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Braces for Idiopathic Scoliosis in Adolescents

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Study Design. Cochrane systematic review.

Objective. To evaluate the efficacy of bracing in adolescent patients with adolescent idiopathic scoliosis (AIS).

Summary of Background Data. AIS is a 3-dimensional deformity of the spine. Although AIS can progress during growth and cause a surface deformity, it is usually not symptomatic. However, in adulthood, if the final spinal curvature surpasses a certain critical threshold, the risk of health problems and curve progression is increased. Braces are traditionally recommended to stop curvature progression in some countries and criticized in others. They generally need to be worn full time, with treatment extending over years.

Methods. The following databases (up to July 2008) were searched with no language limitations: the Cochrane Central Register of Controlled Trials, MEDLINE (from January 1966), EMBASE (from January 1980), and CINHAL (from January 1982), and reference lists of the articles. An extensive handsearch of the gray literature was also conducted. Randomized controlled trials (RCTs) and prospective cohort studies were searched for comparing braces with no treatment, other treatment, surgery, and different types of braces. Two review authors independently assessed trial quality and extracted data.

Results. We included 2 studies. There was very low quality evidence from 1 prospective cohort study with 286 girls that a brace curbed curve progression at the end of growth (success rate, 74% [95% confidence interval {CI}: 52%–84%]), better than observation (success rate, 34% [95% CI: 16%–49%]) and electrical stimulation (success rate, 33% [95% CI: 12%–60%]). There is low-quality evidence from 1 RCT with 43 girls that a rigid brace is more successful than an elastic one (SpineCor) at curbing curve progression when measured in Cobb degrees, but there were no significant differences between the 2 groups in the subjective perception of daily difficulties associated with wearing the brace.

Conclusion. There is very low quality evidence in favor of using braces, making generalization very difficult. Further research could change the actual results and our confidence in them; in the meantime, patients' choices should be informed by multidisciplinary discussion. Future research should focus on short- and long-term patient-centered outcomes, in addition to measures such as Cobb angles. RCTs and prospective cohort studies should follow both the Scoliosis Research Society and Society on Scoliosis Orthopedic and Rehabilitation Treatment criteria for bracing studies.

Key words: adolescent idiopathic scoliosis, brace, RCT, systematic review. **Spine 2010;35:1285–1293**

Description of the Condition

Scoliosis is a 3-dimensional deformity of the spine.[1] In its most common form, idiopathic scoliosis (70%–80% of cases), the causes are unknown.[2] Adolescent idiopathic scoliosis (AIS) is discovered at 10 years of age or older,[3] and is defined as a curve of at least 10°, measured on a standing radiograph using the Cobb technique.[2] Although the prevalence of AIS is 0.9% to 12% in the general population, almost 10% of those diagnosed with AIS will require some form of treatment. Furthermore, up to 0.1% of the population is at risk of surgery.[1,4] A severe form of AIS is more commonly found in women. Typically, AIS does not cause any health problems during growth (except for extreme cases). However, the resulting surface deformity frequently has a negative impact on adolescents, which can give rise to quality of life (QOL) issues and, in the worst cases, psychologic disturbances.[5–8]Adolescent patients are generally treated in an attempt to halt the progressive nature of the deformity. No treatments succeed in full correction to a normal spine, and even reduction of the deformity is difficult.[4,9] If scoliosis surpasses a critical threshold, usually considered to be 30° Cobb, at the end of growth, the risk of health problems in adulthood increases significantly.[4,10] Problems include reduced QOL, disability, pain, increased cosmetic deformity, functional limitations, pulmonary problems sometimes, and possible progression during adulthood.[9–16] Because of this, management of scoliosis also includes the prevention of secondary problems associated with the deformity.[17–19]

Description of the Intervention

Treatment options for the prevention of AIS progression include exercises, bracing, and surgery.[2,18,19–27] Bracing could be defined as the application of external corrective forces to the trunk. This is usually achieved through rigid

