	NR	Treatment A vs. B: 2nd phase results No. of dressings performed: n= 6-15 vs. 14-52 Overall hospitalization (days): 360 vs. 1164	NR
Pullen, 2002[107] Germany Fair	NR	Decrease in necrotic wound area Treatment A: 61.7%(n=37) Treatment B: 57.4%(n=35)	NR	NR	NR	NR	NR	NR
Rhodes, 2001[108] US Poor	NR	NR	Mean time to healing in days: Treatment A: 35, Treatment B: 52 Treatment C: 54 (p=0.005)	NR	NR	Treatment A: One patient had ulcers that continually recurred after healing	New healthy granulation tissue appearance: Treatment A: 2-7 days Treatment B: 6-21 days	NR
Sayag, 1996[109] France Good	75% healed at 8 weeks: Treatment A: 32% Treatment B: 13%	Treatment A: 40% reduction in wound area: 74% Treatment B: Dextranomer: 40% reduction in wound area: 42%	Mean reduction in surface area per week: Treatment A: 2.39 cm^2 Treatment B: .27cm^2 (p=0.0001)	Treatment A: N=2 Treatment B: N=2	NR	NR	NR	Treatment A: 0 patients reported pain Treatment B: 5 patients reported pain

Evidence Table H-5c: Topical Application Trials, continued								
Author, year Country Overall Quality	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis Rate**	**Outcomes: Recurrence Rate**	**Other Outcomes: Specify**	**Harms: Pain**
Shamimi Nouri, 2008(a)[110] Iran Good	Treatment A: 67% of wounds healed Treatment B: 0%	Treatment A: Mean surface area reduced to 7.8cm² Treatment B: Mean surface area reduced to 16.7cm² (p=0.008)	Treatment A: 67% healed completely in 1 year 33% healed by 50-80% in 1 year Treatment B: 11% of patients had PU that healed by 50-80% in 1 year	NR	NR	NR	NR	NR
Siponnen, 2008[114] Finland Poor	Treatment A: 94% ulcers Treatment B: 44%(n=4), p=0.003	NR	Authors report: Speed of ulcer healing was significantly faster in treatment A group (p=0.013)	Treatment A: 1 month 10 ulcers with positive cultures, 1 patient given antibiotics Note: although not routinely done, 2 ulcers were positive for bacteria at 6 months Treatment B: 1 month 14 ulcers with positive cultures, 6 patients given antibiotics Note: no results shown at 6 months	NR	NR	Treatment A vs. Treatment B 6 months Width, mean (cm): 0.2 vs. 1.8 (p=0.011) Depth, mean (mm): 0.6 "Significantly better": 6% (n=1) vs.55% (n=6) "unimproved":0%(n=0) vs. 9% (n=1), (p=0.003)	NR

Evidence Table H-5c: Topical Application Trials, continued								
Author, year Country Overall Quality	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis Rate**	**Outcomes: Recurrence Rate**	**Other Outcomes: Specify**	**Harms: Pain**
Subbanna, 2007[112] India Good	NR	NR	NR	NR	NR	NR	Reduction in PUSH 3.0 rating (%), Treatment A vs. Treatment B 19.53vs. 11.39 difference 8.14), (p=0.261) Reduction in ulcer size (%), Treatment A vs. Treatment B 47.83vs. 36.03, difference 11.8 (p=0.132) Reduction in ulcer volume (%), Treatment A vs. Treatment B 53.94vs. 55.76, difference -1.81 (p=0.777)	NR
Tytgat, 1988[113] Belgium Poor	Mean epithelialization comparison with baseline: Treatment A: Week 1-1.8 (p=significant) Week 2-2.2 ((p=significant) Week 3- 2.3 (p=significant) Treatment B: Week 1-1.4 Week 2-:1.4 (p=significant) Week 3- 1.3	Treatment A: Reduction in wound area at 3 weeks: 81% (p=significant) Mean wound area (comparison with baseline) mm^2 Week 1--1255 (p=significant) Week 2- -2776 (p=significant) Week 3-3080 (p=significant) Treatment B: Placebo Reduction in wound area at 3 weeks: 16% Wound area (comparison with baseline) mm2 Week 1-155 Week 2--263 (p=significant) Week 3-195	NR	NR	NR	NR	Treatment A vs. Treatment B Mean change from baseline in granulation: Week 1- vs. 1.0 Week 2-1.6 vs. 1.0 Week 3-1.9 vs. 0.0 % of patients with pronounced granulation at Week 3: 75% vs. 0 Mean change from baseline in Erythema Week1- 0.5 vs. 0.2 Week 2- 0.4 vs. 1.3 ((p=significant) Week 3- 0.0 vs. 0.5	NR

Evidence Table H-5c: **Topical Application** **Trials, continued**								
Author, year **Country** **Overall Quality**	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis Rate**	**Outcomes: Recurrence Rate**	**Other Outcomes: Specify**	**Harms: Pain**
Zeron, 2007[114] Mexico and Spain Poor	Treatment A: 42% Treatment B: 33%	Reduction in ulcer size (mean): Treatment A: from 3.4 to 1.14 cm Treatment B: 2.9 to 1.58 cm (p= nonsignificant)	Treatment A: Mean ulcer reduction of 6.6mm/week Treatment B: NR	NR	NR	NR	NR	NR

Evidence Table H-5c: Topical Application Trials, continued								
Author, year Country Overall Quality	**Harms: Dermatologic Complications**	**Harms: Bleeding**	**Harms: Infection**	**Other Harms: Specify**	**Severe Adverse Events**	**Withdrawal due to Adverse Events**	**Overall Adverse Events Rate**	**Funding Source**
Agren, 1985[93] Sweden Poor	NR	NR	NR	NR	NR	NR	NR	NR
Alvarez, 2000[94] US Fair	NR	NR	Treatment A: Bacterial count at baseline 5.6 CFU/mL Bacterial count at 4 weeks 4.6 CFU/mL Treatment B: Bacterial count at baseline 5.4CFU/mL Bacterial count at 4 weeks: 5.0 CFU/mL	NR	NR	0	0	NR
Burgos, 2000(a)[95] Spain Good	Treatment A: 6.5% (n=3) in presented one adverse reaction each (rash, one patient; necrosis in ulcer bed, Treatment B: 24 hour group rash, necrosis in ulcer bed, ulcer worsening: 2.2% (each) 48 hour group necrosis in ulcer bed: 4.3%	NR	Treatment A: 0% (n=0) Treatment B: 2.2%(n=1)	NR	NR	Treatment A: n=1 Treatment B: N=2	Treatment A: 6.5% Treatment B 6.5%	Knoll SA, Madrid
Burgos, 2000(b)[96] Spain Fair	Treatment A: Dermatistis in 5.6% (n=1) of patients Treament B: Erythema and exudates increase in 5.2% (n=1) of patients	NR	Treatment A: Treatment B:	Treatment B: Erythema and odor increase in 5.2% (n=1) patients	NR	0	Relative risk of adverse reaction occurrence (RRC/H) was 0.500 (95% CI, 0.041 to 6.048)	NR
Chuangsuwanich, 2011[54] Thailand Fair	NR	NR	NR	NR	NR	NR	NR	NR

Evidence Table H-5c: Topical Application Trials, continued								
Author, year Country Overall Quality	**Harms: Dermatologic Complications**	**Harms: Bleeding**	**Harms: Infection**	**Other Harms: Specify**	**Severe Adverse Events**	**Withdrawal due to Adverse Events**	**Overall Adverse Events Rate**	**Funding Source**
Felzani, 2011[97] Italy Poor	NR	NR	NR	NR	NR	NR	NR	NR
Gerding, 1992[98] US Poor	NR	NR	NR	NR	NR	NR	NR	Supported in part by grant from InnoVisions, Inc.
Graumlich, 2003[99] US Good	NR	NR	NR	NR	NR	NR	NR	Retirement research foundation
Guthrie, 1989[100] US Fair	NR	NR	NR	NR	NR	NR	NR	NET/Ben Franklin Technology Center
Hollisaz, 2004[101] Iran Good	NR	NR	NR	NR	NR	NR	NR	Jaonbazan Medical and Engineering Research Center
Hsu, 2000[102] Taiwan Poor	NR	NR	NR	NR	NR	NR	NR	Funding from Department of Health
Kuflik, 2001[103] US Poor	NR	NR	NR	NR	NR	Treatment A: One patient with Stage II ulcer discontinued due to non-improvement without deterioration Treatment B: Two patients with Stage I ulcers terminated due to worsening	NR	Topix Pharmaceuticals, Inc.
Levasseur, 1991[104] Australia Poor	NR	NR	NR	NR	NR	NR	NR	Schumacher Pharmaceuticals
Muller, 2001[105] Germany and The Netherlands Poor	NR	NR	NR	NR	NR	NR	NR	Knoll AG, Ludwigshafen, Germany
Nisi, 2005[106] Italy Poor	NR	NR	NR	NR	NR	NR	NR	NR

Evidence Table H-5c: Topical Application Trials, continued								
Author, year Country Overall Quality	**Harms: Dermatologic Complications**	**Harms: Bleeding**	**Harms: Infection**	**Other Harms: Specify**	**Severe Adverse Events**	**Withdrawal due to Adverse Events**	**Overall Adverse Events Rate**	**Funding Source**
Pullen, 2002[107] Germany Fair	Treatment A: 6 skin related adverse events reported in 5 patients Treatment B: 5 skin related adverse events reported in 5 patients	NR	NR	NR	NR	NR	Treatment A:118 adverse events reported in 45 patients in the Treatment B:103 in 34 patients	NR
Rhodes, 2001[108] US Poor	NR	NR	NR	NR	NR	NR	NR	NR
Sayag, 1996[109] France Good	Treatment A: NR Treatment B: 1 patient had skin irritation, 1 reported pruritus	Treatment A: NR Treatment B: 3 patients had bleeding during dressing changes	Treatment A: 2 patients had infection Treatment B: 2 patients had infection	Hypergranulation: Treatment A: 1 patient Treatment B:3 patients Deterioration of PU or stagnation after four weeks of treatment: Treatment A: 2 patients Treatment B:15 patients	NR	NR	Treatment A: 4 Treatment B: 15	Les Laboratories Brothier
Shamimi Nouri, 2008(a)[110] Iran Good	NR	NR	NR	NR	NR	NR	NR	ParsRoos Co.
Sipponen, 2008[111] Finland Poor	Allergic skin reaction: Treatment A: NR Treatment B: 13% (n=1)	NR	See outcomes	Number of wound revisions: Treatment A vs. Treatment B 28% (n=5) vs. 64% (n=7), (p=0.078)	NR	Treatment A: 13% (n=1) due to allergic skin reaction	NR	Lappish Cultural Foundation grant to A.S. (author)
Subbanna, 2007[112] India Good	NR	NR	NR	NR	NR	NR	NR	Intramural research funds from Christian Medical College, Vellore
Tytgat, 1988[113] Belgium Poor	NR	NR	NR	NR	NR	NR	NR	NR
Zeron, 2007[114] Mexico and Spain Poor	NR	NR	NR	NR	NR	NR	NR	NR

Evidence Table H-5d. Topical application observational studies

Author, Year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Duration of Followup	Study Setting:
Harding, 1996[115] US Poor	Phase II, open, prospective uncontrolled study	Stage II PU with a minimum of 5 CM^2	Known sensitivity to study medication, a history of bleeding disorders, pregnant or lactating women, unwilling or unable to cooperate, and chronic or debilitating illness	NR/NR/NR/50	Age (Mean): 75 years Female: 56% Race: NR	All stage II	Collagenase ABC	NA	NA	28 days	Hospital
Hindryckx, 1990[116] Belgium Poor	Unmatched prospective cohort	Inpatients with a decubitus ulcer with bacterial and/or fungal contamination	Leukopenia, general anti-biotherapy treatment during treatment with silver sulfadiazine cream, pregnancy, known allergy to sulfanilamides and/or components of the silver sulfadiazine cream	NR/NR/21/21	Age (Mean) 75.7 years Female: 62% Race: NR	NR	Topical: Silver sulfadiazine cream plus pressure relief measures (e.g. position changes, gel cushions, water mattress)	NA	NA	Minimum of 3 weeks (results up to week 8 of followup shown)	Hospital

Evidence Table H-5d. Topical application observational studies

Author, Year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Duration of Followup	Study Setting:
Narayanan, 2005[117] US Fair	Retrospective review	Documentation of at least 1 PU (stage I or II) during the study period.	NR	NR/NR/861/861	Age: < 60 years:10.0% 60-69 years: 10.1% 70-79 years:22.1% 80-89 years: 36.4% 90+ years: 20.6% % Female: 67.1% Caucasian: 83.3%	Stage I 24.6% vs. 8.8% vs. 66.7% Stage II: 10.6% vs. 21.8% vs. 67.7%	Balsam Peru, hydrogenated castor oil and trypsin (BCT) ointment-Xenaderm	BCT and Other	Other only	Until healed	Nursing home
Sherman, 1995[118] US Poor	Prospective controlled study	Patients whose PU had existed for at least one month	Patients with acute cellulites or underlying osteomyelitis	NR/NR/8/8	Age (Mean): 58 Female: 0% Race: NR	Stage: II: N=22 III: N=33 IV: N=3 Location: Sacrum: N=22 Lateral Foot: N=22 Ischium: N=1 Heel: N=1 Other: N=1	Maggot therapy	Usual care	NR	3 to 4 weeks	NR

Evidence Table H-5d. Topical application observational studies

Author, Year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Duration of Followup	Study Setting:
Sherman, 2002[119] US Poor	Observational	Patients with nonhealing wounds, found to be appropriate for maggot therapy and informed consent.	Underlying osteomyelitis or rapidly advancing infection in need of surgery.	NR/NR/103/92	Age: 64 years Female: NR Race: NR	All stage III PU Location: Foot and ankle: 21% (N=10) vs. 255 (N=11) Leg, knee, thigh: 6% (N=3) vs. 125 (N=5) Sacrum, ischium, trochanter: 695 (N=34) vs. 58% (N=25) Other: 4% (N=2) vs. 5% (N=2)	Maggot therapy-Maggots applied to wound at 5-8 per cm2 density for two 48 hour cycles each week.	Conventional treatment	NA	At least two weeks	Hospital
Wang, 2010[120] China Poor	Retrospective study	Infected diabetic foot ulcers or pressure ulcers after spinal cord injury	Systemic infection, positive blood bacterial cultures, gangrene of lesion	NR/NR/18/18	Age (mean): 48 Female: 33% Race: NR	NR	Maggot larvae were placed on a wound and covered with sterile gauze dressing soaked in saline. Both were changed every day.	Traditional dressing method	NR	Until healing	Hospital

Evidence Table H-5d: Topical Application Observational Studies, continued								
Author, year Country Overall Quality Rating	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis Rate**	**Outcomes: Recurrence Rate**	**Outcomes: Pain**	**Other Outcomes: Specify**
Harding, 1996[115] US Poor	NR	Treatment A: Baseline vs Day 28: 20.63 CM^2 vs 17.78 CM^2 (p=0.017)	NR	NR	NR	NR	NR	Odour, pus, inflammation, and necrosis scores all improved from baseline (p <0.001)
Hindryckx, 1990[116] Belgium Poor	NR	Treatment A: 85% (n=18)positive clinical evolution of pressure sores (disappearance of necrosis, development of granulation tissue, decrease in size) 14% (n=3) negative clinical evolution of pressure sores (increase in size)	NR	Treatment A: 57% (n=12) had secondary microorganisms in wounds	NR	NR	0% (n=0)reported pain during dressing changes; 80% (n=17) had wound pain at start of treatment and 64% (n=11_ 11/17 pain had subsided during treatment	475 (n=10) achieved wound sterilization (no bacteria found for at least 2 consecutive weeks); sterilization achieved in 1-3 weeks for heel ulcers (n=6) and 1-5 weeks in sacrum ulcers (n=4); sterilization achieved in 4 cases of *S. Aureus* primary infection after 1 week and in an infection with gram-negative bacteria after 1-5 weeks
Narayanan, 2005[117] US Fair	NR	Treatment groups A vs. B vs. C Mean duration of treatment for all ulcers in days (healed, not healed) Initial stage 1 wounds 72.1 vs. 94 vs. 87.6 Initial stage 2 wounds 81.4 vs. 151.5 vs. 157.2	Time to heal, adjusted for covariates, all treated wounds with complete MDS data Treatment groups A vs. B vs. C Initial stage 1 Mean number of days (95% CI): 31.3 (-7.7 to 70.4) vs. 74.9 (42.6 to 107.2) vs. 62.3 (45.5 to 79.2) Initial Stage 2 Mean number of days (95% CI): 57.2 (44.0 to 70.4) vs. 70.5 (60.9 to 80.2) vs. 63.6 (58.9 to 68.3)	NR	NR	NR	NR	Percent of patients with wounds healed, adjusted for covariates, all patients with MDS data Treatment groups A vs. B vs. C Initial stage 1, % patients (95% CI): 74.3% (47.6 to 101.0) vs. 63.7% (44.4 to 83.0) vs. 37.4% (27.3 to 47.6) Initial Stage 2, % patients (95% CI) 53.1% (37.7 to 68.5) vs. 37.2% (28.5 to 45.9) vs. 37.1% (32.9 to 41.4) Initial stage 1 or 2, % patients (95% CI) (p<0.05 for Group A vs. B or C) 58.6% vs. 42.8% vs. 37.1%

Evidence Table H-5d: Topical Application Observational Studies, continued								
Author, year Country Overall Quality Rating	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis Rate**	**Outcomes: Recurrence Rate**	**Outcomes: Pain**	**Other Outcomes: Specify**
Sherman, 1995[118] US Poor	NR	NR	Percent reduction per week: Treatment A: 22% Treatment B: 22% increase (p<0.001)	NR	NR	NR	NR	NR
Sherman, 2002[119] US Poor	Treatment A: 39% Treatment B: 21% (p<0.001)	Treatment A: -7.3 CM^2 Treatment B: +6.3 CM^2 (p<0.05)	Average time to complete healing: Treatment A: 13.4 weeks Treatment B: 12 weeks	NR	NR	NR	NR	NR
Wang, 2010 China[120] Poor	100% in both treatment groups	NR	Time to wound healing: Treatment A, 18.7 days Treatment B, 30.6 days (p=0.04)	All PU were infected at baseline, time to bacterial negativity was reported: Treatment A: 10.4 days Treatment B: 18.7 days (p=0.022)	NR	NR	NR	NR

Evidence Table H-5d: Topical Application Observational Studies, continued								
Author, year Country Overall Quality Rating	**Harms: Pain**	**Harms: Dermatologic Complications**	**Harms: Bleeding**	**Harms: Infection**	**Other Harms: Specify**	**Severe Adverse Events**	**Withdrawal due to Adverse Events**	**Overall Adverse Events Rate**
Harding, 1996[115] US Poor	Treatment A: N=1	NR	NR	NR	NR	NR	NR	NR
Hindryckx, 1990[116] Belgium Poor	0% (n=0)reported pain during dressing changes; 80% (n=17) had wound pain at start of treatment, 64% (n=11) pain had subsided during treatment	NR	NR	50% (n=12)had secondary microorganisms in wounds	NR	NR	NR	NR
Narayanan, 2005[117] US Fair	NR	NR	NR	NR	NR	NR	NR	NR
Sherman, 1995[118] US Poor	NR	NR	NR	NR	NR	NR	NR	NR
Sherman, 2002[119] US Poor	Treatment A: 0% Treatment B: 4% reported discomfort	NR	NR	NR	NR	NR	NR	NR
Wang, 2010[120] China Poor	Treatment A: Authors report that 1 patient in the combined group (diabetic foot and PU) reported bearable pain	NR	NR	NR	NR	NR	NR	NR

Evidence Table H-5e. Biological therapies trials and observational studies

Author, year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number screened/ eligible/ enrolled/ analyzed	Age Sex Race	Intervention Type:	Ulcer Type/Severity at Baseline (Intervention Onset)	Treatment A	Treatment B	Treatment C	Treatment D
Danon, 1997[121] Israel Poor	Observational	Patients with PU hospitalized during a 1 year period in a geriatric hospital	No exclusion criteria	NR/NR/199 /199	Age (Mean): 80 years Female: 56% Race: NR	Local Wound Applications: Biologics	NR	Macrophage suspension (0.05 mL/injection) injected at 0.5-1 cm from the ulcer's edge all around the ulcer's periphery, at 1 cm between injection points. Macrophage treatment only given one time Ringer solution compress on a cotton gauze pad, kept moist with Ringer solution, and changed daily n=72	Conventional treatments of ulcers, including Polydine, Eusol, Silverol, Debrizan, Ringer, Saline, Granuflex, hydrogels, etc. n=127	NA	NA

Evidence Table H-5e: Biological Therapies Trials and Observation-al Studies, continued											
Author, year Country Overall Quality Rating	**Study Type**	**Eligibility Criteria**	**Exclusion Criteria**	**Number screened/ eligible/ enrolled/ analyzed**	**Age Sex Race**	**Intervention Type:**	**Ulcer Type/Severity at Baseline (Intervention Onset)**	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**
Hirshberg, 2001[122] US Poor	Trial	PU surface area between 15-120 cm^2, calcium alginate mold weight of ≥10 g following debridement at baseline visit, target ulcer present for at least 4 weeks, serum albumin concentration ≥2.5 g/dL, ulcer, bacterial counts of <105 per gram of tissue and no beta-hemolytic streptococci or malignancy on biopsy	Osteomyelitis, alginate mold weight ≤10 g after debridement, use of topical antibiotics, disinfectants, autolytic, enzymatic debridement experimental, nonapproved or investigational drug use within one month or during trial, malignancy, use of systemic corticosteroids >20 mg per day, immunosuppressive therapy, patients whose target ulcer failed to heal with previous cytokine therapy or who received radiation therapy, pregnant, nursing, or of childbearing age women (not using birth control).	270/NR/NR/ 14	Age (Mean):44 Female: 45% Race: NR	Local Wound Applications: Biologics	Stage III, IV	1.0 mcg/cm2 transforming growth factor-beta3 (TGF-beta3) 1x daily plus standardized wound care n=4	2.5 mcg/cm2 TGF-beta3 1x daily plus standardized wound care. n=5	Placebo gel 1x daily plus standardized wound care. n=5	NA
Landi, 2003[123] Italy Good	Trial	PU, from 1 cm^2 to 30 cm^2 in total area	Lesions developed >1 month before admission, terminal illness, diabetes, peripheral vascular disease	Number screened: NR/70/38/36	Age (Mean): 80 Female: 72% Race: NR	Local Wound Applications: Biologics	Stage II: N=3 N=3 Stage III: N=9 vs. N=13 Stage IV: N=5 vs. N=1 Stage V: N=1 vs. N=1	2.5S murine nerve growth factor solution 1x daily plus daily local care.) n=18	Salt solution 1x daily plus daily local care. n=18	NA	NA

Evidence Table H-5e: Biological Therapies Trials and Observation-al Studies, continued											
Author, year Country Overall Quality Rating	**Study Type**	**Eligibility Criteria**	**Exclusion Criteria**	**Number screened/ eligible/ enrolled/ analyzed**	**Age Sex Race**	**Intervention Type:**	**Ulcer Type/Severity at Baseline (Intervention Onset)**	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**
Mustoe, 1994[124] US Poor	Trial	Stage III, IV PU in an adult, surface area between 4-100 cm^2, no evidence of cellulitis or malignant neoplasms	Venous or arterial vascular disorder directly implicated in the cause of the ulcer; significant endocrine disease, immunosuppressive disease, sepsis, pregnancy or lactation, active abuse of alcohol/drugs, unstable renal hepatic, hematological or cardiac disease; evidence of malignant neoplasms; use of immunotherapy, cytotoxic chemotherapy, or investigational drugs	NR/NR/52/44 (41 had complete alginate mold weight data and were used as n for some analyses)	Age: 72years Female: 66% Race,: Caucasian: 52%	Local Wound Applications: Biologics	Treatment A: Stage III: 27% vs. 25% vs. 21% Stage IV: 73% vs75% vs. 79%,: Location: Ischium: 20% vs. 17% vs. 29% Sacrum: 33% vs. 42% vs. 43% Trochanter: 27 Other: 20 vs. 255 vs. 75	100 µg/mL rDPGF-BB topical spray 1x daily in addition to moist saline gauze dressings and mechanical debridement as needed N=15	300 µg/mL rDPGF-BB topical spray 1x daily in addition to moist saline gauze dressings and mechanical debridement as needed N=12	Placebo N=14	NA
Payne, 2001[125] US Poor	Trial	PU involving any tissue from a bony prominence to the subcutaneous tissue (grad III, IV)	None	NR/NR/61/59 Complete follow-up data for 54	Age: NR Female: NR Race: NR	Local Wound Applications: Biologics	NR	Sequential topical GM-CSF/bFGF 1x daily	bFGF alone 1x daily	GM-CSF 1x daily	Placebo 1x daily

