3M
Cavilon™
Skin Care Solutions

EVIDENCE SUMMARY

3M™ Cavilon™ Advanced Skin Protectant

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Focus Key

- PERFORMANCE
- RADIATION THERAPY
- Ps PERISTOMAL
- Pw PERIWOUND
- I INCONTINENCE-ASSOCIATED DERMATITIS (IAD)

Case Type

- Se CASE SERIES
- St CASE STUDY

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CASE STUDIES AND CASE SERIES

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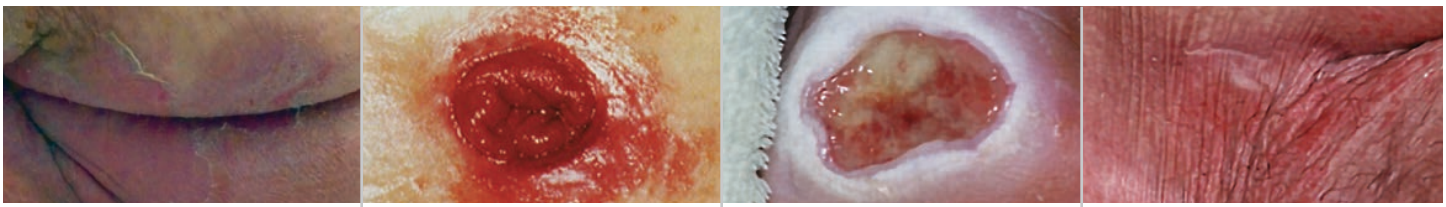
The significance of healthcare acquired skin damage.

Healthcare-acquired skin damage represents negative clinical outcomes that may result in potential complications such as infection, pain and suffering, and a poor patient experience. In addition, skin damage has been shown to increase the work and cost of care.[1]

Exposure over time to factors such as irritants, moisture, friction, shear and adhesives can lead to conditions of skin breakdown, including:

Moisture-Associated Skin Damage (MASD)



Incontinence-Associated Dermatitis (IAD)

Severe inflammation caused by liquid stool, mixed incontinence or urine, which can lead to destruction of the epidermis.

Peristomal Skin Damage

Problem stomas, poor stoma location and high-volume output, especially that of liquid stool, can contribute to skin injury that can rapidly progress to erosion.

Periwound Skin Damage

This type of skin damage is often associated with wounds that produce large quantities of drainage, such as venous ulcers or infected wounds.

Intertriginous Dermatitis (ITD)

Skin damage between skin surfaces due to the interaction of friction and moisture.

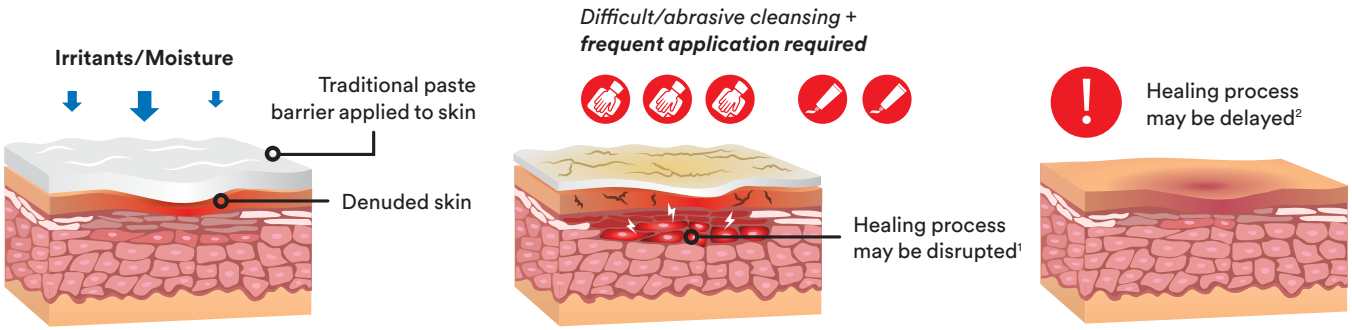
1. Brennan MR, Milne CT, Agrell-Kann M, Ekholm BP. Clinical Evaluation of a Skin Protectant for the Management of Incontinence-Associated Dermatitis: An Open-Label, Nonrandomized, Prospective Study. *J Wound Ostomy Continence Nurs*. 2017;44(2):172-180. doi:10.1097/WON.0000000000000307

Limitations of traditional skin protectants.

Moisture barrier creams, ointments and pastes have long been the standard of care for skin protection, but these products have been shown to:

- Not be effective for preventing and managing skin damage
- Not last as long as you need them to
- Not adhere to wet, weepy, damaged skin
- May interfere with healing
- May cause discomfort upon application, during wear and cleansing
- Not stay in place on the skin
- Be difficult to clean and remove, and may cause additional skin damage
- Interfere with skin assessment
- Not be suitable around an ostomy or fistula

How traditional protectants work.



2. Been RA, Bernatchez SF, Conrad-Vlasak DM, Asmus RA, Ekholm BP, Parks PJ. *In vivo* methods to evaluate a new skin protectant for loss of skin integrity. *Wound Repair Regen.* 2016:24(5):851-859. doi:10.1111/wrr.12455

See the science of skin protection at work.

Cavilon Advanced Skin Protectant represents a revolutionary technology for management of skin damage and protection of at-risk skin. Its formulation is unlike any other skin protectant or moisture barrier, but what makes it so different?

Unique, elastomeric polymer

The polymer forms a coating that can elongate and conform, avoiding the cracking seen with other moisture barriers. This assures greater barrier integrity, durability and protection against challenging irritants such as liquid stool and gastric fluid.

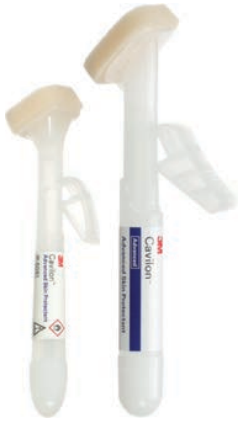
Revolutionary polymer-cyanoacrylate system

The cyanoacrylate enables attachment of the skin protectant to damaged skin that is wet and weeping. Once on the skin, the protective coating creates an environment that repels irritants and supports healing and comfort.

Remember: if a moisture barrier product cannot reliably attach to the underlying skin, it is not capable of reliable protection.

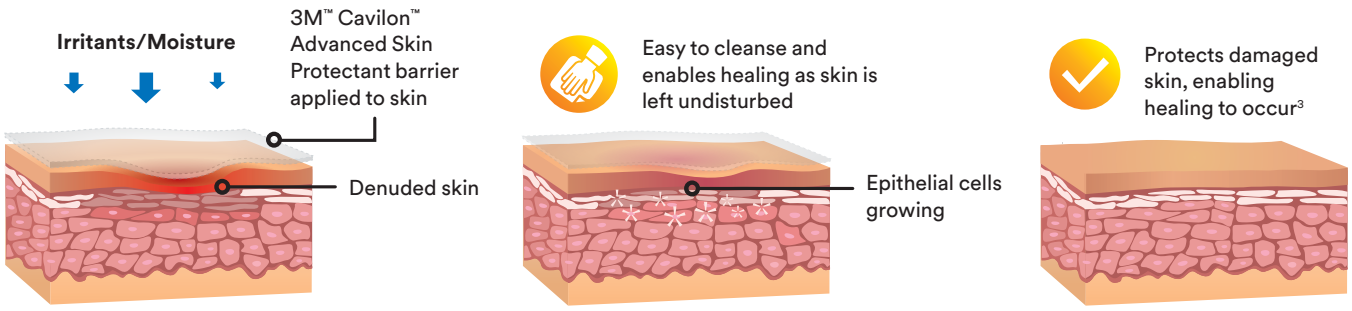
Non-stinging solvent

The polymer-cyanoacrylate system is delivered onto the skin by a non-stinging solvent.



