Braces for idiopathic scoliosis in adolescents (Review)

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[Intervention Review]

Braces for idiopathic scoliosis in adolescents

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ABSTRACT

Background

Adolescent Idiopathic Scoliosis (AIS) is a three-dimensional deformity of the spine. While 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.

Objectives

To evaluate the efficacy of bracing in adolescent patients with AIS.

Search strategy

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), CINHAL (from January 1982) and reference lists of articles. An extensive handsearch of the grey literature was also conducted.

Selection criteria

Randomised controlled trials and prospective cohort studies comparing braces with no treatment, other treatment, surgery, and different types of braces.

Data collection and analysis

Two review authors independently assessed trial quality and extracted data.

Main results

We included two studies. There was very low quality evidence from one prospective cohort study with 286 girls that a brace curbed curve progression at the end of growth (success rate 74% (95% CI: 52% to 84%)), better than observation (success rate 34% (95% CI:16% to 49%)) and electrical stimulation (success rate 33% (95% CI:12% to 60%)). There is low quality evidence from one 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 two groups in the subjective perception of daily difficulties associated with wearing the brace.

Authors' conclusions

There is very low quality evidence in favour 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-centred outcomes, in addition to measures such as Cobb angles. RCTs and prospective cohort studies should follow both the Scoliosis Resarch Society (SRS) and Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT) criteria for bracing studies.

PLAIN LANGUAGE SUMMARY

Braces for idiopathic scoliosis in adolescents

Scoliosis is a condition where the spine is curved in three dimensions (from the back the spine appears to be shaped like an "s"). It is often idiopathic, or having an unknown cause. The most common type of scoliosis is discovered at 10 years of age or older, and is defined as a curve that measures at least 10° (called a Cobb angle; measured on x-ray). Because of the unknown cause and age of diagnosis, it is called Adolescent idiopathic scoliosis (AIS).

While there are usually no symptoms, the appearance of AIS frequently has a negative impact on adolescents. Increased curvature of the spine can present health risks in adulthood and in the elderly. Braces are one intervention that may stop further progression of the curve. They generally need to be worn full time, with treatment lasting for two to four years. However, bracing for this condition is still controversial, and questions remain about how effective it is.

This review included two studies; one multicenter international cohort study (a study where treatment groups were defined according to the centre where patients were treated) of 286 girls and a randomised controlled study (an experimental study that randomised the participants to treatment groups) 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 one male with scoliosis for every seven females), making it very difficult to generalize the results to males. Due to the very low quality of the evidence in favour of bracing, patients and their parents should regard these results with caution and discuss their treatment options with a multi-professional team.

Further research is very likely to change the results and our confidence in them.

BACKGROUND

Description of the condition

Scoliosis is a three-dimensional deformity of the spine (Parent 2005). In its most common form, idiopathic scoliosis (70% to 80% of cases), the causes are unknown (SRS 2007). Adolescent idiopathic scoliosis (AIS) is discovered at 10 years of age or older (Weinstein 1999), and is defined as a curve of at least 10°, measured on a standing radiograph using the Cobb technique (SRS 2007). While 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 (Parent 2005; Lonstein 2006). A severe form of AIS is more commonly found in females. 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 that can give rise to quality of life (QoL) issues and in the worst cases, psychological disturbances (MacLean 1989; Freidel 2002a, Freidel 2002b; Reichel 2003). 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 (Danielsson 2001a; Lonstein 2006). 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 (Lonstein 2006; Negrini 2006b). Problems include reduced quality of life, disability, pain, increased cosmetic deformity, functional limitations, sometimes pulmonary problems, and possible progression during adulthood (Pehrsson 1992; Mayo 1994; Danielsson 2001a; Pehrsson 2001; Danielsson 2003a; Danielsson 2003b; Weinstein 2003; Negrini 2006b). Because of this, management of scoliosis also includes the prevention of secondary problems associated with the deformity (Negrini 2006a; Weiss 2006a; Weiss 2006b).

Description of the intervention

Treatment options for the prevention of AIS progression include exercises, bracing, and surgery (Rowe 1997; Negrini 2003; Lenssink 2005; Negrini 2005; Negrini 2006c; Rigo 2006a; Weiss 2006a; Weiss 2006b; SRS 2007; Negrini 2008b; Romano 2008). Bracing could be defined as the application of external corrective forces to the trunk. This is usually achieved through rigid supports, but elastic bands are also used (Coillard 2003; Rigo 2006a; SRS 2007). Treatment commences when the curve is diagnosed as progressive or exceeds a threshold, which is usually considered to be between 25 and 30° Cobb (Negrini 2005; Richards 2005; Lonstein 2006; Weiss 2006a; SRS 2007). Braces should generally be worn full-time (at least 20 hours per day) with treatment lasting from two to four years, until the end of bone growth (Katz 2001; Landauer 2003; Rahman 2005; SRS 2006). All this causes a significant impact on the lives of children and adolescents (Noonan 1997; Climent 1999; Odermatt 2003; Ugwonali 2004; Vasiliadis 2006a).

How the intervention might work

The mechanical forces and the external and proprioceptive inputs due to bracing change the unnatural loading, asymmetrical movements and neuromuscular control; this facilitates proper spinal growth, neuromotor re-organization, and change of motor behaviours (Coillard 2002; Lupparelli 2002; Castro 2003; Odermatt 2003; Weiss 2004; Negrini 2006c; Stokes 2006; Grivas 2008; Smania 2008).

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 centres of the UK, USA and elsewhere (Rowe 1997; SRS 2007). Besides quality of life and psychological issues (Fällström 1986; Noonan 1997; Climent 1999; Ugwonali 2004; Vasiliadis 2006a), 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 (Goldberg 1993; Dickson 1999a; Dickson 1999b; SRS 2007). To date, reviews on braces have been mainly narrative, have not considered the key issue of evaluating the methodological quality of the studies in the review, and have not included all existing studies (Rowe 1997; Lenssink 2005; Dolan 2007a; Negrini 2007). 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 is to evaluate the efficacy of bracing for adolescents with idiopathic scoliosis versus no treatment or other treatments, on quality of life, disability, pulmonary disorders, progression of the curve, and psychological and cosmetic issues.