Evidence Table H-5e: Biological Therapies Trials and Observation-al Studies, continued											
Author, year Country Overall Quality Rating	**Study Type**	**Eligibility Criteria**	**Exclusion Criteria**	**Number screened/ eligible/ enrolled/ analyzed**	**Age Sex Race**	**Intervention Type:**	**Ulcer Type/Severity at Baseline (Intervention Onset)**	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**
Payne, 2004[126] US Good	Trial	Age>18 years; stage III sacral PU; ulcer free of necrotic tissue and debridement; ulcer present for 2-24 months; ulcer area is >5 cm^2 and l<50 cm^2; if more than one ulcer, the distance between ulcers is > 10 cm; ulcer is due solely to pressure damage.	Stage I, II, IV PU; more than 3 stage III, IV PUs; evidence of undermining, tunneling, or sinus tracts > 1 cm after debridement; previous treatment with a surgical flap procedure; bacterial colonization; decrease or increase in ulcer size of 50% during the screening period; underlying non-pressure ulcer etiology.	NR/NR/34/ 34	Age (Mean): 69 years Female: 32% Race: Caucasian: 82% African-American: 15%% Other: 3%	Local Wound Applications: Biologics	All Stage III Location: Sacral: 67% Trochanter: 24% Ischium: 9%	Dermagraft (human dermal fibroblast-derived substitute) up to 2x weekly in conjunction with conventional treatment N=18	Non-adherent dressing, saline-moistened gauze and Allevyn. N=16	NA	NA

Evidence Table H-5e: Biological Therapies Trials and Observation-al Studies, continued											
Author, year Country Overall Quality Rating	**Study Type**	**Eligibility Criteria**	**Exclusion Criteria**	**Number screened/ eligible/ enrolled/ analyzed**	**Age Sex Race**	**Intervention Type:**	**Ulcer Type/Severity at Baseline (Intervention Onset)**	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**
Rees, 1999[127] US Fair	Trial	≥18 years, 1 - 3 chronic (stage III or IV NPUAP) PU (primary or recurrent) without involvement of bone tissue, PU volume between 10 ml and 150 ml, inclusive, following debridement at the baseline visit, PU present for at least 4 weeks despite previous treatment, located where pressure could be off loaded for the duration of the study, and albumin concentrations >2.5g/dl, total lymphocyte count> 1000 and concentrations of vitamin A and C within the normal range	Osteomyelitis, after debridement PU volume <10ml or >150ml, topical antibiotics, antiseptics, enzymatic debriding agents or other agents that would interfere with study evaluations used within 7 days preceding randomization, PU from electrical, chemical or radiation insult, cancer patients, concomitant diseases, treatment or medication that would deleteriously affect healing or interfere w/ evaluation of study medication, pregnant, nursing or of childbearing potential and not using birth control	NR/NR/124/ 124	Age (Mean): 49 years Female: 16% Race: NR	Local Wound Applications: Biologics	NR	Becaplermin gel 100µg/g alternated with placebo gel every 12 hours N=31	Becaplermin gel 300 µg/g alternated with placebo gel every 12 hours N=32	Becaplermin gel 100 µg/g 2x daily N=30	Placebo gel 2x daily N=31

Evidence Table H-5e: Biological Therapies Trials and Observation-al Studies, continued											
Author, year Country Overall Quality Rating	**Study Type**	**Eligibility Criteria**	**Exclusion Criteria**	**Number screened/ eligible/ enrolled/ analyzed**	**Age Sex Race**	**Intervention Type:**	**Ulcer Type/Severity at Baseline (Intervention Onset)**	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**
Robson, 1992(a)[128] Robson, 1992(b)[129] US Poor	Trial - double-blind, placebo-controlled, phase I/II study	Consenting adult inpatients (ages 21-56) with stage III or IV, of area 25-95 cm, was randomly allocated placebo or rPDGF-BB at 1 µg/ml, 10 µg/ml, or 100 µg/ml, daily for 28 days.	Patients with diabetes	NR/NR/20/20	Age (Mean)33 years Female: NR Race: NR	Local Wound Applications: Biologics	NR	1µg/ml recombinant homodimeric platelet derived growth factor (rPDGF- BB) 1x daily N=4 Total test material applied daily was calculated from a dose of 0 01 ml/cm ulcer surface. After the daily treatment, the wound was left open for 15 minutes to allow absorption of rPDGF-BB by the wound surface. The ulcer crater was packed with fresh sterile gauze and sealed closed with `Biobrane' Pressure-relieving devices were used as appropriate. Patients were repositioned every 2 hours throughout the treatment period	10 µg/ml rPDGF-BB 1x daily Total test material applied daily was calculated from a dose of 0 01 ml/cm ulcer surface. After the daily treatment, the wound was left open for 15 minutes to allow absorption of rPDGF-BB by the wound surface. The ulcer crater was packed with fresh sterile gauze and sealed closed with `Biobrane' Pressure-relieving devices were used as appropriate. Patients were repositioned every 2 hours throughout the treatment period N=4	100 µg/ml rPDGF- BB 1x daily Total test material applied daily was calculated from a dose of 0 01 ml/cm ulcer surface. After the daily treatment, the wound was left open for 15 minutes to allow absorption of rPDGF-BB by the wound surface. The ulcer crater was packed with fresh sterile N=5 gauze and sealed closed with `Biobrane' Pressure-relieving devices were used as appropriate. Patients were repositioned every 2 hours throughout the treatment period	Placebo (not described) N=7

Evidence Table H-5e: Biological Therapies Trials and Observation-al Studies, continued											
Author, year Country Overall Quality Rating	**Study Type**	**Eligibility Criteria**	**Exclusion Criteria**	**Number screened/ eligible/ enrolled/ analyzed**	**Age Sex Race**	**Intervention Type:**	**Ulcer Type/Severity at Baseline (Intervention Onset)**	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**
Robson, 1994[130] US Poor	Trial	Both sexes, >18 years old, 28 days of hospitalization, wound volume 10-100cm3 and a depth of >2cm or to the boney prominence, located on sacrum, ischium, trochanter	Pregnant or lactating women, significant renal, hepatic, cardiac, or hematologic disease, endocrine disease such as diabetes mellitus, neoplastic disease producing PU, arterial or venous disorders, lack of cooperation or suitability, inability to consent, whirlpool therapy, HIV positive, use of investigational drugs before study entry, treatment of PU with cytokines within last 3 months	NR/NR/26/26	Age: NR Female: NR Race: NR	Local Wound Applications: Biologics	All grade III or IV	Interleukin:0.01 ug/cm2/day (1.0 ug/ml)	Interleukin: 0.1 ug/cm2/day (10 ug/ml)	Interleukin: 1.0 ug/cm2/day (100 ug/ml)	Placebo

Evidence Table H-5e: Biological Therapies Trials and Observation-al Studies, continued											
Author, year Country Overall Quality Rating	**Study Type**	**Eligibility Criteria**	**Exclusion Criteria**	**Number screened/ eligible/ enrolled/ analyzed**	**Age Sex Race**	**Intervention Type:**	**Ulcer Type/Severity at Baseline (Intervention Onset)**	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**
Robson, 2000[131] US Poor	Trial	Patients age 28-70 with PU on the truncal area involving any tissue from bony prominence to subcutaneous tissue (grade III/IV), ulcer duration of > 8 weeks, and an initial ulcer volume of 10-200 cm^3	Significant diabetes mellitus, renal insufficiency, vasculitis, or hepatic, immunologic, cardiac, or hemorrhagic disease; malignant or neoplastic disease, except for adequately treated skin cancers; significant malnutrition, systemic steroidal therapy, immunotherapy, or chemotherapy; cytokine therapy within 90 days or investigational drug study within 30 days	NR/NR/NR/ 61	Age(Mean): 50 years Female: NR Race: Caucasian – 84% Black – 11% Hispanic: 5%	Local Wound Applications: Biologics	All stage III or IV	Granulocyte-macrophage/colony-stimulating factor (GM-CSF) 1x daily for 35 days N=15	Basic fibroblast growth factor (bFGF) 1x daily for 35 days N=15	Sequential GM-CSF 1x daily for 10 days of GM-CSF followed by 1x daily for 25 days of bFGF N=16	Placebo N=15

Evidence Table H-5e: Biological Therapies Trials and Observation-al Studies, continued											
Author, year Country Overall Quality Rating	**Study Type**	**Eligibility Criteria**	**Exclusion Criteria**	**Number screened/ eligible/ enrolled/ analyzed**	**Age Sex Race**	**Intervention Type:**	**Ulcer Type/Severity at Baseline (Intervention Onset)**	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**
Robson, 1992(c)[132] US Poor	Trial - randomized, blinded, placebo-controlled trial	Patients 18-65 years, PUs: 10-200 cm^3 as measured by alginate mold, hospitalized, mechanical debridement (if necessary): at least 24 hours before initiation of treatment, laboratory findings: normal or clinically insignificant abnormalities on pretreatment CBC, coagulation, chemistry, urinalysis panels	Arterial or venous disorder, or vasculitis as cause for ulcerated wound, clinically significant systemic disease, significant malnutrition, recent use of steroidal therapy, penicillin allergy	NR/NR/50/49	Age (Mean): 38 years Female: 25% Race: Caucasian37% Black:46% Hispanic:16%	Local Wound Applications: Biologics	NR	Recombinant basic fibroblast growth factor (bFGF): 1x daily/22 days Tier 1: Low-dose bFGF (100 mcg/mL/cm2) Tier 2: High-dose bFGF (1000 mcg/mL/cm2) Tier 3: Intermediate-dose bFGF (500 mcg/mL/cm2) N=35 Drug application was performed according to the specific tier after irrigation of the ulcer crater with normal saline. The given drug dosage was applied from a spray applicator, after which the wound was exposed to the ambient air for 15 minutes to allow the medication to adsorb to the wound surface. After this time, the ulcer crater was packed with fresh saline-moistened sterile gauze. 12 hours later the saline-moistened gauze was changed, but no additional medication was applied.	Placebo 1x daily (not described) N=14	NA	NA

Evidence Table H-5e: Biological Therapies Trials and Observation-al Studies, continued											
Author, year Country Overall Quality Rating	**Study Type**	**Eligibility Criteria**	**Exclusion Criteria**	**Number screened/ eligible/ enrolled/ analyzed**	**Age Sex Race**	**Intervention Type:**	**Ulcer Type/Severity at Baseline (Intervention Onset)**	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**
Scevola, 2010[133] Italy Poor	Prospective randomized controlled open clinical pilot trial	Patients were in a compensated stable nutritional status.	Metabolic, endocrine and collagen pathologies, ischemic cardiopathy, corticosteroid or immunosuppressive therapy, obesity, malignancies, and organ failure	NR/NR/13/13 PU N=16	Age: NR Female: 23% Race: NR	Local Wound Applications: Biologics	Location: Sacral: 10 Ischiatic: 6	(GEL dressing) Allogenic Platelet Gel Protocol - gel applied directly to the clean wound bed using a sterile syringe; the ulcer was then covered with a polyurethane sponge/semi-permeable film dressing system Platelet gel prepared in a Petri dish blending 4–8 ml of concentrated platelet preparation, including at least 2×10^{10} platelets, with 2–4 ml of plasma activated with Calcium Chloride Ulcers were treated 2x/week for 8 weeks (total of 16 applications) N=8	(NO GEL dressing) Standard Protocol – Detorsion: Saline at room temperature Dressing: Packing with 10% iodoform impregnated gauzes or Sodium/Alginate foams or Cadexomer Iodine powder and/or Vacuum Assisted Closure therapy Perilesional areas: Zinc Oxide paste or Silver Sulfadiazine in high contamination risk area (i.e. perineum) N=8	NA	NA

Evidence Table H-5e: Biological Therapies Trials and Observation-al Studies, continued											
Author, year Country Overall Quality Rating	**Study Type**	**Eligibility Criteria**	**Exclusion Criteria**	**Number screened/ eligible/ enrolled/ analyzed**	**Age Sex Race**	**Intervention Type:**	**Ulcer Type/Severity at Baseline (Intervention Onset)**	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**
Zuloff-Shani, 2010[134] Israel Poor	Observational	Admitted to the rehabilitation wards following acute stroke, hip fractures, amputations, or deconditioning following acute illnesses. Patients were eligible once they suffered at least one PU at stage III and/or IV, as defined by the EPUAP lasting >30 days, regardless of gender or associated comorbidities. Could also have anemia, renal or hepatic disease, hypoalbuminemia, use of steroids, chemotherapy, or other immuno-compromising drugs	PU at stages other than stage III and/or IV, or a significant acute life threatening medical condition that might interfere with treatment results	NR/NR/131/ 100 PU N=213	Age (Mean): 78 years, Females: 59% Race: NR	Local Wound Applications: Biologics		SOC: Wounds were surgically debrided, if necessary, and then treated by a variety of SOC treatments, including alginate containing dressings, polyurethane dressings, carboxymethylcel lulose dressings, activated charcoal dressings with silver, hydrocolloids, hydrogels, silver containing dressings, gauze pads absorbed with Ringer (Hartman) solution, eusol, antibiotics and ointments containing steroids, silver containing ointments N=30 (leg ulcers)	AMS: Injected by a sterile disposable 2 ml syringe with a 25G needle. The AMS suspension (0.1 ml/injection) was injected at the entire wound bed, at 1 cm between injection points. (for deep wounds, AMS was poured directly into the wound). Following AMS, sterile gauze well soaked with AMS was applied for 24 hours. Wounds were covered either with gauze pads absorbed with lactated Ringer's (Hartman) solution or one of the following dressings: alginate containing dressings, polyurethane dressings, or carbo-xymethylcellulose dressings. In case of extensive exudates, silver containing dressings were applied. AMS injection was repeated in accordance with the wound condition (mean time between injections - 4 weeks) n= 45 (leg ulcers)	NA	NA

Evidence Table H-5e: Biological Therapies Trials, continued									
Author, year Country Overall Quality Rating	**Duration of Treatment/ Followup**	**Study Setting**	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis Rate**	**Outcomes: Recurrence Rate**	**Other Outcomes: Specify**
Danon, 1997[121] Israel Poor	Single treatment / 12 months	Geriatric Hospital	Treatment A: 27% (n=36) complete wound healing. Treatment B: 6% (n=15) (p<0.001)	NR	NR	NR	NR	NR	NR
Hirshberg, 2001[122] US Poor	16 weeks or until ulcer healed	Wound care center	Treatment A: None Treatment B: n=1 achieved complete wound closure with no drainage	Treatment A: Mean relative surface area of target ulcer at visit 4, cm^2 0.8 Mean relative surface area of target ulcer at termination of trial, cm^2 0.3 Treatment B/C Mean relative surface area of target ulcer at visit 4, cm^2 Treatment B: 0.5 Treatment C: 0.9 Mean relative surface area of target ulcer at termination of trial, cm^2 Treatment B: 0.4 Treatment C: 0.7 Significant reduction in mean relative surface areas, Treatment B vs. Treatment C, during initial weeks of trial p<0.05	NR	NR	Treatment A: None Treatment B: n=2	NR	Surface volumes Volume decreased significantly, Treatment A vs. Treatment C, p<0.05 Mean relative volumes (cm3) at termination were Treatment A 0.7, Treatment B 0.2, Treatment C 0.3

Evidence Table H-5e:
Biological Therapies
Trials, continued

Author, year Country Overall Quality Rating	Duration of Treatment/ Followup	Study Setting	Outcomes: Complete Wound Healing	Outcomes: Wound Surface Area	Outcomes: Healing Time	Outcomes: Infection Rate	Outcomes: Osteomyelitis Rate	Outcomes: Recurrence Rate	Other Outcomes: Specify
Landi, 2003[123] Italy Good	6 weeks	Nursing home	Treatment A: 44%) (N=8) Treatment B: 6%, (N=1) (p=0.009)	Treatment A: 6 weeks Mean area, mm2: 274 +/- 329 Reduction in ulcer area (raw), mm2: 738 +/- 393 Reduction in ulcer area (adjusted), mm2: natural log of area reduction 6.5 +/- 0.3 Treatment B: 6 weeks Mean area, mm2: 526 +/- 334, p=0.022 Reduction in ulcer area, mm2: 485 +/- 384, p=0.034 Reduction in ulcer area (adjusted), mm2: natural log of area reduction 5.9 +/- 0.3, p<0.001 adjustment for confounders including baseline ulcer area, location, ulcer duration	Topical application of Treatment A showed statistically significant acceleration of healing process (no p-value provided) 4 weeks total area reduced by nearly 50% in all ulcers of treatment A Complete healing within 3 weeks, Treatment A: n=2 Treatment B: n=1 Complete healing within 4 weeks, n=2 Complete healing within 5 weeks, n=1 Complete healing within 6 weeks, n=3	NR	NR	NR	Treatment A vs. Treatment B Ulcer improvement by >3 stages, 28%(n=5) vs. 0 Ulcer improvement by 2 stages, 50%(n=9) vs. 11%(n=2) Ulcer improvement by 1 stage, 22%(n=4) vs. 44%(n=8), (p<0.001) No ulcer improvement, 44%(n=8) of Treatment B
Mustoe, 1994[124] US Poor	28 days/5 months	Nursing homes and hospitals	Treatment A 38% of PU had complete wound healing at 5 months Treatment B 21% Treatment C 14% of PU had complete wound healing at 5 months	% Decrease in volume at day 29: Treatment A 71% Treatment B 60% Treatment C 17% (p=0.056)	No statistically significant difference in 50% healing time	NR	NR	Treatment A: 0% Treatment B: 40% of PU healed during treatment and recurred during followup	NR

Evidence Table H-5e: Biological Therapies Trials, continued									
Author, year Country Overall Quality Rating	**Duration of Treatment/ Followup**	**Study Setting**	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis Rate**	**Outcomes: Recurrence Rate**	**Other Outcomes: Specify**
Payne, 2001[125] US Poor	35 days/1 year	Nursing Home	No difference between complete healing in groups	NR	No difference in healing times between groups	NR	NR	Overall recurrence rate of 17%	NR
Payne, 2004[126] US Good	Variable treatment/26 weeks	Multi-center	Treatment A: 11% complete wound healing Treatment B: 13%	Treatment A: Median ulcer area reduction at week 12: 50% for patients who had complete healing 39% for patients who had incomplete healing Median ulcer volume reduction 41% for patients who had complete healing Treatment B: Median ulcer area reduction 34% for patients who had complete healing 17% for patients who had incomplete healing Median ulcer volume reduction 17% for patients who had complete healing	NR	Treatment A: 17% (n=3) Treatment B: 19% (n=3)	NR	NR	NR

Evidence Table H-5e:
Biological Therapies
Trials, continued

Author, year Country Overall Quality Rating	Duration of Treatment/ Followup	Study Setting	Outcomes: Complete Wound Healing	Outcomes: Wound Surface Area	Outcomes: Healing Time	Outcomes: Infection Rate	Outcomes: Osteomyelitis Rate	Outcomes: Recurrence Rate	Other Outcomes: Specify
Rees, 1999[127] US Fair	16 weeks	Multi-center	Treatment A: 23% Treatment B: 19% Treatment C: 0% Treatment A vs. Treatment C: (p=0.005) Treatment B vs. Treatment C: (p=0.008)	NR	NR	Treatment D 3% Treatment C: 3% in 100 µg/g BID	Treatment A: 6% Treatment B: 3% Treatment C: 3% Treatment D: 0%	NR	Becaplermin 100µg/g vs. 300µg/g vs. 100µg/g BID vs. placebo Incidence of ≥90% healing: 58% vs. 59% vs. 405 vs. 29%, 100µ/g vs. placebo (p=0.021), 300µg/g vs. placebo (p=0.014) Median relative ulcer volume at 16 weeks: 0.07 vs. 0.05 vs. 0.15 vs. 0.27, 100µ/g vs. placebo (p=0.013), 300µg/g vs. placebo (p=0.011)
Robson, 1992(a)[128] Robson, 1992(b)[129] US Poor	29-day trial/ followup at 2 weeks and 1, 2, 3 and 5 months post discharge and treatment	NR	NR	NR	NR	NR	NR	NR	
Robson, 1994[130] US Poor	28 days	Hospital	NR	NR	NR	NR	NR	NR	Ulcer volume reduction was the response examined, no significant differences were found between treatment groups

Evidence Table H-5e:
Biological Therapies
Trials, continued

Author, year Country Overall Quality Rating	Duration of Treatment/ Followup	Study Setting	Outcomes: Complete Wound Healing	Outcomes: Wound Surface Area	Outcomes: Healing Time	Outcomes: Infection Rate	Outcomes: Osteomyelitis Rate	Outcomes: Recurrence Rate	Other Outcomes: Specify
Robson, 2000[131] US Poor	35 days/1 year	Hospital	NR	NR	NR	NR	NR	NR	Treatment A vs. B vs. C vs. D Day 36 ulcer volume, mean (cm3): 12.02+/-11.88 vs. 7.24+/-6.11 vs. 16.83+/-25.75 vs. 14.24+/-13.66 All patients: 12.65+/-16.24 Day 36 ulcer volume, median (cm3): 9.29 (range 0.88-40.62) vs. 4.42 (range 0.22-20.80) vs. 7.48 (range 0.22-99.65) vs. 8.85 (range 2.12-45.84), p=0.57 All patients: 7.26 (range 0.22-99.65) Percent wound closure on day 36, mean: 67+/-24 vs. 75+/-19 vs. 68+/-21 vs. 71+/-11 All patients: 70+/-19 Percent wound closure on day 36, median (range): 70 (3-93) vs. 79 (42-99) vs. 73 (29-98) vs. 72 (39-84), p=0.69 All patients: 73 (3-99) Text: significantly more patients treated with cytokine achieved >85% decrease in ulcer volume (p=0.03); significantly more patients in Treatment B had >85% (p=0.02)

Evidence Table H-5e: Biological Therapies Trials, continued									
Author, year Country Overall Quality Rating	**Duration of Treatment/ Followup**	**Study Setting**	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis Rate**	**Outcomes: Recurrence Rate**	**Other Outcomes: Specify**
Robson, 1992(c)[132] US Poor	30 days acute phase of followup then patients discharged with followup evaluations at 1, 3 and 5 months	Hospital	>70% Wound Closure at 21 days: 69% (N=9)3, (p=0.041)	70% volume reduction: Treatment A: 60%(n=21) Treatment B: 29%(n=4)	NR	NR	NR	NR	NR
Scevola, 2010[133] Italy Poor	8 weeks/14 weeks after start of treatment (6 weeks after end of treatment)	NR	NR	NR	NR	NR	NR	NR	Pre-albumin (p=0.08) and albumin (p=0.041) values appeared slightly improved in both groups at the end of the study
Zuloff-Shani, 2010[134] Poor	12 months/NR		Treatment A: Complete wound healing: (leg ulcer subset) Complete wound healing: (leg ulcer subset): 18% vs. 69.9%, p<0.001 Number of patients with all wounds fully closed: 2 (5.3%) vs. 39 (59.1%), p<0.001 Wounds Completely Closed: wound level - 13.3% vs. 69.5%, p<0.001 patient level - 33.7% vs. 76.2%, p<0.001 Treatment B: Complete wound healing (All patients, includes diabetic ulcers): Percentage of completely closed wounds significantly better for AMS. (p<0.001)	NR	Treatment A: Median healing time: 117.7 (38–368) days Median healing time: (leg ulcer subset): SOC – 125 days (range: 26-368) (p>0.05) Treatment B: Median healing time: 86.7 (15–422) days, p=0.49 Median healing time: (leg ulcer subset): AMS – 57 days (range:1-394) (p>0.05)	NR	NR	NR	NR

Evidence Table H-5e: Biological Therapies Trials, continued									
Author, year Country Overall Quality Rating	**Harms: Pain**	**Harms: Dermatologic Complications**	**Harms: Bleeding**	**Harms: Infection**	**Other Harms: Specify**	**Severe Adverse Events**	**Withdrawal due to Adverse Events**	**Overall Adverse Events Rate**	**Funding Source**
Danon, 1997[121] Israel Poor	NR	NR	NR	NR	NR	NR	NR	NR	Teva Medical LTD, Israel.
Hirshberg, 2001[122] US Poor	NR	NR	NR	NR	NR	NR	Treatment B: n=2 developed osteomyelitis Treatment C: n=1 due to unsatisfactory therapeutic effects	21%	Office of Research and Development, Medical Research Service, Department of Veterans Affairs
Landi, 2003[123] Italy Good	NR	NR	NR	NR	NR	NR	NR	NR	Progetto Finalizzato Invecchiamento of the Italian National Research Council, inter*RAI*
Mustoe ,1994[124] US Poor	NR	Treatment A: Tunneling of the ulcer, exuberant granulation tissue, erythema with purulent drainage Treatment B: NR	NR	Treatment A: None Treatment B: n=1	Treatment A: Tunneling of the ulcer: n=1 exuberant granulation tissue: n=1 erythema with purulent drainage: n=1 Treatment B: NR	None	None	10%	Amgen Inc.
Payne, 2001[125] US Poor	NR	NR	NR	NR	NR	NR	NR	NR	NIAMS, National Institutes of Health, Schering-Plough Research Institute, Scios, Inc.
Payne, 2004[126] US Good	NR	NR	NR	NR	NR	NR	NR	NR	Smith and Nephew, Inc.