Cavilon Advanced Skin Protectant is also breathable, allowing for moisture-vapor transmission that helps keep skin comfortable. Plus, it does not require removal, and the surface is easily cleansed — making wear easier for patients and care easier for staff.

How Cavilon Advanced Skin Protectant works.



3. 3M data on file. EM-05-01 3924.

Durability of an advanced skin protectant compared with other commercially available products in healthy human volunteers

Mathisen M, Grove G, Houser T, Bernatchez SF. Durability of an advanced skin protectant compared with other commercially available products in healthy human volunteers. *Wounds*. 2018 Sep;30(9):310-316. Epub 2018 Jun 25.

FOCUS

PERFORMANCE

DESIGN

A controlled, randomized, prospective, open-label study to evaluate the durability of an elastomeric, advanced skin protectant applied to intact skin when compared to three commercially available products indicated for compromised skin integrity.

METHODS

The study enlisted 21 healthy human volunteers. Eight black carbon pigment circles measuring 0.75 inches in diameter were applied to bilateral forearms (four circles per forearm for purposes of duplication). The elastomeric, advanced skin protectant (Cavilon Advanced Skin Protectant) and the other three commercially available products indicated for compromised skin integrity were applied randomly 1:1 over the activated carbon circles. Study participants went about normal routine for a duration of seven days. Digital photographs aided in documenting and calculating the amount of activated carbon. Digital imaging was performed at day zero before and after product application, and at days one, two, three, four and seven to discern pigment loss. Carbon integrated optical density (CIOD) was assessed. It was assumed that loss of the protective product would correlate with the diminishment of the activated carbon.

KEY FINDINGS

Cavilon Advanced Skin Protectant outperformed the other tested products, demonstrating no appreciable wear by day seven; whereas the three tested products had <50% remaining on the skin at the same time point. Cavilon Advanced Skin Protectant was more durable as measured by the percent barrier remaining at varying timepoints relative to the other products.

RESULTS

There were
no significant changes in CIOD
observed over time for Cavilon Advanced Skin Protectant (p=.46).

Relative to day one, the CIOD for two other tested products was significantly higher at days three, four, and seven (p<.01). For another tested product, CIOD was significantly higher at days four and seven (p<.01). CIOD was significantly lower for sites using Cavilon Advanced Skin Protectant compared to the other three tested products.

There were no significant changes in percent barrier remaining observed over time for Cavilon Advanced Skin Protectant (p>.99).

Skin protectants made of curable polymers: effect of application on local skin temperature

Walt MJ, Atwood N, Bernatchez SF, Ekholm BP, Asmus R. Skin protectants made of curable polymers: effect of application on local skin temperature. *Adv Wound Care (New Rochelle).* 2017 Apr 1;6(4):109-114. doi:10.1089/wound.2016.0705

FOCUS

PERFORMANCE

DESIGN

A controlled, randomized, prospective, open-label study to evaluate the effect of an elastomeric, advanced skin protectant applied to intact skin on local skin temperature.

METHODS

The study enlisted 12 healthy human volunteers. The elastomeric, advanced skin protectant (Cavilon Advanced Skin Protectant) and an analogous cyanoacrylate-based comparator product, as control, were applied to 3 x 3 in^2 area on the mid-anterior area of bilateral thighs. Per a randomization schedule, Cavilon Advanced Skin Protectant was applied to one thigh and the control product was applied to the contralateral thigh. Volunteers were seated for 30 minutes to acclimate to room temperature. A thermographic camera system was employed to record baseline measurements and the second image was recorded 15 seconds after product application to both thighs, and the terminal image was recorded six minutes post product application.

KEY FINDINGS

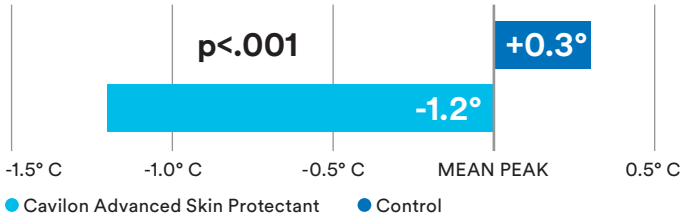
The formulation of Cavilon Advanced Skin Protectant, which yields an endothermic reaction post application may be favored when applied to compromised skin relative to formulations that are pure cyanoacrylate.

RESULTS

Cavilon Advanced Skin Protectant demonstrated an endothermic reaction leading to **a reduction in skin surface temperature.**

Whereas, the control product demonstrated an exothermic reaction and a slight elevation in skin surface temperature. There was a statistically significant difference in skin surface temperature between the interventions at all time points (p<.001).

Changes to mean peak temperature



The difference in the peak changes was statistically significant between the products (p<.001).

Clinical evaluation of a skin protectant for the management of incontinence-associated dermatitis: an open-label, nonrandomized, prospective study

Brennan MR, Milne CT, Agrell-Kann M, Ekholm BP. Clinical evaluation of a skin protectant for the management of incontinence-associated dermatitis: an open-label, nonrandomized, prospective study. *J Wound Ostomy Continence Nurs.* Mar/Apr 2017;44(2):172-180. doi:10.1097/WON.0000000000000307

FOCUS

I IAD

DESIGN

A non-randomized, prospective, open-label study to evaluate the efficacy of an elastomeric, advanced skin protectant in the management of incontinence-associated dermatitis (IAD) (category 1 or category 2).

METHODS

Inclusion criteria and exclusion criteria were delineated. No comparison group was included. For a duration of maximum three weeks, Cavilon Advanced Skin Protectant was applied twice weekly to skin exposed to urine or feces. Skin Assessment Tool (SAT) was used to evaluate the perianal skin, crease of buttocks, left and right buttocks, left and right posterior/medial thigh. Patient use of the Wong-Baker FACES® self-assessment pain scale documented/scored pain pertaining to IAD and its management. Buttocks and thighs were cleansed prior to assessments and photography. Primary endpoint was change in IAD score from baseline to conclusion of patient participation.

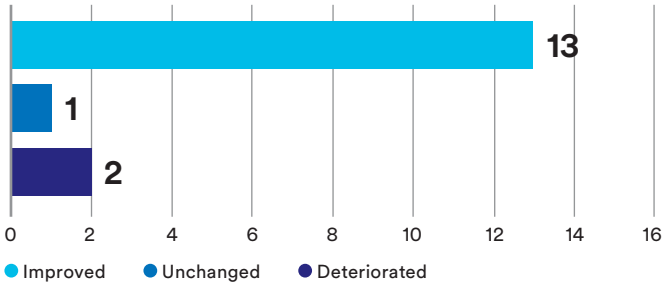
KEY FINDINGS

In these patients with IAD (category 1 or 2), Cavilon Advanced Skin Protectant was effective in IAD management in the presence of continued incontinence. In this study, Cavilon Advanced Skin Protectant use was associated with a significant reduction in both IAD scores and IAD-associated pain scoring.