METHODS

Criteria for considering studies for this review

Types of studies

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

Types of participants

All patients who were 10 years of age or older (until the end of bone growth) when diagnosed as having adolescent idiopathic scoliosis 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, neurological, metabolic, post-traumatic, etc) diagnosed according to the Scoliosis Resarch Society (SRS) criteria (SRS 2006) were excluded.

Types of interventions

The experimental interventions under consideration were all types of rigid, semi-rigid 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, quality of life, and psychological 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 (Negrini 2006b). 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 more than 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, CINAHL.
The updated search strategy recommended by the Cochrane Back Review Group for RCTs (Furlan 2009) was used and adapted for cohort studies. The strategy included subject headings (MeSH) and text words. These included methodological terms, disorder terms, and treatment terms, and are listed in full for MEDLINE, EMBASE and CINAHL (Appendix 1; Appendix 2; Appendix 3).

Searching other resources

The following strategies were also included:

1. The reference lists of all relevant papers were screened.
2. The main electronic sources of ongoing trials (National Research Register, meta-Register of Controlled Trials; Clinical Trials) were searched.
3. The grey literature, including conference proceedings, PhD theses and unpublished work conducted by manufacturers that are likely to contain trials relevant to the review was screened.
4. 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 Appendix 4 and Appendix 5.

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 two 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 papers. Data on the population, study characteristics, and results were then extracted independently by two review authors. Any disagreement was discussed and a third review author 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 five questions outlined by Shekelle 1994 and recommended by the Cochrane Back Review Group (Furlan 2009; Appendix 8). 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 CCTs in this review was assessed using the 12 criteria recommended by the Cochrane Back Review Group (Higgins 2008;Furlan 2009), as outlined in Appendix 6. The Newcastle-Ottawa Scale (NOS scale, Wells 2008) was used to assess the prospective cohort studies. The NOS scale assesses three broad areas: selection bias, attrition bias, and detection bias. See Appendix 7 for details. 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 (SM) and by an expert in the clinical field (SN).

Measures of treatment effect

Dichotomous outcomes were analysed by calculating the relative risk (RR) for each trial, with the uncertainty in each result expressed with 95% confidence intervals (CI). Continuous outcomes were analysed by calculating the mean difference (MD) or the standardized mean difference (SMD) with 95% CI.

Data synthesis

Meta-analysis was not performed because only one RCT and one prospective cohort study were retrieved. So the preplanned investigation of heterogeneity, sensitivity analysis excluding studies with high risk of bias, and subgroup analysis for studies at low risk of bias was 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 (Furlan 2009).

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of ongoing 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 two papers could be included in the final review; one RCT (Wong 2008) compared two different types of braces, and one prospective controlled trial compared bracing versus observation and electrical stimulation with a follow-up at 16 years in a subgroup of patients (Nachemson 1995). Two protocols of RCTs were also found: one currently underway in the US (Weinstein 2009), and another in the Netherlands that failed to recruit patients (Bunge 2008). One meeting abstract was also considered (Rivard 2002). 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 2008 compared two different types of braces: a rigid underarm orthosis (21 patients) versus an elastic soft one (SpineCor) (22 patients). Nachemson 1995 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. Nachemson 1995 observed two 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 two centres 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 2008 trial was 45 months, while the Nachemson 1995 study followed their patients until maturity (up to four years). Danielsson and colleagues followed a subset of all Swedish patients from this study for 16 years after treatment (range 10.9 to19.4 years), including a braced (Malmö = 41 patients) and observed (Göteborg = 65 patients) group (Nachemson 1995).

Participants: In the Wong 2008 study, 43 girls with adolescent idiopathic scoliosis, a mean age of 12.5 years and a mean Cobb angle of 24.3° were considered. In the Nachemson 1995 study, 240 girls with adolescent idiopathic scoliosis, 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 (Wong 2008). The prospective cohort study (Nachemson 1995) was a multinational study conducted in three centres in the UK, four centres in the USA, one centre in Canada and two centres in Sweden.

See Characteristics of included studies.