Evidence Table H-5e: Biological Therapies Trials, continued									
Author, year Country Overall Quality Rating	**Harms: Pain**	**Harms: Dermatologic Complications**	**Harms: Bleeding**	**Harms: Infection**	**Other Harms: Specify**	**Severe Adverse Events**	**Withdrawal due to Adverse Events**	**Overall Adverse Events Rate**	**Funding Source**
Rees, 1999[127] US Fair	NR	Skin ulceration, rash erythema-numbers, NR	NR	Treatment A n=0 Treatment B: n=0 Treatment C: n=1 Treatment D: n=1	Becaplermin 100µg/g vs. 300µg/g vs. 100µg/g BID vs. placebo Sepsis: 0 vs. 1 vs. 0 vs. 0 Condition aggravated: 0 vs. 1 vs. 1 vs. 0	None	Treatment A: 3.2%(N=1)	NR	Johnson & Johnson, Inc.
Robson, 1992(a)[128] Robson, 1992(b)[129] US Poor	NR	NR	NR	NR	NR	NR	NR	NR	Grant from California Biotechnology, Inc.
Robson, 2000[131] US Poor	NR	NR	NR	NR	NR	NR	NR	NR	National Institutes of Health; Schering-Plough Research Institute; Scios, Inc.
Robson, 1992(c)[132] US Poor	NR	NR	NR	See outcomes	Surgical ablation not required by any patients in Treatment C but required in 8 patients from other groups combined (p=0.09)	NR	NR	NR.	NR
Robson, 1994[130] US Poor	NR	NR	NR	NR	NR	NR	NR	NR	NR
Scevola, 2010[133] Italy Poor	NR	NR	NR	NR	NR	NR	NR	NR	NR

Evidence Table H-5e: Biological Therapies Trials, continued									
Author, year Country Overall Quality Rating	**Harms: Pain**	**Harms: Dermatologic Complications**	**Harms: Bleeding**	**Harms: Infection**	**Other Harms: Specify**	**Severe Adverse Events**	**Withdrawal due to Adverse Events**	**Overall Adverse Events Rate**	**Funding Source**
Zuloff-Shani, 2010[134] Israel Poor	NR	NR	NR	NR	NR	NR	NR	There were no adverse and/or serious adverse events related to AMS treatment. However, during the study an overall of 18.2% (12/66) of the patients in the AMS group and 23.7% (9/38) in the SOC group died (p=0.61).	RoseTree London, MDA Israel

Evidence Table H-6: Local Wound Applications (Dressings, Topical Applications, and Biological Therapies) Quality Rating*

Evidence Table H-6a. Local wound applications trial quality rating

Author Year Country	Appropriate Randomization Technique	Allocation concealment adequate?	Groups (intervention and control) similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Reporting of: a) attrition b) crossovers c) adherence d) contamination	Dropout rate <20 percent	Intention-to-treat analysis	Appropriate Statistical Analyses	Risk of Bias (Quality Rating)	Funding Source
Agren, 1985[93] Sweden	No	No	Yes	Yes	Yes	a) Yes b) Unclear c) Unclear d) Unclear	No	Yes	Yes	Poor	NR
Alm, 1989[43] Sweden	No	Unclear	Yes	No	Yes	a) Yes b) Unclear c) Unclear d) Unclear	Yes	Unclear	Yes	Fair	NR
Alvarez, 2000[94] US	No	No	Yes	Yes	No	a) Yes b) Unclear c) Unclear d) Unclear	Yes	Unclear	Yes	Fair	NR
Bale, 1997[44] UK	No	Unclear	Yes	Yes	Unclear	a) Yes b) Unclear c) Unclear d) Unclear	No	Yes	Yes	Fair	Smith and Nephew
Bale, 1998(b)[45] UK	No	Unclear	Yes	Yes	Not Reported	a) Yes b) Unclear c) Unclear d) Unclear	No	Unclear	Yes	Poor	NR
Bale, 1998(a)[46] UK	No	Unclear	Yes	Yes	Not Reported	a) Yes b) Unclear c) Unclear d) Unclear	No	Unclear	Yes	Poor	Smith and Nephew
Banks, 1994(a)[50] UK	Unclear	Unclear	No	Yes	No	a) No b) No c) Yes d) No	Yes	Yes	Unclear	Poor	Calgon Vestal
Banks, 1994(b)[48] UK	No	No	Yes	Yes	No	a) No b) No c) No d) No	Yes	Yes	Yes	Poor	NR

Evidence Table H-6a. Local wound applications trial quality rating

Author Year Country	Appropriate Randomization Technique	Allocation concealment adequate?	Groups (intervention and control) similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Reporting of: a) attrition b) crossovers c) adherence d) contamination	Dropout rate <20 percent	Intention-to-treat analysis	Appropriate Statistical Analyses	Risk of Bias (Quality Rating)	Funding Source
Belmin, 2002[49] France	Unclear	Unclear	Yes	Yes	Yes	a) No b) No c) Yes d) No	Yes	Yes	Yes	Fair	Laboratoires Urgo
Bito, 2012[50] Japan	Yes	No	Yes	Yes	No	a) No b) No c) No d) No	Yes	Unclear	Yes	Good	Division of Health for the Elderly at Japanese Ministry of Health

Evidence Table H-6a: Local Wound Applications Trial Quality Rating, continued											
Author Year Country	**Appropriate Randomization Technique**	**Allocation concealment adequate?**	**Groups (intervention and control) similar at baseline?**	**Eligibility criteria specified?**	**Outcome assessors masked?**	**Reporting of: a) attrition b) crossovers c) adherence d) contamination**	**Dropout rate <20 percent**	**Intention-to-treat analysis**	**Appropriate Statistical Analyses**	**Risk of Bias (Quality Rating)**	**Funding Source**
Brod, 1990[51] US	No	No	Yes	Yes	No	a) No b) No c) Unclear d) No	Yes	No	Yes	Poor	Acme/Chaston Division, National Patent Development Corp
Brown-Etris, 2008[52] US	Unclear	Unclear	Yes	Yes	No	a) No b) No c) No d) No	Yes	Yes	Yes	Fair	3M
Burgos, 2000(a)[95] Spain	Yes	Unclear	Yes	Yes	Yes	a) No b) No c) Yes d) No	Yes	Yes	Yes	Good	Laboratories Knoll
Burgos, 2000(b)[96] Spain	Unclear	Unclear	Yes	Yes	Yes	a) No b) No c) Yes d) No	Yes	Yes	Yes	Fair	Knoll, SA
Chang, 1998[53] Malaysia	Unclear	Unclear	Unclear	Yes	No	a) No b) No c) No d) No	Yes	Yes	Yes	Poor	Bristol-Myers Squibb
Chuangsuwanich, 2011[54] Thailand	Yes	No	Yes	Yes	No	a) No b) No c) No d) No	Yes	Yes	Yes	Fair	NR
Colin, 1996[55] Multinational	Unclear	Unclear	Yes	Yes	No	a) No b) No c) Yes d) No	Yes	Yes	Unclear	Poor	NR
Colwell, 1993[56] US	No	No	Yes	Yes	No	a) Yes b) Unclear c) Unclear d) Unclear	No	Yes	Yes	Poor	Bristol Myers Squib

Evidence Table H-6a: Local Wound Applications Trial Quality Rating, continued											
Author Year Country	**Appropriate Randomization Technique**	**Allocation concealment adequate?**	**Groups (intervention and control) similar at baseline?**	**Eligibility criteria specified?**	**Outcome assessors masked?**	**Reporting of: a) attrition b) crossovers c) adherence d) contamination**	**Dropout rate <20 percent**	**Intention-to-treat analysis**	**Appropriate Statistical Analyses**	**Risk of Bias (Quality Rating)**	**Funding Source**
Darkovich, 1990[57] US	No	No	Unclear	Yes	No	a) No b) Unclear c) Unclear d) Unclear	Unclear	Unclear	Yes	Poor	NR
Day, 1995[58] US, UK and Canada	No	No	Yes	Yes	Unclear (NA?)	a) Yes b) Unclear c) Unclear d) Unclear	Yes	Yes	Yes	Fair	NR
Felzani, 2011[97] Italy	No	No	Yes	Yes	Unclear	a) Yes b) Unclear c) Unclear d) Unclear	Yes	Unclear	Unclear	Poor	NR
Gerding, 1992[98] US	Yes	Yes	Unclear	Yes	Yes (Blinded)	a) Unclear b) Unclear c) Unclear d) Unclear	Unclear	Unclear	Unclear	Poor	NR
Gorse, 1987[59] US	No	No	Yes	Yes	Not Reported	a) Unclear b) Unclear c) Unclear d) Unclear	Unclear	Yes	Yes	Poor	NR
Graumlich, 2003[99] US	Yes	Yes	Yes	Yes	Yes	a) No b) No c) Yes d) No	Yes	Yes	Yes	Good	Retirement research foundation
Guthrie, 1989[100] US	Yes	Yes	Yes	Yes	Yes (reported)	a) Yes b) Unclear c) Unclear d) Unclear	Yes	Unclear	Yes	Fair	NET/Ben Franklin Technology Center
Hirshberg, 2001[122] US	Unclear	Unclear	No	Yes	Unclear	a) No b) No c) Yes d) No	No	Yes	Yes	Poor	US Dept of Veterans Affairs

Evidence Table H-6a: Local Wound Applications Trial Quality Rating, continued											
Author Year Country	**Appropriate Randomization Technique**	**Allocation concealment adequate?**	**Groups (intervention and control) similar at baseline?**	**Eligibility criteria specified?**	**Outcome assessors masked?**	**Reporting of: a) attrition b) crossovers c) adherence d) contamination**	**Dropout rate <20 percent**	**Intention-to-treat analysis**	**Appropriate Statistical Analyses**	**Risk of Bias (Quality Rating)**	**Funding Source**
Hollisaz, 2004[101] Iran	Yes	Yes	Yes	Yes	Yes	a) No b) No c) No d) No	Yes	Yes	Yes	Good	Iran government agency
Honde, 1994[60] Japan	Yes	Unclear	Yes	Yes	No	a) No b) No c) Yes d) No	Yes	Yes	Yes	Fair	Synthelabo Recherche
Hsu, 2000[102] Japan	No	No	Yes	Yes	Unclear	a) Unclear b) Unclear c) Unclear d) Unclear	Unclear	Yes	Yes	Poor	NR
Kaya, 2005[61] Turkey	Unclear	Unclear	Yes	Yes	Unclear	a) No b) No c) No d) No	Yes	Unclear	No	Poor	NR
Kerihuel, 2010[62] France	Yes	Yes	No	Yes	Yes	a) No b) No c) Yes d) No	Yes	Yes	Yes	Good	Systagenix
Kim, 1996[63] Korea	Unclear	Unclear	No	Yes	Unclear	a) No b) Yes c) No d) No	Yes	Yes	Yes	Poor	NR
Kloth, 2002[64] US	No	No	Unclear	Yes	Unclear	a) Unclear b) Unclear c) Unclear d) Unclear	No	Yes	Yes	Fair	Augustine Medical Inc
Kraft, 1993[65] US	Unclear	Unclear	Unclear	Yes	Unclear	a) No b) No c) Yes d) No	Yes	Yes	No	Poor	Calgon Vestal

Evidence Table H-6a: Local Wound Applications Trial Quality Rating, continued

Author Year Country	Appropriate Randomization Technique	Allocation concealment adequate?	Groups (intervention and control) similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Reporting of: a) attrition b) crossovers c) adherence d) contamination	Dropout rate <20 percent	Intention-to-treat analysis	Appropriate Statistical Analyses	Risk of Bias (Quality Rating)	Funding Source
Kuflik, 2001[103] US	Unclear	Unclear	No	No	Unclear	a) Yes b) No c) No d) No	Yes	Yes	Unclear	Poor	TopixPharmaceuticals
Kurzuk-Howard, 1985[66] US	No	No	No	No	No	a) No b) No c) Yes d) No	No	Unclear	No	Poor	Acme United
Landi, 2003[123] Italy	Yes	Yes	Yes	Yes	Yes	a) NA b) No c) No d) No	Yes	Yes	Yes	Good	Italian National Research Council
LeVasseur, 1991[104] Australia	No	No	No	No	Yes	a) Yes b) Unclear c) Unclear d) Unclear	No	Yes	Yes	Poor	NR
Matzen, 1999[67] Denmark	Unclear	Unclear	Yes	Yes	Unclear	a) No b) No c) Yes d) No	Yes	Yes	Yes	Poor	NR
Meaume, 2003[69] France	Yes	Yes		Yes	No	a) No b) No c) No d) No	Yes	Yes	Yes	Fair	NR
Meaume, 2005[68] France	Yes	No	Yes	Yes	Unclear	a) Yes b) Unclear c) Unclear d) Unclear	Yes	Yes	Yes	Fair	NR
Motta, 1999[70] US	Unclear	Unclear	No	Yes	Unclear	a) No b) No c) No d) No	Yes	Yes	Unclear	Poor	AcryMed

Evidence Table H-6a: Local Wound Applications Trial Quality Rating, continued

Author Year Country	Appropriate Randomization Technique	Allocation concealment adequate?	Groups (intervention and control) similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Reporting of: a) attrition b) crossovers c) adherence d) contamination	Dropout rate <20 percent	Intention-to-treat analysis	Appropriate Statistical Analyses	Risk of Bias (Quality Rating)	Funding Source
Mulder, 1993[71] US	Yes	Unclear	No	Yes	No	a) No b) No c) Yes d) No	Yes	No	Yes	Poor	NR
Muller, 2001[105] Germany and The Netherland	Unclear	Unclear	Yes	Yes	Unclear	a) No b) No c) Yes d) No	Yes	No	Yes	Poor	Knoll AG
Mustoe, 1994[124] US	Unclear	Unclear	Yes	Yes	Unclear	a)Yes b) No c) Yes d) No	No	No	Yes	Poor	Amgen
Neill, 1989[72] US	No	No	Yes	Yes	No	a) Unclear b) Unclear c) Unclear d) Unclear	Unclear	Unclear	Yes	Poor	3M Company, Medical-Surgical Division
Nisi, 2005[106] Italy	Unclear	Unclear	Unclear	Yes	Unclear	a) No b) No c) No d) No	Unclear	Unclear	Unclear	Poor	NR
Oleske, 1986[73] US	Unclear	Unclear	No	Yes	No	a) Yes b) No c) No d) No	Yes	Yes	No	Poor	Chicago Community Trust
Payne, 2001[125] US	Yes	Yes	Yes	Yes	Yes	a) Yes b) No c) No d) No	Yes	Yes	Yes	Poor	Grant O01-AR42967 from NIAMS, National Institutes of Health *Schering-Plough Reasearch Institute and Scois, Inc., provided cytokines used in this study*

Evidence Table H-6a: Local Wound Applications Trial Quality Rating, continued

Author Year Country	Appropriate Randomization Technique	Allocation concealment adequate?	Groups (intervention and control) similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Reporting of: a) attrition b) crossovers c) adherence d) contamination	Dropout rate <20 percent	Intention-to-treat analysis	Appropriate Statistical Analyses	Risk of Bias (Quality Rating)	Funding Source
Payne, 2004[126] US	Yes	Yes	Yes	Yes	No	a)Yes b) No c) Yes d) No	Yes	Yes	Yes	Good	Smith & Nephew, Inc.
Payne, 2009[74] US	Yes	Unclear	No	Yes	No	a) No b) No c) Yes d) No	Yes	Yes	Yes	Poor	NR
Price, 2000[75] UK	Yes	Yes	Yes	Yes	NA	a) Yes b) No c) No d) No	Yes	Yes	Yes	Good	NR
Pullen, 2002[107] Germany	No	No	Yes	Yes	Yes	a) Yes b) Unclear c) Unclear d) Unclear	No	Yes	Yes	Fair	NR
Rees, 1999[127] US	Unclear	Unclear	Yes	Yes	Unclear	a) No b) No c) No d) No	Yes	Yes	Yes	Fair	Johnson & Johnson
Rhodes, 2001[108] US	No	No	Yes	Yes	Unclear (NA?)	a) Yes b) Unclear c) Unclear d) Unclear	Yes	Unclear	Yes	Poor	NR
Robson, 1992(a)[128] Robson, 1992(b)[129] US	No	No	Yes	Yes	Yes	a) Yes b) Unclear c) Unclear d) Unclear	Yes	Unclear	Yes	Poor	NR
Robson, 1992(c)[132] US	No	No	Unclear	Yes	YEs	a) No b) Unclear c) Unclear d) Unclear	Unclear	Unclear	Yes	Poor	NR

Evidence Table H-6a: Local Wound Applications Trial Quality Rating, continued											
Author Year Country	**Appropriate Randomization Technique**	**Allocation concealment adequate?**	**Groups (intervention and control) similar at baseline?**	**Eligibility criteria specified?**	**Outcome assessors masked?**	**Reporting of: a) attrition b) crossovers c) adherence d) contamination**	**Dropout rate <20 percent**	**Intention-to-treat analysis**	**Appropriate Statistical Analyses**	**Risk of Bias (Quality Rating)**	**Funding Source**
Robson, 1994[130] US	No	No	Yes	Yes	No	a) Yes b) No c) No d) No	Yes	Unclear	Yes	Poor	Immunex
Robson, 2000[131] US	No	No	Yes	Yes	Yes	a) No b) Unclear c) Unclear d) Unclear	Unclear	Unclear	Yes	Poor	NR
Sayag, 1996[109] France	Yes	Yes	Yes	Yes	NA	a) Yes b) Unclear c) Unclear d) Unclear	Yes	Yes	Yes	Good	NR
Scevola, 2010[133] Italy	Unclear	Unclear	Unclear	Yes	No	a) No b) No c) Yes d) No	No	Unclear	Yes	Poor	NR
Sebern, 1986[76] Sebern, 1989[77] US	Yes	No	Yes	Yes	NA	a) Yes b) Unclear c) Unclear d) Unclear	Yes	No	Yes	Poor	NR
Seeley, 1999[78] US	No	No	Yes	Yes	No	a) Yes b) Unclear c) Unclear d) Unclear	Yes	Yes	Yes	Fair	NR
Shamimi Nouri, 2008a[110] Iran	Yes	Yes	Yes	Yes	Unclear	a) Yes b) No c) No d) No	Yes	Yes	Yes	Poor	ParsRoos C.
Sipponen, 2008[111] Finland	No	No	No	No	No	a) No b) No c) No d) No	Unclear	Yes	Yes	Poor	NR

Evidence Table H-6a: Local Wound Applications Trial Quality Rating, continued

Author Year Country	Appropriate Randomization Technique	Allocation concealment adequate?	Groups (intervention and control) similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Reporting of: a) attrition b) crossovers c) adherence d) contamination	Dropout rate <20 percent	Intention-to-treat analysis	Appropriate Statistical Analyses	Risk of Bias (Quality Rating)	Funding Source
Small, 2002[79] South Africa	Yes	Unclear	Yes	Yes	Unclear	a) Yes b) Unclear c) Unclear d) Unclear	No	Yes	Yes	Fair	NR
Subbanna, 2007[112] India	Yes	No	Yes	Yes	Yes	a) Yes b) Unclear c) Unclear d) Unclear	Yes	Unclear	Yes	Good	NR
Thomas, 1997[80] UK	NA	NA	Yes	Yes	No	a) Unclear b) Unclear c) Unclear d) Unclear	Unclear	Unclear	Unclear	Poor	NR
Thomas, 1998[81] US	No	No	Yes	Yes	Unclear	a) Yes b) Unclear c) Unclear d) Unclear	No	Unclear	Yes	Poor	Seebum Laboratories
Thomas, 2005[82] US	Yes	Yes	Yes	Yes	NA	a) Unclear b) Unclear c) Unclear d) Unclear	Yes	Yes	Yes	Good	NR
Tytgat, 1988[113] Belgium	No	No	Unclear	Unclear	Unclear	a) Unclear b) Unclear c) Unclear d) Unclear	Unclear	Unclear	Yes	Poor	NR
Whitney, 2001[83] US	No	No	Yes	Yes	No	a) Yes b) Unclear c) Unclear d) Unclear	No	Yes	Yes	Fair	Augustine Medical Inc
Winter, 1990[84] UK	No	No	Yes	Yes	Not Reported	a) Yes b) Yes c) Yes d) No	Yes	Unclear	Yes	Poor	Coloplast LTD

Evidence Table H-6a: Local Wound Applications Trial Quality Rating, continued

Author Year Country	Appropriate Randomization Technique	Allocation concealment adequate?	Groups (intervention and control) similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Reporting of: a) attrition b) crossovers c) adherence d) contamination	Dropout rate <20 percent	Intention-to-treat analysis	Appropriate Statistical Analyses	Risk of Bias (Quality Rating)	Funding Source
Xakellis,1992[88] US	No	Unclear	Yes	Yes	No	a) Unclear b) Unclear c) Unclear d) Unclear	Yes	Yes	Yes	Fair	Family Health Foundation of America and ConvaTec
Yapucu Gunes, 2007[86] Turkey	No	No	Yes	Yes	No	a) Unclear b) Unclear c) Unclear d) Unclear	Yes	Unclear	Yes	Fair	NR
Yastrub, 2004[87] US	Unclear	Unclear	Unclear	No	Unclear	a) No b) No c) Yes d) No	Yes	No	Yes	Poor	NR
Zeron, 2007[114] Mexico	Yes	Yes	Yes	Yes	Yes	a) Unclear b) Unclear c) Unclear d) Unclear	Yes	Yes	Yes	Poor	NR

*Note: Non-comparative studies used for evaluation of harms only were quality rated but not presented in the evidence tables due to the paucity of reportable data in these studies. Our tables include only studies of comparative effectiveness.

Evidence Table H-6b. Local wound applications observational studies quality rating

Author Year Country	(1) Did the study attempt to enroll all (or a random sample of) patients meeting inclusion criteria, or a random sample (inception cohort)?	(2) Were the groups comparable at baseline on key prognostic factors (e.g., by restriction or matching)?	(3) Did the study maintain comparable groups through the study period?	(4) Did the study use accurate methods for ascertaining exposures and potential confounders?	(5) Were outcome assessors and/or data analysts blinded to the exposure being studied?	(6) Did the article report attrition?	(7) Did the study perform appropriate statistical analyses on potential confounders?	(8) Is there important differential loss to follow-up or overall high loss to follow-up?	(9) Were outcomes pre-specified and defined, and ascertained using accurate methods?	Quality	Funding Source
Danon, 1997[121]	Yes	No	Unclear	No	Unclear	No	No	Unclear	Unclear	Poor	NR
Harding, 1996[115] US	Unclear	NA	NA	NA	No	No	NA	Unclear	Unclear	Poor	Advance Biofactures Corp
Hindryckx, 1990[116] Belgium	Unclear	NA	NA	NA	No	No	NA	No	Unclear	Poor	NR
Meaume, 2007[88] France	Unclear	No	No	Unclear	Unclear	Yes	No	No	No	Fair	NR
Moody, 1991[89] US	Unclear	NA	NA	Unclear	No	Yes	NA	Yes	No	Poor	NR
Narayanan, 2005[117] US	NA (retrospective)	Yes	NA	Yes	NA (retrospective)	NA (retrospective)	Yes	No	Yes	Fair	NR

Evidence Table H-6b. Local wound applications observational studies quality rating

Author Year Country	(1) Did the study attempt to enroll all (or a random sample of) patients meeting inclusion criteria, or a random sample (inception cohort)?	(2) Were the groups comparable at baseline on key prognostic factors (e.g., by restriction or matching)?	(3) Did the study maintain comparable groups through the study period?	(4) Did the study use accurate methods for ascertaining exposures and potential confounders?	(5) Were outcome assessors and/or data analysts blinded to the exposure being studied?	(6) Did the article report attrition?	(7) Did the study perform appropriate statistical analyses on potential confounders?	(8) Is there important differential loss to follow-up or overall high loss to follow-up?	(9) Were outcomes pre-specified and defined, and ascertained using accurate methods?	Quality	Funding Source
Parnell, 2005[90] Country not reported	No	No	No	Unclear	Unclear	Yes	No	No	Unclear	Poor	NR
Sherman, 1995[118] US	Yes	NA	NA	No	No	Yes	Unclear	Yes	Yes	Poor	Spinal Cord Research Foundation & CA Paralyzed Veterans of America
Sherman, 2002[119] US	No	No	No	Yes	No	No	No	No	Yes	Poor	Paralyzed Veterans of America, Andrus Foundation
Stoker, 1990[91] UK	No	Unclear	Unclear	Unclear	No	Yes	Unclear	Yes	Yes	Poor	Coloplast LTD
Viamontes, 2003[92] US	Yes	No	No	Unclear	No	NA (retrospective)	No	NA (retrospective)	Unclear	Poor	NR
Wang, 2010[120] China	No	Yes	Yes	Unclear	No	Yes	No	No	Yes	Poor	National Natural Science Foundation of China
Zuloff-Shani, 2010[134] Israel	Yes	No	Unclear	Unclear	No	No	No	No	No	Poor	Rosetree Trust

Evidence Table H-7: Surgery

Evidence Table H-7a: Surgery Trials*

Author, year Country Overall Quality Rating	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset)	Proportion Treatment Naïve	Treatment A	Treatment B	Treatment C	Duration of Followup	Study Setting
Juri, 1987[135] Argentina Poor	Nursing home patients admitted to hosp ital, PU stage III and IV	Mentally incapacitating diseases Conditions that could have influenced the results of the study Young patients	66/NR/60/60	Age (Mean): 66.5 years Female: NR Race: NR	Surgery - debridement with closure by tissue flap or skin graft	Stage III or IV	NR	CO2 laser surgery	Conventional surgery	NA	Until hospital discharge - up to 76 days	Hospital

Evidence Table H-7a: Surgery Trials,* continued								
Author, year Country Overall Quality Rating	**Outcomes: Complete Wound Healing**	**Outcomes: Wound Surface Area**	**Outcomes: Healing Time**	**Outcomes: Infection Rate**	**Outcomes: Osteomyelitis Rate**	**Outcomes: Recurrence Rate/Flap Failure**	**Outcomes: Pain**	**Other Outcomes: Specify**
Juri, 1987[135] Argentina Poor	NR	NR	NR	Treatment A: 11/30 (36.7%) Treatment B: 14/30 (46.7%), p<0.005	NR	Failure rate: Treatment A: 19% (5) Treatment B: 24% (6) p=NS	NR	Hospital Days: Treatment A: 25 Treatment B: 58 p<0.01

Evidence Table H-7a: Surgery Trials,* continued								
Author, year Country Overall Quality Rating	**Harms: Pain**	**Harms: Dermatologic Complications**	**Harms: Bleeding**	**Harms: Infection**	**Other Harms: Specify**	**Severe Adverse Events**	**Withdrawal due to Adverse Events**	**Overall Adverse Events Rate**
Juri, 1987[135] Argentina Poor	NR	NR	Blood Loss: Treatment A: 2.1cm^3/cm^2 Treatment B: 2.6 cm^3/cm^2 p<0.01	NR	NR	Mortality Treatment A: 4/30 (13.3%), Treatment B: 5/30 (16.7%), NS	NR	NR

* Observational studies for the Surgical Interventions section of the report were assessed and data was extracted into evidence tables, however, due to the paucity of reported data, we have opted to present only the key details and results of these studies in the in-text summary tables included within the body of the report (Table 12).