RESULTS

The study enrolled 16 patients (mean age 70.9 years) at multiple study sites over a five-month period. Patients met inclusion criteria for IAD (category 1 or 2). Mean duration of IAD prior to enrollment was 11.3 days. Participants had urinary, fecal or double incontinence. Median incontinence episodes per patient per day was three and total incontinence episodes per patient for the study duration was 34.5 (median). At the conclusion of IAD management using Cavilon Advanced Skin Protectant, the median percent change in IAD scores was 96% (p=.13).

Changes in SAT score with Cavilon Advanced Skin Protectant



In four patients with epidermal skin loss, complete re-epithelialization was noted with four to six applications of Cavilon Advanced Skin Protectant.

Nine patients that reported pain at enrollment noted a substantially reduced FACES score at the study's conclusion (p=.009).

Effect of 3M™ Cavilon™ Advanced Skin Protectant on adhesion to skin: characteristics of six wound care dressings

Behr L, Wood M, Brown B, Ekholm BP. Effect of 3M™ Cavilon™ Advanced Skin Protectant on adhesion to skin: characteristics of six wound care dressings. 3M Data on File. Study 05-013121.

FOCUS

PERFORMANCE

DESIGN

An observational, case-control, open-label study to investigate the effect of an elastomeric, advanced skin protectant applied to intact skin on the adhesion properties of various wound care dressings (Dressing A*, B†, C‡, D§, E**, and F††).

METHODS

The study enlisted 24 healthy human volunteers. Per a randomization schedule, Cavilon Advanced Skin Protectant was applied to test sites on volunteers and remaining test sites were treated with soap and water as a control. Six different wound care dressings (Dressings A–F) were used, and a portion (0.75 x 3 in^2) of the adhesive border was evaluated. The following parameters were assessed: peel force at removal, product lift, adhesive residue, edge residue, contact dermatitis, and skin stripping. Assessment time points for the test sites were within 5–15 minutes post application to assess initial adhesion (T0), 24 hours (T24) and 72 hours (T72).

* 3M™ Tegaderm™ High Performance Foam Adhesive Dressing (3M Company; St. Paul, MN)
† 3M™ Tegaderm™ Silicone Foam Border Dressing (3M Company; St. Paul, MN)
‡ 3M™ Tegaderm™ Absorbent Clear Acrylic Dressing (3M Company; St. Paul, MN)
§ Mepilex® Border Dressing (Mölnlycke Health Care; Gothenburg, Sweden)
** Allevyn◊ Life (Smith & Nephew; Watford, England, UK)
†† Optifoam® Adhesive Dressing (Medline Industries, Inc.; Northfield, IL)

KEY FINDINGS

Adhesion is not compromised.

The effective use of adhesive products is not compromised by the application of Cavilon Advanced Skin Protectant. Despite statistical differences, the adhesion properties of dressings using silicone or acrylate adhesives were satisfactory.

RESULTS

At all time points (T0, T24, T72), there was no statistically significant difference in mean adhesion noted between Cavilon Advanced Skin Protectant test sites and soap and water test sites using Dressings B, D, E, and F.

For all time points (T0, T24, T72), the mean adhesion to skin of Dressing A to the Cavilon Advanced Skin Protectant test site was **significantly higher** relative to the control site.

For time point T72, Dressing C demonstrated a significantly higher mean adhesion to skin at test sites with Cavilon Advanced Skin Protectant relative to the control site.

Evaluation of skin cleansers on the integrity of 3M™ Cavilon™ Advanced Skin Protectant

Behr L, Mathisen M, Smith G, Walters SA. Evaluation of skin cleansers on the integrity of 3M™ Cavilon™ Advanced Skin Protectant. 3M Data on File. Study 05-012907.

FOCUS

PERFORMANCE

DESIGN

An observational, case-control, open-label study to determine the integrity of an elastomeric, advanced skin protectant applied to intact skin following the application of skin cleansers (Cleanser A*, B†, C‡, D§, E**, and F††).

METHODS

The study enlisted 18 healthy human volunteers. Six 1-inch diameter pigmented circles were applied to bilateral forearms (three circles per forearm) as test sites. The elastomeric, advanced skin protectant (Cavilon Advanced Skin Protectant) was applied to each test site. Test sites were cleansed 15 times daily for a duration of four days. To determine film remaining, a visual assessment was performed.

KEY FINDINGS

Cavilon Advanced Skin Protectant maintained integrity for 48 hours and up to 72 hours despite frequent cleansing regimens using diverse tested cleansers.

RESULTS

Pigment intensity (i.e., amount of pigment remaining on skin) was considered a measurement of Cavilon Advanced Skin Protectant remaining and barrier durability.

DAY 2

Following two days (30 cleansings), >90% of pigment was **intact in 90% of subjects' data points.**

DAY 3

Following three days (45 cleansings), >90% of pigment was **intact in 71% of subjects' data points.**

DAY 4

Following four days (60 cleansings), ≥90% of pigment was **intact in 27.8% of subjects' data points (5 of 18).**

* 3M™ Cavilon™ Bathing & Cleansing Wipe (3M Company; St. Paul, MN)
† Sage® Comfort Bath® Washcloths (Stryker; Kalamazoo, MI)
‡ 3M™ Cavilon™ No-Rinse Skin Cleanser (3M Company; St. Paul, MN)
§ Sensi-care® Perineal Skin Cleanser (ConvaTec Group plc; Reading, Berkshire, England)
** Remedy® Antimicrobial Cleanser (Medline Industries, Inc.; Northfield, IL)
†† Water

Effect of 3M™ Cavilon™ Advanced Skin Protectant on adhesion of ostomy products

Behr L, Rauch D, Wood M, Walters SA, Ekholm B. Effect of 3M™ Cavilon™ Advanced Skin Protectant on adhesion of ostomy products. 3M Data on File. Study 05-013122 and Study 05-013374.

FOCUS

Ps PERISTOMAL

DESIGN

An observational, case-control, open-label study to determine the effect of an elastomeric, advanced skin protectant applied to intact skin on the adhesion properties of ostomy products.

METHODS

The study enlisted 24 healthy human volunteers. Per a randomization schedule, test sites were prepared using either an elastomeric, advanced skin protectant (Cavilon Advanced Skin Protectant) or soap and water as a control. Seven different ostomy products (Product A*, B†, C‡, D§, E**, F††, and G‡‡) were applied to the treated test sites. Testing the wear characteristics occurred for a duration of 96 hours. Adhesive performance of the skin barrier material of the ostomy products was evaluated.

KEY FINDINGS

The application of Cavilon Advanced Skin Protectant does not interfere with the effective adhesion of common ostomy barriers.

RESULTS

No effective adhesion interference

There were no significant prep effects pertaining to mean scores for wear, lift from skin, erythema, edema, skin stripping and trace denudation, pain at removal, or residue for Products A-D. For Products E-G, there were no significant differences between the intervention and the control with respect to mean scores for wear duration, erythema, edema, skin stripping and residue.