Excluded studies

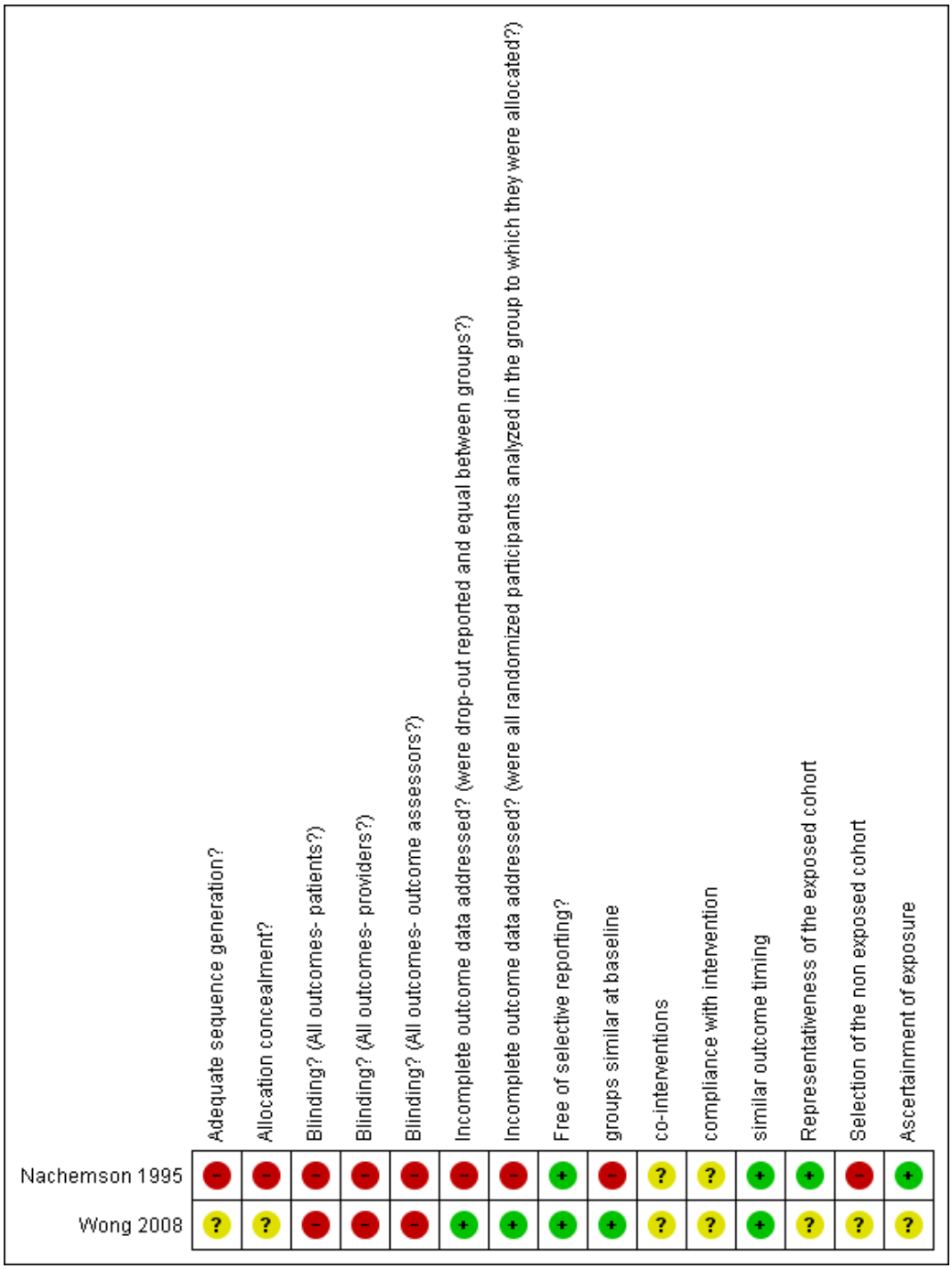
117 papers were excluded for the following main reasons: 43 were retrospective, 35 were prospective but without concurrent controls and 39 were excluded for other reasons.

See table of Characteristics of included studies for further details.

Risk of bias in included studies

See Figure 1.

Figure 1. Methodological quality summary: review authors' judgements about each methodological quality item for each included study.



Allocation

Only one 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, 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 to the electrical stimulation or observation-only groups.

No adjustment for the most important confounding factors was performed. Information on compliance and co-interventions 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 study (Nachemson 1995), bracing demonstrated higher efficacy than electrical stimulation or observation. At three years, the success rates (defined as less than six degrees increase of the curve) were 80% for bracing (95% CI: 66% to 88%), 46% for observation (95% CI: 25% to 56%), and 39% for electrical stimulation (95% CI:19% to 59%); the rates at four years were 74% (95% CI: 52% to 84%), 34% (95% CI:16% to 49%) and 33% (95% CI:12% to 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 six degrees or more until skeletal maturity (log-rank test P < 0.0005).

Over the long-term (16 years), patients braced or observed progressed more than 5° (range 5° to 21°); while this progression meant that braced patients returned to the pre-treatment levels (31.9° now versus 33.0° at start), 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 one 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 study (Wong 2008), 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 one RCT (N = 43), that a rigid brace curbs curve progression more successfully than an elastic one.

Quality of life

Whilst the rigid brace caused significantly more problems with heat (85% versus 27%), as well as difficulties with donning and doffing, the patients using the elastic braces had difficulties with toileting (Wong 2008).

There is low quality evidence from one 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 two studies were found. One randomised controlled trial comparing rigid and elastic orthoses (Wong 2008) provided low quality evidence in favour of rigid braces versus a soft, elastic one. A prospective cohort study comparing a brace with observation or electrical stimulation (Nachemson 1995) provided very low quality evidence in favour of bracing.

We found no papers that investigated primary outcomes (pulmonary disorders, disability, back pain, quality of life, psychological and cosmetic issues) or male subjects in the short (end of growth) and long-term (in adulthood). According to the Wong 2008 RCT, there were no significant differences found in the subjective perception of the ability to perform daily activities due to 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 one male for every seven females), 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 (Nachemson 1995), 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 four countries and on two continents (Europe and North America). The paper had some risks of bias in terms of differences at the baseline among the groups, moreover, these were in favour of the control group, since the patients with the worst curves (as in the braced group) have been reported to have worse results with bracing (Coillard 2007; Dolan 2007; Janicki 2007; Negrini 2009a). Moreover, the highest risk of progression is seen in the youngest patients (Dolan 2007) (as the pre-menarchal ones in the braced group). Due to 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 favour 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 (Nachemson 1995; Wong 2008) and impairs everyday life for asymptomatic patients with the aim of solving possible future disabilities (Negrini 2006b). Moreover, a committed, multidisciplinary team (physician, orthotist, physiotherapist, parents and patient) is needed to achieve compliance and good results (Negrini 2009). 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 one arm of the study that may oblige them to wear plastic for long periods of time. Despite these difficulties, a RCT looking at the efficacy of brace treatment is well underway (Weinstein 2009), financed with more than USD 5 million by the U.S. 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, due to some of the previously listed issues (Bunge 2008), 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" (Bunge 2008). This obviously is a strong argument to do RCTs before starting interventions, but Bunge discusses the fact that a 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, a RCT on bracing versus 'watchful waiting' is considered unethical by many specialists (Rigo 2006a; Dolan 2007a), and patients rarely accept inclusion in such a study (Bunge 2008). In fact, the investigators of the current U.S. RCT had to discuss the ethical issues with U.S. specialists before planning the trial (Dolan 2007a).