Evidence Table H-8: Surgery Quality Rating

Evidence Table H-8a. Surgery trials quality rating

Author, Year Country	Appropriate Randomization Technique?	Allocation Concealment Adequate?	Groups (Intervention and Control) Similar at Baseline?	Eligibility Criteria Specified?	Outcome Assessors Masked?	Reporting of: a) Attrition, b) Crossovers, c) Adherence, d) Contamination?	Dropout Rate <20 Percent?	Intention-to-treat Analysis?	Appropriate Statistical Analyses?	Overall Quality Rating	Funding Source
Juri, 1987[135] Argentina	No	No	No (NR)	No	No	a) No b) No c),No d) No	Yes	Unclear	Yes	Poor	NR

Evidence Table H-8b. Surgery observational studies quality rating

Author, Year Country	(1) Did the study attempt to enroll all (or a random sample of) patients meeting inclusion criteria, or a random sample (inception cohort)?	(2) Were the groups comparable at baseline on key prognostic factors (e.g., by restriction or matching)?	(3) Did the study maintain comparable groups through the study period?	(4) Did the study use accurate methods for ascertaining exposures and potential confounders?	(5) Were outcome assessors and/or data analysts blinded to the exposure being studied?	(6) Did the article report attrition?	(7) Did the study perform appropriate statistical analyses on potential confounders?	(8) Is there important differential loss to followup or overall high loss to followup?	(9) Were outcomes pre-specified and defined, and ascertained using accurate methods?	Overall Quality Rating	Funding Source
Foster, 1997a[136] US	Yes	Yes	Unclear	Unclear	No	NA	Yes	Unclear	Yes	Fair	NR
Foster, 1997b[137] US	Yes	Unclear	Unclear	Unclear	No	NA	Yes	No	Yes	Fair	NR
Kierney, 1998[138] US	Yes	Unclear	Unclear	Yes	No	No	Yes	No	Yes	Fair	NR
Schryvers, 2000[139] Canada	Yes	No	No	Unclear	No	No	Unclear	No	Yes	Fair	NR
Yamamoto, 1997[140] Japan	Unclear	Unclear	Unclear	Unclear	No	No	Yes	No	Yes	Fair	NR

Evidence Table H-9: Adjunctive

Evidence Table H-9a. Adjunctive trial and observational studies

Author, year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset) Stage Size (mean) Location
Adegoke, 2001[141] Nigeria Fair	Randomized trial	Patients presenting with multiple pressure ulcers admitted to the neurology wards of the University College Hospital, Ibadan, Nigeria.	Patients that were smokers	NR/NR/7/6	Age (Mean):44 years Female: NR Race: NR	Adjunctive: Electrical Stimulation vs. sham	Stage: 100% Stage IV Size (mean): 15.8 vs. 15.4 mm^2 Location: greater trochanter - 2 vs. 1 sacrum - 1 vs. 2
Adunsky, 2005[142] Israel Fair	Randomized trial	Only in-patients, with stage III degree non-diabetic pressure ulcers lasting 30 days, age>18 years, informed consent, ulcer duration less than 24 months, ulcer size greater than 1 cm^2 but smaller than 50 cm^2, no recent history (minimum of 30 days) of growth factors or vacuum-assisted treatment.	Patients with ulcers other than 3 degree (stage III), liver function enzymes higher than twice the upper limit of normal values, renal failure with creatinine>2 mg%, anemia (hemoglobin<10 g%), albumin<2.6 g%, and patients having a pacemaker. Patients with significant medical disorder that might interfere with treatment results, patients with recent (2 months) use of steroids, chemotherapy, or other immunocompromising drugs.	NR/NR/63/63	Age (Mean): 71 years Female: 35% Race: NR	Adjunctive: Electrical Stimulation vs. sham	Stage: NR Size (mean): 7.5 vs. 7.6 cm^2 Location: sacrum – 25 trochanters – 13 legs – 13 buttocks – 4 ischium – 2
Ahmad, 2008(a)[143] Ahmad, 2008(b)[144] Saudi Arabia Fair	Randomized trial	Chronic pressure ulcer, Stage II ulcers (Article uses Yarkony-Kirk grade criteria)	Cardiac pacemaker; peripheral vascular diseases; active osteomyelitis; pregnant; receiving long-term radiation therapy, steroid therapy or chemotherapy.	NR/NR/60/60	Age (Mean): 39 years Female: 53% Race: NR	Adjunctive: Electrical Stimulation (high voltage pulsed galvanic current (HVPC))	Stage: II Size (mean cm^2): 7.12 vs. 7.12 vs. 7.14 vs. 7.21 Location: NR

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued							
Author, year Country Overall Quality Rating	**Study Type**	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type**	**Ulcer Type/Severity at Baseline (Intervention Onset) Stage Size (mean) Location**
Baker, 1996[145] US Fair	Randomized trial	Patients with spinal cord injuries (SCI) and one or more pressure ulcers.	NR	NR/NR/80/80	Age (Mean): 36 years Female: 18% Race: White - 43% Black - 29% Other - 28%	Adjunctive: Electrical Stimulation	Stage: NR Size (mean): 6.6 vs. 2.4 vs. 8.5 vs. 8.6 cm^2 Location: foot - 13% vs. 9% vs. 7% vs. 8% thigh - 15% vs. 23% vs. 26% vs. 16% ischial - 30% vs. 33% vs. 24% vs. 40% sacral - 30% vs. 33% vs. 24% vs. 36% other - 5% vs. 5% vs. 14% vs. 36%
Burke, 1998*[146] US Fair	Randomized trial	VA inpatients presenting with either a Grade III or IV pressure ulcer.	NR	NR/NR/18/ 18(42 PU)	Age (Mean): NR Female: NR Race: NR	Adjunctive: Hydrotherapy	Stage: Grade III or IV – 100% Size (mean): NR Location: NR
Comorosan, 1993[147] Romania Fair	Trial	Ministry of Health (Romania) in terminal stages of life, chronically ill, or neurologically impaired. Patients had stage II and III ulcers.	NR	NR/NR/30/30	Age (Mean): 72 years Female: 56% Race: NR	Adjunctive: Electromagnetic pulse	Stage: II - 67% III - 33% Size (mean): 5.6 cm2 Location: Sacrum - 23% Buttock - 30% Other - 47%

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued							
Author, year Country Overall Quality Rating	**Study Type**	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type**	**Ulcer Type/Severity at Baseline (Intervention Onset) Stage Size (mean) Location**
Dehlin, 2003[148] Denmark Fair	Randomized trial	Patients with stage III (Shea grade II or III score) pressure ulcer, ulcer location on the trunk or foot, ulcer age 2 weeks to 6 months, initial area 1-20 cm^2, and patients age >65 years.	Patients with unstable diabetes mellitus (HbA1c >10%), serious or terminal malignancy or terminal illness, treatment with radiotherapy or cytotoxins, suspected or proven osteomyelitis, antibiotic treatment of ulcer within 2 weeks , use of corticosteroids, (>10mg/day of prednisone) significant abnormal blood tests in the month before inclusion, pacemaker, photosensitivity or sensitivity to electromagnetic radiation, life expectancy < 3 months, and participation in any other clinical study during the last month.	NR/NR/201/164	Age (Mean):84 years Female: 65% Race: NR	Adjunctive: Light Therapy	Stage: (Shea) Stage II - 56% vs. 50% Stage III - 44% vs. 50% Size (mean): NR Location: Foot - 55% vs. 55% Trunk - 45% vs. 45% Ulcer age (mean): 49 vs. 57 days
Dehlin, 2007[149] Denmark Fair	Randomized trial	Patients with stage III (Shea grade II or III score) pressure ulcer, ulcer location on the trunk or foot, ulcer age 2 weeks to 6 months, initial area 1-20 cm^2, and patients age >65 years.	Patients with unstable diabetes mellitus (HbA1c >10%), serious or terminal malignancy or terminal illness, treatment with radiotherapy or cytotoxins, suspected or proven osteomyelitis, antibiotic treatment of ulcer within 2 weeks , use of corticosteroids, (>10mg/day of prednisone) significant abnormal blood tests in the month before inclusion, pacemaker, photosensitivity or sensitivity to electromagnetic radiation, life expectancy < 3 months, and participation in any other clinical study during the last month.	NR/NR/163/163 (including 87 subjects from 2003 study)	Age (Mean): 84 years Female: 61% Race: NR	Adjunctive: Light Therapy	Stage: (Shea) Stage II/III – 100% Size (mean): 4.1 vs. 4.7cm^2 Location: Foot - 41% vs. 46% Trunk - 59% vs. 54% Ulcer age (mean): 41 vs. 46 days

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued

Author, year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset) Stage Size (mean) Location
Durovic, 2008[150] Serbia Fair	Prospective, randomized, single-blind study	Patients with stage I–III ulcer; absence of relative contraindications for using of polarized light; absence of deterioration of a common disease or attack of new disease; and a patient's agreement to participate in the study.	Patients previously in the study to treat their current pressure ulcer; skin grafting was planned within one week; nutrition was poor, as indicated by albumin levels below 3.0 g/dL; presence of local or general infection, particularly the sacral (pilonidal) sinus or the sacral osteomyelitis; necessity for drugs that can affect the skin and delay in healing, specially steroids, immunosuppressive agents, antineoplastic drugs and anticoagulants.	NR/48/40/40	Age (Mean):65 years Female: 45% Race: NR	Adjunctive: Light Therapy	Stage: I-III Size (mean):Surface Area (cm^2) - 15.10 vs. 19.15, p=0.18 Location: Low part of back - 0 vs. 5% Right-low part of back 5% vs. 0 Right buttock - 5% vs. 0 Left buttock - 5% vs. 5% Both buttocks - 0 vs. 10% Sacral area - 50% vs. 25% Right sacral-buttock area - 5% vs. 0 Right iliac spine - 0 vs. 5% Left hip - 15% vs. 15% Right hip - 0 vs. 5% Right heel - 5% vs. 20% Left heel - 10% vs. 10%
Ford, 2002[151] US Fair	Randomized trial	Presence of stage III or IV ulcer for 4 or more weeks; albumin greater than or equal to 2.0; age 21–80; and ulcer volume after debridement = 10–150 ml.	Fistulas to organs or body cavities; malignancy in the wound; pregnant or lactating female; Hashimoto thyroiditis, Graves disease, iodine allergy, systemic sepsis; electrical burn, radiation exposure, chemical exposure; cancer, connective tissue disease, chronic renal or pulmonary disease, uncontrolled diabetes, corticosteroids or immunosuppressive agents; cardiac pacemaker; ferromagnetic clamps; or recent placement of orthopedic hardware.	NR/NR/28/22	Age (Mean): 41.7 vs. 54.4 years Female: NR Race: NR	Adjunctive: Negative Pressure Wound Therapy	Stage: Stage II & III – 100% Size (mean): NR Location: Ischial - 25.7% Sacral - 48.6% Lateral malleolar - 11.4% Trochanteric - 2.9% Calcaneal - 11.4%

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued							
Author, year Country Overall Quality Rating	**Study Type**	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type**	**Ulcer Type/Severity at Baseline (Intervention Onset) Stage Size (mean) Location**
Gentzkow, 1991[152] US and Canada Fair	Randomized trial	Patients with open pressure ulcers at Stage II, III or IV at 9 centers in the US and Canada.	Ulcers were excluded if they were totally occluded by eschar, had bleeding or involved major blood vessels; located presternal, periorbital, or laryngeal/pharyngeal; occurred in pregnant patients; patients with cardiac pacemakers; osteomyelitis or peripheral vascular problems predisposing them to thrombosis; cancerous; patients on long-term steroid therapy, chemotherapy, radiation therapy, or were very obese.	NR/NR/49(ulcers)/40(ulcers)	Age (Mean): 63 years Female: 45% Race: NR	Adjunctive: Electrical Stimulation	Stage: Stage II - 5% vs. 0% Stage III - 73% vs. 76% Stage IV - 21% vs. 24% Size (mean): 12.5 vs. 19.2 cm^2 Location: Hip/Ischium - 32% vs. 42% Sacrum/Coccyx - 42% vs. 19% Leg/Foot - 26% vs. 38%
Griffin, 1991[153] US Fair	Randomized trial	Male, complete/incomplete spinal cord injury (SCI), pelvic pressure ulcer stage II-IV.	Severe cardiac disease; cardiac arrhythmia; uncontrolled autonomic dysreflexia or used a pacemaker.	NR/NR/20/17	Age (Median): 29 years Female: 0% (Male:100%) Race: NR	Adjunctive: Electrical Stimulation	Treatment vs. placebo stage II: 25% vs. 22.2% stage III: 62.5% vs. 66.6% stage IV: 12.5% vs. 11.1% Size (mean mm^2): 234.1 vs. 271.8 Location: pelvic area
Gupta, 2009[154] India Fair	Randomized trial	Inpatients with neurological disorders having one or more stage III or IV clean and non-infected ulcers.	Patients with cardiac pacemakers and pregnant women were excluded from the study. Nonischemic ulcers and ulcers with underlying osteomyelitis were also excluded from the study.	NR/NR/12/12	Age (Mean): 28 years Female: 25% Race: Non-white - 100%	Adjunctive: Electromagnetic Therapy	Stage: Stage III - 37% Stage IV - 43% Size (mean): NR Location: NR

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued							
Author, year Country Overall Quality Rating	**Study Type**	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type**	**Ulcer Type/Severity at Baseline (Intervention Onset) Stage Size (mean) Location**
Ho, 2010[155] US Fair	Cohort - Multicenter, observational study	Hospitalized inpatients at the SCI centers associated with 10 VA Medical Facilities; male or female inpatients (aged ≥18 years) with SCI and at least 1 Stage III/IV (indicating a severe wound) ulcer of the pelvic region.	Patients elected to have reconstructive flap surgery of the target pressure ulcer; patients with known osteomyelitis who had not been, or refused to be, adequately treated with appropriate antibiotic treatment and/or surgical procedures (as determined by the patients' physician); no resolution of osteomyelitis after 3 months of antibiotic and/or surgical care; psychopathology that may conflict with study objectives; Previous diagnosis of active malignant disease at any time during the patient's lifetime; life expectancy <12 months; History of nephrosis, hemodialysis, or chronic ambulatory peritoneal, dialysis therapy; history of AIDS, at immunologic risk of infectious complications within the past 6 months; known hypersensitivity to anabolic steroid medications ,coronary artery disease, significant occlusive vascular disease, or congestive heart failure; or inability/unwillingness to provide informed consent.	NR/NR/86/86	Age (Mean): 55 years Female: 2% Race: White - 56% African American - 37% Asian - 1% Hispanic - 5%	Adjunctive: Negative Pressure Wound Therapy	Stage: Stage III (mean) - 1 vs. <1 ulcers Stage IV(mean) - 2 vs. 2 ulcers Size (mean) - NR Location: Ischial - 42% vs. 52% Perineal - 2% vs. 0% Sacral - 43% vs. 48% Trochanter - 13% vs. 0%

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued							
Author, year Country Overall Quality Rating	**Study Type**	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type**	**Ulcer Type/Severity at Baseline (Intervention Onset) Stage Size (mean) Location**
Ho, 2012[156] US Fair	Prospective, randomized trial	Inpatients who had SCI and were receiving standard wound care for stage III and IV pelvic pressure ulcers; aged older than 18 years;☐ No preserved sensory function in the area of the pressure ulcers; Stage III and IV pelvic (coccygeal, ischial, or trochanteric region) pressure ulcers; clinically clean wound area (i.e., no necrotic tissue, no odor, and no exudate or minimal serosanguinous exudate only); No surrounding erythema or other evidence of cellulitis; ☐No tunneling, no actual or possible connection to body cavities, and no fistula; No malignancy or vascular disease associated with the area of tissue breakdown; No significant active systemic disease, such as heart disease, renal failure, diabetes, or end-stage cancer; Pressure ulcers with maximum diameters of 3 to 15 cm at recruitment into the study; No antibiotic therapy for 7 days before recruitment into the study.	NR	267/28/28/28	Age (Mean):56 years Female: NR Race: NR	Adjunctive: Pulsatile Lavage	Stage: Stage II or III - 100% Size (mean) – Ulcer volume – 6.54 vs. 10.56 cm^3 Location: Sacrococcygeal - 50% vs. 29% Ischial - 50% vs. 57% sacrococcygeal Buttock - 0% vs. 14%
Houghton, 2010[157] Canada Good	Randomized trial	Patients with paraplegia/ quadriplegia caused by congenital, medical or traumatic SCI, 18 years and older, living in the community, stage II-IV PU, 1-20 cm^2 for at 3+ months, able to participate for at least 3 months.	Serious or multiple medical conditions that would limit healing, condition that was contraindicated for EST (cardiac pacemaker, osteomyelitis, pregnancy, cancer).	67/34/34/31	Age (Mean): 51 years Female: 42% Race: NR	Adjunctive: Electrical Stimulation	Stage: stage II: 22.2% vs. 6.2% stage III: 22.2% vs. 37.5% stage IV: 55.5% vs. 43.7% stage X: 0% vs. 12.5% Size (mean cm^2): 2.73 vs. 3.38 Location: buttock region, foot, ankle and knee (NPUAP stage X: unstageable)

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued							
Author, year Country Overall Quality Rating	**Study Type**	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type**	**Ulcer Type/Severity at Baseline (Intervention Onset) Stage Size (mean) Location**
Iordanou, 2002[158] Greece Fair	Observational	Patients with pressure ulcers of 1st, 2nd and 3rd grades (Torrance); pressure ulcers on the buttocks, trochanters, sacrum, shoulders and legs; each patient had to have two pressure ulcers, one of which received the polarized therapy (experimental) and the other acting as comparator; and the larger ulcer of each patient was chosen as the experimental ulcer.	Presence of skin necrosis on the ulcers; previous or planned surgical excision of the pressure ulcer; and patients in palliative care (in very poor clinical status).	NR/NR/55/32	Age (Mean): 67 years Female: NR Race: NR	Adjunctive: Light Therapy	Stage (Torrance): 1-3 Stages I-III : 100% Size (mean): 2.84 vs. 2.10 cm^2 Location: Buttocks/trochanters/ sacrum/shoulders/legs - 100%
Kloth, 1988[159] US Fair	Randomized trial	Patients between 20 and 89 years of age, All patients in the study had intact peripheral nervous systems and stage IV ulcers that had eroded into or through muscle.	NR	NR/NR/16/ 16	Age (Mean): 69 years Female: NR Race: NR	Adjunctive: Electrical Stimulation	Stage: Stage IV - 100% Size (mean) - 4.08 cm^2 Location:
Lucas, 2003[160] Netherlands Fair	Randomized trial	Consecutive patients with stage III pressure ulcers.	Patients with ulcers other than stage III (full-thickness skin defect extending into adipose tissue).	NR/NR/86/79	Age (Mean):82 years Female: 63% Race: NR	Adjunctive: Laser Therapy	Stage III - 100% Size (mean): 350 vs. 317 mm^2 Location (n= 47 vs. 39): Gluteal - 8 vs. 4 Sacrum/Coccyx - 14 vs. 14 Greater trochanter - 1 vs. 0 Med. Femoral condyle - 0 vs. 1 Calcaneus - 14 vs. 13 Med. Fem. Cond. - 1 vs. 1 Lat. Malleolus - 5 vs. 3 Other - 0 vs. 0
Lucas, 2000(a)[161] Netherlands Fair	Randomized trial	Consecutive patients with stage III pressure ulcers.	Patients with ulcers other than stage III (full-thickness skin defect extending into adipose tissue).	NR/NR/20/16	Age (Median): 88 years Female: 88% Race: NR	Adjunctive: Laser Therapy	Stage III - 100% Size (mean): 94 vs. 82.5 mm^2 Location (n= 8 vs. 8): Gluteal - 1 vs. 3 Sacrum/Coccyx - 2 vs. 2 Calcaneus - 2 vs. 2 Med. Fem. Cond. - 1 vs. 1 Lat. Malleolus - 2 vs. 0 Other - 0 vs. 0

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued							
Author, year Country Overall Quality Rating	**Study Type**	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type**	**Ulcer Type/Severity at Baseline (Intervention Onset) Stage Size (mean) Location**
Maeshige, 2010[162] Japan Fair	Randomized trial	Treatment naive inpatients who were receiving standard wound care including surgical debridement, topical antimicrobials and pressure redistribution, presence of National Pressure Ulcer Advisory Panel (NPUAP) stage III or IV pressure ulcers.	clinical signs of local wound infection, extensive necrotic tissue, diabetes mellitus type 2 and/or peripheral arterial disease.	NR/NR/5/5	Age (Mean): 82 years Female: 60% Race: Non-white - 100%	Adjunctive: Ultrasound	7 ulcers/5 patients Stage III: 4/7 ulcers Stage IV: 3/7 ulcers Size (mean): 14.65 cm^2 Location: ilium - 1/7 lateral malleolus - 2/7 sacrum - 2/7 fibula/tibia - 2/7
McDiarmid, 1985[163] UK Fair	Randomized trial	Patients over 18 years or age with pressure sores referred by physiotherapy and nursing staff in three Bristol hospitals; pressure sores had not had radiotherapy in the area over the past 6 months.	Evidence of deep vein thrombosis (DVT); sores not limited to superficial tissue not extending beyond the dermis; pressure on the sore not capable of being removed; malignancies in the area to be treated.	NR/NR/40/18	Age (Mean): NR Female: NR Race: NR	Adjunctive: Ultrasound	Stage: NR Size (mean) NR: Location: NR
Nussbaum, 1994[164] UK Fair	Randomized trial	Hospitalized patients at Lyndhurst Spinal Cord Centre with a diagnosis of spinal cord injury (SCI) and skin wounds.	NR	NR/NR/20/20	Age (Mean):41 years Female: 11% Race: NR	Adjunctive: Laser Therapy	Stage: NR Size (mean): 2.1 vs. 1.9 vs. 2.8 cm^2 Location: NR
Onigbinde, 2010[165] South Africa Poor	Cohort	Absence of previous skin breakdown or wound prior to being admitted, presence of bilateral pressure sores on the lower limbs; a stable regimen of medications during the course of the study including the antibiotic ciproflaxin; a wound duration of at least 8 weeks; and age between 35-55 years.	Patients with diabetes, malnutrition, dermatitis, or with metallic implants	NR/NR/10/10	Age (Mean): 45 years Female: 80% Race: NR	Adjunctive: Light Therapy	Stage: NR Size (mean): Treatment A: 76.5 cm2 Treatment B: 43.8 cm2 Location: gluteal - 60% heel - 40%