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supports, but elastic bands are also used.[2,25,28] Treatment commences when the curve is diagnosed as progressive or exceeds a threshold, which is usually considered to be between 25° and 30° Cobb.[2,4,18,23,29] Braces should generally be worn full-time (at least 20 hours per day) with treatment lasting from 2 to 4 years, until the end of bone growth.[30–33] All this causes a significant impact on the lives of children and adolescents.[34–38]

How the Intervention Might Work

The mechanical forces and the external and proprioceptive inputs because of bracing change the unnatural loading, asymmetrical movements, and neuromuscular control; this facilitates proper spinal growth, neuromotor reorganization, and change in motor behaviors.[24,36,39–45]

Why It Is Important to Do This Review

Currently, the bracing of patients with AIS is controversial. It is considered standard treatment in continental Europe, but not in many centers of the United Kingdom, the United States, and elsewhere.[2,20] Besides QOL and psychologic issues,[34,35,37,38,46] bracing has been widely criticized on the basis that there is a paucity of evidence that it has a positive effect on the natural history of the disease.[2,47–49] To date, reviews on braces have been mainly narrative, have not considered the key issue of evaluating the methodologic quality of the studies in the review, and have not included all existing studies.[20,22,50,51] A Cochrane review would significantly help clinicians decide whether the sacrifices required by children to wear braces are indeed worthwhile.

Objectives

The primary aim of this review was to evaluate the efficacy of bracing for adolescents with idiopathic scoliosis versus no treatment or other treatments, on QOL, disability, pulmonary disorders, progression of the curve, and psychologic and cosmetic issues.

■ Materials and Methods

Criteria for Considering Studies for This Review

Types of Studies. Primary analysis included all randomized controlled trials (RCTs) and controlled clinical trials (trials in which the methods of allocating people to a trial are not strictly random). Because a pilot test anticipated that very few RCTs would be found, secondary analysis included prospective cohort studies.

Types of Participants. All patients who were aged 10 years or older (until the end of bone growth) when diagnosed as having AIS were included. Only studies in which bone maturity was evaluated by the Risser sign, wrist radiographs, or both were included. Studies in which patients presented with any type of secondary scoliosis (congenital, neurologic, metabolic, posttraumatic, etc.) diagnosed according to the Scoliosis Research Society (SRS) criteria[33] were excluded.

Types of Interventions. The experimental interventions under consideration were all types of rigid, semirigid, and elastic braces (defined as the application of external corrective forces to the trunk with the intention of providing significant corrective forces to the spine), worn for a specific number of hours per day for a specific number of years. All possible control interventions and comparisons were considered.

Types of Outcome Measures

Primary Outcomes. The primary outcome measures were pulmonary disorders, disability, back pain, QOL, and psychologic and cosmetic issues. Only validated measurements were included in this review, and minimal clinically important differences discussed case by case.

Secondary Outcomes. The secondary outcome measures were clinical and radiographic parameters.[10] Very short (any result before the end of bone growth), short (results at the end of bone growth), and long-term (results in adulthood) outcomes were considered. Progression of scoliosis was measured by:

- Cobb angle in degrees (absolute values)
- Number of patients who had progressed by >5° Cobb (minimal clinically important difference)

Adverse effects, as outlined in identified trials, were also reported.

Search Methods for Identification of Studies

Electronic Searches. A comprehensive search (up to July 2008) was undertaken to identify all relevant studies in the following electronic databases: The Cochrane Central Register of Controlled Trials (*The Cochrane Library* 2008, issue 3), MEDLINE, EMBASE, and CINAHL.

The updated search strategy recommended by the Cochrane Back Review Group for RCTs[52] was used and adapted for cohort studies. The strategy included subject headings (MeSH) and text words. These included methodologic terms, disorder terms, and treatment terms, and are listed in full for MEDLINE, EMBASE, and CINAHL (Appendices 1–3; Supplementary Digital Content; available at:).

Searching Other Resources. The following strategies were also included:

- The reference lists of all relevant articles were screened.
- The main electronic sources of ongoing trials (National Research Register, meta-Register of Controlled Trials; and Clinical Trials) were searched.
- The gray literature, including conference proceedings, PhD theses, and unpublished work conducted by manufacturers that are likely to contain trials relevant to the review was screened.
- Investigators and authors in this field were contacted for information on unpublished or incomplete trials.
- All searches included non-English-language studies. When considered likely to meet inclusion criteria, studies published in languages other than English were translated. The sources handsearched and the years considered are listed in Tables 1 and 2 (Supplementary Digital Content, available at: http://links.lww.com/BRS/A437).