The mean lift from skin in sites treated with Cavilon Advanced Skin Protectant was reduced relative to control sites using soap and water, but slightly more pain (mean pain scores ranged from 1.39 to 2.08 versus 1.00 to 1.83 on a 1–10 scale) upon removal. The difference in pain scores may suggest better adhesion (less lift) noted for those products.

* Coloplast Assura® (Coloplast A/S; Humlebæk, Denmark)
† Stomahesive® (ConvaTec Group plc; Reading, Berkshire, England)
‡ SoftFlex Barrier (Hollister Incorporated; Libertyville, IL)
§ Flextend Barrier (Hollister Incorporated; Libertyville, IL)
** FlexWear Barrier (Hollister Incorporated; Libertyville, IL)
†† Coloplast SenSura® (Coloplast A/S; Humlebæk, Denmark)
‡‡ SURFIT® Durahesive® (ConvaTec Group plc; Reading, Berkshire, England)

Management of incontinence-associated dermatitis patients using a skin protectant in acute care: a case series

Acton C, Ivins N, Bainbridge P, Browning P. Management of incontinence-associated dermatitis patients using a skin protectant in acute care: a case series. *J Wound Care*. 2020 Jan 2;29(1):18-26. doi:10.12968/jowc.2020.29.1.18

FOCUS

I IAD

Se CASE SERIES

DESIGN

A case series to evaluate the effectiveness of Cavilon Advanced Skin Protectant to manage incontinence-associated dermatitis (IAD) in patients within an acute health care setting that present with moisture-associated skin damage (MASD) in the sacral/genital region.

METHODS

The evaluation was conducted within an acute care National Health Service (NHS) hospital. Per the Ghent Global IAD (GLOBIAD) categorization tool, moisture lesions and/or IAD were inclusion criteria. Patients that required topical antifungal or analgesic treatments to the IAD managed area were excluded. There was no control group. No patients were treated for IAD solely. No additional skin protectant products were employed. The Wong-Baker FACES® scale was enlisted to assess pain before area cleansing and immediately following product application. Cavilon Advanced Skin Protectant was applied to areas with IAD and areas considered at risk. Cavilon Advanced Skin Protectant was reapplied every three to four days or at clinician discretion. Both baseline and post application photographs were taken for purposes of evaluation. Patients were evaluated until healing, discharge, or withdrawal from study.

KEY FINDINGS

Cavilon Advanced Skin Protectant applied every three days may effectively manage category 1 and 2 IAD resulting from MASD and/or incontinence. Cavilon Advanced Skin Protectant can adhere to severely denuded skin.

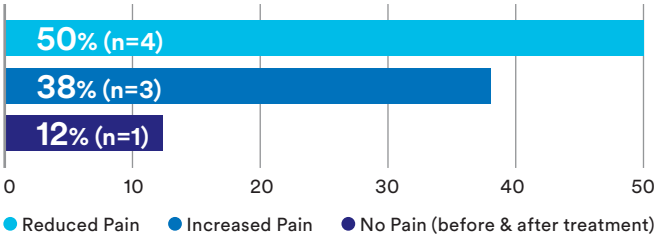
RESULTS

Eighteen patients were recruited over an 11-month period. Four were excluded. The mean age was 72 years (range: 44–91 years), 83% were female, with 94% demonstrating fecal incontinence, and 83% being incontinent for both urine and feces. Each patient presented with comorbidities. Category 2 IAD (denuded skin) was present in 72% of patients. IAD was localized exclusively to the posterior torso or the anterior torso in 78% and 6% of patients, respectively. Patients with signs of infection represented 17% (n=3) of study participants. Of the 14 patients, one patient was excluded due to an adverse event.

Out of 13 patients,

85% (n=11) achieved resolution of IAD. Cavilon Advanced Skin Protectant was applied 2.28 times per week. The mean duration of treatment was 14 days (range: 7–37 days).

Eight patients were able to complete the FACES assessment



Clinical evaluation of new advanced barrier film for management of incontinence-associated dermatitis

Churairat Chaichana, Maimuna Sungkhao, Aree Punkerd, Uriawan Samranrat

FOCUS

I IAD

St CASE STUDY

DESIGN

A nine-patient case series (participatory action study) to clinically evaluate a topical, elastomeric advanced skin protectant for skin management due to incontinence-associated dermatitis (IAD).

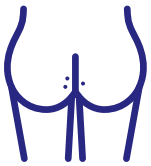
METHODS

Study included patients afflicted with either liquid fecal incontinence or moderate IAD. Cavilon Advanced Skin Protectant was applied per instructions for use to denuded and affected areas. Cavilon Advanced Skin Protectant was applied every three days over said areas. Skin condition was evaluated daily by comparing a photograph taken the previous day.

KEY FINDINGS

In a majority of these patients, there was noted improvement in the characteristics of IAD and skin management following Cavilon Advanced Skin Protectant use. Less discomfort during cleansing and after application were noted by patients able to self-report pain.

RESULTS



Following Cavilon Advanced Skin Protectant use,
eight of nine patients
demonstrated improvement in IAD.

Deterioration was noted in a single patient. In three patients that presented with skin loss and erythema, complete re-epithelialization was realized after two to three applications of Cavilon Advanced Skin Protectant. After a single application of Cavilon Advanced Skin Protectant in five patients, significant improvement was noted in damaged skin. Post application and over the duration of the study, four of eight self-evaluating patients reported a reduction in pain score (zero to mild) at cleansing and product reapplication when compared to the severe pain associated with their IAD prior to the participatory action study.

Findings of a multiple-patient evaluation of an advanced elastomeric barrier to treat incontinence-associated dermatitis in a large acute trust

Sian Fumarola, Senior Clinical Nurse Specialist Tissue Viability and Continence, and Lauren Viability Nurse, University Hospitals of North Midlands NHS Trust

FOCUS

I IAD

St CASE STUDY

DESIGN

A multi-patient, single-center, observational study to evaluate an elastomeric advanced skin protectant for incontinence-associated dermatitis (IAD).

METHODS

Selection criteria included patients with moderate to severe IAD. Patients were selected from multiple wards (Intensive Treatment Unit/High Dependency Unit, Renal, Surgical, Gastrointestinal, and Pediatric). Cavilon Advanced Skin Protectant was applied twice per week. Other skin barrier products were excluded. Regular cleansing consisted of plain water with dry wipes. Bathing wipes without dimethacone-based barriers were also used. Tissue Viability Team applied Cavilon Advanced Skin Protectant and assessed patient outcomes. Clinical photography was enlisted to record the progression of incontinence management approach using Cavilon Advanced Skin Protectant. Pain scores (0-5 scale) were also documented. Tissue Viability Team members were surveyed to evaluate Cavilon Advanced Skin Protectant and patient experience/feedback.

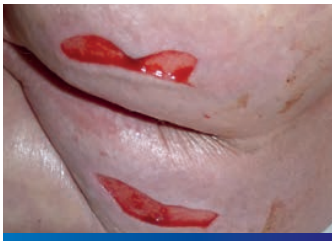
KEY FINDINGS

In this study, Cavilon Advanced Skin Protectant was effective in managing IAD.