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued

Author, year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset) Stage Size (mean) Location
Ozdemir, 2011[166] Turkey Fair	Randomized trial	Patients with stage II or III pressure sores due to immobilization as a result of hemiplegic, paraplegic, other neurological disorders, and amputation operations.	Pressure sores that were borderline to surgery and stage IV.	NR/NR/45/40	Age (Mean): 63 years Female: NR Race: NR	Adjunctive: Electromagnetic Therapy	Stage: NR Stage II – 80% vs. 60% Stage III – 10% vs. 40% Size (mean): NR Location: Sacrum - 21.05% vs. 20% Gluteus - 21.05% vs. 15% Trochanter - 10.52% vs. 15% Heels - 21.05% vs. 25% Other - 31.57% vs. 25%
Salzberg, 1995[167] US Fair	Randomized trial	Spinal cord-injured patients with pressure ulcers admitted to the Veteran's Administration Medical Center at Castle Point, NY over a 2-year period.	Patients with more than 1 ulcer, recent ulcer surgery, with a cardiac pacemaker, intercurrent disease, active cellulitis, sepsis, terminal illness or end-stage renal disease (ESRD), and patients with Stage I or IV pressure ulcers.	NR/NR/30/30	Age(Mean): 54 years Female: NR Race: NR	Adjunctive: Electromagnetic Therapy	Area: 14 vs. 33 cm^2, p=0.089 Granulation %: 23 vs. 45, p=0.210 Epithelization %: 8 vs. 10, p=0.222 Stage II - partial thickness skin loss involving epidermis and dermis, superficial presenting as deep crater, abrasion, blister, or shallow crater Stage III - full thickness skin loss involving damage or necrosis of subcutaneous tissue which may have extended down to, but not through, underlying fascia and presenting as a deep crater with or without undermining adjacent tissue

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued							
Author, year Country Overall Quality Rating	**Study Type**	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type**	**Ulcer Type/Severity at Baseline (Intervention Onset) Stage Size (mean) Location**
Schubert, 2001[168] Sweden Fair	Randomized trial	Elderly patients with Stage 2 or 3 pressure ulcer, newly admitted to an orthopedic or a geriatric ward, were asked to enter the study.	NR	NR/NR/74/59	Age (Mean): 85 years Female: 64% Race: NR	Adjunctive: Light Therapy	Stage: Stage 2/3 - 100% Size (under 10.0 cm^2): 92% vs. 94% Location: Trunk - 68% vs. 83%
Schwien, 2005[169] US Poor	Retrospective cohort study	Start of care and end of care between July 1, 2002 and September 30, 2004; one Stage III or one Stage IV pressure ulcer; and primary diagnosis of 707.0 decubitus chronic skin ulcer.	Patients who died at home; enteral or parenteral nutrition therapy; high risk factors of heavy smoking, alcohol dependency, or drug dependency; poor or unknown overall prognosis; or secondary diagnoses of uncontrolled diabetes, cancer, systemic infections, or related to malnutrition/ anemias/ proteinemia.	1,941,039/ 134,147/ 2,348/ 2,348(60 NPWT)	Age (Mean): 68.2 years Female: 56% Race: NR	Adjunctive: Negative Pressure Wound Therapy	Stage: Stage III - 7/60(24%) vs. 756/2288 (44%) Stage IV - 14/60(45%) vs. 337/2288(59%) Size (mean): NR Location:
Srivastava, 2010[170] India Poor	Prospective longitudinal interventional study (cohort)	Patients with large to moderate sacral pressure ulcers	NR	NR/NR/55/55	Age (Mean):NR Female:NR Race:NR	Adjunctive: Negative Pressure Wound Therapy	Stage Size (mean): NR Location: Sacral - 100%

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued							
Author, year Country Overall Quality Rating	**Study Type**	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type**	**Ulcer Type/Severity at Baseline (Intervention Onset) Stage Size (mean) Location**
Taly, 2004[171] India Good	Randomized trial	Patients with spinal cord disorders and admitted to the rehabilitation ward with pressure ulcers or who developed ulcers during their stay in the ward were eligible for the study. Pressure ulcers were divided into the conventional 4 stages: stage 1, nonblanching erythema of intact skin; stage 2, partial thickness skin loss; stage 3, full-thickness skin loss; and stage 4, extension into muscle and bone. 7 Pressure ulcers of the conventional stages 2, 3, and 4 were included in the study.	Subjects with photosensitivity, ulcers from other causes, necrotic tissue in ulcers that would interfere with the application of laser, flask-shaped ulcers that cannot be adequately exposed to laser, pressure ulcers with underlying osteomyelitis, or pressure ulcers requiring surgical intervention at the time of first assessment were excluded.	129/40/35/29	Age (Mean): 32 years Female: 23% Race: NR	Adjunctive: Laser Therapy	Stage: 2/3/4; 21 (32.8%) on the sacrum, 18 (28.1%) on the greater trochanter, 9 (14.1%) on the gluteal region, 2 (3.1%) on the lateral malleolus, 2 (3.1%) on the elbow, 1 (1.6%) on the ischial tuberosity, 1 (1.6%) on the heel, and 10 (15.6%) on other sites. Size (mean) Location: 55 at stage 2, 8 at stage 3, and at stage 4. Most ulcers evolved after hospitalization: 33 ulcers (51.6%) developed in an acute care facility, 13(20.3%) in a rehabilitation ward, and 18 (28.1%) at home. These ulcers could be attributed to prolonged lying in bed, 49 (76.6%); improper transfers, 10 (15.6%); and prolonged sitting, 5 (6.3%).

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued

Author, year Country Overall Quality Rating	Study Type	Eligibility Criteria	Exclusion Criteria	Number Screened/ Eligible/ Enrolled/ Analyzed	Age Sex Race	Intervention Type	Ulcer Type/Severity at Baseline (Intervention Onset) Stage Size (mean) Location
ter Riet, 1995[172] ter Riet, 1996[173] Netherlands Good	Randomized trial	Patients with stage II, III, or IV pressure ulcers (i.e., partial-thickness skin loss or worse") from 11 nursing homes and one hospital located in the south of the Netherlands. If a patient had multiple ulcers, we used two hierarchical criteria to choose one ulcer for inclusion in the trial.	Patients with difficulties with swallowing or frequent vomiting (poor compliance with AA regimen); osteomyelitis in the ulcer area (healing very unlikely); idiopathic hemochromatosis, thalassemia major, and sideroblastic anemia (in these three diseases, AA supplementation is contraindicated); and Cushing's syndrome or Cushing's disease, pregnancy, radiotherapy in the ulcer area, and the use of antineoplastic agents or systemic glucocorticosteroids (all because of hormonal alterations in collagen synthesis). Terminally ill patients; patients for whom surgical treatment of the ulcer, other than debridement, had been planned, patients taking vitamin C supplements in excess of 50 mg per day. Patients with stage II ulcers (partial-thickness skin loss) could participate only if deep ithelialization had persisted for at least 7 days without interruption. Patients with leg ulcers had to have a positive history of pressure on that site to be eligible.	NR/NR/88/88	Age (Mean): 81 years Female: 75% Race: NR	Adjunctive: Ultrasound	Stage: Stage II/III - 80% vs. 83.7% Stage IV - 20% vs. 16.3% Size (mean): Wound surface area cm^2 (%) 0.01-1.00 - 42.2% vs. 34.9% 1.01-5.00 - 40% vs. 44.2% 5.01-10.0 - 15.6% vs. 11.6% >10.0 - 2.2% vs. 9.3% Location: Trunk - 60% vs. 58.1%
Wanner, 2003[174] Switzerland Fair	Randomized trial	Patients admitted with a pressure sore of the pelvic region, deeper than stage II (at least a penetration in the subcutaneous fat).	Pressure sores not in the pelvic region; depth of the pressure sore was less than stage III.	34/24/24/22	Age (Mean): 51 years Female: 31% Race: NR	Adjunctive: Negative Pressure Wound Therapy	Stage: II+ (Daniel et al.) Size (mean): 50 ml vs. 42 ml Location: Pelvic region

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued							
Author, year Country Overall Quality Rating	**Study Type**	**Eligibility Criteria**	**Exclusion Criteria**	**Number Screened/ Eligible/ Enrolled/ Analyzed**	**Age Sex Race**	**Intervention Type**	**Ulcer Type/Severity at Baseline (Intervention Onset) Stage Size (mean) Location**
Wood, 1993[175] US Fair	Randomized trial	Patients with chronic pressure ulcers.	NR	NR/NR/71/71	Age (mean years): 75 years Female: 45% Race: White – 100% PU stage II-III (article uses grade PU criteria)	Adjunctive: Electrical Stimulation	Stage: Stage III - 100% Size (mean) - NR Location: leg - 15/31 vs. 16/41 coccyx - 7/31 vs. 9/41 hip - 2/31 vs. 10/41 buttock - 5/31 vs. 5/41 other - 2/31 vs. 3/41

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**	**Complete Wound Healing**	**Wound Surface Area**	**Healing Time**	**Infection Rate**	**Osteomyelitis Rate**
Adegoke, 2001[141] Nigeria Fair	A: IDC plus nursing care - after cleaning ulcers covered with sterile gauze soaked in 0.9% saline. 2 pieces of aluminum plate electrodes were cut to sizes slightly larger than the individual ulcers, wrapped in 6 layers of lint soaked in 0.9% saline. IDC turned on and gradually increased intensity until a "minimal perceptible contraction" was observed, then reduced slightly so no visible contraction could be observed. The rest to surge ratio was 2:1 at 30 Hz with rectangular wave forms for a duration of 45 minutes	B: placebo IDC plus nursing care - after cleaning ulcers covered with sterile gauze soaked in 0.9% saline. 2 pieces of aluminum plate electrodes were cut to sizes slightly larger than the individual ulcers, wrapped in 6 layers of lint soaked in 0.9% saline. IDC turned on and gradually increased intensity until a "minimal perceptible contraction" was observed, then reduced slightly so no visible contraction could be observed. The rest to surge ratio was 2:1 at zero Hz with rectangular wave forms for a duration of 45 minutes	NA	NA	NR	Treatment A: Change in surface area: baseline to week 4 - 22.2% Treatment B: Change in surface area: baseline to week 4 - 2.6%	NR	NR	NR

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**	**Complete Wound Healing**	**Wound Surface Area**	**Healing Time**	**Infection Rate**	**Osteomyelitis Rate**
Adunsky, 2005[142] Israel Fair	A:Treatment Group (TG): DDCT treatment, electrical currents are transferred to the healthy skin surrounding the necrotic wound area, through the use of soft external electrodes placed on the healthy skin surrounding the wound. The treatment consisted initially of three such 20-min sessions daily, reduced to two daily sessions after 14 days. Ulcers were covered with hydrocolloid or collagen dressings after treatment Treatment period lasted for 8-weeks	B: Placebo Group (PG): placebo-DDCT treatment, zero currents are transferred to the healthy skin surrounding the necrotic wound area, through the use of soft external electrodes placed on the healthy skin surrounding the wound. The treatment consisted initially of three such 20-min sessions daily, reduced to two daily sessions after 14 days. ulcers were covered with hydrocolloid or collagen dressings after treatment Treatment period lasted for 8-weeks	NA	NA	Treatment A: End of followup: 10/35(35.7%) End of treatment: 5/35(14.3%) Treatment B: End of followup: 9/28(25.7%), End of treatment: 3/28(10.7%),	Treatment A: Day 45: 11.15 Day 147: 2.53 Treatment B: Day 45: 16.7 cm^2, Day 147: 2.88 cm^2,	Speed of wound closure: Mean time to complete closure: Treatment A: 63.4 Treatment B: 89.7	NR	NR

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**	**Complete Wound Healing**	**Wound Surface Area**	**Healing Time**	**Infection Rate**	**Osteomyelitis Rate**
Ahmad, 2008(a)[143] Ahmad, 2008(b)[144] Saudi Arabia Fair	A: HVPC for 45 minutes daily for 7 days	B: HVPC for 60 minutes daily for 7 days	C: HVPC for 120 minutes daily for 7 days	D: Comparator - VPC for 45 minutes daily for 7 days (voltage maintained at zero)	NR	Treatment A: Wound surface areas decreased (cm^2) to: 5.1 Treatment B: Wound surface areas decreased (cm^2) to: 0.6 Treatment C: Wound surface areas decreased (cm^2) : 0.64 cm^2 Treatment D: Wound surface areas decreased (cm^2): 5.39	Mean healing rate (cm^2 /week): 0.40 1.30. 1.30. 0.27	NR	NR
Baker, 1996[145] US Fair	A: Asymmetric biphasic (A) - 3 treatment sessions/30 minutes x 5 days/week for 4 weeks or until healing Amp - below contraction Phase duration - 100 microsec frequency - 50 pulses/s	B: Symmetric biphasic (B) - 3 treatment sessions/30 minutes x 5 days/week for 4 weeks or until healing Amp - below contraction Phase duration - 300 µsec frequency - 50 pulses/s	C: Microcurrent (MC) - 3 treatment sessions/30 minutes x 5 days/week for 4 weeks or until healing Amp - 4 mA Phase duration - 10 µsec frequency - 1 pulses/s	D: Comparator (C) - 3 treatment sessions/30 minutes x 5 days/week for 4 weeks or until healing Amp - 0 Phase duration - 100 µsec frequency - 1 pulses/s	NR	Treatment A: Change in surface area (%/week): 36.4 Treatment B: Change in surface area (%/week): 29.7 vs. Treatment C: Change in surface area (%/week): 23.3 Treatment D: Change in surface area (%/week): 32.7	NR	NR	NR

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**	**Complete Wound Healing**	**Wound Surface Area**	**Healing Time**	**Infection Rate**	**Osteomyelitis Rate**
Burke, 1998*[146] US Fair	A: (non-whirlpool) conservative treatment – debridement, saline irrigation, and dressing of wounds with 4x4 cotton pads soaked with saline solution. Dressings changed 2x/day	B: (whirlpool) conservative treatment plus hydrotherapy in a whirlpool with water warmed to 96 to 98 °F. The jet stream of the whirlpool was positioned so that no pressure ulcer would be directly exposed to the stream, reducing the risk of granulation tissue damage by water agitation. Each wound received 20 min of whirlpool therapy once per day.	NA	NA	Healing: Group B > A, p=0.0435	Treatment A: Change in surface area: 27% Treatment B: Change in surface area: 58%	NR	NR	NR
Comorosan, 1993[147] Romania Fair	A: Control - conventional therapy - H2O2 cleansing and local applications of talcum powder, methylene blue in solution and tetracycline at undefined intervals for 3-5 weeks	B: Placebo - conventional therapy plus placebo Diapulse treatment applied to ulcer area directly through dressings for 30 minutes/2x day at 6 hour intervals for 3-5 weeks	C: Diapulse Treatment - conventional therapy plus Diapulse treatment - standard 117 volts, 27.12 MHz, at 80-600 pulse/sec applied to ulcer area directly through dressings for 30 minutes/2x day at 6 hour intervals for 3-5 weeks	NA	Complete healing at end of treatment (3-4 weeks): Treatment A: 0% Treatment B: 0% Treatment C: 85%	NR	Mean healing time (weeks): Treatment A: NR Treatment B: NR Treatment C: 3.5	NR	NR

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**	**Complete Wound Healing**	**Wound Surface Area**	**Healing Time**	**Infection Rate**	**Osteomyelitis Rate**
Dehlin, 2003[148] Denmark Fair	A: Local wound treatment - protection of the ulcer area, regular turning schedule, emollient/moisturizing cream around ulcer, pressure-reducing mattress and/or cushion for wheel-chair bound patients, hydrocellular/hydrocolloid dressings monochromatic phototherapy treatment - probe containing 30 diodes emitting infrared light at 956 nm and 80 diodes emitting red light 637 nm, placed 3 cm above ulcer and administered in identical sequence for every session week 1 - 5x/week for 9 minutes weeks 2/4/6/8/10 - 5x/week for 6 minutes weeks 3/5/7/9/11 - 3x/week for 6 minutes	B: Local wound treatment - protection of the ulcer area, regular turning schedule, emollient/moisturizing cream around ulcer, pressure-reducing mattress and/or cushion for wheel-chair bound patients, hydrocellular/hydrocolloid dressings placebo light treatment - emitting no infrared or red light was administered for every session week 1 - 5x/week for 9 minutes weeks 2/4/6/8/10 - 5x/week for 6 minutes weeks 3/5/7/9/11 - 3x/week for 6 minutes	NA	NA	Treatment A: Complete healing: 34/78(43.6%) . Treatment B: Complete healing: 34/78(39.5%)	Reductions in wound surface area over time in both groups were statistically significant (p=<0.0001) but there was no statistically significant difference in reduction of wound surface area (p=0.18)	Time until total healing was assessed every week for 12 weeks or until complete healing	NR	NR

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**	**Complete Wound Healing**	**Wound Surface Area**	**Healing Time**	**Infection Rate**	**Osteomyelitis Rate**
Dehlin, 2007[149] Denmark Fair	A: Local wound treatment - protection of the ulcer area, regular turning schedule, emollient/moisturizing cream around ulcer, pressure-reducing mattress and/or cushion for wheel-chair bound patients, hydrocellular/hydrocolloid dressings monochromatic phototherapy treatment - probe containing 30 diodes emitting infrared light at 956 nm and 80 diodes emitting red light 637 nm, placed 3 cm above ulcer and administered in identical sequence for every session week 1 - 5x/week for 9 minutes weeks 2/4/6/8/10 - 5x/week for 6 minutes weeks 3/5/7/9/11 - 3x/week for 6 minutes	B: Local wound treatment - protection of the ulcer area, regular turning schedule, emollient/moisturizing cream around ulcer, pressure-reducing mattress and/or cushion for wheel-chair bound patients, hydrocellular/hydrocolloid dressings placebo light treatment - emitting no infrared or red light was administered for every session week 1 - 5x/week for 9 minutes weeks 2/4/6/8/10 - 5x/week for 6 minutes weeks 3/5/7/9/11 - 3x/week for 6 minutes	NA	NA	Treatment A: Complete healing: 43/79(54.4%) Treatment B: Complete healing: 50/84(59.5%)	Treatment A: Mean normalized reduction in pressure ulcer size at week 12 - 0.79 Normalized weekly reduction in pressure ulcer size over time - 15.1% Treatment B: Mean normalized reduction in pressure ulcer size at week 12 - 0.50, Normalized weekly reduction in pressure ulcer size over time 10.9%	Time until total healing was assessed every week for 12 weeks or until complete healing	NR	NR

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**	**Complete Wound Healing**	**Wound Surface Area**	**Healing Time**	**Infection Rate**	**Osteomyelitis Rate**
Durovic, 2008[150] Serbia Fair	A: (E - experimental group) - standard cleaning and dressing - application of a gauze with normal saline (NaCl), then a dry gauze, next it a cotton wool and adhesive strip Polarized light therapy using a linear polarized light source (Bioptron lamp settings - wavelength: 400–2000 nm; degree of polarization: > 95%; power density: 40 mW/cm^2; light energy: 2,4 J/cm^2) performed for 6 min/day at a distance of 10 cm, 5 x week/4 weeks	B: (C - comparator group) - standard cleaning and dressing - application of a gauze with normal saline (NaCl), then a dry gauze, next it a cotton wool and adhesive strip	NA	NA	NR	Treatment A: Surface of the pressure ulcers (cm^2) - 10.80 Treatment B: Surface of the pressure ulcers (cm^2) - 22.97	NR	NR	NR
Ford, 2002[151] US Fair	A: VAC dressings were changed Mondays, Wednesdays, and Fridays (manufacturer recommends dressing changes every 48 hours).	B: HP dressings were changed once or twice daily, depending on the degree of wound drainage. Strict pressure reduction with the appropriate beds and positioning was instituted. The Healthpoint System (HP) offers a second innovative approach to the management of pressure ulcers. It consists of three FDA-approved gel products—Accuzyme, Iodosorb, and Panafil— each targeted to optimize a particular macroscopic phase of wound healing.	NA	NA	Complete wound healing: 2/20(10%) vs. 2/15 (13%)	Treatment A: Change in wound surface area: 36.9 x 40.0 cm Mean reduction in ulcer volume - 57% Treatment B: Change in wound surface area: 18.7 x 19.0 cm Mean reduction in ulcer volume - 25%	NR	NR	15/35 wounds (42.9%) were suspicious for osteomyelitis and underwent bone biopsy and MRI.

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**	**Complete Wound Healing**	**Wound Surface Area**	**Healing Time**	**Infection Rate**	**Osteomyelitis Rate**
Gentzkow, 1991[152] US and Canada Fair	A: Sham treatment	B: Dermapulse stimulator - pulsed electrical current for 30 minutes/2x daily/4 weeks pulse rate: 2 pps/350 microseconds intensity: 0-150 mA	NA	NA	Complete wound healing: 23.4% vs. 49.8%, p=0.042	NR	NR	NR	NR
Griffin, 1991[153] US Fair	A: HVPC for 1 hour daily for 20 days	B: Placebo HVPC for 1 hour daily for 20 days, no current flowed through to patient	NA	NA	Complete wound healing was reported at 5 days, 10 days, 15 days and 20 days	Median wound surface area decrease of 80% at 20 days	Median wound surface area decrease at 5 days: 32% 10 days: 47% 15 days: 20%	NR	NR

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**	**Complete Wound Healing**	**Wound Surface Area**	**Healing Time**	**Infection Rate**	**Osteomyelitis Rate**
Gupta, 2009[154] India Fair	A: Standard pressure ulcer care with daily dressing with normal saline PEMF: exposure to 1 Hz frequency sine waves with 30 mili-Ampere current intensity/45 minutes/day/5x week/30 sessions using "Pulsatron" equipment (couch encircled by a metallic frame. Homogenous pulsating electromagnetic field is generated by metallic frame which encircles a "couch" on which the subject lies either supine or prone for the duration of the treatment)	B: Standard pressure ulcer care with daily dressing with normal saline Placebo/Sham: 0 Hz frequency sine waves with 0 mili-Ampere current intensity/45 minutes/day/5x week/30 sessions using "Pulsatron" equipment	NA	NA	Treatment A: (n=13 ulcers on 12 subjects) Complete healing of pressure ulcers in less than 30 sessions: 2/12(16.7%) Healing of the ulcers (NPUAP ulcer stage) at the end of the study A (p=0.008) BJWAT scores at admission and discharge p=0.001 Treatment B: (b=11 ulcers on 6 subjects): Complete healing of pressure ulcers in less than 30 sessions: 0/6(0%) Healing of the ulcers (NPUAP ulcer stage) at the end of the study p=0.014 BJWAT scores at admission and discharge p=0.003	NR	Mean duration of the illness at the beginning of study was 6.42 months (1 to 20 months) Mean duration of pressure ulcer was 103.75 days (10 to 420 days).	NR	NR

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**	**Complete Wound Healing**	**Wound Surface Area**	**Healing Time**	**Infection Rate**	**Osteomyelitis Rate**
Ho, 2010[155] US Fair	A: Standard wound care - pressure relief (e.g., low-air-loss mattress, turning, etc), debridement (e.g., sharp, mechanical, enzymatic), routine dressing changes, biophysical modalities (e.g., hydrotherapy), and cleansing as appropriate.	B: Standard wound care - pressure relief (e.g., low-air-loss mattress, turning, etc), debridement (e.g., sharp, mechanical, enzymatic), routine dressing changes, biophysical modalities (e.g., hydrotherapy), and cleansing as appropriate. Negative Pressure Wound Therapy	NA	NA	NR	Treatment A: Mean wound surface area decrease - 50% Treatment B: Mean wound surface area decrease - 43%,	NR	NR	NR
Ho, 2012[156] US Fair	A: Pulsatile lavage + standard wound care protocol (dressing changes and pressure relief with the use of a low air-loss mattress and turning every 2 hours. Low pressure lavage: battery-powered system consisting of a portable handheld pump that produces pulsed jets of fluid	B: Sham treatment + standard wound care protocol.	NA	NA	NR	Treatment A: Mean wound surface area decrease – 1.95 cm^2(1.3 x 1.5 cm) Treatment B: Mean wound surface area decrease – 0.3 cm^2(1.5 x 0.2 cm)	Treatment A: Mean volume decrease over time (at 3 weeks) – 4 cm^3 Treatment B: Mean volume decrease over time (at 3 weeks) –2 cm^3	NR	NR
Houghton, 2010[157] Canada Good	A: HVPC frequency of 100 Hz for 20 minutes, 10 Hz for 20 minutes and 20 minutes off, 8 hours a day for at least 3 months + standard wound care (SWC)	B: standard wound care (SWC) included nutrition, wound dressing and continence management which was customized for each patient as necessary	NA	NA	42.9% achieved complete wound healing	70% mean decrease in wound surface area p=0.048	42.9% achieved complete wound healing at 3 months	NR	NR

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**	**Complete Wound Healing**	**Wound Surface Area**	**Healing Time**	**Infection Rate**	**Osteomyelitis Rate**
Iordanou, 2002[158] Greece Fair	A: Standard care - turning the subjects every 2–3 hours, provision of electric pressure relieving overlay and a 30° lateral side-lying position given to avoid friction and shearing forces. Concerning the ulcers, these were of 1st, 2nd and 3rd grades without necrotic tissue; thus, the concentration was on two essential components of cleaning and dressing. Cleaning solution of choice was 0.9% sodium chloride and the dressing was chosen to match ulcer stage. Polarized light therapy - energies delivered were typically 4 J/cm^2 per min, degree of polarization of > 95% using a 20 W Bioptron electrical lamp. The treatment consisted of polarized treatment for 5 min per day/5 days per week/2 weeks	A: Standard care - turning the subjects every 2–3 hours, provision of electric pressure relieving overlay and a 30° lateral side-lying position given to avoid friction and shearing forces. Concerning the ulcers, these were of 1st, 2nd and 3rd grades without necrotic tissue; thus, the concentration was on two essential components of cleaning and dressing. Cleaning solution of choice was 0.9% sodium chloride and the dressing was chosen to match ulcer stage.	NA	NA	NR	Treatment A: Change in Wound Size (mean): -.54 Treatment B: Change in Wound Size (mean): -.06 cm^2	NR	NR	NR