All these problems precluded RCTs for many years in this area, while there are no strong potential conflicts of interest, because no industry is involved; braces are individually made by orthotists in little teams with physicians (Negrini 2009). Paradoxically, it is not the presence but the lack of money that could explain why little research has been conducted in this field (Negrini 2008) and why a RCT has never been done. Nevertheless, other RCTs could be started that have cautious inclusion and outcome criteria, and involve a number of centres in patients recruitment. Whilst waiting for the results of RCTs, it is important to consider other study designs to gather more evidence. Apart from that used by Alf Nachemson (Nachemson 1995), the SRS Bracing Committee has proposed another possible study design to address methodological criteria for bracing studies (Richards 2005).

Compliance and the standard of bracing (Negrini 2009) should also be considered. In fact, the wide range of results in brace studies (Dolan 2007) 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 Orthopaedic and Rehabilitation Treatment (SOSORT) with the Guidelines on "Standards of management of idiopathic scoliosis with corrective braces in everyday clinics and in clinical research" (Negrini 2009).

The SRS and SOSORT criteria for bracing should be considered the methodological and management standards to be followed in future research studies, and will allow meta-analysis to be performed on solid methodological criteria.

The SRS criteria have been followed in four published papers (Janicki 2007; Coillard 2007; Aulisa 2009; Negrini 2009a); two of which also fulfil the SOSORT criteria (Aulisa 2009; Negrini 2009a) (Appendix 9). From these studies it could be concluded that:

- high variability among results of bracing is confirmed.
- respecting SOSORT criteria give better results (Aulisa 2009; Negrini 2009a).
- soft braces (Coillard 2007) have better results than some rigid braces (Janicki 2007), but not other rigid braces (Aulisa 2009; Negrini 2009a).

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 QoL, disability, back pain, etc (primary aims). This approach comes from the fact that

scoliosis is progressive during growth, and if the curves surpasse 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 (quality of life, 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, while only minor side effects were cited in the considered studies (Wong 2008). Both included studies mimic clinical reality (Nachemson 1995; Wong 2008).

Quality of the evidence

The quality of evidence in favour of bracing is very low; that in favour 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" (Dolan 2007) 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 paper 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 papers in English were considered, while those adding exercises to bracing were excluded. It was not possible to obtain a good uniformity of methods and outcomes among the papers, even if subgroup analysis was attempted. These problems could be overcome following the SRS criteria for bracing studies (Richards 2005). Moreover, excluding papers that add exercises to bracing should not be done in the future, because according to SOSORT criteria (Negrini 2009), this is a management criterion to increase compliance. In fact, papers including exercises (Maruyama 2003; Rigo 2003; Weiss 2003; Negrini 2008a; Negrini 2009a) report very low surgery rates (2% to 7% for efficacy analysis, 10% to 14% for worst case analysis), comparable to the best results in the bracing papers reported above.

AUTHORS' CONCLUSIONS

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 favour 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 (Negrini 2008; Negrini 2009).

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. Due to 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 randomised to centres that do bracing, versus centres that don't. Scoliosis Centres are not generally nearby, and the outpatient approach would require travelling, reducing the possible feasibility. Another option is studies conducted according to the SRS (Richards 2005) and SOSORT (Negrini 2009) criteria for bracing to allow comparability, such as :

1. Prospective multicentre cohort studies (with a similar research design to Nachemson 1995)
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.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Nachemson 1995

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
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 observation 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
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???)
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
Notes	

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	No	prospective cohort study
Allocation concealment?	No	prospective cohort study
Blinding? All outcomes- patients?	No	blinding of patients not possible for the kind of interventions compared (brace vs no treatment)
Blinding? All outcomes- providers?	No	blinding of providers not possible for the kind of interventions compared (brace vs no treatment)
Blinding? All outcomes- outcome assessors?	No	roentgenograms read by providers
Incomplete outcome data addressed? were drop-out reported and equal between groups?	No	7% lost at follow-up in the control group; 21% lost at follow-up in the experimental group COMMENT: percentage unbalanced be-

Nachemson 1995 (*Continued*)

		tween groups, but worst case analysis performed
Incomplete outcome data addressed? were all randomized participants analyzed in the group to which they were allocated?	No	"the patients lost at follow-up were included in the survivorship analysis for the time they were in the study" "the 23 patients who dropped out from the brace group were analysed in the worst-case analysis and considered as treatment failure" COMMENT: only the patients who dropped out from the experimental group were included in the worst case analysis
Free of selective reporting?	Yes	
groups similar at baseline?	No	Comparability of cohorts on the basis of the design or analysis: more patients with severe scoliosis (30° to 35° in the brace group (65% vs 42%); fewer patients with imbalance in the brace group (25% vs 46%); menarche at baseline: 57% in the observation group, 41% in the brace group. No adjustment for most important confounding factors COMMENT: differences at the baseline were in favour of the control group
co-interventions?	Unclear	not reported
compliance with intervention?	Unclear	not reported
similar outcome timing?	Yes	all patients received a roentgenogram every four months before menarche and every six months after menarche
Representativeness of the exposed cohort?	Yes	truly representative of the average adolescents with scoliosis
Selection of the non exposed cohort?	No	drawn from a different source
Ascertainment of exposure?	Yes	secure record (e.g. clinical records)

Wong 2008

Methods	randomised controlled trial

Wong 2008 (*Continued*)

Participants	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: 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	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
Notes	