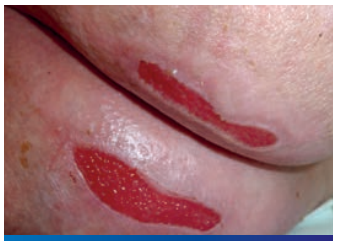
RESULTS

The durability of Cavilon Advanced Skin Protectant allowed for it to be applied less frequently relative to regular skin barrier products. Patients reported reduced pain with Cavilon Advanced Skin Protectant usage. Tissue Viability Team surveys documented increased patient comfort, increased patient compliance regarding cleansing and repositioning.

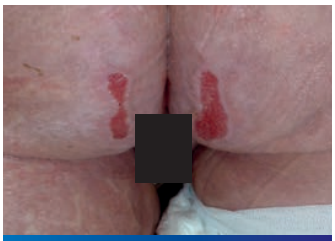
Application day 1



Application day 2



Application day 3



Application day 4

Use of a high endurance elastometric skin protectant to treat severe IAD and MASD

Valerie Hanssens Msc. Wound Care Specialist – UZ Brussel, Belgium

FOCUS

I IAD

St CASE STUDY

DESIGN

A case series of challenging clinical conditions characterized by painful, partial thickness lesions associated with incontinence-associated dermatitis (IAD) and moisture-associated skin damage (MASD) managed using an elastomeric advanced skin protectant.

METHODS

Cavilon Advanced Skin Protectant was applied to patients afflicted with rectovaginal fistula resulting in a GLOBIAD Cat. 2A, a leaking gastrostomy, or a high output enterocutaneous fistula (ECF).

KEY FINDINGS

After the application of Cavilon Advanced Skin Protectant, these patients with challenging clinical conditions experienced a reduction in discomfort. In these patients Cavilon Advanced Skin Protectant was effective in the management of severe excoriated skin lesions (IAD and MASD).

RESULTS

Patient One was afflicted with rectovaginal fistula resulting in a GLOBIAD Cat. 2A, and had excoriated skin localized to the perineum, perianal skin and buttocks. Cavilon Advanced Skin Protectant was applied to cleansed skin, a silicon interface was added to address residual tackiness with a diaper. The patient noted being pain free 12 hours after Cavilon Advanced Skin Protectant use. After 10 days and three applications (every two to three days) of Cavilon Advanced Skin Protectant, full epithelialization was achieved and the GLOBIAD Cat. 2A was healed.

Patient Two was afflicted with a leaking gastrostomy for several days. Cavilon Advanced Skin Protectant was applied to the compromised periwound skin surrounding the gastrostomy. The patient noted being pain free 24 hours after Cavilon Advanced Skin Protectant use. In this patient, full epithelialization was achieved after a single application of Cavilon Advanced Skin Protectant despite persistent irritant exposure.

Patient Three was afflicted with a high output (750 mL) ECF between the small intestines and skin. The use of Cavilon Advanced Skin Protectant facilitated the use of ostomy paste mixed with alcohol to fill cavity and prevent leakage. Cavilon Advanced Skin Protectant was applied every two days when ostomy appliances were changed.

Efficacy of new skin protectant (acrylic polymers+2-octyl cyanoacrylate) in high risk for incontinence-associated dermatitis (IAD) patient

Wasana Kijpotjanee ET RN, Budsara Sitthikhet ET RN, Morakot Sanamat RN, Thongnin Theerattanasatit RN, Chanchana Churos RN, Nuntaporn Sornsriwichai RN DD, Sukanyada Ratanakulchaiwat RN DD

FOCUS

I IAD

St CASE STUDY

DESIGN

An observational study to assess the incorporation of an elastomeric advanced skin protectant into a skin management protocol to reduce the incidence of irritant exposure in patients at high-risk for developing IAD.

METHODS

Study included patients within a Neurology Intensive Care Unit (ICU) afflicted with high-frequency liquid fecal incontinence stemming from laxative usage. Skin care (CDA bundle protocol) encompassed 1) Cleansing for irritant removal by using a no-rinse, pH-balanced skin cleanser, 2) pat Dry, and 3) skin protection via the Application of Cavilon Advanced Skin Protectant. In the CDA bundle protocol, Cavilon Advanced Skin Protectant replaced the use of a no-sting barrier film for skin protection. Cavilon Advanced Skin Protectant was applied every three days and skin condition was evaluated on a daily basis.

KEY FINDINGS

In these patients, the use of Cavilon Advanced Skin Protectant helped to provide protection against skin breakdown despite persistent exposure to irritants associated with liquid fecal incontinence. Improvement in skin condition was noted with fewer applications of Cavilon Advanced Skin Protectant compared to the prior practice of applying a no-sting barrier film for skin protection.

RESULTS

Four patients with mild IAD and liquid fecal incontinence received Cavilon Advanced Skin Protectant for skin protection. Erythema of the epidermis improved after an initial application of Cavilon Advanced Skin Protectant.

In all cases, no skin breakdown was noted following one to two applications of Cavilon Advanced Skin Protectant throughout the duration of laxative treatment.

Use of acrylate polymer plus 2-octylcyanoacrylate for severe incontinence-associated dermatitis (IAD) management (a case study)

Rungrat Koetsawat and Tatsanee Junon

FOCUS

I IAD

St CASE STUDY

DESIGN

Case study concerning an 87-year-old, bedridden, female patient with severely damaged, moist, or wet skin resultant of severe IAD, who received an elastomeric advanced skin protectant as an intervention.

METHODS

Skin care as part of incontinence management enlisted the use of Cavilon Advanced Skin Protectant. Prior to the application of Cavilon Advanced Skin Protectant, affected areas were cleansed using a no-rinse skin cleanser. Cavilon Advanced Skin Protectant was applied every two days on denuded and affected skin.

KEY FINDINGS

For this patient, application of Cavilon Advanced Skin Protectant was sufficient to manage skin impacted by severe IAD. An increase in patient comfort denoted by a reduction in reported pain scores was associated with Cavilon Advanced Skin Protectant use during perineal care.

RESULTS

An 87-year-old, bedridden, female patient underwent laparoscopic cholecystectomy. Her prior medical history included chronic kidney disease and respiratory failure. For a week, she experienced frequent, high-volume, diarrhea with colitis, and was treated with antibiotics. Given the mild IAD localized to her perineal skin, skin barrier use transitioned to twice daily application of an acrylate barrier cream. Cleansing using tap water occurred after each episode of incontinence. Subsequently, the perineal skin deteriorated, and the patient presented with severe IAD to both buttocks and the posterior thighs. To manage the damaged skin, 20% zinc cream and a topical cream with 1% w/w of silver sulfadiazine were applied. The NRS pain score for this patient was moderate to severe during perineal care. Due to the presentation of severe IAD, skin management transitioned to use of Cavilon Advanced Skin Protectant. After the initial application, erythema was reduced.

Following the second application,

30% erosive skin healed, and a pink wound bed along with epithelialization along the wound edges were noted.

Pain score was zero to mild during product application, wear, and perineal cleansing.

Case series using an advanced silicone-based polymer skin protectant for the clinical management of patients with moisture-associated skin damage (MASD)

Laforet K, Dias J, Muhammad S. Case series using an advanced silicone-based polymer skin protectant for the clinical management of patients with moisture-associated skin damage (MASD). Poster presented at: Canadian Association of Wound Care (CAWC); 2017.

FOCUS

Pw PERIWOUND

Se CASE SERIES

DESIGN

A seven-patient case series encompassing diverse MASD etiologies managed using an elastomeric advanced skin protectant.