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**	**Complete Wound Healing**	**Wound Surface Area**	**Healing Time**	**Infection Rate**	**Osteomyelitis Rate**
Kloth, 1988[159] US Fair	A: Treatment group - DynaWave® Model 12 high voltage, monophasic twin-pulsed generator* in this study and arbitrarily set the stimulus variables at a frequency of 105 Hz, an intraphase interval of 50 µsec, and a voltage just below that capable of producing a visible muscle contraction (100-175 V). At 100 V with an intraphase interval of 100 µsec, the single-phase charge was calculated at about 1.6 µC with a total-pulse charge accumulation of 342 µC/sec. 45 minutes of ESTR applied to the ulcer site once a day, five days a week.	B: Comparator group - Comparator Group had electrodes applied in the same manner as patients in the Treatment Group, but the voltage was maintained at zero	NA	NA	Complete wound healing: 100% vs. NR	Treatment A: Change in surface area: 4.08 cm^2 Treatment B: Change in surface area: 5.20 cm^2	Treatment A: Mean healing rate: 44.8%/week Treatment B: Mean healing rate: 11.59%/week	NR	NR

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**	**Complete Wound Healing**	**Wound Surface Area**	**Healing Time**	**Infection Rate**	**Osteomyelitis Rate**
Lucas, 2003[160] Netherlands Fair	A: Comparator - consensus decubitus intervention - information and instruction of the patient, wound cleansing, simple moist dressings, and frequent alteration of the patient's position.	B: Consensus decubitus intervention - information and instruction of the patient, wound cleansing, simple moist dressings, and frequent alteration of the patient's position. LLLT treatments - using an LLLT device with a microprocessor-controlled, multiple monochromatic optical source probe . The handheld probe with 12 70 W monochromatic infrared GaAs-diodes (gallium arsenide) operated at a wavelength of 904 nm in a 830 Hz, pulse frequency mode with an average beam power of 8 mW and a radiant exposure of 1 J/cm^2 covered an area of 30 cm^2.	NA	NA	NR	Treatment A: Absolute improvement (mm^2) mean: 138 Treatment B: Absolute improvement (mm^2) mean: 48	NR	NR	NR

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**	**Complete Wound Healing**	**Wound Surface Area**	**Healing Time**	**Infection Rate**	**Osteomyelitis Rate**
Lucas, 2000(a)[161] Netherlands Fair	A: Consensus decubitus intervention - information and instruction of the patient, wound cleansing, simple moist dressings, and frequent alteration of the patient's position. LLLT treatments - using an LLLT device with a microprocessor-controlled, multiple monochromatic optical source probe . The handheld probe with 12 70 W monochromatic infrared GaAs-diodes (gallium arsenide) operated at a wavelength of 904 nm in a 830 Hz, pulse frequency mode with an average beam power of 8 mW and a radiant exposure of 1 J/cm^2 covered an area of 30 cm^2.	B: Consensus decubitus intervention - information and instruction of the patient, wound cleansing, simple moist dressings, and frequent alteration of the patient's position.	NA	NA	NR	Treatment A: Change in median wound surface area (mm^2): 83% Treatment B: Change in median wound surface area (mm^2):95%	NR	NR	NR

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**	**Complete Wound Healing**	**Wound Surface Area**	**Healing Time**	**Infection Rate**	**Osteomyelitis Rate**
Maeshige, 2010[162] Japan Fair	A: ultrasound irradiation (US) administered to the pressure ulcer through the same dressing used for 2–4 weeks - The area of dressing in which exudate seeped fully was covered with US gel, US irradiation was applied with the dressing in place - 1 MHz was used for all ulcers at 0.5 W/cm^2 at the wound surface - 3 MHz was used for ulcers close to the bone at 0.5 W/cm^2 at the wound surface	B: standard treatment with dressings that promote a moist wound healing environment All pressure ulcers were covered with a hydrocolloid dressing. -To avoid US reflection, a polyurethane film was placed over the hydrocolloid dressing; any air bubbles between the layers were removed. - The area of dressing in which exudate seeped fully was covered with US gel, US irradiation was applied with the dressing in place - 1 MHz was used for all ulcers at 0.5 W/cm^2 at the wound surface - 3 MHz was used for ulcers close to the bone at 0.5 W/cm^2 at the wound surface	NA	NA	DESIGN score: A(n=4) vs. B (n=3) Stage III - 3/4 vs. 1/3 Stage IV- 1/4 vs. 2/3 End of Study Complete healing: NR	Change in Wound Size (mean): 5.04 cm^2	Healing time (mean): 108.25 vs. 97 days		
McDiarmid, 1985[163] UK Fair	A: Ultrasound: treatment minimum of 5 minutes for all pressure sores up to 3m^2 (additional minute for each added 0.5 cm^2) for a maximum 10 minutes/3x week Frequency - 3 MHz peak intensity - 0.8W cm^{-2}	B: Mock ultrasound (placebo)	NA	NA	Healed at end of treatment: 10/21 (41%) vs. 8/19(42%)	NR	Mean: 32 vs. 36 days	NR	NR

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**	**Complete Wound Healing**	**Wound Surface Area**	**Healing Time**	**Infection Rate**	**Osteomyelitis Rate**
Nussbaum, 1994[164] UK Fair	A: Comparator - This group received standard wound care only, consisting of wound cleansing twice daily using Hygeol* (1:20),+ Jelonet dressings to keep the wound surface moist, and avoidance of lying the wound, using coupling gel for contact, for 5 minutes per 5 cm^2 of wound area.	B: Ultrasound/Ultra-violet C (US/UVC) - Ultrasound treatment was applied using an Omnisound 3000, IP which was calibrated by the manufacturer at the start of the study. The size of the treatment head was 5 cm^2, and treatment was delivered at a frequency of 3 MHz and at an SATA intensity of 0.2 w/cm^2 (1:4 pulse ratio). Ultrasound was applied to intact skin surrounding the wound, using coupling gel for contact, for 5 minutes per 5 cm^2 of wound area. The US and UVC treatments were alternated 1x day/5 days/week	C: Control groupl	NA	NR	Treatment A: Change in wound surface area: 32.4% Treatment B: 53.5% Treatment C: 23.7%	NR	NR	NR
Onigbinde, 2010[165] South Africa Poor	A: traditional saline-wet-to-moist (WM) wound dressing, and high-intensity ultraviolet B radiation - (UVB) lamp (Philips 8P3114) at 3 inches from the wound surface, using progressively increased exposure duration with each session (3/4, 1, 2, 2 1/2, 3, 4 and 5 minutes for the first 7 sessions). Wounds radiated 1x every 3 days/ 6 weeks. Skin surrounding wound was protected with 2 mm thickness of Vaseline and cotton wool	B: traditional saline-wet-to-moist (WM) wound dressing	NA	NA	NR	Change in Mean Ulcer Surface Area (cm2): Treatment A: 59.9 Treatment B:16.4	NR	NR	NR

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**	**Complete Wound Healing**	**Wound Surface Area**	**Healing Time**	**Infection Rate**	**Osteomyelitis Rate**
Ozdemir, 2011[166] Turkey Poor	A: Magnetotherapy group - magnetic field treatment was applied on a daily basis for 30 minutes, with a 10 x 10 ms pulse, at intervals of 30 ms, and a frequency of 25 Hz, and 9*5ms pulse at intervals of 212 ms and a frequency of 4,6 Hz with a magnitude of 15 mT (150G) for a duration of 15 days. The surface areas of the pressure sores were recorded at the onset of treatment (1st day), on the 7th and the 15th days on transparency papers, templates were made and converted onto milimetric graphic papers. The squares inside the drawings were counted and the surface area was calculated in terms of square centimeters.	B: Control group	NA	NA	NR	No significant differences in size (Day 1-7) Day 1 : p=0.871 Day 7:: p=1.67 Day 15: p<0.001	Treatment A: Healing time (mean) 10.80 days Treatment B: 18.85 days	NR	NR

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**	**Complete Wound Healing**	**Wound Surface Area**	**Healing Time**	**Infection Rate**	**Osteomyelitis Rate**
Salzberg, 1995[167] US Fair	A: Placebo (sham)	B: Diapulse current - 27.12 MHz at 80-600 pulses/sec, a pulse width of 65 microseconds, a duty cycle between 0.5% and 3.9%, and a per pulse power range between 293-975 peak watts	NA	NA	Treatment A: Stage II (n=10 vs. 10) week 1: 84% End of Study Complete healing: 9/15 Stage III (n=5 vs. 5) week 1: NR End of Study Complete healing: 3/5(60%) Treatment B: Stage II (n=10 vs. 10) week 1: 40% End of Study Complete healing: 6/15 Stage III (n=5 vs. 5) week 1: NR End of Study Complete healing: 0/5(0%)	Change in surface area: Stage II (n=10 vs. 10): NR Stage III (n=5 vs. 5): 70.6% vs. 20.7%	Mean Healing Time Stage II: NR Stage III: 43 days	NR	NR

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**	**Complete Wound Healing**	**Wound Surface Area**	**Healing Time**	**Infection Rate**	**Osteomyelitis Rate**
Schubert, 2001[168] Sweden Fair	A: (Group 1) Conventional/standard ulcer therapy - not described	B: (Group 2) Conventional/standard ulcer therapy - not described Phototherapy with pulsed monochromatic light (PML): A probe contained both 30 diodes, which could emit infrared light at 956 nm, and 80 diodes, which could emit red light at 637 nm. Treatments lasted 9 min each time using a regimen with pulse repetition frequency varied between 15.6 Hz and 8.58 kHz. Patients were followed for 10 weeks or until the ulcer was healed, whichever occurred first. The number of treatments given per week was as follows: Week 1: 5 x week; Week 2: 4 x week Week 3: 2 x week Week 4+: 1 x week	NA	NA	NR	NR	Healing rate (mm^2/week): 0.200 vs. 0.298, $p<0.05$ (healing rate was 49% higher in treatment group (Group 2) than in comparator (Group 1)	NR	NR
Schwien, 2005[169] US Poor	A: Negative Pressure Wound Therapy (NPWT) - specific technologies and treatment used not reported	B: Comparison group - standard care through end of treatment, specific treatments not reported	NA	NA	NR	NR	NR	NR	NR

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**	**Complete Wound Healing**	**Wound Surface Area**	**Healing Time**	**Infection Rate**	**Osteomyelitis Rate**
Srivastava, 2010[170] India Poor	A: Negative pressure device (NPD) included sterilized piece of foam, a low power continuous suction apparatus (Romovac) and transparent polyurethane adhesive dressing (Opsite). Perforated end of drainage tube was placed on wound surface and other exiting 10cms away from wound margin connected to Romovac. Sterilized foam was trimmed to size and geometry of wound as cover. Opsite closed the wound with an airtight seal. The bellow of Romovac charged to attain negative pressure. Recharging was done in 5–6 hrs. Wound inspected and dressing changed every 5–7 days.	B: Conventional dressing	NA	NA	Mean decrease in wound area: At 10 days - Treatment A: 13% Treatment B: 8% At 3 weeks - Treatment A: 33% Treatment B: 15%	NR	NR	NR	NR

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**	**Complete Wound Healing**	**Wound Surface Area**	**Healing Time**	**Infection Rate**	**Osteomyelitis Rate**
Taly, 2004[171] India Good	A: Usual care - daily dressing with sterile gauze soaked in normal saline and pressure relief with either a water mattress or a split mattress. multi-wave light therapy - 14 treatments were given, 1 every alternate day, 3 times a week, until the ulcer healed or the ulcer received 14 exposures. Each ulcer was divided into 10cm^2 squares. During every session, each square was exposed for 60 seconds. The central 820nm laser source was surrounded by 45 supraluminous diodes of different wavelengths. Energy applied to the ulcer was calculated by using the formula: energy delivered = (power/spot size)(time). Energy given was 4.5J/cm^2.	B: Usual care - daily dressing with sterile gauze soaked in normal saline and pressure relief with either a water mattress or a split mattress. sham treatment - multi-wave light therapy - 14 treatments were given, 1 every alternate day, 3 times a week, during which the multi wavelength light therapy source was held over the ulcer after switching off the beam	NA	Ulcer healing was defined as the complete closure of the wound with healthy scar tissue. Eschar was removed before application of intervention. Ulcers with eschar at the end of the study period were considered not healed. Complete Healing (ulcers)- Treatment A: 18/35 (51%) Treatment B: 14/29 (48%),	NR	The mean time taken for the ulcers to heal from the day of randomization was 2.45 2.06 weeks in the treatment group and 1.78 2.13 weeks in the comparator group. This difference was not statistically significant (t .987, P .330). The PSST score and the stage of the 32 ulcers that did not heal during the study	NR	NR	NR

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**	**Complete Wound Healing**	**Wound Surface Area**	**Healing Time**	**Infection Rate**	**Osteomyelitis Rate**
ter Riet, 1995[172] ter Riet, 1996[173] Netherlands Good	A: Sham treatment - duration varied according to formula: treatment area estimate + effective radiating area (at the face of the transducer) x 3 minutes (minimum treatment duration was 3 minutes 45 seconds) at 1 x day/5 days /week for 6 weeks (60 treatments) Frequency - 0 MHz Pulse duration - 0 ms Pulse repetition frequency - 0 Hz	B: Ultrasound therapy - Treatment duration varied according to formula: treatment area estimate + effective radiating area (at the face of the transducer) x 3 minutes (minimum treatment duration was 3 minutes 45 seconds) at 1 x day/5 days /week for 6 weeks (60 treatments) Frequency - 3.28 MHz Pulse duration - 2 ms Pulse repetition frequency - 100 Hz	NA	NA	NR	Mean surface reduction (cm^2) – Treatment A: 0.18 Treatment B: 0.31	Mean healing rate (cm/week) - 0.18 vs. 0.13, p=0.18	NR	NR
Wanner, 2003[174] Switzerland Fair	A: In the vacuum-assisted group we used the equipment obtained from KCI Mediscus consisting of drainage tubes, polyvinyl foam, a transparent polyurethane dressing, and a vacuum suction pump. Continuous subatmospheric pressure of 125 mm Hg was applied. The dressings were changed after two to seven days, depending on the amount of fluid produced by the wound (when the canister was full).	B: Our standardized treatment of deep pressure sores is surgical debridement followed by a period of wound preparation and, Nelly closure with a flap. After debridement we started the local treatment on the first day after the operation. In the wet-to-dry/wet-to-wet (traditional) group the dressings consisted of gauze soaked with Ringer's solution. These dressings were changed three times a day until clean granulation tissue was observed. From then on, we kept the wound wet with Ringer solution and changed the dressings one to three times a day to keep the wound moist.	NA	NA		Wound size in the two groups (ml) (n = 11 in each group) Wound volume (ml) Vacuum-assisted closure Wet-to-dry/ wet-to-wet Range 3–132 5–68 Mean (SD) 50 (33) 42 (16)	Time to reach 50% health: 27 days vs. 28 days	NR	NR

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued									
Author, year Country Overall Quality Rating	**Treatment A**	**Treatment B**	**Treatment C**	**Treatment D**	**Complete Wound Healing**	**Wound Surface Area**	**Healing Time**	**Infection Rate**	**Osteomyelitis Rate**
Wood, 1993[175] US Fair	A: PLIDC of 600*m*A with frequency of approx 0.8Hz / 3x week until healing	B: non-PLIDC sham, current delivery output was impeded	NA	NA	Complete wound healing - 58% vs. NR	Change in surface area: Treatment A: NR Treatment B: 72.9% decreased more than 80% in size	Speed of wound closure: NR vs. 58%(8 weeks)	NR	NR

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued						
Author, year Country Overall Quality Rating	**Recurrence Rate**	**Other: Specify**	**Duration of Followup**	**Study setting: Hospital Nursing Home/LTC facility Community Other: Specify**	**Pain**	**Dermatologic Complications**
Adegoke, 2001[141] Nigeria Fair	NR	NR	NR	Hospital	NR	NR
Adunsky, 2005[142] Israel Fair	NR	NR	147 days	Hospital	NR	Skin irritation - 2 vs. 0 patients
Ahmad, 2008(a)[143] Ahmad, 2008(b)[144] Saudi Arabia Fair	NR	NR	5 weeks	Investigating sites	NR	NR
Baker, 1996[145] US Fair	NR	NR	Every 2-4 weeks until healing	Hospital	NR	NR
Burke, 1998*[146] US Fair	NR	NR	Followup until complete healing	Hospital	NR	NR
Comorosan, 1993[147] Romania Fair	NR	NR	NR	Hospital (Social Care Unit)	NR	NR
Dehlin, 2003[148] Denmark Fair	NR	NR	Followup until complete healing	Hospital	NR	NR
Dehlin, 2007[149] Denmark Fair	NR	NR	Followup until complete healing	Hospital	NR	NR
Durovic, 2008[150] Serbia Fair	NR	Total PUSH score of the pressure ulcers - 7.35 vs. 11.85, p=0.00003	NR	Hospital	NR	NR
Ford, 2002[151] US Fair	NR	NR	Followup ranged from 3 to 10 months.	Hospital	NR	NR
Gentzkow, 1991[152] US and Canada Fair	NR	NR	4 weeks after end of treatment	Hospital	NR	NR
Griffin, 1991[153] US Fair	NR	NR	20 days	Hospital	NR	NR

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued						
Author, year **Country** **Overall Quality Rating**	**Recurrence Rate**	**Other: Specify**	**Duration of Followup**	**Study setting:** **Hospital** **Nursing Home/LTC facility** **Community** **Other: Specify**	**Pain**	**Dermatologic Complications**
Gupta, 2009[154] India Fair	NR	NR	The mean duration of stay in the rehabilitation unit was 98.66 days (24-193 days). The number of treatment sessions in patients ranged from 22-30, mean of 29.06.	Hospital	NR	NR
Ho, 2010[155] US Fair	NR	NR	NR	Hospital	NR	NR
Ho, 2012[156] US Fair	NR	NR	1 x week for 3 weeks during treatment	Hospital	NR	NR
Houghton, 2010[157] Canada Good	NR	NR	6 months	Community	NR	NR
Iordanou, 2002[158] Greece Fair	NR	NR	At the end of each week, experimental and comparator ulcers were reassessed and a detailed report was completed, no additional followup after end of treatment reported	Hospital	NR	NR
Kloth, 1988[159] US Fair	NR	NR	NR	Hospital	NR	NR
Lucas, 2003[160] Netherlands Fair	NR	NR	NR	Hospital	NR	NR
Lucas, 2000(a)[161] Netherlands Fair	NR	NR	NR	Hospital	NR	NR
Maeshige, 2010[162] Japan Fair	NR	NR	NR	Hospital	NR	NR
McDiarmid, 1985[163] UK Fair	NR	NR	NR	Hospital	NR	NR

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued						
Author, year Country Overall Quality Rating	**Recurrence Rate**	**Other: Specify**	**Duration of Followup**	**Study setting: Hospital Nursing Home/LTC facility Community Other: Specify**	**Pain**	**Dermatologic Complications**
Nussbaum, 1994[164] UK Fair	NR	NR	NR	Hospital	NR	NR
Onigbinde, 2010[165] South Africa Poor	NR	Change in Mean Ulcer Volume (ml): Treatment A: 26.2 Treatment B: 2.1	NR	Hospital	NR	NR
Ozdemir, 2011[166] Turkey Poor	NR	NR	NR	Hospital	NR	NR
Salzberg, 1995[167] US Fair	NR	NR	NR	Hospital	NR	NR
Schubert, 2001[168] Sweden Fair	NR	NR	NR	Hospital	NR	NR
Schwien, 2005[169] US Poor	NR	Rates of hospitalization: 35% vs. 48%, p<0.05. Rates of hospitalization due to wound problems: 5% vs. 14%, p<0.01. Rates of emergent care for wound problems: 0% vs. 8%, p=0.01.	NR	Home health agencies	NR	NR
Srivastava, 2010[170] India Poor	NR	Mean decrease in wound depth: At 10 days - 32% vs. 10% At 3 weeks - 98% vs. 36%	NR	Hospital	NR	NR
Taly, 2004[171] India Good	NR	2 weeks after completion of treatment protocol	Hospital	NR	NR	NR
ter Riet, 1995[172] ter Riet, 1996[173] Netherlands Good	NR	NR	6 weeks after end of treatment	Hospital	Pain - 1/43 vs. 1/45 patients complained of the US therapy being painful at times	NR

Evidence Table H-9a: Adjunctive Trial and Observational Studies, continued						
Author, year **Country** **Overall Quality Rating**	**Recurrence Rate**	**Other: Specify**	**Duration of Followup**	**Study setting:** **Hospital** **Nursing Home/LTC facility** **Community** **Other: Specify**	**Pain**	**Dermatologic Complications**
Wanner, 2003[174] Switzerland Fair	NR	NR	The endpoint was defined as when the wound volume had decreased by 50%, because all ulcers were then closed with a flap	Hospital	NR	NR
Wood, 1993[175] US Fair	NR	NR	8 weeks	Hospital	NR	NR

Abbreviations: LTC, long-term care; NR, not reported.