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	sequence generation not reported "Forty-three subjects were recruited and randomly assigned to two groups"
Allocation concealment?	Unclear	not stated
Blinding? All outcomes- patients?	No	blinding of patients not possible for the kind of interventions compared (rigid brace vs dynamic SpineCor brace)
Blinding? All outcomes- providers?	No	blinding of providers not possible for the kind of interventions compared (rigid brace vs dynamic SpineCor brace)
Blinding? All outcomes- outcome assessors?	No	patients are outcome assessors for treatment acceptance; radiographic measurements were taken for scoliosis progression, probably not blinded
Incomplete outcome data addressed? were drop-out reported and equal between groups?	Yes	no drop-outs
Incomplete outcome data addressed? were all randomized participants analyzed in the group to which they were allocated?	Yes	no drop-outs
Free of selective reporting?	Yes	
groups similar at baseline?	Yes	groups comparable for mean age, age at menarche, Risser's sign, AP Cobb angle degree, Apical Verebral Rotation degrees, Trunk listing

Wong 2008 (*Continued*)

co-interventions?	Unclear	information about co-intervention not reported
compliance with intervention?	Unclear	information about compliance not reported
similar outcome timing?	Yes	all subjects received radiographs after the first month and then every three months; all subjects completed a feedback questionnaire at 3rd, 9th and18th months of intervention
Representativeness of the exposed cohort?	Unclear	not applicable
Selection of the non exposed cohort?	Unclear	not applicable
Ascertainment of exposure?	Unclear	not applicable

Characteristics of excluded studies *[ordered by study ID]*

Allington 1996	retrospective
Andersen 2006	follow up retrospective non controlled study
Avellanet 2006	case report
Basset 1986	retrospective
Basset 1987	retrospective
Becchetti 1990	not controlled
Bernard 2005	retrospective
Bowen 2001	prospective with retrospective control group
Bullmann 2004	prospective no control group
Bunge 2007	retrospective
Bunnell 1980	prospective without control group
Carman 1985	retrospective
Carr 1980	follow up retrospective not controlled study
Cassella 1991	review

(*Continued*)

Castro 2003	not controlled
Charlopain 1998	retrospective
Cheung 2007	retrospective
Coillard 1999	not controlled
Coillard 2003	not controlled
Coillard 2007	not controlled
Cottalorda 2005	no end growth results
D'Amato 2001	prospective with literature control group
Danielsson 2001	follow up of retrospective study
Danielsson 2001a	follow up with healty control group
Danielsson 2006	follow up with no relevant data
Den Boer 1999	prospective controlled with hystorical cohort
Dickson 1999	review
Dobosiewicz 2006	not controlled
Durham 1990	retrospective not controlled
Dziri 1991	retrospective not controlled
Ebenbichler 1994	review
Edmosson 1977	follow up not controlled
El Sayyad 1994	RCT including juvenile and adolescent idiopatic scoliosis (6-16 years)
Emans 1986	retrospective not controlled
Feise 2005	not relevant topic
Fernandez-Feliberti 1995	prospective controlled including both juvenile and adolescent IS (8-15 years old)
Fisher 1987	prospective with retrospective control group. Controls were matched to patients
Fällström 1986	follow up with no relevant data

(*Continued*)

Gabos 2004	retrospective
Geissele 1991	not relevant topic
Gepstein 2002	retrospective controlled study
Goldberg 1981	retrospective
Gore 1981	screening, notr controlled
Green 1986	retrospective, not controlled
Griffet 1996	not controlled
Griffet 2000	not relevant topic
Grivas 2003	retrospective with literature control group. Included also 2 patients <10 years
Haefeli 2006	retrospective follow up
Hanks 1998	retrospective
Hassan 1983	not controlled
Hensinger 2007	editorial
Hopf 1985	case series
Howard 1998	retrospective
Janicki 2007	retrospective
Kahanovitz 1982	not controlled
Karol 2001	not controlled
Katz 1997	retrospective
Keiser 1976	retrospective
Kohashi 1996	not relevant topic
Korovessis 2000	prospective not controlled
Kotwicki 2002	retrospective not controlled
Kumano 1992	not controlled

(*Continued*)

Little 2000	retrospective
Lonstein 1994	retrospective
Lou 2004	not controlled
Lou 2005	not controlled
Mellencamp 1977	retrospective
Miller 1984	retrospective
Minami 1982	not controlled
Miyasaki 1980	not controlled
Moe 1970	retrospective
Mollon 1984	no primary research paper
Montgomery 1989	retrospective controlled
Montgomery 1990	retrospective
Mouilleseaux 1984	no primary research paper
Mounier 1984	no primary research paper
Negrini 2007	prospective with retrospective control group
Noonan 1996	juvenile patients
O'Donnel 1988	retrospective
O'Neill 2005	retrospective
Park 1977	retrospective
Peltonen 1988	not controlled
Peterson 1995	prospective not relevant
Pham 2007	retrospective
Piazza 1990	retrospective
Price 1990	prospective not controlled

(*Continued*)

Price 1997	not controlled
Rahman 2005	prospective not controlled
Rigo 2003	literature control group
Roach 1998	retrospective
Robinson 1999	juvenile scoliosis
Rosso 1998	not controlled
Rowe 1997	metanalysis
Schmitt 1987	juvenile and adolescent IS (7-16 years old)
Schraudebach 1974	juvenile and adolescent IS
Scoloveno 1990	retrospective
Shirado 1995	not relevant topic
Skaggs 1996	letter to the editor
Spoonamore 2004	retrospective
Tonseth 2005	retrospective
Trivedi 2001	retrospective not controlled
Upadhyay 1995	not controlled
Van Rhijn 2002	not controlled
Van Rhijn 2003	retrospective
Veldhuizen 2001	not controlled
Vijermans 2004	retrospective
Watanabe 2005	not relevant topic
Weigert 2006	retrospective
Weiss 2003	retrospective
Weiss 2005	case series

(*Continued*)