METHODS

Study duration was six weeks (or less), but contingent upon patient's clinical need. Warm tap water or 0.9% NaCl solution was used for cleansing of affected skin followed by drying via patting with woven gauze. Cavilon Advanced Skin Protectant was applied per instructions for use. Patient assessment occurred twice weekly to gauge for pain, erythema, maceration, inflammation, irritation or skin degradation.

KEY FINDINGS

In these patients, Cavilon Advanced Skin Protectant was effective in the management of MASD arising from different etiologies. The breathable, waterproof, and flexible properties of Cavilon Advanced Skin Protectant when applied to skin demonstrated positive outcomes in these study patients.

RESULTS

Cavilon Advanced Skin Protectant was applied to seven patients afflicted with either periwound moisture-associated dermatitis (n=4), cellulitis secondary to incontinence-associated dermatitis (IAD; n=1), and peristomal moisture-associated dermatitis (n=2). Cavilon Advanced Skin Protectant was re-applied weekly and as required. Cavilon Advanced Skin Protectant was capable of quick and easy application to wet or denuded skin. Patients noted less discomfort shortly after application. There was noted improvement in the characteristics of MASD for all seven patients.

Evaluation of a polymer-cyanoacrylate skin protectant in managing patients with moisture-associated skin damage (MASD) in a tertiary care hospital

Li C, Chan VWS, Traille M, Mistry S, Vurgun S, Teague L. Evaluation of a polymer-cyanoacrylate skin protectant in managing patients with moisture-associated skin damage (MASD) in a tertiary care hospital. Poster presentation.

FOCUS

I IAD

Se CASE SERIES

DESIGN

Case series and product evaluation

METHODS

18 patients with MASD had Cavilon Advanced Skin Protectant applied per manufacturer instructions across Intensive Care (n=9), Medicine (n=7), and Surgery (n=2) departments. Product performance was measured by ease of application, ease of cleansing, patient comfort on application, and patient comfort during cleaning.

KEY FINDINGS

Staff, patient, and caregiver feedback indicated that Cavilon Advanced Skin Protectant was an effective and well-tolerated skin protectant for various types of MASD. Patients reported decreased pain associated with MASD after Cavilon Advanced Skin Protectant was added to their care regimen. Cavilon Advanced Skin Protectant has the potential to positively impact patient comfort, quality of life, and dignity.

A case study using a novel elastomeric barrier for the treatment of severe incontinence-associated dermatitis for an acutely unwell patient with antibiotic related diarrhoea in an intensive care setting

Sarah Pointer, Tissue Viability Nurse, Maidstone and Tunbridge Well NHS Trust

FOCUS

I IAD

St CASE STUDY

DESIGN

Case study concerning a 62-year-old female patient with hydronephrosis, who was admitted to the intensive care unit (ICU) and received an elastomeric advanced skin protectant for management of extensive excoriation to buttocks following antibiotic related diarrhoea.

METHODS

Installation of a right ureteric stent for hydronephrosis was index procedure for hospital admission. Patient was transferred to ICU and intubated after experiencing hypoxia. Antibiotics were administered for urosepsis following urine microscopy, culture, and sensitivity assays. Inotropic support was provided for rapid atrial fibrillation. A fecal management system was installed after 24 hours of antibiotic related diarrhoea. Cavilon Advanced Skin Protectant was applied to extensive excoriation to buttocks.

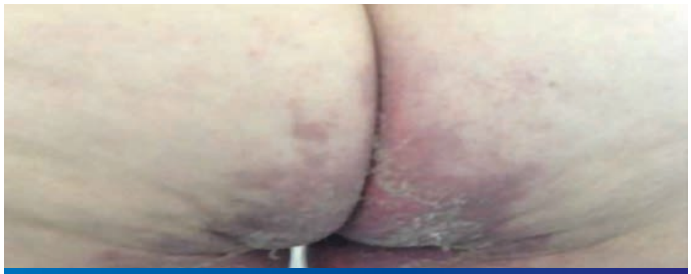
KEY FINDINGS

Cavilon Advanced Skin Protectant demonstrated durability and provided protection during incontinence-associated dermatitis (IAD) management. In this patient, Cavilon Advanced Skin Protectant was effective in helping to resolve her IAD, which facilitated a faster discharge.

RESULTS

A 62-year-old female patient had Cavilon Advanced Skin Protectant applied to cleansed skin. For this patient, a single application of Cavilon Advanced Skin Protectant was sufficient to help resolve the IAD. She noted a reduction in soreness and tenderness that helped to improve her comfort while in bed. Cavilon Advanced Skin Protectant allowed for the IAD affected area to receive complete coverage in one application to protect against liquid stool and skin cleansers.

Day one
First Application of Cavilon Advanced Skin Protectant



Day four
Review following the application of Cavilon Advanced Skin Protectant

A case study using a novel elastomeric barrier for the treatment of severe incontinence-associated dermatitis (IAD) in an acute and community setting

Russell F, Nurse Consultant Tissue Viability. A case study using a novel elastomeric barrier for the treatment of severe incontinence-associated dermatitis (IAD) in an acute and community setting. NHS Grampian.

FOCUS

I IAD

St CASE STUDY

DESIGN

Case study concerning a 55-year-old female patient with severe skin loss/moisture lesions, who was admitted to the hospital and received an elastomeric advanced skin protectant as an intervention.

METHODS

Cavilon Advanced Skin Protectant was applied to skin cleansed with dry wipes wet in warm water or gauze swabs wet in water following episodes of soiling.

KEY FINDINGS

After the initial application of Cavilon Advanced Skin Protectant, this patient noted reduced pain from IAD. In this patient, Cavilon Advanced Skin Protectant was effective in moisture lesion management and helping to resolve her IAD.

RESULTS

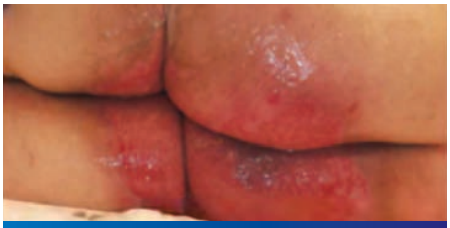
A 55-year-old female patient previously diagnosed with rectal cancer had undergone chemotherapy and 29 fractions of radiotherapy. Patient was referred to Tissue Viability Service for evaluation of perianal region and apron folds affected by IAD. Cavilon Advanced Skin Protectant was applied to cleansed skin.

After six days, significant physical improvement with the wound was noted. After the third application, the patient was discharged home with a referral to District Nurses.

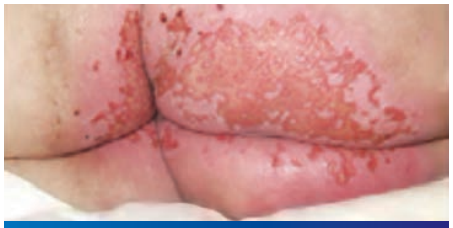
For this patient,

four applications

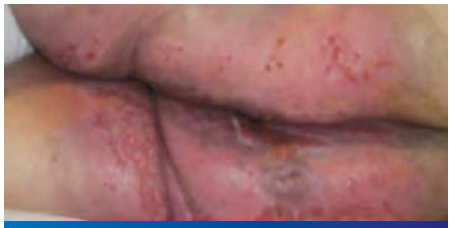
of Cavilon Advanced Skin Protectant was sufficient to help resolve the IAD.