Data Collection and Analysis

Selection of Studies. Two review authors independently evaluated the search results by reading the titles and abstracts.

Potentially relevant studies were obtained in full text and independently assessed for inclusion by 2 review authors, who resolved disagreement through discussion. A third review author was contacted if disagreements persisted.

Data Extraction and Management. A standardized data extraction form was prepared and used to extract data from the included articles. Data on the population, study characteristics, and results were then extracted independently by 2 review authors. Any disagreement was discussed and a third review author was consulted if disagreements persisted. Key findings were summarized in narrative format and assessed for inclusion in meta-analysis where possible.

Clinical Relevance of Results. The review authors assessed each trial for its clinical relevance by using the 5 questions outlined by Shekelle *et al*[53] and recommended by the Cochrane Back Review Group[52] (Table 3; Supplementary Digital Content; available at: http://links.lww.com/BRS/A437). All important outcomes for each comparison were discussed. The main conclusions were clinical, because our main aim was to give clinicians state-of-the-art information, according to relevant studies on this issue.

Assessment of Risk of Bias in Included Studies. The risk of bias of RCTs and controlled clinical trials in this review was assessed using the 12 criteria recommended by the Cochrane Back Review Group,[52] as outlined in Table 4 (Supplementary Digital Content; available at: http://links.lww.com/BRS/A437). The Newcastle-Ottawa Scale[54] was used to assess the prospective cohort studies. The Scale assesses 3 broad areas: selection bias, attrition bias, and detection bias (Table 5; Supplementary Digital Content, available at: http://links.lww.com/BRS/A437). Two review authors independently assessed the risk of bias of the included studies. Any disagreement between the review authors was resolved by discussion, including input from a third independent reviewer if required. Risk of bias assessment was not blinded to trial authors, institution, or journal. Assessment was done by an expert in methodology (S.M.) and by an expert in the clinical field (S.N.).

Measures of Treatment Effect. Dichotomous outcomes were analyzed by calculating the relative risk for each trial, with the uncertainty in each result expressed with 95% confidence intervals (CI). Continuous outcomes were analyzed by calculating the mean difference or the standardized mean difference with 95% CI.

Data Synthesis. Meta-analysis was not performed because only 1 RCT and 1 prospective cohort study were retrieved. Thus, the preplanned investigation of heterogeneity, sensitivity analysis excluding studies with high risk of bias, and subgroup analysis for studies at low risk of bias were not performed. The overall quality of the evidence for each outcome was assessed. We used an adapted GRADE approach, as recommended by the Cochrane Back Review Group.[52]

■ Results

Description of Studies

Results of the Search. We found 1272 titles from the electronic search; 13 studies were identified with the handsearch. A total of 128 full texts were reviewed.

Included Studies. Only 2 articles could be included in the final review (Table 6):1 RCT[55] compared 2 different types of braces, and 1 prospective controlled trial compared bracing versus observation and electrical stimulation with a follow-up at 16 years in a subgroup of patients.[56] Two protocols of RCTs were also found (Table 7; Supplementary Digital Content; available at: http://links.lww.com/BRS/A437): 1 currently underway in the United States,[57] and another in the Netherlands that failed to recruit pa-