Evidence Table H-10: Adjunctive Quality Rating*

Evidence Table H-10a. Adjunctive trial quality rating

Author, Year Country	Appropriate Randomization Technique	Allocation concealment adequate?	Groups (intervention and control) similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Reporting of: a) Attrition b) Crossovers, c) Adherence d)Contamination	Dropout Rate <20 Percent	Intention-to-treat Analysis	Appropriate Statistical Analyses	Quality	Funding Source
Adegoke, 2001[141] Nigeria	Unclear	Unclear	Yes	Yes	Yes	a) No b) No c) Yes d) No	Yes	No	Yes	Fair	NR
Adunsky, 2005[142] Israel	Yes	Yes	Yes	Yes	Yes	a) No b) No c) No d) No	No	Yes	Yes	Fair	Lifewave Medical Devices Company
Ahmad, 2008(a)[143] Ahmad, 2008(b)[144] Saudi Arabia Fair	Unclear	No	Yes	Yes	Unclear	a) No b) No c) No d) No	Unclear	Unclear	Yes	Fair	NR
Arashi 2011*[176] Arashi 2010*[177] Japan	No	No	Yes	Yes	No	a) No b) No c) No d) No	No	Yes	Yes	Fair	Risk-Taking Fund for Technology Development from the Japan Science and Technology Agency
Baker, 1996[145] US	Unclear	No	Yes	No	Yes	a) Yes b) Yes c) Yes d) No	Yes	Unclear	Unclear	Fair	National Institute on Disability Research and Rehabilitation
Burke, 1998*[146] US	Unclear	Unclear	Yes	Yes	Unclear	a) No b) No c) No d) No	No	No	Yes	Fair	NR
Comorosan, 1993[147] Romania	Unclear	Unclear	Yes	No	Unclear	a) No b) No c) No d) No	Yes	Yes	No	Fair	NR
Dehlin, 2003[148] Denmark	Unclear	Unclear	Yes	Yes	Unclear	a) No b) No c) No d) No	Yes	No	Yes	Fair	Biolight International AB

Evidence Table H-10a. Adjunctive trial quality rating

Author, Year Country	Appropriate Randomization Technique	Allocation concealment adequate?	Groups (intervention and control) similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Reporting of: a) Attrition b) Crossovers, c) Adherence d)Contamination	Dropout Rate <20 Percent	Intention-to-treat Analysis	Appropriate Statistical Analyses	Quality	Funding Source
Dehlin, 2007[149] Denmark	Unclear	Unclear	Yes	Yes	Yes	a) No b) No c) No d) No	Unclear	Yes	Yes	Fair	Biolight International AB
Durovic, 2008[150] Serbia	Yes	No	Yes	Yes	Yes	a) Yes b) No c) No d) No	Yes	No	Yes	Fair	NR
Edsberg, 2002*[178] US	Unclear	Unclear	Yes	Yes	Unclear	a) No b) No c) No d) No	No	No	Yes	Fair	NR
Feedar 1985[179] US	Unclear	Unclear	Unclear	Yes	No	a) No b) No c) No d) No	No	No	Unclear	Poor	NR
Ford, 2002[151] US	Yes	Unclear	No	Yes	Yes	a) Yes b) Yes c) Yes d) No	Unclear	No	Yes	Fair	Alpha Omega Alpha Student Research Fellowship, Plastic Surgery Education Foundation Scientific Essay Award and grants by the Plastic Surgery Education Foundation and Kinetic Concepts (San Antonio, TX)
Gentzkow, 1991[152] Canada	Unclear	No	Yes	Yes	Unclear	a) Yes b) Yes c) No d) No	Yes	No	Yes	Fair	NR
Griffin, 1991[153] US	Unclear	No	Yes	Yes	No	a) Yes b) No c) Yes d) No	Yes	No	Yes	Fair	Foundation for Physical Therapy Inc.
Gupta, 2009[154] India	Yes	No	Yes	Yes	Unclear	a) Yes b) No c) Yes d) No	Yes	Yes	Yes	Fair	None

Evidence Table H-10a. Adjunctive trial quality rating

Author, Year Country	Appropriate Randomization Technique	Allocation concealment adequate?	Groups (intervention and control) similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Reporting of: a) Attrition b) Crossovers, c) Adherence d)Contamination	Dropout Rate <20 Percent	Intention-to-treat Analysis	Appropriate Statistical Analyses	Quality	Funding Source
Ho, 2012[156] US	Unclear	No	Yes	Yes	No	a) No b) No c) No d) No	Unclear	Unclear	Yes	Fair	Department of Veterans Affairs Rehabilitation Research and Development Service.
Houghton, 2010[157] US	Yes	Yes	Yes	Yes	Unclear	a) Yes b) No c) Yes d) No	Yes	Yes	Yes	Good	Ontario Neurotrauma Foundation, Prizm Medical, The Roho Group, Argentum medical and Dermasciences Canada
Kloth, 1988[159] US	Yes	Unclear	Yes	No	Unclear	a) Yes b) Yes c) No d) No	Yes	Yes	No	Fair	NR
Kloth, 2002*[64] US	Yes	Yes	Yes	Yes	Yes	a) Yes b) No c) No d) No	No	No	Yes	Fair	NR
Larking, 2010*[180] UK	Yes	Yes	Yes	Yes	Unclear	a) Yes b) No c) No d) No	No	No	Yes	Fair	NR
Lucas, 2003[160] Netherlands	No	No	Yes	Yes	Yes	a) Yes b) Yes c) Yes d) Yes	Yes	No	Yes	Fair	NR
Lucas, 2000(a)[161] Netherlands	No	No	Yes	Yes	Yes	a) Yes b) No c) No d) No	Yes	Yes	Yes	Fair	Stichting Fondsenwervingsacties Volsgezondheid (Funding Health Charities, The Netherlands)
Maeshige, 2010[162] Japan	Yes	No	Yes	Yes	Yes	a) Yes b) No c) No d) No	Yes	Unclear	No	Fair	NR
McDiarmid, 1985[163] UK	Yes	Unclear	Unclear	Yes	Unclear	a) No b) No c) No d) No	Unclear	No	Yes	Fair	NR

Evidence Table H-10a. Adjunctive trial quality rating

Author, Year Country	Appropriate Randomization Technique	Allocation concealment adequate?	Groups (intervention and control) similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Reporting of: a) Attrition b) Crossovers, c) Adherence d)Contamination	Dropout Rate <20 Percent	Intention-to-treat Analysis	Appropriate Statistical Analyses	Quality	Funding Source
Nussbaum, 1994[164] UK	No	No	Yes	No	Yes	a) Yes b) No c) No d) No	No	No	Unclear	Fair	NR
Ozdemir, 2011[166] Turkey	Unclear	Unclear	Yes	Yes	No	a) No b) No c) No d) No	Yes	No	Yes	Fair	NR
Salzberg, 1995[167] US	No	Unclear	Yes	Yes	Unclear	a) No b) No c) No d) No	No	No	Yes	Fair	Eastern Paralyzed Veterans Association (Jackson Heights, NY)
Schubert, 2001[168] Sweden	Yes	No	Yes	No	No	a) No b) No c) No d) No	Yes	No	Yes	Fair	Karolinska Institutet, Gun and Bertil Stohne's foundation, Biolight International
Stefanovska, 1993*[181] Slovenia	Unclear	Unclear	Unclear	No	Unclear	a) No b) No c) No d) No	No	No	Yes	Poor	Ministry of Science and Technology of the Republic of Slovenia, the Yugoslavia/USA Joint Board, the US National institute for Disability & Rehabilitation Research, Department of Education, and the Commission of the European Communities, Directorate General for Science Research & Development, International Scientific Cooperation, Brussels
Taly, 2004[171] India	Yes	No	Yes	Yes	Yes	a) Yes b) No c) Yes d) No	Yes	Yes	Yes	Good	National Institute of Mental Health and Neurosciences (Bangalore, India)

Evidence Table H-10a. Adjunctive trial quality rating											
Author, Year Country	Appropriate Randomization Technique	Allocation concealment adequate?	Groups (intervention and control) similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Reporting of: a) Attrition b) Crossovers, c) Adherence d)Contamination	Dropout Rate <20 Percent	Intention-to-treat Analysis	Appropriate Statistical Analyses	Quality	Funding Source
ter Riet, 1995[172] ter Riet, 1996[173] Netherlands	Yes	Yes	Yes	Yes	unclear	a) No b) No c) No d) No	No	Yes	Yes	Good	NR
Ullah, 2007[182] Bangladesh	Yes	Unclear	No	No	Unclear	a) No b) No c) No d) No	No	No	Yes	Fair	NR
Wanner, 2003[174] Switzerland	No	No	No	Yes	No	a) Yes b) No c) No d) No	Yes	No	Yes	Fair	NR
Wood, 1993[175] US	No	No	Yes	No	Unclear	a) Yes b) No c) No d) No	Yes	Yes	Yes	Fair	NR

Abbreviations: NR, not reported.

* Direct evidence comparing one intervention with another was limited. Our ability to derive indirect evidence from comparisons across studies was also limited due to variability in study population, design; outcomes measured, and sample size. As a result, some treatment intervention types (vibration therapy [185], hydrotherapy[154], extracorporeal shock wave therapy [188], noncontact normothermic wound therapy [67], and hyperbaric oxygen [186]), as well as some poor quality studies (electrical stimulation [189]) have not been included in direct comparative effectiveness analyses or included in evidence tables, but have been evaluated for quality in Appendix H. Non-comparative studies used for evaluation of harms only were quality rated but not presented in the evidence tables due to the paucity of reportable data in these studies. Our tables include only studies of comparative effectiveness.

Evidence Table H-10b. Adjunctive observational studies quality rating

Author, Year Country	(1) Did the study attempt to enroll all (or a random sample of) patients meeting inclusion criteria, or a random sample (inception cohort)?	(2) Were the groups comparable at baseline on key prognostic factors (e.g., by restriction or matching)?	(3) Did the study maintain comparable groups through the study period?	(4) Did the study use accurate methods for ascertaining exposures and potential confounders?	(5) Were outcome assessors and/or data analysts blinded to the exposure being studied?	(6) Did the article report attrition?	(7) Did the study perform appropriate statistical analyses on potential confounders?	(8) Is there important differential loss to followup or overall high loss to followup?	(9) Were outcomes pre-specified and defined, and ascertained using accurate methods?	Quality	Funding Source
Ho, 2010[155] US	Unclear	Yes	Yes	Unclear	Unclear	No	No	No	Yes	Fair	Department of Veteran Affairs (VA), SCI Service and Rehabilitation Research and Development Center for Excellence for the Medical Consequences of SCI,
Iordanou, 2002[158] Greece	Unclear	Yes	Yes	Unclear	Unclear	Yes	No	No	Unclear	Fair	NR
Onigbinde, 2010[165] South Africa	Unclear	Unclear	Unclear	Unclear	Unclear	No	No	Unclear	Yes	Poor	NR
Schwien, 2005[169] US	Unclear	Unclear	Unclear		Unclear	No	Unclear	NR	Yes	Poor	NR
Srivastava, 2010[170] India	Unclear	Unclear	Unclear	No	Unclear	No	No	Unclear	Yes	Poor	NR

Abbreviations: NR, not reported.

References

1. Allman RM, Walker JM, Hart MK, et al. Air-fluidized beds or conventional therapy for pressure sores. A randomized trial. Annals of Internal Medicine. 1987 Nov;107(5):641-8. PMID: 3310792.

2. Branom R, Rappl LM. "Constant force technology" versus low-air-loss therapy in the treatment of pressure ulcers.[Erratum appears in Ostomy Wound Manage 2001 Nov;47(11):6]. Ostomy Wound Management. 2001 Sep;47(9):38-46. PMID: 11889743.

3. Caley L, Jones S, Freer J, et al. Randomized Prospective Trial: Treatment Outcomes and Cost-Effectiveness of Two Types of Low-Air-Loss Therapy. 9th Annual Clinical Symposium on Pressure Ulcer and Wound Management. Nashville, TN. 1994:1-2.

4. Clark M DIP. A randomised controlled trial comparing the healing of pressure sores upon two pressure-redistributing seat cushions. Proceedings of the 7th European European Conference on Advances in Wound Management. 1997.

5. Day A, Leonard F. Seeking quality care for patients with pressure ulcers. Decubitus. 1993 Jan;6(1):32-43. PMID: 8427642.

6. Devine B. Alternating pressure air mattresses in the management of established pressure sores. Journal of Tissue Viability. 1995;5(3):94-8.

7. Evans D, Land L, Geary A. A clinical evaluation of the Nimbus 3 alternating pressure mattress replacement system. Journal of Wound Care. 2000 Apr;9(4):181-6. PMID: 11933303.

8. Land L, Evans D, Geary A, et al. A clinical evaluation of an alternating-pressure mattress replacement system in hospital and residential care settings. Journal of Tissue Viability. 2000 Jan;10(1):6-11. PMID: 10839090.

9. Ferrell BA, Osterweil D, Christenson P. A randomized trial of low-air-loss beds for treatment of pressure ulcers. Journal of the American Medical Association. 1993;269(4):494-7. PMID: 8338511.

10. Groen HW, Groenier KH, Schuling J. Comparative study of a foam mattress and a water mattress. Journal of Wound Care. 1999 Jul;8(7):333-5. PMID: 10776222.

11. Izutsu T, Matsui T, Satoh T, et al. Effect of rolling bed on decubitus in bedridden nursing home patients. Tohoku Journal of Experimental Medicine. 1998 Feb;184(2):153-7. PMID: 9605022.

12. Jackson BS, Chagares R, Nee N, et al. The effects of a therapeutic bed on pressure ulcers: an experimental study. Journal of Enterostomal Therapy. 1988 Nov-Dec;15(6):220-6. PMID: 3204209.

13. Keogh A, Dealey C. Profiling beds versus standard hospital beds: effects on pressure ulcer incidence outcomes. Journal of Wound Care. 2001 Feb;10(2):15-9. PMID: 12964222.

14. Makhsous M, Lin F, Knaus E, et al. Promote pressure ulcer healing in individuals with spinal cord injury using an individualized cyclic pressure-relief protocol. Advances in Skin & Wound Care. 2009 Nov;22(11):514-21. PMID: 20026933.

15. Malbrain M, Hendriks B, Wijnands P, et al. A pilot randomised controlled trial comparing reactive air and active alternating pressure mattresses in the prevention and treatment of pressure ulcers among medical ICU patients. Journal of Tissue Viability. 2010 Feb;19(1):7-15. PMID: 20079647.

16. Mulder G, Taro N, Seeley J, et al. A study of pressure ulcer response to low air loss beds vs. conventional treatment. Journal of Geriatric Dermatology 1994;2(3):87-91.

17. Munro BH, Brown L, Heitman BB. Pressure ulcers: one bed or another? Geriatric nursing (New York, N.Y.). 1989;10(4):190-2. PMID: 2777121.

18. Nixon J, Nelson EA, Cranny G, et al. Pressure relieving support surfaces: a randomised evaluation. Health Technology Assessment (Winchester, England). 2006 Jul;10(22):iii-iv, ix-x, 1-163. PMID: 16750060.

19. Rosenthal MJ, Felton RM, Nastasi AE, et al. Healing of advanced pressure ulcers by a generic total contact seat: 2 randomized comparisons with low air loss bed treatments. Archives of Physical Medicine & Rehabilitation. 2003 Dec;84(12):1733-42. PMID: 14669176.

20. Russell L, Reynolds TM, Carr J, et al. Randomised controlled trial of two pressure-relieving systems. Journal of Wound Care. 2000(a) Feb;9(2):52-5. PMID: 11933280.

21. Russell L, Reynolds T, Carr J, et al. A comparison of healing rates on two pressure-relieving systems. British Journal of Nursing. 2000(b) Dec 8-2001 Jan 10;9(22):2270-80. PMID: 12271193.

22. Russell L, Reynolds TM, Towns A, et al. Randomized comparison trial of the RIK and the Nimbus 3 mattresses. British Journal of Nursing. 2003(a) Feb 27-Mar 12;12(4):254, 6-9. PMID: 12671572.

23. Strauss MJ, Gong J, Gary BD, et al. The cost of home air-fluidized therapy for pressure sores. A randomized controlled trial. Journal of Family Practice. 1991 Jul;33(1):52-9. PMID: 2056290.

24. Ochs RF, Horn SD, van Rijswijk L, et al. Comparison of air-fluidized therapy with other support surfaces used to treat pressure ulcers in nursing home residents. Ostomy Wound Management. 2005 Feb;51(2):38-68. PMID: 15699554.

25. Valente SA, Greenough Iii WB, DeMarco SL, et al. More expensive surfaces are not always better. Kuwait Medical Journal. 2012;44(1):40-5.

26. Warner DJ. A clinical comparison of two pressure-reducing surfaces in the management of pressure ulcers. Decubitus. 1992 May;5(3):52-5, 8-60, 2-4. PMID: 1596352.

27. Benati G, Delvecchio S, Cilla D, et al. Impact on pressure ulcer healing of an arginine-enriched nutritional solution in patients with severe cognitive impairment. Archives of Gerontology & Geriatrics - Supplement. 2001;7:43-7. PMID: 11431045.

28. Cereda E, Gini A, Pedrolli C, et al. Disease-specific, versus standard, nutritional support for the treatment of pressure ulcers in institutionalized older adults: a randomized controlled trial. Journal of the American Geriatrics Society. 2009 Aug;57(8):1395-402. PMID: 19563522.

29. Chernoff R. The effect of a high protein fomula (Replete) on decubitus ulcer healing in long term tube fed institutionalized patients. Journal of the American Dietetic Association. 1990;90(130).

30. Desneves KJ, Todorovic BE, Cassar A, et al. Treatment with supplementary arginine, vitamin C and zinc in patients with pressure ulcers: a randomised controlled trial. Clinical Nutrition. 2005 Dec;24(6):979-87. PMID: 16297506.

31. Lee SK, Posthauer ME, Dorner B, et al. Pressure ulcer healing with a concentrated, fortified, collagen protein hydrolysate supplement: a randomized controlled trial. Advances in Skin & Wound Care. 2006 Mar;19(2):92-6. PMID: 16557055.

32. Leigh B, Desneves K, Rafferty J, et al. The effect of different doses of an arginine-containing supplement on the healing of pressure ulcers. Journal of Wound Care. 2012;21(3):150-6. PMID: 22399084.

33. Meaume S, Kerihuel JC, Constans T, et al. Efficacy and safety of ornithine alpha-ketoglutarate in heel pressure ulcers in elderly patients: results of a randomized controlled trial. Journal of Nutrition, Health & Aging. 2009 Aug;13(7):623-30. PMID: 19621198.

34. Myers SA, Takiguchi S, Slavish S, et al. Consistent wound care and nutritional support in treatment. Decubitus. 1990 Aug;3(3):16-28. PMID: 2119183.

35. Ohura T, Nakajo T, Okada S, et al. Evaluation of effects of nutrition intervention on healing of pressure ulcers and nutritional states (randomized controlled trial). Wound Repair & Regeneration. 2011 May-Jun;19(3):330-6. PMID: 21539650.

36. Ter Riet G, Kessels AGH, Knipschild PG. Randomized clinical trial of ascorbic acid in the treatment of pressure ulcers. Journal of Clinical Epidemiology. 1995;48(12):1453-60. PMID: 8543959.

37. Van Anholt RD, Sobotka L, Meijer EP, et al. An arginine- and micronutrient-enriched nutritional supplement accelerates pressure ulcer healing and reduces wound care in non-malnourished patients. EWMA Journal. 2010 49, 2010;10(2):45.

38. Barnes P, Jr., Sauter TE, Zaheri S. Subnormal prealbumin levels and wound healing. Texas Medicine. 2007 Aug;103(8):65-8. PMID: 19113064.

39. Breslow RA, Hallfrisch J, Guy DG, et al. The importance of dietary protein in healing pressure ulcers. Journal of the American Geriatrics Society. 1993;41(4):357-62. PMID: 8463519.

40. Brewer S, Desneves K, Pearce L, et al. Effect of an arginine-containing nutritional supplement on pressure ulcer healing in community spinal patients. Journal of Wound Care. 2010 Jul;19(7):311-6. PMID: 20616774.

41. Houston S, Haggard J, Williford J, Jr., et al. Adverse effects of large-dose zinc supplementation in an institutionalized older population with pressure ulcers [4]. Journal of the American Geriatrics Society. 2001;49(8):1130-2. PMID: 11555083.

42. Yamamoto T, Fujioka M, Kitamura R, et al. Evaluation of nutrition in the healing of pressure ulcers: are the EPUAP nutritional guidelines sufficient to heal wounds. European Pressure Ulcer Advisory Panel. Wounds: A Compendium of Clinical Research & Practice. 2009;21(6):153-7.

43. Alm A, Hornmark AM, Fall PA, et al. Care of pressure sores: a controlled study of the use of a hydrocolloid dressing compared with wet saline gauze compresses. Acta Dermato-Venereologica. Supplementum. 1989;149:1-10. PMID: 2694713.

44. Bale S, Squires D, Varnon T, et al. A comparison of two dressings in pressure sore management. Journal of Wound Care. 1997 Nov;6(10):463-6. PMID: 9455271.

45. Bale S, Hagelstein S, Banks V, et al. Costs of dressings in the community. Journal of Wound Care. 1998(b) Jul;7(7):327-30. PMID: 9791356.

46. Bale S, Banks V, Haglestein S, et al. A comparison of two amorphous hydrogels in the debridement of pressure sores. Journal of Wound Care. 1998 (a) Feb;7(2):65-8. PMID: 9543975.

47. Banks V, Bale SE, Harding KG. Comparing two dressings for exuding pressure sores in community patients. Journal of Wound Care. 1994(a);3(4):175-8.

48. Banks V, Bale S, Harding K. The use of two dressings for moderately exuding pressure sores. Journal of Wound Care. 1994(b);3(3):132-4.

49. Belmin J, Meaume S, Rabus M-T, et al. Sequential treatment with calcium alginate dressings and hydrocolloid dressings accelerates pressure ulcer healing in older subjects: a multicenter randomized trial of sequential versus nonsequential treatment with hydrocolloid dressings alone. Journal of the American Geriatrics Society. 2002 Feb;50(2):269-74. PMID: 12028208.

50. Bito S, Mizuhara A, Oonishi S, et al. Randomised controlled trial evaluating the efficacy of wrap therapy for wound healing acceleration in patients with NPUAP stage II and III pressure ulcer. BMJ Open. 2012;2:e000371. PMID: 22223842.

51. Brod M, McHenry E, Plasse TF, et al. A randomized comparison of poly-hema and hydrocolloid dressings for treatment of pressure sores. Archives of Dermatology. 1990 Jul;126(7):969-70. PMID: 2193631.

52. Brown-Etris M, Milne C, Orsted H, et al. A prospective, randomized, multisite clinical evaluation of a transparent absorbent acrylic dressing and a hydrocolloid dressing in the management of Stage II and shallow Stage III pressure ulcers. Advances in Skin & Wound Care. 2008 Apr;21(4):169-74. PMID: 18385577.

53. Chang KW, Alsagoff S, Ong KT, et al. Pressure ulcers--randomised controlled trial comparing hydrocolloid and saline gauze dressings. Medical Journal of Malaysia. 1998 Dec;53(4):428-31. PMID: 10971989.

54. Chuangsuwanich A, Charnsanti O, Lohsiriwat V, et al. The efficacy of silver mesh dressing compared with silver sulfadiazine cream for the treatment of pressure ulcers. Journal of the Medical Association of Thailand. 2011 May;94(5):559-65. PMID: 21675444.

55. Colin D, Kurring PA, Yvon C. Managing sloughy pressure sores. Journal of Wound Care. 1996 Nov;5(10):444-6. PMID: 9117814.

56. Colwell JC, Foreman MD, Trotter JP. A comparison of the efficacy and cost-effectiveness of two methods of managing pressure ulcers. Decubitus. 1993 Jul;6(4):28-36. PMID: 8297488.

57. Darkovich SL, Brown-Etris M, Spencer M. Biofilm hydrogel dressing: a clinical evaluation in the treatment of pressure sores. Ostomy Wound Management. 1990 Jul-Aug;29:47-60. PMID: 2202317.

58. Day A, Dombranski S, Farkas C, et al. Managing sacral pressure ulcers with hydrocolloid dressings: results of a controlled, clinical study. Ostomy Wound Management. 1995 Mar;41(2):52-4, 6, 8 passim. PMID: 7598778.

59. Gorse GJ, Messner RL. Improved pressure sore healing with hydrocolloid dressings. Archives of Dermatology. 1987 Jun;123(6):766-71. PMID: 3555355.

60. Honde C, Derks C, Tudor D. Local treatment of pressure sores in the elderly: amino acid copolymer membrane versus hydrocolloid dressing. Journal of the American Geriatrics Society. 1994 Nov;42(11):1180-3. PMID: 7525682.

61. Kaya AZ, Turani N, Akyuz M. The effectiveness of a hydrogel dressing compared with standard management of pressure ulcers. Journal of Wound Care. 2005 Jan;14(1):42-4. PMID: 15656468.

62. Kerihuel JC. Effect of activated charcoal dressings on healing outcomes of chronic wounds. Journal of Wound Care. 2010 May;19(5):208, 10-2, 14-5. PMID: 20505594.

63. Kim YC, Shin JC, Park CI, et al. Efficacy of hydrocolloid occlusive dressing technique in decubitus ulcer treatment: a comparative study. Yonsei Medical Journal. 1996 Jun;37(3):181-5. PMID: 8826783.

64. Kloth LC, Berman JE, Nett M, et al. A randomized controlled clinical trial to evaluate the effects of noncontact normothermic wound therapy on chronic full-thickness pressure ulcers. Advances in Skin & Wound Care. 2002 Nov-Dec;15(6):270-6. PMID: 12477979.

65. Kraft MR, Lawson L, Pohlmann B, et al. A comparison of Epi-Lock and saline dressings in the treatment of pressure ulcers. Decubitus. 1993 Nov;6(6):42-4, 6, 8. PMID: 8286026.

66. Kurzuk-Howard G, Simpson L, Palmieri A. Decubitus ulcer care: a comparative study. Western Journal of Nursing Research. 1985 Feb;7(1):58-79. PMID: 3850687.

67. Matzen S, Peschardt A, Alsbjorn B. A new amorphous hydrocolloid for the treatment of pressure sores: a randomised controlled study. Scandinavian Journal of Plastic & Reconstructive Surgery & Hand Surgery. 1999 Mar;33(1):13-5. PMID: 10207960.

68. Meaume S, Vallet D, Morere MN, et al. Evaluation of a silver-releasing hydroalginate dressing in chronic wounds with signs of local infection.[Erratum appears in J Wound Care. 2005 Nov;14(10):479]. Journal of Wound Care. 2005 Oct;14(9):411-9. PMID: 16240620.

69. Meaume S, Van De Looverbosch D, Heyman H, et al. A study to compare a new self-adherent soft silicone dressing with a self-adherent polymer dressing in stage II pressure ulcers. Ostomy Wound Management. 2003 Sep;49(9):44-51. PMID: 14581709.

70. Motta G, Dunham L, Dye T, et al. Clinical efficacy and cost-effectiveness of a new synthetic polymer sheet wound dressing. Ostomy Wound Management. 1999 Oct;45(10):41, 4-6, 8-9. PMID: 10687651.

71. Mulder GD, Altman M, Seeley JE, et al. Prospective randomized study of the efficacy of hydrogel, hydrocolloid, and saline solution -- moistened dressings on the management of pressure ulcers. Wound Repair & Regeneration. 1993;1(4):213-8. PMID: 17166097.

72. Neill K, Conforti C, Kedas A, et al. Pressure sore response to a new hydrocolloid dressing. Wounds: A Compendium of Clinical Research & Practice. 1989;1:173-85.

73. Oleske DM, Smith XP, White P, et al. A randomized clinical trial of two dressing methods for the treatment of low-grade pressure ulcers. Journal of Enterostomal Therapy. 1986 May-Jun;13(3):90-8. PMID: 3519718.

74. Payne WG, Posnett J, Alvarez O, et al. A prospective, randomized clinical trial to assess the cost-effectiveness of a modern foam dressing versus a traditional saline gauze dressing in the treatment of stage II pressure ulcers. Ostomy Wound Management. 2009 Feb;55(2):50-5. PMID: 19246785.

75. Price P, Bale S, Crook H, et al. The effect of a radiant heat dressing on pressure ulcers. Journal of Wound Care. 2000 Apr;9(4):201-5. PMID: 11933306.

76. Sebern MD. Pressure ulcer management in home health care: efficacy and cost effectiveness of moisture vapor permeable dressing. Archives of Physical Medicine & Rehabilitation. 1986 Oct;67(10):726-9. PMID: 3533007.