Day zero
Presentation to Tissue Viability Service and first application of Cavilon Advanced Skin Protectant (in hospital)



Day three
Second application of Cavilon Advanced Skin Protectant (in hospital)



Day six
Third application of Cavilon Advanced Skin Protectant (discharged home)

3M™ Cavilon™ Advanced Skin Protectant for the management of radiation dermatitis in cancer patients: where are we now?

Van Bever L, Claes S, Tournel K, Pannekoeke L, Robijns J, Bulens P. 3M™ Cavilon™ Advanced Skin Protectant for the management of radiation dermatitis in cancer patients: where are we now? Poster presentation.

FOCUS

RADIATION THERAPY

Se CASE SERIES

DESIGN

Case series with historical control

METHODS

Cavilon Advanced Skin Protectant was applied to skin after radiation therapy. Cavilon Advanced Skin Protectant patient's skin outcomes were compared to the skin outcomes of historical patients with similar radiation therapy regimens.

KEY FINDINGS

Cavilon Advanced Skin Protectant attaches to moist and wet skin, even in difficult body regions. It supports wound healing and protects skin from external irritants. No significant product build-up was observed when applied up to six layers and measured on water equivalent phantom material.

Comparing IAD and financial outcome with a novel skin protectant

Van Houdenhove M. Pressure Ulcer Prevention Coach, Rehabilitation Unit – A.Z. Sint-Maria Halle, Belgium.

FOCUS

I IAD

St CASE STUDY

DESIGN

Case study concerning an 87-year-old male patient with a severe urinary tract infection (UTI), who was subsequently diagnosed with GLOBIAD Cat. 2A and received an elastomeric advanced skin protectant for incontinence-associated dermatitis (IAD). Financial outcome of wound treatment was also evaluated.

METHODS

The UTI was treated with an antibiotic regimen. Pressure injury was managed using compresses and wound dressings. Incontinence management consisted of gentle cleansing using 3M™ Cavilon™ Bathing Wipes prior to application of Cavilon Advanced Skin Protectant and placement of diaper. VAS pain score (Wong-Baker FACES® scale) was used to document patient pain before and after the application of Cavilon Advanced Skin Protectant. Cavilon Advanced Skin Protectant was applied three times per week.

KEY FINDINGS

In this patient, Cavilon Advanced Skin Protectant was effective in helping to resolve his IAD. The total cost to healing time was approximately ¼ of cost of common wound treatment with less than a ⅓ of the common healing time.

RESULTS

Patient noted a reduction in pain after Cavilon Advanced Skin Protectant application. VAS pain score prior to Cavilon Advanced Skin Protectant application was 2/10 and 1/10 at the first and second applications, respectively. VAS pain score after Cavilon Advanced Skin Protectant application was 0/10 for both the first and second applications. The cost per application was € 12,00 for each application of Cavilon Advanced Skin Protectant. For this patient, two applications of Cavilon Advanced Skin Protectant were sufficient to help resolve the IAD. After the application of Cavilon Advanced Skin Protectant was discontinued, incontinence management transitioned to a protocol using 3M™ Cavilon™ Continence Care Wipes and 3M™ Cavilon™ Durable Barrier Cream every 48 hours. The total cost to healing time was € 24,00.

Cost-effectiveness for protective moisture-associated skin damage (MASD) in elderly patients with applicator contains a polymeric-cyanoacrylate solution

Wongviseskarn J, Mayuraluk J. Cost-effectiveness for protective moisture-associated skin damage (MASD) in elderly patients with applicator contains a polymeric-cyanoacrylate solution. Poster presentation.

FOCUS

Pw PERIWOUND

I IAD

Se CASE SERIES

DESIGN

Case series

METHODS

Five patients above 60 years of age, three with incontinence-associated dermatitis (IAD) and two patients with peripheral artery disease (PAD), had Cavilon Advanced Skin Protectant applied to effected areas. IAD patients were evaluated once a day and PAD patients were evaluated after 14 days with dressing change.

KEY FINDINGS

Following the application of Cavilon Advanced Skin Protectant, periwound skin condition improved in patients with IAD and MASD. Cavilon Advanced Skin Protectant use protected the periwound skin, helped decrease incidence of MASD and IAD, reduced cost of care, and improved patient quality of life.

The effect of a high endurance polymeric skin protectant on friction and shear stress

Asmus R, Bodkhe R, Ekholm B, Thayer D, Bradley J. The effect of a high endurance polymeric skin protectant on friction and shear stress. Poster presented at: 2018 Symposium on Advanced Wound Care; 2018; Las Vegas, NV, and 2019 National Pressure Ulcer Advisory Panel Annual Conference; 2019; St Louis, MO.

FOCUS

PERFORMANCE

DESIGN

Bench study (laboratory assay) to evaluate the effect of a topical elastomeric, advanced skin protectant on friction and shear stress.

METHODS

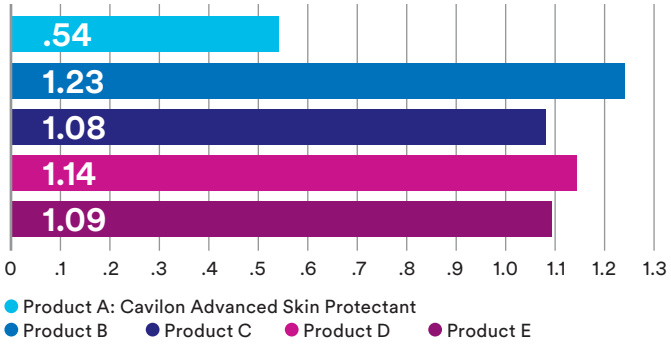
A slip/peel tester was used for measuring peel, release, and coefficient of friction (CoF). A piece of 100% cotton cloth was placed on the platen of the slip/peel tester. The sled of the slip/peel tester was coated with a layer of 3M™ Tegaderm™ gel followed by coverage using 3M™ Tegaderm™ film. The bottom of the covered sled received coatings of products being tested (Product A*, B†, C‡, D§, or E**). The product-coated sled was then attached to the tether of the slip/peel tester. The slip/peel tester measured and calculated the frictional force and CoF. Testing of each product encompassed six repeated measures.

KEY FINDINGS

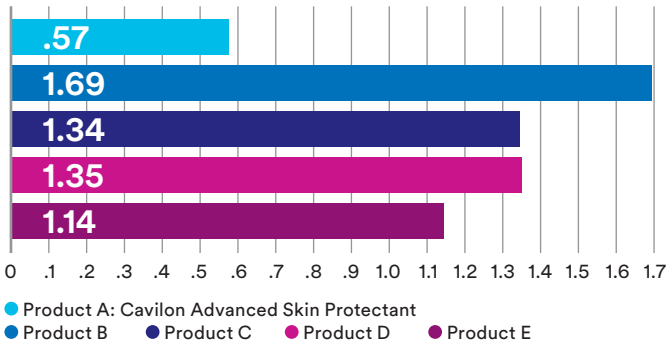
In this bench study, Cavilon Advanced Skin Protectant was more effective in protecting against friction-related exposure relative to the other products tested.