Table 6. Characteristics of Included Studies

	Nachemson 1995	Wong 2008
Methods	Multicentre multinational prospective cohort trial. Eight centres enrolled; included only physicians who firmly believed in effectiveness of bracing or who firmly believed that bracing was ineffective. Each physician consecutively enrolled all patients who met the inclusion criteria and prescribed only one treatment	Randomised controlled trial
Participants	240 girls with adolescent idiopathic scoliosis; mean age 12.7 years; Cobb angle degree 30° to 35°: 42% of patients in the observation group and 65% in the brace group; Cobb angle degree 20° to 29°: 58% in the observantion group, 35% in the brace group; menarche at baseline: 57% in the observation group, 41% in the brace group; imbalance: 46% in the observational group, 25% in the brace group	43 female adolescents diagnosed with progressive scoliosis. mean age 12.5 years; mean menarche at 12.7 years. Mean Risser's sign 0.4; mean AP Cobb angle degree: 24.3°
Interventions	Experimental intervention: plastic brace worn for at least 16 hours a day; 111 patients Control intervention: observation only; 129 patients. (who received the electrical stimulation referred to in the text???)	Experimental intervention: dynamic orthosis named "SpineCor" worn for 23 hours a day; 22 subjects control intervention: conventional rigid spinal orthosis worn 23 hours a day; 21 subjects
Outcomes	Failure of treatment as measured by an increase of the curve of 6° or more, noted on two consecutive roentgenograms performed every four months before menarche and every six months after menarche	Patients acceptance assessed by feedback questionnaire with 16 questions in VAS scale progression of scoliosis as measured by percentage of patients without documented progression and still managed with the original treatment

tients.[58] One meeting abstract was also considered (Table 7; Supplementary Digital Content; available at: http://links.lww.com/BRS/A437).[59] However, results from this study were not included because after asking the authors directly, we discovered that the study is still underway, and the preliminary results were measured in patients still wearing a brace.

Types of Treatments. Wong *et al*[55]compared 2 different types of braces: a rigid underarm orthosis (21 patients) versus an elastic soft one (SpineCor; 22 patients). Nachemson *et al*[56] compared a rigid underarm orthosis (111 patients) with electrical stimulation (46 patients) or observation only (129 patients). In both studies, orthosis were to be worn 23 hours per day.[56] Nachemson *et al*[56] observed 2 groups of physicians, those who firmly believed in the effectiveness of treatment with a brace, and those who firmly believed that a brace was ineffective and thus managed their patients with careful observation; at 2 centers the use of lateral electrical surface stimulation was advocated, and they were allowed to enter their patients in the study.

Duration of the Trials. The duration of the Wong *et al*[55] trial was 45 months, whereas the Nachemson *et al*[56] study followed their patients until maturity (up to 4 years). Danielsson *et al*[60] followed a subset of all Swedish patients from this study for 16 years after treatment (range, 10.9–19.4 years), including a braced (Malmö = 41 patients) and observed (Göteborg = 65 patients) group.

Participants. In the Wong *et al*[55] study, 43 girls with AIS, a mean age of 12.5 years, and a mean Cobb angle of 24.3° were considered. In the Nachemson *et al*[56] study, 240 girls with AIS, with a mean age of 12.7 years, and Cobb angles ranging from 20° to 35° were included.

Countries in Which the Studies Were Conducted. The RCT was conducted in Hong Kong.[55] The prospective cohort study[56] was a multinational study conducted in 3 centers in the United Kingdom, 4 centers in the Unites States, 1 center in Canada, and 2 centers in Sweden.

Excluded Studies. One hundred and seventeen articles were excluded for the following main reasons: 43 were retrospective, 35 were prospective but without concurrent controls, and 39 were excluded for other reasons.

Risk of Bias in Included Studies

Risk of bias in included studies have been summarized in Table 8 and Figure 1.