Weiss 2006	no brace treatment
Wever 2002	not controlled
Wiley 2000	retrospective
Willers 1993	follow up not controlled
Yamouchi 1986	retrospective follow up
Ylikoski 1989	not controlled
Yrjonen 2006	prospective with retrospective control group

Characteristics of ongoing studies *[ordered by study ID]*

Bunge 2008

Trial name or title	Dutch randomised controlled treatment trial
Methods	randomised controlled trial; blinding of outcome assessor
Participants	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.
Interventions	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
Outcomes	Cobb angle health-related quality of life (HRQol) compliance with brace
Starting date	2006
Contact information	Bunge EM. e.bunge@erasmusmc.nl
Notes	

Rivard 2002

Trial name or title	A prospective randomised study of the natural history of idiopathic scoliosis versus treatment with the SpineCor brace
Methods	randomised controlled trial
Participants	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 intervention: SpineCor brace; N = 29 patients control intervention:no treatment; N = 36 patients
Outcomes	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	not reported
Contact information	
Notes	interim results drawn from an abstract of a conference proceeding

Weinstein 2009

Trial name or title	Bracing in adolescent idiopathic scoliosis trial (BrAIST)
Methods	Randomised parallel controlled single blind (outcome assessor) 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°
Interventions	experimental: brace (TLSO) applied for at least 18 hours per day control: watchful waiting
Outcomes	Progression of Cobb angle to greater than 50° cessation of skeletal growth clinical measures radiographic measures psychosocial measures
Starting date	February 2007
Contact information	Weinstein SL, tel: 319-356-1872; stuart-weinstein@iuowa.edu
Notes	

DATA AND ANALYSES

This review has no analyses.

APPENDICES

Appendix 1. MEDLINE search strategy

1 Comparative Study/
2 exp Evaluation Studies/
3 exp Follow-Up Studies/
4 exp Prospective Studies/
5 exp Cross-Over Studies/
6 exp Epidemiologic Studies/
7 exp Case-Control Studies/
8 exp Cohort Studies/
9 exp Cross-Sectional Studies/
10 (cohort adj (study or studies)).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
11 cohort analy$.mp. [mp=title, original title, abstract, name of substance word, subject heading word]
12 (follow up adj (study or studies)).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
13 (observational adj (study or studies)).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
14 longitudinal.mp. [mp=title, original title, abstract, name of substance word, subject heading word]
15 retrospective.mp. [mp=title, original title, abstract, name of substance word, subject heading word]
16 cross sectional.mp. [mp=title, original title, abstract, name of substance word, subject heading word]
17 control$.mp. [mp=title, original title, abstract, name of substance word, subject heading word]
18 prospective$.mp. [mp=title, original title, abstract, name of substance word, subject heading word]
19 volunteer.mp. [mp=title, original title, abstract, name of substance word, subject heading word]
20 or/1-19
21 exp "Clinical Trial [Publication Type]"/
22 randomized.ab,ti.
23 placebo.ab,ti.
24 dt.fs.
25 randomly.ab,ti.
26 trial.ab,ti.
27 groups.ab,ti.
28 or/21-27
29 Animals/
30 Humans/
31 29 not (29 and 30)
32 28 not 31
33 20 not 31
34 32 or 33
35 exp Spinal Diseases/
36 exp Scoliosis/
37 scoliosis.mp.
38 or/35-37

39 exp Braces/
40 brace$.mp.
41 bracing.mp.
42 exp Orthotic Devices/
43 exp Orthopedic Equipment/
44 limit 43 to yr="1902 - 1975"
45 or/39-42
46 44 or 45
47 exp Adolescent/
48 adolescen$.mp.
49 47 or 48
50 38 and 45 and 49
51 34 and 50

Appendix 2. EMBASE search strategy

1 exp Clinical Study/
2 exp Case Control Study/
3 exp Family Study/
4 exp Longitudinal Study/
5 exp Retrospective Study/
6 exp Prospective Study/
7 exp Cohort Analysis/
8 (cohort adj (study or studies)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
9 (case control adj (study or studies)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
10 (follow up adj (study or studies)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
11 (observational adj (study or studies)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
12 (epidemiologic$ adj (study or studies)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
13 (cross sectional adj (study or studies)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
14 exp Comparative Study/
15 evaluation study.mp.
16 follow-up study.mp. or exp Follow Up/
17 Crossover Procedure/
18 prospective$.mp.
19 exp VOLUNTEER/
20 or/1-19
21 Clinical Article/
22 exp Clinical Study/
23 Clinical Trial/
24 Controlled Study/
25 Randomized Controlled Trial/
26 Major Clinical Study/
27 Double Blind Procedure/
28 Multicenter Study/
29 Single Blind Procedure/
30 Phase 3 Clinical Trial/

31 Phase 4 Clinical Trial/
32 crossover procedure/
33 placebo/
34 or/21-33
35 allocat$.mp.
36 assign$.mp.
37 blind$.mp.
38 (clinic$ adj25 (study or trial)).mp.
39 compar$.mp.
40 control$.mp.
41 cross?over.mp.
42 factorial$.mp.
43 follow?up.mp.
44 placebo$.mp.
45 prospectiv$.mp.
46 random$.mp.
47 ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).mp.
48 trial.mp.
49 (versus or vs).mp.
50 or/35-49
51 34 and 50
52 20 or 51
53 Human/
54 Nonhuman/
55 exp ANIMAL/
56 Animal Experiment/
57 54 or 55 or 56
58 53 not 57
59 52 not 57
60 58 or 59
61 exp SPINE/
62 exp Spine Disease/
63 exp SCOLIOSIS/
64 exp Idiopathic Scoliosis/
65 scoliosis.mp.
66 or/61-65
67 exp Brace/
68 brace$.mp.
69 bracing.mp.
70 exp ORTHOTICS/
71 exp orthopedic equipment/
72 or/67-71
73 Adolescent/
74 adolescen#.mp.
75 73 or 74
76 66 and 72 and 75
77 60 and 76