RESULTS

Mean static CoF



Mean kinetic CoF



Product A also had a lower mean static CoF and lower mean kinetic CoF when compared to an untreated control (Static CoF=1.04; Kinetic CoF=1.05).

* Cavilon Advanced Skin Protectant (3M Company; St. Paul, MN)
† Calmoseptine® Ointment (Calmoseptine Inc.; Huntington Beach, CA)
‡ Critic-Aid® Clear Moisture Barrier Ointment (Coloplast A/S; Humlebæk, Denmark)
§ Calazime™ Skin Protectant Paste (Medline Industries, Inc.; Northfield, IL)
** Sensi-care® Protective Barrier (ConvaTec Group plc; Reading, Berkshire, England)

In vivo methods to evaluate a new skin protectant for loss of skin integrity

Been RA, Bernatchez SF, Conrad-Vlasak DM, Asmus RA, Ekholm BP, Parks PJ. *In vivo* methods to evaluate a new skin protectant for loss of skin integrity. *Wound Repair Regen.* 2016 Sep;24(5):851-859. doi:10.1111/wrr.12455

FOCUS

PERFORMANCE

DESIGN

An integrated preclinical testing strategy to evaluate the formulation of Cavilon Advanced Skin Protectant in three different animal models to note degree of skin irritation, management of minor hemorrhaging and exudate, and re-epithelialization.

METHODS

To evaluate protection against irritants in an intact skin model, male, hairless guinea pigs (n=24) were enlisted. Porcine models with partial-thickness wounds were used to evaluate the management of minor hemorrhaging and exudate (n=6) and to evaluate re-epithelialization in skin exposed to irritants (n=7). Animals were anesthetized. For skin cleansing prior to testing, either isopropyl alcohol or isopropyl alcohol washes and betadine surgical scrub was performed. To challenge the skin, a pancreatin solution (simulated irritant) was applied to the cotton padding of a Hill Top Chamber and placed over the sites. In the guinea pig model, six 1.5 x 1.5 in^2 sites were distributed bilaterally (three sites/side) along the spine. One site was untreated (internal control). Five sites were treated with Cavilon Advanced Skin Protectant and allowed to dry (five minutes). In the porcine models, ten 2 x 2 in^2 sites were distributed bilaterally (five sites/side) along the spine. One site was untreated (internal control). Wounds were randomized to untreated controls or to be treated with Cavilon Advanced Skin Protectant and allowed to dry (five minutes). In one porcine model, gauze weight at 96 hours was measured to calculate the amount of fluid absorbed from each wound. In the other porcine model, tissue excised (0.5 x 2.2 in^2) from wounds at 96 hours was processed and histological evaluations measured percent re-epithelialization.

KEY FINDINGS

Untreated sites had 8.5 times more irritation than sites treated with Cavilon Advanced Skin Protectant. At T0 and after 96 hours, untreated wounds produced 2.9 and 1.9 times the amount of wound fluid, respectively compared to Cavilon Advanced Skin Protectant treated wounds. Given the greater level of re-epithelialization observed at 96 hours, Cavilon Advanced Skin Protectant was an effective barrier against simulated incontinence fluid.

RESULTS

0.2 vs. 1.7

In the guinea pig model, there was a **statistically significant reduction** in the mean normalized irritation score (Cavilon Advanced Skin Protectant Treated = 0.2 vs. Untreated = 1.7; p<0.001).

In the first porcine model, 12 sites were untreated, and 48 sites were treated with Cavilon Advanced Skin Protectant. Immediately following wound creation (T0), treated wounds yielded 0.083 g of fluid versus 0.238 g of fluid in untreated wounds (p=0.001). At 96 hours, treated wounds yielded 2.231 g of fluid versus 4.328 g of fluid in untreated wounds (p<0.001). In the second porcine model, 35 sites were untreated, and 35 sites were treated with Cavilon Advanced Skin Protectant. According to least square estimates, mean percent re-epithelialization in wounds treated with Cavilon Advanced Skin Protectant was 80.6% ± 5.7% versus 62.2% ± 5.7% for untreated wounds (p=0.003).

In vitro skin irritation: effect of new skin protectant formulations on epidermal viability

Brandwein D. *In vitro* skin irritation: effect of new skin protectant formulations on epidermal viability. 3M Data on File. Study ToxDocs 13-296, ST-452.

FOCUS

PERFORMANCE

DESIGN

Bench study (laboratory assay) to evaluate the impact of diverse formulations of an elastomeric, advanced skin protectant on human epidermal irritation.

METHODS

Test formulations of an elastomeric, advanced skin protectant (Cavilon Advanced Skin Protectant) were applied to a human epidermal tissue model, which is validated for skin irritation. To categorize irritation, an MTT assay using tetrazolium dye was enlisted to assess tissue viability. Additionally, cytokine levels (IL-1a and IL-8) released into the tissue culture media following exposure to Cavilon Advanced Skin Protectant were measured. The testing periods were at 6, 24 and 48 hours.

KEY FINDINGS

In this human epidermal tissue model, Cavilon Advanced Skin Protectant did not adversely affect the tissue viability.

RESULTS

During the testing period, tissue models exposed to all formulations demonstrated high viability and secreted similar levels of inflammatory cytokines and were similar to the negative control. Whereas, tissue models demonstrated reduced viability and an increase in inflammatory cytokine secretion following exposure to positive control substances for irritation and sensitization over the testing period.

Effect on microbial growth of a new skin protectant formulation

Stoffel J, Bernatchez SF. Effect on microbial growth of a new skin protectant formulation. *Adv Wound Care (New Rochelle)*. 2017 Mar 1;6(3):73-79. doi:10.1089/wound.2016.0706

FOCUS

PERFORMANCE

DESIGN

In vitro bench study (laboratory assay) to evaluate whether an elastomeric, advanced skin protectant supports the growth of microorganisms.

METHODS

A microbial growth inhibition assay was performed. A film derived from 100 µL of Cavilon Advanced Skin Protectant was applied to a partial area within a 90 x 15 mm polystyrene Petri dish filled with agar. A band ~ 2 cm in width was centrally located across the plate. Agar plates were seeded with diverse microorganism (three yeast species and 10 bacterial species). Among the microorganisms seeded were Gram-positive (e.g., *Staphylococcus aureus*) and Gram-negative bacteria (*Pseudomonas aeruginosa*), and several yeast (*Candida sp.*).

KEY FINDINGS

In this *in vitro* study, Cavilon Advanced Skin Protectant did not support the growth of microorganisms associated with areas of the skin generally impacted by incontinence-associated dermatitis.

RESULTS

48 Hr.

After a 48-hour incubation period, a clear zone where the Cavilon Advanced Skin Protectant film had been applied noted no microbial growth. However, a full lawn was noted in the untreated areas of the plate.

Ordering Information

Cavilon Advanced Skin Protectant

	Cat. No	Size	Items/Box
A	5050	2.7 ml applicator	20
B	5051	0.7 ml applicator	20

For more information, contact your 3M Health Care Sales Representative, call the 3M Health Care Customer Helpline at **1-800-228-3957** or visit **3M.com/Cavilon**.

NOTE: Specific indications, contraindications, warnings, precautions and safety information exist for these products and therapies. Please consult a clinician and product instructions for use prior to application. Rx only.

As with any case study, the results and outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary depending on the patient's circumstances and condition.

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