Table 8. Characteristics of Ongoing Studies

	Weinstein 2009	Bunge 2008	Rivard 2002
Study name	Bracing in adolescent idiopathic scoliosis trial (BrAIST)	Dutch randomised controlled treatment trial	A prospective randomised study of the natural history of idiopathic scoliosis versus treatment with the SpineCor brace
Methods	Randomised parallel controlled single blind (outcome assessor) trial	Randomised controlled trial; blinding of outcome assessor	Randomised controlled trial
Participants	Adolescents (10 to 15 years), male and female, with diagnosis of AIS, pre-menarchal or post-menarchal no more than 1 year, primary Cobb angle between 20° and 40°	Adolescents (8 to15 years) male and female, not yet treated with brace or surgery, skeletally immature (Risser grade 0 to 1 to 2); Cobb angle between 22 and 29 with established progression of more than 5 degree or between 30 and 35 degree	65 patients ; mean age 12 years; mean Cobb angle degree 20 ± 5 in the control group; 22 ± 5 in the brace group; high risk of progression as measured by increase of Cobb angle of 5° or more within the last 6 months
Interventions	Experimental: brace (TLSO) applied for at least 18 hours per day control: watchful waiting	Experimental: Boston brace worn full time; allowed to attend physical therapy if they want control: no brace; allowed to attend physical therapy if they want	Experimental intervention: SpineCor brace; N = 29 patients control intervention:no treatment; N = 36 patients
Outcomes	Progression of Cobb angle to greater than 50° cessation of skeletal growth clinical measures radiographic measures psychosocial measures	Cobb angle health-related quality of life (HRQol) compliance with brace	Progression of scoliosis as measured by number of patients improved, stable or worsened at the last available visit (length of follow up not specified)
Starting date	February 2007	2006	Not reported
Contact information	Weinstein SL, tel: 319-356-1872; stuart-weinstein@iuowa.edu	Bunge EM e.bunge@erasmusmc.nl	
Notes			Interim results drawn from an abstract of a conference proceeding

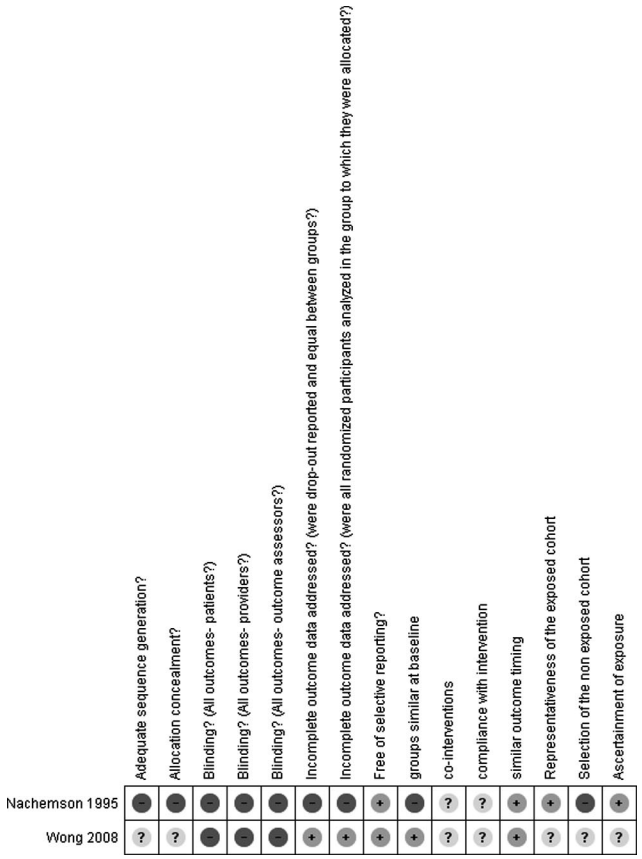

Figure 1. Methodologic quality summary: review authors' judgments about each methodologic quality item for each included study.

Allocation. Only 1 RCT was retrieved. The method used for random sequence generation and for concealment of allocation was not reported.

Blinding. Neither the RCT nor the prospective cohort study could be blinded for patients and providers because of the kind of intervention assessed (brace). The outcome assessor was not blinded in either study.

Incomplete Outcome Data. In the RCT, no drop-outs from the study were reported. In the prospective cohort study, the percentage of loss at follow-up was unbalanced between groups (21% in the experimental group and 7% in the control group).

Selective Reporting. Both studies were free of selective reporting.

Other Potential Sources of Bias. In terms of group similarity at baseline, the RCT groups were similar for the main prognostic factors. In the prospective cohort study, the brace group had more patients with severe scoliosis, fewer patients with imbalance, and fewer patients with menarche at baseline compared with the electrical stimulation or observation-only groups.

No adjustment for the most important confounding factors was performed. Information on compliance and cointerventions were not reported in either study. The timing of outcome assessing was similar among groups in both studies in the first part of follow-up.