77. Sebern MD. Cost and efficacy of pressure ulcer management in a metropolitan visiting nurse association. Decubitus. 1989 Aug;2(3):58-9. PMID: 2775474.

78. Seeley J, Jensen JL, Hutcherson J. A randomized clinical study comparing a hydrocellular dressing to a hydrocolloid dressing in the management of pressure ulcers. Ostomy Wound Management. 1999 Jun;45(6):39-44, 6-7. PMID: 10655861.

79. Small N, Mulder M, Mackenzie MJ, et al. A comparative analysis of pressure sore treatment modalities in community settings. Curationis. 2002 Feb;25(1):74-82. PMID: 12096575.

80. Thomas S, Banks V, Bale S, et al. A comparison of two dressings in the management of chronic wounds. Journal of Wound Care. 1997 Sep;6(8):383-6. PMID: 9341430.

81. Thomas DR, Goode PS, LaMaster K, et al. Acemannan hydrogel dressing versus saline dressing for pressure ulcers. A randomized, controlled trial. Advances in Wound Care. 1998 Oct;11(6):273-6. PMID: 10326343.

82. Thomas DR, Diebold MR, Eggemeyer LM. A controlled, randomized, comparative study of a radiant heat bandage on the healing of stage 3-4 pressure ulcers: a pilot study. Journal of the American Medical Directors Association. 2005 Jan-Feb;6(1):46-9. PMID: 15871870.

83. Whitney JD, Salvadalena G, Higa L, et al. Treatment of pressure ulcers with noncontact normothermic wound therapy: healing and warming effects. Journal of Wound, Ostomy, & Continence Nursing. 2001 Sep;28(5):244-52. PMID: 11557928.

84. Winter A, Hewitt H. Testing a hydrocolloid. Nursing Times. 1990 Dec 12-8;86(50):59-62. PMID: 2255648.

85. Xakellis. Hydrocolloid versus saline-gauze dressings in treating pressure ulcers: a cost-effectiveness analysis. Arch Phys Med Rehabil. . 1992;73:463-9. PMID: 1580775.

86. Yapucu Gunes U, Eser I. Effectiveness of a honey dressing for healing pressure ulcers. Journal of Wound, Ostomy, & Continence Nursing. 2007 Mar-Apr;34(2):184-90. PMID: 17413836.

87. Yastrub DJ. Relationship between type of treatment and degree of wound healing among institutionalized geriatric patients with stage II pressure ulcers... reprinted with permission from the author and Nurse Practitioner Associates for Continuing Education. Care Management Journals. 2004;5(4):213-8.

88. Meaume S, Ourabah Z, Charru P, et al. Optimizing wound care with a new lipido-colloid dressing (Urgotul Duo). British Journal of Nursing. 2007 Mar 22-Apr 11;16(6):S4, S6, S8 passim. PMID: 17505400.

89. Moody M. Calcium alginate: a dressing trial. Nursing Standard. 1991;5(50):3-6. PMID: 1911033.

90. Parnell LKS, Ciufi B, Gokoo CF. Preliminary use of a hydrogel containing enzymes in the treatment of stage II and stage III pressure ulcers. Ostomy Wound Management. 2005 Aug;51(8):50-60. PMID: 16234576.

91. Stoker FM. A major contributor. Evaluation of Comfeel Pressure Relieving Dressing. Professional Nurse. 1990 Sep;5(12):644-53. PMID: 2217219.

92. Viamontes L, Temple D, Wytall D, et al. An evaluation of an adhesive hydrocellular foam dressing and a self-adherent soft silicone foam dressing in a nursing home setting. Ostomy Wound Management. 2003 Aug;49(8):48-52, 4-6, 8. PMID: 14631663.

93. Agren MS, Stromberg HE. Topical treatment of pressure ulcers. A randomized comparative trial of Varidase and zinc oxide. Scandinavian Journal of Plastic & Reconstructive Surgery. 1985;19(1):97-100. PMID: 3895409.

94. Alvarez OM, Fernandez-Obregon A, Rogers RS, et al. Chemical debridement of pressure ulcers: a prospective, randomized, comparative trial of collagenase and papain/urea formulations. Wounds: A Compendium of Clinical Research & Practice. 2000;12(2):15-25.

95. Burgos A, Gimenez J, Moreno E, et al. Collagenase ointment application at 24- versus 48-hour intervals in the treatment of pressure ulcers. A randomised multicentre study. Clinical Drug Investigation. 2000;19(6):399-407.

96. Burgos A, Gimenez J, Moreno E, et al. Cost, efficacy, efficiency and tolerability of collagenase ointment versus hydrocolloid occlusive dressing in the treatment of pressure ulcers. A comparative, randomised, multicentre study. Clinical Drug Investigation. 2000;19(5):357-65.

97. Felzani G, Spoletini I, Convento A, et al. Effect of lysine hyaluronate on the healing of decubitus ulcers in rehabilitation patients. Advances in Therapy. 2011 May;28(5):439-45. PMID: 21499725.

98. Gerding GA, Browning JS. Oxyquinoline-containing ointment vs. standard therapy for stage I and stage II skin lesions. Dermatology Nursing. 1992 Oct;4(5):389-98. PMID: 1482629.

99. Graumlich JF, Blough LS, McLaughlin RG, et al. Healing pressure ulcers with collagen or hydrocolloid: A randomized, controlled trial. Journal of the American Geriatrics Society. 2003;51(2):147-54. PMID: 12558709.

100. Guthrie M, Diakiw J, Zaydon AC, et al. A randomized double-blind clinical study of dermagran dual therapeutic system in the treatment of decubitus ulcers. Wounds: A Compendium of Clinical Research and Practice. 1989;1(3):142-54.

101. Hollisaz MT, Khedmat H, Yari F. A randomized clinical trial comparing hydrocolloid, phenytoin and simple dressings for the treatment of pressure ulcers [ISRCTN33429693]. BMC Dermatology. 2004;4(1):18. PMID: 15601464.

102. Hsu YC, Chang HH, Chen MF, et al. Therapeutic effect of sheng-ji-san on pressure ulcers. American Journal of Chinese Medicine. 2000;28(3-4):391-9. PMID: 11154053.

103. Kuflik A, Stillo JV, Sanders D, et al. Petrolatum versus Resurfix ointment in the treatment of pressure ulcers. Ostomy Wound Management. 2001 Feb;47(2):52-6. PMID: 11235499.

104. LeVasseur SA, Helme RD. A double-blind clinical trial to compare the efficacy of an active based cream F14001 against a placebo non-active based cream for the treatment of pressure ulcers in a population of elderly subjects. Journal of Advanced Nursing. 1991 Aug;16(8):952-6. PMID: 1779084.

105. Muller E, van Leen MW, Bergemann R. Economic evaluation of collagenase-containing ointment and hydrocolloid dressing in the treatment of pressure ulcers. Pharmacoeconomics. 2001;19(12):1209-16. PMID: 11772156.

106. Nisi G, Brandi C, Grimaldi L, et al. Use of a protease-modulating matrix in the treatment of pressure sores. Chirurgia Italiana. 2005 Jul-Aug;57(4):465-8. PMID: 16060184.

107. Pullen R, Popp R, Volkers P, et al. Prospective randomized double-blind study of the wound-debriding effects of collagenase and fibrinolysin/deoxyribonuclease in pressure ulcers. Age & Ageing. 2002 Mar;31(2):126-30. PMID: 11937475.

108. Rhodes RS, Heyneman CA, Culbertson VL, et al. Topical phenytoin treatment of stage II decubitus ulcers in the elderly. Annals of Pharmacotherapy. 2001 Jun;35(6):675-81. PMID: 11408983.

109. Sayag J, Meaume S, Bohbot S. Healing properties of calcium alginate dressings. Journal of Wound Care. 1996 Sep;5(8):357-62. PMID: 8954425.

110. Shamimi Nouri K, Karimian R, Nasli E, et al. Topical application of Semelil (ANGIPARS(trademark)) in treatment of pressure ulcers: A randomized clinical trial. Daru. 2008;16(SUPPL. 1):54-7.

111. Sipponen A, Jokinen JJ, Sipponen P, et al. Beneficial effect of resin salve in treatment of severe pressure ulcers: a prospective, randomized and controlled multicentre trial. British Journal of Dermatology. 2008 May;158(5):1055-62. PMID: 18284391.

112. Subbanna PK, Margaret Shanti FX, George J, et al. Topical phenytoin solution for treating pressure ulcers: a prospective, randomized, double-blind clinical trial. Spinal Cord. 2007 Nov;45(11):739-43. PMID: 17279096.

113. Tytgat H, Van Asch H. Topical ketanserin in the treatment of decubitus ulcers: A double-blind study with 2% ketanserin ointment against placebo. Advances in Therapy. 1988;5(4):143-52.

114. Zeron HM, Krotzsch Gomez FE, Munoz REH. Pressure ulcers: a pilot study for treatment with collagen polyvinylpyrrolidone. International Journal of Dermatology. 2007 Mar;46(3):314-7. PMID: 17343594.

115. Harding KG, Bale S, Stock J, et al. A multi-center comparison of a hydrocellular adhesive dressing and a hydrocolloid dressing in the management of stage II and III pressure ulcers. 9th Annual Symposium on Advanced Wound Care and 6th Annual Medical Research Forum on Wound Repair. 1996.

116. Hindryckx P, De Cuyper C, Hendrickx B, et al. The treatment of infected decubitus ulcers with 1% silver sulfadiazine cream. Current Therapeutic Research - Clinical and Experimental. 1990;48(3):535-9.

117. Narayanan S, Van Vleet J, Strunk B, et al. Comparison of pressure ulcer treatments in long-term care facilities: clinical outcomes and impact on cost. Journal of Wound, Ostomy, & Continence Nursing. 2005 May-Jun;32(3):163-70. PMID: 15931146.

118. Sherman RA, Wyle F, Vulpe M. Maggot therapy for treating pressure ulcers in spinal cord injury patients. Journal of Spinal Cord Medicine. 1995 Apr;18(2):71-4. PMID: 7640976.

119. Sherman RA. Maggot versus conservative debridement therapy for the treatment of pressure ulcers. Wound Repair & Regeneration. 2002 Jul-Aug;10(4):208-14. PMID: 12191002.

120. Wang S-y, Wang J-n, Lv D-c, et al. Clinical research on the bio-debridement effect of maggot therapy for treatment of chronically infected lesions. Orthopaedic Audio-Synopsis Continuing Medical Education [Sound Recording]. 2010;2(3):201-6. PMID: 22009949.

121. Danon D, Madjar J, Edinov E, et al. Treatment of human ulcers by application of macrophages prepared from a blood unit. Experimental Gerontology. 1997 Nov-Dec;32(6):633-41. PMID: 9785089.

122. Hirshberg J, Coleman J, Marchant B, et al. TGF-beta3 in the treatment of pressure ulcers: a preliminary report. Advances in Skin & Wound Care. 2001 Mar-Apr;14(2):91-5. PMID: 11899912.

123. Landi F, Aloe L, Russo A, et al. Topical treatment of pressure ulcers with nerve growth factor: a randomized clinical trial. Annals of Internal Medicine. 2003 Oct 21;139(8):635-41. PMID: 14568851.

124. Mustoe TA, Cutler NR, Allman RM, et al. A phase II study to evaluate recombinant platelet-derived growth factor-BB in the treatment of stage 3 and 4 pressure ulcers. Archives of Surgery. 1994 Feb;129(2):213-9. PMID: 8304833.

125. Payne WG, Ochs DE, Meltzer DD, et al. Long-term outcome study of growth factor-treated pressure ulcers. American Journal of Surgery. 2001 Jan;181(1):81-6. PMID: 11248182.

126. Payne WG, Wright TE, Ochs D, et al. An exploratory study of dermal replacement therapy in the treatment of stage III pressure ulcers. Journal of Applied Research. 2004;4(1):12-23.

127. Rees RS, Robson MC, Smiell JM, et al. Becaplermin gel in the treatment of pressure ulcers: a phase II randomized, double-blind, placebo-controlled study. Wound Repair & Regeneration. 1999 May-Jun;7(3):141-7. PMID: 10417749.

128. Robson MC, Phillips LG, Thomason A, et al. Platelet-derived growth factor BB for the treatment of chronic pressure ulcers. Lancet. 1992 Jan 4;339(8784):23-5. PMID: 1345953.

129. Robson MC, Phillips LG, Thomason A, et al. Recombinant human platelet-derived growth factor-BB for the treatment of chronic pressure ulcers. Annals of Plastic Surgery. 1992;29(3):193-201. PMID: 1524367.

130. Robson LE. Safety and effect of topical recombinant human interleukin-1beta in the management of pressure sores. Wound Repair & Regeneration. 1994 Jul;2(3):177-81. PMID: 17156109.

131. Robson MC, Hill DP, Smith PD, et al. Sequential cytokine therapy for pressure ulcers: clinical and mechanistic response. Annals of Surgery. 2000 Apr;231(4):600-11. PMID: 10749622.

132. Robson MC, Phillips LG, Lawrence WT, et al. The safety and effect of topically applied recombinant basic fibroblast growth factor on the healing of chronic pressure sores. Annals of Surgery. 1992 Oct;216(4):401-6; discussion 6-8. PMID: 1417189.

133. Scevola S, Nicoletti G, Brenta F, et al. Allogenic platelet gel in the treatment of pressure sores: a pilot study. International Wound Journal. 2010 Jun;7(3):184-90. PMID: 20455960.

134. Zuloff-Shani A, Adunsky A, Even-Zahav A, et al. Hard to heal pressure ulcers (stage III-IV): efficacy of injected activated macrophage suspension (AMS) as compared with standard of care (SOC) treatment controlled trial. Archives of Gerontology & Geriatrics. 2010 Nov-Dec;51(3):268-72. PMID: 20034682.

135. Juri H, Palma JA. CO2 laser in decubitus ulcers: a comparative study. Lasers in Surgery & Medicine. 1987;7(4):296-9. PMID: 3683061.

136. Foster RD, Anthony JP, Mathes SJ, et al. Flap selection as a determinant of success in pressure sore coverage. Archives of Surgery. 1997(a) Aug;132(8):868-73. PMID: 9267271.

137. Foster RD, Anthony JP, Mathes SJ, et al. Ischial pressure sore coverage: A rationale for flap selection. British Journal of Plastic Surgery. 1997(b);50(5):374-9. PMID: 9245873.

138. Kierney PC, Engrav LH, Isik FF, et al. Results of 268 pressure sores in 158 patients managed jointly by plastic surgery and rehabilitation medicine. Plastic & Reconstructive Surgery. 1998 Sep;102(3):765-72. PMID: 9727442.

139. Schryvers OI, Stranc MF, Nance PW. Surgical treatment of pressure ulcers: 20-year experience. Archives of Physical Medicine & Rehabilitation. 2000 Dec;81(12):1556-62. PMID: 11128889.

140. Yamamoto Y, Tsutsumida A, Murazumi M, et al. Long-term outcome of pressure sores treated with flap coverage. Plastic & Reconstructive Surgery. 1997 Oct;100(5):1212-7. PMID: 9326782.

141. Adegoke BO, Badmos KA. Acceleration of pressure ulcer healing in spinal cord injured patients using interrupted direct current. African Journal of Medicine & Medical Sciences. 2001 Sep;30(3):195-7. PMID: 14510128.

142. Adunsky A, Ohry A, Group D. Decubitus direct current treatment (DDCT) of pressure ulcers: results of a randomized double-blinded placebo controlled study. Archives of Gerontology & Geriatrics. 2005 Nov-Dec;41(3):261-9. PMID: 15998547.

143. Ahmad ET. High voltage pulsed galvanic stimulation: effect of treatment durations on healing of chronic pressure ulcers. Indian Journal of Physiotherapy & Occupational Therapy. 2008;2(3):1-5. PMID: 21991123.

144. Ahmad ET. High-voltage pulsed galvanic stimulation: effect of treatment duration on healing of chronic pressure ulcers. Annals of Burns & Fire Disasters. 2008;21(3):124-8. PMID: 21991123.

145. Baker LL, Rubayi S, Villar F, et al. Effect of electrical stimulation waveform on healing of ulcers in human beings with spinal cord injury. Wound Repair & Regeneration. 1996 Jan-Mar;4(1):21-8. PMID: 17129344.

146. Burke DT, Ho CHK, Saucier MA, et al. Effects of hydrotherapy on pressure ulcer healing. American Journal of Physical Medicine and Rehabilitation. 1998;77(5):394-8. PMID: 9798830.

147. Comorosan S, Vasilco R, Arghiropol M, et al. The effect of diapulse therapy on the healing of decubitus ulcer. Romanian Journal of Physiology (Bucuresti). 1993 Jan-Jun;30(1-2):41-5. PMID: 7982015.

148. Dehlin O, Elmstahl S, Gottrup F. Monochromatic phototherapy in elderly patients: a new way of treating chronic pressure ulcers?.[Erratum appears in Aging Clin Exp Res. 2003 Dec;15(6):519]. Aging-Clinical & Experimental Research. 2003 Jun;15(3):259-63. PMID: 14582689.

149. Dehlin O, Elmstahl S, Gottrup F. Monochromatic phototherapy: effective treatment for grade II chronic pressure ulcers in elderly patients. Aging-Clinical & Experimental Research. 2007 Dec;19(6):478-83. PMID: 18172370.

150. Durovic A, Maric D, Brdareski Z, et al. The effects of polarized light therapy in pressure ulcer healing. Vojnosanitetski Pregled. 2008 Dec;65(12):906-12. PMID: 19160985.

151. Ford CN, Reinhard ER, Yeh D, et al. Interim analysis of a prospective, randomized trial of vacuum-assisted closure versus the healthpoint system in the management of pressure ulcers. Annals of Plastic Surgery. 2002 Jul;49(1):55-61; discussion PMID: 12142596.

152. Gentzkow GD, Pollack VP, Kloth LC, et al. Improved healing of pressure ulcers using Dermapulse, a new electrical stimulation device. Wounds: A Compendium of Clinical Research and Practice. 1991;3(5):158-70.

153. Griffin JW, Tooms RE, Mendius RA, et al. Efficacy of high voltage pulsed current for healing of pressure ulcers in patients with spinal cord injury. Physical Therapy. 1991 Jun;71(6):433-42; discussion 42-4. PMID: 2034707.

154. Gupta A, Taly AB, Srivastava A, et al. Efficacy of pulsed electromagnetic field therapy in healing of pressure ulcers: A randomized control trial. Neurology India. 2009 Sep-Oct;57(5):622-6. PMID: 19934563.

155. Ho CH, Powell HL, Collins JF, et al. Poor nutrition is a relative contraindication to negative pressure wound therapy for pressure ulcers: preliminary observations in patients with spinal cord injury. Advances in Skin & Wound Care. 2010 Nov;23(11):508-16. PMID: 20975334.

156. Ho CH, Bensitel T, Wang X, et al. Pulsatile lavage for the enhancement of pressure ulcer healing: a randomized controlled trial. Physical Therapy. 2012;92(1):38-48. PMID: 21949432.

157. Houghton PE, Campbell KE, Fraser CH, et al. Electrical stimulation therapy increases rate of healing of pressure ulcers in community-dwelling people with spinal cord injury. Archives of Physical Medicine & Rehabilitation. 2010 May;91(5):669-78. PMID: 20434602.

158. Iordanou P, Baltopoulos G, Giannakopoulou M, et al. Effect of polarized light in the healing process of pressure ulcers.[Erratum appears in Int J Nurs Pract 2002 Apr;8(2):116]. International Journal of Nursing Practice. 2002 Feb;8(1):49-55. PMID: 11831427.

159. Kloth LC, Feedar JA. Acceleration of wound healing with high voltage, monophasic, pulsed current.[Erratum appears in Phys Ther 1989 Aug;69(8):702]. Physical Therapy. 1988 Apr;68(4):503-8. PMID: 3258429.

160. Lucas C, van Gemert MJC, de Haan RJ. Efficacy of low-level laser therapy in the management of stage III decubitus ulcers: a prospective, observer-blinded multicentre randomised clinical trial. Lasers in Medical Science. 2003;18(2):72-7. PMID: 12928815.

161. Lucas C, Coenen CHM, De Haan RJ. The effect of low level laser therapy (LLLT) on stage III decubitus ulcers (pressure sores); A prospective randomised single blind, multicentre pilot study. Lasers in Medical Science. 2000;15(2):94-100. PMID: 12928815.

162. Maeshige N, Fujiwara H, Honda H, et al. Evaluation of the combined use of ultrasound irradiation and wound dressing on pressure ulcers. Journal of Wound Care. 2010 Feb;19(2):63-8. PMID: 20216490.

163. McDiarmid T, Burns PN, Lewith GT, et al. Ultrasound and the treatment of pressure sores. Physiotherapy. 1985;71(2):66-70.

164. Nussbaum EL, Biemann I, Mustard B. Comparison of ultrasound/ultraviolet-C and laser for treatment of pressure ulcers in patients with spinal cord injury. Physical Therapy. 1994 Sep;74(9):812-23; discussion 24-5. PMID: 8066108.

165. Onigbinde AT, Olafimihan KF, Ojoawo A, et al. The effect of ultraviolet radiation (type B) on decubitus ulcers. Internet Journal of Allied Health Sciences & Practice. 2010;8(1):1-6.

166. Ozdemir F, Kasapoglu M, Oymak F, et al. Efficiency of magnetic field treatment on pressure sores in bedridden patients. Balkan Medical Journal. 2011;28(3):274-8.

167. Salzberg CA, Cooper-Vastola SA, Perez FJ, et al. The effects of non-thermal pulsed electromagnetic energy (DIAPULSE) on wound healing of pressure ulcers in spinal cord-injured patients: a randomized, double-blind study. Wounds: A Compendium of Clinical Research & Practice. 1995 Jan-Feb;7(1):11-6.

168. Schubert V. Effects of phototherapy on pressure ulcer healing in elderly patients after a falling trauma. A prospective, randomized, controlled study. Photodermatology, Photoimmunology & Photomedicine. 2001 Feb;17(1):32-8. PMID: 11169174.

169. Schwien T, Gilbert J, Lang C. Pressure ulcer prevalence and the role of negative pressure wound therapy in home health quality outcomes. Ostomy Wound Management. 2005 Sep;51(9):47-60. PMID: 16230764.

170. Srivastava RN. An innovative, cost-effective, negative pressure device for management of bedsores in traumatic paraplegia. Spine Journal. 2010;10(9):86S-7S.

171. Taly AB, Sivaraman Nair KP, Murali T, et al. Efficacy of multiwavelength light therapy in the treatment of pressure ulcers in subjects with disorders of the spinal cord: A randomized double-blind controlled trial. Archives of Physical Medicine & Rehabilitation. 2004 Oct;85(10):1657-61. PMID: 15468027.

172. Ter Riet G. Correction: Randomised clinical trial of ultrasound treatment for pressure ulcers (British Medical Journal (22nd April) (1040-1041)). British Medical Journal. 1995;310(6990):1300.

173. Ter Riet G, Kessels AGH, Knipschild P. A randomized clinical trial of ultrasound in the treatment of pressure ulcers. Physical Therapy. 1996;76(12):1301-12. PMID: 8959999.

174. Wanner MB, Schwarzl F, Strub B, et al. Vacuum-assisted wound closure for cheaper and more comfortable healing of pressure sores: a prospective study. Scandinavian Journal of Plastic & Reconstructive Surgery & Hand Surgery. 2003;37(1):28-33. PMID: 12625392.

175. Wood JM, Evans PE, 3rd, Schallreuter KU, et al. A multicenter study on the use of pulsed low-intensity direct current for healing chronic stage II and stage III decubitus ulcers. Archives of Dermatology. 1993 Aug;129(8):999-1009. PMID: 8352625.

176. Arashi M, Sugama J, Sanada H, et al. Vibration therapy accelerates healing of Stage I pressure ulcers in older adult patients. Advances in Skin & Wound Care. 2010 Jul;23(7):321-7. PMID: 20562541.

177. Arashi M, Sugama J, Sanada H. Vibration Therapy Accelerates Healing of Stage I Pressure Ulcers in Older Adult Patients. Journal of Wound, Ostomy & Continence Nursing; 2011. p. S8-S.

178. Edsberg LE, Brogan MS, Jaynes CD, et al. Topical hyperbaric oxygen and electrical stimulation: exploring potential synergy. Ostomy Wound Management. 2002 Nov;48(11):42-50. PMID: 12426451.

179. Feedar JAK, LC. Acceleration of wound healing with high voltage pulsating direct current (abstract). Phys Ther. 1985(65):741.

180. Larking AM, Duport S, Clinton M, et al. Randomized control of extracorporeal shock wave therapy versus placebo for chronic decubitus ulceration. Clinical Rehabilitation. 2010 Mar;24(3):222-9. PMID: 20156981.

181. Stefanovska A. Treatment of chronic wounds by means of electric and electromagnetic fields. Part 2. Value of FES parameters for pressure sore treatment. Medical & Biological Engineering & Computing. 1993 May;31(3):213-20. PMID: 8412373.

182. Ullah MO. A study to detect the efficacy of Micro-current Electrical Therapy on decubitus wound. Journal of Medical Sciences. 2007;7(8):1320-4.