Appendix 3. CINAHL search strategy

1 exp Prospective Studies/
2 exp Case Control Studies/
3 exp Correlational Studies/
4 exp Nonconcurrent Prospective Studies/
5 exp Cross Sectional Studies/
6 (cohort adj (study or studies)).mp. [mp=title, subject heading word, abstract, instrumentation]
7 (observational adj (study or studies)).mp. [mp=title, subject heading word, abstract, instrumentation]
8 Randomized Controlled Trials.mp.
9 clinical trial.pt.
10 exp Clinical Trials/
11 (clin$ adj25 trial$).tw.
12 ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).tw.
13 exp PLACEBOS/
14 placebo$.tw.
15 random$.tw.
16 exp Study Design/
17 (latin adj square).tw.
18 exp Comparative Studies/
19 exp Evaluation Research/
20 Follow-Up Studies.mp.
21 exp Prospective Studies/
22 (control$ or prospectiv$ or volunteer$).tw.
23 Animals/
24 or/1-22
25 24 not 23
26 Randomized Controlled Trials.mp.
27 clinical trial.pt.
28 exp Clinical Trials/
29 (clin$ adj25 trial$).tw.
30 ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).tw.
31 exp PLACEBOS/
32 placebo$.tw.
33 random$.tw.
34 exp Study Design/
35 (latin adj square).tw.
36 exp Comparative Studies/
37 exp Evaluation Research/
38 Follow-Up Studies.mp.
39 exp Prospective Studies/
40 (control$ or prospectiv$ or volunteer$).tw.
41 Animals/
42 or/26-40
43 42 not 41
44 exp SPINE/
45 exp Spinal Diseases/
46 exp SCOLIOSIS/
47 scoliosis.mp.
48 or/44-47
49 exp Orthoses/
50 brace$.mp.
51 bracing.mp.

52 or/49-51
53 exp Adolescence/
54 adolescen$.mp.
55 53 or 54
56 48 and 52 and 55
57 43 and 56

Appendix 4. Journals handsearched

Journal	Language	From	To
Acta Orthopaedica and Traumatologica Hellenica	Greek	1948	2008
Annales Academiae Medicae Silesiensis	Polish	1997	2007
Annales de Kinésithérapie	French	1978	2007
Cahiers de Kinésithérapie	French	1978	1997
Chinesiologia Scientifica	Italian	1978	2007
Chirurgia Narzadow Ruchu i Ortopedia Polska	Polish	1997	2007
Fizjoterapia	Polish	1993	2006
Fizjoterapia Polska	Polish	2001	2007
Ginnastica Medica, Medicina Fisica e Riabilitazione	Italian	1953	2007
Journal of Japanese Orthopaedic Association,	Japanese	1963	1995
Journal of Japanese Scoliosis Research Society	Japanese	1988	2006
Journal of Japanese Spine society	Japanese	1990	2007
Kinésithérapie Scientifique	French	1978	2007
Kultura Fizyczna	Polish	1997	2007
Kwartalnik Ortopedyczny	Polish	1991	2007

(*Continued*)

Medycyna Manualna	Polish	1997	2006
Ortopedia Traumatologia Rehabilitacja	Polish	1999	2007
Postepy Rehabilitacji	Polish	1997	2007
Rehabilitacja Medyczna	Polish	1997	2007
Rehabilitacja w Praktyce	Polish	2006	2007
Résonances Européennes Du Rachis	French	1994	2007

Appendix 5. Conference proceedings handsearched

Society	Language	From	To	Single years
American Physical Therapy Association	English			1991; 1992
Back Pain Society	English			1990
British Scoliosis Society	English			1992; 1999; 2000; 2006
Chartered Society of Physiotherapists	English			1994; 1999; 2000; 2006
European Spinal Defomities Society	English			1994
Groupe Europeen Kinesitherapique de travail de scoliose	French			1991; 1992
International Research Society of Spinal Deformities published in the research into spinal deformities series	English	1996	2008	

(*Continued*)

Phillip Zorab Symposium	English			1979
Polskie Towarzystwo Ortopedyczne i Traumatologiczne (Polish Orthopedic and Traumatologic Society)	Polish	1978	2006	
Quebec Scoliosis Society	French/English			1994
Scoliosis Research Society - SRS Meeting abstracts	English	2001	2007	
Società Italiana di chirurgia vertebrale - GIS	Italian	1978	2007	
Society on Scoliosis Orthoapedic and Rehabilitation Treatment - SOSORT Meeting abstracts	English	2003	2008	
Surface Topography and Spinal Deformity meetings	English	1980	1994	
World Confederation of Physical Therapy	English			1991; 1995

Appendix 6. Criteria for risk of bias assessment for RCTs and CCTs

1. Was the method of randomisation adequate? A random (unpredictable) assignment sequence. Examples of adequate methods are coin toss (for studies with two groups), rolling a dice (for studies with two or more groups), drawing of balls of different colours, drawing of ballots with the study group labels from a dark bag, computer-generated random sequence, pre-ordered sealed envelops, sequentially-ordered vials, telephone call to a central office, and pre-ordered list of treatment assignments

Examples of inadequate methods are: alternation, birth date, social insurance/security number, date in which they are invited to participate in the study, and hospital registration number

2. Was the treatment allocation concealed? Assignment generated by an independent person not responsible for determining the eligibility of the patients. This person has no information about the persons included in the trial and has no influence on the assignment sequence or on the decision about eligibility of the patient.

Was knowledge of the allocated interventions adequately prevented during the study?

3. Was the patient blinded to the intervention?

This item should be scored "yes" if the index and control groups are indistinguishable for the patients or if the success of blinding was tested among the patients and it was successful.