Effects of Interventions

Progression of Scoliosis.

Brace Versus Observation or Electrical Stimulation (Prospective Cohort Study). According to the Nachemson *et al*[56] study, bracing demonstrated higher efficacy than electrical stimulation or observation. At 3 years, the success rates (defined as <6° increase of the curve) were 80% for bracing (95% CI: 66%–88%), 46% for observation (95% CI: 25%–56%), and 39% for electrical stimulation (95% CI: 19%–59%); the rates at 4 years were 74% (95% CI: 52%–84%), 34% (95% CI: 16%–49%) and 33% (95% CI: 12%–60%) respectively (log-rank test $P < 0.0001$). A worst-case analysis for the bracing group in which the 23 patients who dropped out from the brace arm were considered to have had failed treatment, maintained a highly significant success in preventing progression of 6° or more until skeletal maturity (log-rank test $P < 0.0005$).

Over the long-term (16 years), patients braced or observed progressed >5° (range, 5°–21°); whereas this progression meant that braced patients returned to the pretreatment levels (31.9° now *vs.* 33.0° at start) and observed patients (excluding 11 who were braced and 6 who were fused during growth because of failure) showed an overall progression from the start of treatment of 4.4° (range 5° to 14°). In summary, there is very low quality evidence from 1 cohort study (N = 240) that braces curb curve progression more successfully than observation or electrical stimulation over the long-term.

Rigid Versus Elastic Brace (RCT). According to the Wong *et al*[55] study, in patients with 20° to 30° Cobb angle before skeletal maturity, a rigid brace showed better results than an elastic one (SpineCor) at 45-month follow-up: 31.8% in the SpineCor group failed (curve progression more than 5°) versus 4.7% in rigid brace ($P = 0.046$). In conclusion, there is low-quality evidence from 1 RCT (N = 43) that a rigid brace curbs curve progression more successfully than an elastic one.

Quality of Life. Although the rigid brace caused significantly more problems with heat (85% *vs.* 27%), as well as difficulties with donning and doffing, the patients using the elastic braces had difficulties with toileting.[55] There is low-quality evidence from 1 RCT (N = 43) that a rigid brace is hotter and more difficult to put on and take off than an elastic one, but an elastic one is difficult to maneuver during toileting.

■ Discussion

Summary of Main Results

Despite a comprehensive search of published and unpublished literature, only 2 studies were found. One RCT

comparing rigid and elastic orthoses[55] provided low-quality evidence in favor of rigid braces versus a soft, elastic one. A prospective cohort study comparing a brace with observation or electrical stimulation[56] provided very low quality evidence in favor of bracing.

We found no articles that investigated primary outcomes (pulmonary disorders, disability, back pain, QOL, psychologic, and cosmetic issues) or male subjects in the short (end of growth) and long-term (in adulthood). According to the Wong *et al*[55] RCT, there were no significant differences found in the subjective perception of the ability to perform daily activities because of the brace between the rigid brace and elastic brace groups.

Overall Completeness and Applicability of Evidence

The actual evidence for brace treatment for idiopathic scoliosis only relates to girls (scoliosis affects 1 man for every 7 women), and it is of low to very low quality, when one considers well-conducted RCTs as the gold standard reference for evidence. Nevertheless, the prospective cohort study,[56] even if it is not an RCT, is clinically solid and very relevant because it was a multinational global effort, supported through the SRS, involving 10 clinics in 4 countries and on 2 continents (Europe and North America). The article had some risks of bias in terms of differences at the baseline among the groups; moreover, these were in favor of the control group, because the patients with the worst curves (as in the braced group) have been reported to have worse results with bracing.[51,61–63] Moreover, the highest risk of progression is observed in the youngest patients[51] (as the premenarchal ones in the braced group). Because of the treatments proposed, blinding was not possible; blinded assessment was not performed, but a worst case analysis was added, considering all drop-outs as failures of treatment. This analysis confirmed the results in favor of bracing.

The difficulty in performing RCTs in fields such as educational interventions, rehabilitation, surgery, and psychotherapy is also present in trials that assess bracing in adolescents. This may be because bracing is a very long-term treatment[55,56] and impairs everyday life for asymptomatic patients, with the aim of solving possible future disabilities.[10] Moreover, a committed, multidisciplinary team (physician, orthotist, physiotherapist, parents, and patient) is needed to achieve compliance and good results.[64] This is challenging if the evidence is not strong enough to guide practice; but participation in an RCT requires neutrality on the part of all participants: the physician prescribing treatment, parents who will accept either treatment for their child, and adolescents who face the possibility of being in 1 arm of the study that may oblige them to wear plastic for long periods of time. Despite these difficulties, an RCT looking at the efficacy of brace treatment is well underway,[57] financed with more than US$ 5 million by the US Government through the "National Institute of Arthritis and Musculoskeletal and Skin Diseases."

On the other side, despite being well planned and having conducted a pilot study, the Dutch RCT failed, because of some of the previously listed issues,[58] but the conclusion of the main researcher (an epidemiologist) was that "it is harder to perform a RCT that abolishes or postpones a treatment than a RCT that adds a new treatment."[58] This obviously is a strong argument to do RCTs before starting interventions, but Bunge and de Koning[58] discuss the fact that an RCT on bracing must be planned in most of the countries after the treatment is well established and traditional, and citizens as well as physicians believe in its usefulness. In this situation, an RCT on bracing versus "watchful waiting" is considered unethical by many specialists,[25,65] and patients rarely accept inclusion in such a study. In fact, the investigators of the current US RCT had to discuss the ethical issues with the US specialists before planning the trial.[65]

All these problems precluded RCTs for many years in this area, whereas there are no strong potential conflicts of interest, because no industry is involved; braces are individually made by orthotists in little teams with physicians.[64] Paradoxically, it is not the presence but the lack of money that could explain why little research has been conducted in this field[66] and why an RCT has never been done. Nevertheless, other RCTs could be started that have cautious inclusion and outcome criteria, and involve a number of centers in patient recruitment. While waiting for the results of RCTs, it is important to consider other study designs to gather more evidence. Apart from that used by Nachemson *et al*,[56] the SRS Bracing Committee has proposed another possible study design to address methodologic criteria for bracing studies.[29]

Compliance and the standard of bracing[64] should also be considered. In fact, the wide range of results in brace studies[51] usually leads to a discussion on the methodology of the study and the type of brace used, but the quality of bracing and patients' management should also be considered. These have been faced by the Society on Scoliosis Orthopedic and Rehabilitation Treatment (SOSORT) with the Guidelines on "Standards of management of idiopathic scoliosis with corrective braces in everyday clinics and in clinical research."[64] The SRS and SOSORT criteria for bracing should be considered the methodologic and management standards to be followed in future research studies, and will allow meta-analysis to be performed on solid methodologic criteria.

The SRS criteria have been followed in 4 published articles (Table 9),[61–63,67] 2 of which also fulfill the SOSORT criteria.[61,67] From these studies it could be concluded that:

- high variability among results of bracing is confirmed.
- respecting SOSORT criteria give better results.[61,67]

Table 9. Studies Following the SRS Criteria for Bracing Studies (Richards 2005) Reported in the Literature

Study	Methodology	Brace	Sample	Worsened 6° or More	Over 45° at The And of Treatment	Fused
Janicki 2007	Retrospective	TLSO	48	85%	62.5%	79%
Janicki 2007	Retrospective	Providence	35	69%	42.8%	60%
Coillard 2007	Prospective	SpineCor	170	40.6%	1.2%	25%
Aulisa 2009	Retrospective	PASB	50	0	0	0
Negrini 2009	Retrospective	Various	48	0	0	0

- soft braces[63] have better results than some rigid braces,[62] but not other rigid braces.[61,67]

Clinical Relevance

Generally in the literature, and specifically in the retrieved studies within this review, outcomes other than Cobb degrees are barely considered. This reflects physicians' attitude that during growth, their focus is on avoiding or at least curbing curve progression (secondary aim) to prevent future problems of quality of life, disability, back pain, *etc*. (primary aims). This approach comes from the fact that scoliosis is progressive during growth, and if the curves surpass 30° Cobb at the end of growth, the risk of health problems in adulthood increases. Consequently, results reported in this review are clinically relevant, according to the actual focus in the literature on Cobb degrees as the primary outcome. Nevertheless, the lack of focus on secondary adverse effects of treatment, as well as the absence of the long-term, primary outcome results (QOL, disability, pain) must be underlined and faced in future studies. Both studies reflect the everyday clinical reality of scoliosis treatment.