4. Was the care provider blinded to the intervention? This item should be scored "yes" if the index and control groups are indistinguishable for the care providers or if the success of blinding was tested among the care providers and it was successful
5. Was the outcome assessor blinded to the intervention? Adequacy of blinding should be assessed for the primary outcomes. This item should be scored "yes" if the success of blinding was tested among the outcome assessors and it was successful or:

- **for patient-reported outcomes** in which the patient is the outcome assessor (e.g., pain, disability): the blinding procedure is adequate for outcome assessors if participant blinding is scored "yes"

- **for outcome criteria assessed during scheduled visit and that supposes a contact between participants and outcome assessors** (e.g., clinical examination): the blinding procedure is adequate if patients are blinded, and the treatment or adverse effects of the treatment cannot be noticed during clinical examination

- **for outcome criteria that do not suppose a contact with participants** (e.g., radiography, magnetic resonance imaging): the blinding procedure is adequate if the treatment or adverse effects of the treatment cannot be noticed when assessing the main outcome

- **for outcome criteria that are clinical or therapeutic events** that will be determined by the interaction between patients and care providers (e.g., co-interventions, hospitalisation length, treatment failure), in which the care provider is the outcome assessor: the blinding procedure is adequate for outcome assessors if the item for care provider is scored "yes"

- **for outcome criteria that are assessed from data of the medical forms**: the blinding procedure is adequate if the treatment or adverse effects of the treatment cannot be noticed on the extracted data

Were incomplete outcome data adequately addressed?
6. Was the drop-out rate described and acceptable? The number of participants who were included in the study but did not complete the observation period or were not included in the analysis must be described and reasons given. If the percentage of withdrawals and drop-outs does not exceed 20% for short-term follow-up and 30% for long-term follow-up and does not lead to substantial bias a 'yes' is scored. (N.B. these percentages are arbitrary, not supported by literature).
7. Were all randomised participants analysed in the group to which they were allocated? All randomised patients are reported/ analysed in the group they were allocated to by randomisation for the most important moments of effect measurement (minus missing values) irrespective of non-compliance and co-interventions.
8. Are reports of the study free of suggestion of selective outcome reporting? In order to receive a 'yes', the review author determines if all the results from all pre-specified outcomes have been adequately reported in the published report of the trial. This information is either obtained by comparing the protocol and the report, or in the absence of the protocol, assessing that the published report includes enough information to make this judgment.
Other sources of potential bias:
9. Were the groups similar at baseline regarding the most important prognostic indicators? In order to receive a "yes", groups have to be similar at baseline regarding demographic factors, duration and severity of complaints, percentage of patients with neurological symptoms, and value of main outcome measure(s).
10. Were co-interventions avoided or similar? This item should be scored "yes" if there were no co-interventions or they were similar between the index and control groups.
11. Was the compliance acceptable in all groups? The reviewer determines if the compliance with the interventions is acceptable, based on the reported intensity, duration, number and frequency of sessions for both the index intervention and control intervention(s). For example, physiotherapy treatment is usually administered over several sessions; therefore it is necessary to assess how many sessions each patient attended. For single-session interventions (for ex: surgery), this item is irrelevant.
12. Was the timing of the outcome assessment similar in all groups? Timing of outcome assessment should be identical for all intervention groups and for all important outcome assessments.

Appendix 7. Criteria for the risk of bias assessment of observational studies

Selection bias:

1. Representativeness of the exposed cohort: . Assess whether the sample is truly representative of the average adolescents with scoliosis; somewhat representative of the average adolescents with scoliosis; selected group of adolescents with scoliosis; no description of the derivation of the cohort. This item was added in the Risk of bias table as "other source of bias"

2. Selection of the non exposed cohort: . Assess whether the sample has been drawn from the same community as the exposed cohort; drawn from a different source/community , "no description of the derivation of the non exposed cohort'. This item was added in the Risk of bias table as "other source of bias"

3. Ascertainment of exposure: Information in the study was obtained from a secure record (e.g. clinical records); structured interview; written self report; no description. This item was added in the Risk of bias table as "other source of bias"

4. Comparability of cohorts on the basis of the design or analysis: Either exposed and non-exposed individuals must be matched in the design and/or confounders must be adjusted for in the analysis. Statements of no differences between groups or that differences were not statistically significant are not sufficient for establishing comparability. If the relative risk for the exposure of interest is adjusted for the confounders listed, then the groups will be considered to be comparable on each variable used in the adjustment. Were most important prognostic factors matched? Yes/No. Were unmatched important prognostic factors adjusted for? Yes/No. This item was assessed in the Risk of Bias table under the item "group similar at baseline"

Attrition bias:

5. Complete follow up: assess if: all subjects accounted for; subjects lost to follow up unlikely to introduce bias (lost to follow-up 5%); subjects lost to follow up > 5% and description provided of those lost. This item was assessed in the Risk of Bias table under the item "incomplete outcome data".

Detection bias:

6. Independent blind assessment: Independent or blind assessment stated in the paper, or confirmation of the outcome by reference to secure records (x-rays, medical records, etc.), record linkage, or self report; or no blinding; no description. This item was assessed in the Risk if bias table under the item "blinding of outcome assessor"

Appendix 8. Assessment of Clinial Relevance

1. Are the patients described in detail so that you can decide whether they are comparable to those that you see in your practice?
2. Are the interventions and treatment settings described well enough so that you can provide the same for your patients?
3. Were all clinically relevant outcomes measured and reported?
4. Is the size of the effect clinically important?
5. Are the likely treatment benefits worth the potential harms?

Appendix 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 end 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

(*Continued*)

Negrini 2009	Retrospective	Various	48	0	0	0

HISTORY

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DECLARATIONS OF INTEREST

none noted

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We changed the criteria to assess methodological quality of included studies from that described in the protocol to conform the review to the recommended methods outlined in the Cochrane Handboook 2008 and to the requirements of RevMan5.