No major risks of the intervention have been reported in the literature, whereas only minor side effects were cited in the considered studies.[55] Both included studies mimic clinical reality.[55,56]

Quality of the Evidence

The quality of evidence in favor of bracing is very low; that in favor of hard bracing versus elastic bracing is low.

Potential Biases in the Review Process

The strength of the review is the extensive and comprehensive searches conducted, including many different sources in many languages. The main weakness of the review is the absence of strong studies in this field that do not make it possible to reach any firm conclusions.

Agreements and Disagreements With Other Studies or Reviews

An "evidence-based review"[51] looked at totally different outcomes from those considered here: the "rate of surgery" (failure of treatment) in braced groups ranged between 1.4% and 41%. This article was based on retrospective comparative studies, and on retrospective and prospective case series results, all of which were excluded from the current review. Furthermore, only articles in English were considered, whereas those adding exercises to bracing were excluded. It was not possible to obtain a good uniformity of methods and outcomes among the articles, even if subgroup analysis was attempted. These problems could be overcome by following the SRS criteria for bracing studies.[29] Moreover, excluding articles that add exercises to bracing should not be done in the future, because according to SOSORT criteria,[64] this is a management criterion to increase compliance. In fact, articles including exercises[61,68–71] report very low surgery rates (2%–7% for efficacy analysis and 10%–14% for worst case analysis), comparable to the best results in the bracing articles reported above.

■ Authors' Conclusion

Implications for Practice

Today the only alternative to bracing is the so-called "wait and see" strategy (*i.e*., observation and eventual surgery). The scientific evidence is in favor of bracing, but quality is very low. Therefore, further research could change the actual results and our confidence in them. Once accepted that evidence-based clinical practice comes from the best evidence, combined with clinical expertise and patient preferences, the patient should be made aware of the possible options. The final choice should come from a multidisciplinary shared decision-making discussion, because both surgery and bracing require specific clinical expertise.[64,66]

Implications for Research

The only way to end up with high-quality evidence to support or refute the use of braces is to conduct RCTs despite the existing obstacles. Because of the long time needed to achieve results from RCTs on bracing for AIS, we suggest other possibilities to increase the published evidence. An option could be "expertise-based" trials, where patients are randomized to centers that do bracing, versus centers that do not. Scoliosis centers are not generally nearby, and the outpatient approach would require traveling, reducing the possible feasibility. Another option is studies conducted according to the SRS[29] and SOSORT[64] criteria for bracing to allow comparability, such as:

1. Prospective multicenter cohort studies (with a similar research design to Nachemson *et al*[56])
2. Prospective case series of patients treated and not treated

Moreover, any future study should look at patient outcomes (not just radiographic outcomes of scoliosis progression) as well as adverse effects, so that balanced conclusions may be generated.

■ Key Points

- Bracing for adolescent idiopathic scoliosis is controversial, and questions remain about how effective it is.
- This systematic review retrieved only 2 studies according to Cochrane Institute requirements; 1 multicenter international cohort study of 286 girls and a randomized controlled study of 43 girls.
- There is very low quality evidence that braces are more effective than observation (wait-and-see) or electrical stimulation in curbing the increases in the curves of the spine; there is low-quality evidence that rigid braces are more effective than a soft, elastic one; adverse effects of braces were not discussed.
- Limitations of this review include the sparse data and studies available, and the fact that available studies only included girls (even if there is only 1 man with scoliosis for every 7 women), making it very difficult to generalize the results to men.
- Because of the very low quality of the evidence in favor of bracing, patients and their parents should regard these results with caution and discuss their treatment options with a multiprofessional team; further research is very likely to change the results and our confidence in them.

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