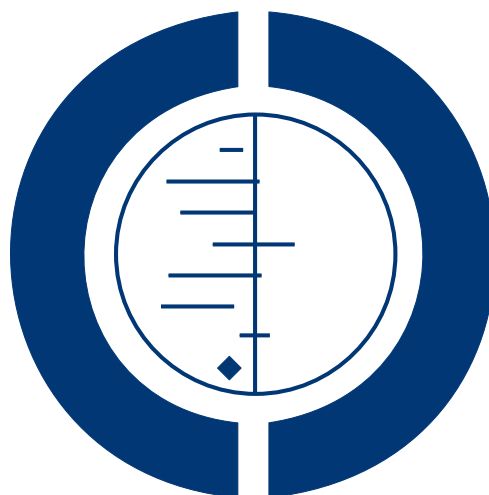


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[Intervention Review]

# Braces for idiopathic scoliosis in adolescents

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## ABSTRACT

### Background

Idiopathic scoliosis is a three-dimensional deformity of the spine. The most common form is diagnosed in adolescence. While adolescent idiopathic scoliosis (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.

### Objectives

To evaluate the efficacy of bracing for adolescents with AIS versus no treatment or other treatments, on quality of life, disability, pulmonary disorders, progression of the curve, and psychological and cosmetic issues.

### Search methods

We searched CENTRAL, MEDLINE, EMBASE, five other databases, and two trials registers up to February 2015 for relevant clinical trials. We also checked the reference lists of relevant articles and conducted an extensive handsearch of grey literature.

### Selection criteria

Randomized controlled trials (RCTs) and prospective controlled cohort studies comparing braces with no treatment, other treatment, surgery, and different types of braces for adolescent with AIS.

### Data collection and analysis

We used standard methodological procedures expected by The Cochrane Collaboration.

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## Main results

We included seven studies (662 participants). Five were planned as RCTs and two as prospective controlled trials. One RCT failed completely, another was continued as an observational study, reporting also the results of the participants that had been randomized.

There was very low quality evidence from one small RCT (111 participants) that quality of life (QoL) during treatment did not differ significantly between rigid bracing and observation (mean difference (MD) -2.10, 95% confidence interval (CI) -7.69 to 3.49). There was very low quality evidence from a subgroup of 77 adolescents from one prospective cohort study showing that QoL, back pain, psychological, and cosmetic issues did not differ significantly between rigid bracing and observation in the long term (16 years).

Results of the secondary outcomes showed that there was low quality evidence that rigid bracing compared with observation significantly increased the success rate in 20° to 40° curves at two years' follow-up (one RCT, 116 participants; risk ratio (RR) 1.79, 95% CI 1.29 to 2.50). There was low quality evidence that elastic bracing increased the success rate in 15° to 30° curves at three years' follow-up (one RCT, 47 participants; RR 1.88, 95% CI 1.11 to 3.20).

There is very low quality evidence from two prospective cohort studies with a control group that rigid bracing increases the success rate (curves not evolving to 50° or above) at two years' follow-up (one study, 242 participants; RR 1.50, 95% CI 1.19 to 1.89) and at three years' follow-up (one study, 240 participants; RR 1.75, 95% CI 1.42 to 2.16). There was very low quality evidence from a prospective cohort study (57 participants) that very rigid bracing increased the success rate (no progression of 5° or more, fusion, or waiting list for fusion) in adolescents with high degree curves (above 45°) (one study, 57 adolescents; RR 1.79, 95% CI 1.04 to 3.07 in the intention-to-treat (ITT) analysis).

There was low quality evidence from one RCT that a rigid brace was more successful than an elastic brace at curbing curve progression when measured in Cobb degrees in low degree curves (20° to 30°), with no significant differences between the two groups in the subjective perception of daily difficulties associated with wearing the brace (43 girls; risk of success at four years' follow-up: RR 1.40, 1.03 to 1.89). Finally, there was very low quality evidence from one RCT (12 participants) that a rigid brace with a pad pressure control system is no better than a standard brace in reducing the risk of progression.

Only one prospective cohort study (236 participants) assessed adverse events: neither the percentage of adolescents with any adverse event (RR 1.27, 95% CI 0.96 to 1.67) nor the percentage of adolescents reporting back pain, the most common adverse event, were different between the groups (RR 0.72, 95% CI 0.47 to 1.10).

## Authors' conclusions

Due to the important clinical differences among the studies, it was not possible to perform a meta-analysis. Two studies showed that bracing did not change QoL during treatment (low quality), and QoL, back pain, and psychological and cosmetic issues in the long term (16 years) (very low quality). All included papers consistently showed that bracing prevented curve progression (secondary outcome). However, due to the strength of evidence (from low to very low quality), further research is very likely to have an impact on our confidence in the estimate of effect. The high rate of failure of RCTs demonstrates the huge difficulties in performing RCTs in a field where parents reject randomization of their children. This challenge may prevent us from seeing increases in the quality of the evidence over time. Other designs need to be implemented and included in future reviews, including 'expertise-based' trials, prospective controlled cohort studies, prospective studies conducted according to pre-defined criteria such as the Scoliosis Research Society (SRS) and the international Society on Scoliosis Orthopedic and Rehabilitation Treatment (SOSORT) criteria. Future studies should increase their focus on participant outcomes, adverse effects, methods to increase compliance, and usefulness of physiotherapeutic scoliosis specific exercises added to bracing.

## PLAIN LANGUAGE SUMMARY

### Braces for idiopathic scoliosis in adolescents

#### Review question

We reviewed the evidence about the effect of bracing on pulmonary disorders (lung diseases), disability, back pain, quality of life, and psychological and cosmetic issues in adolescent with idiopathic scoliosis. We found seven studies. We looked at randomized controlled trials (RCTs) and prospective controlled cohort studies (CCTs).

#### Background

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#### Braces for idiopathic scoliosis in adolescents (Review)

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Scoliosis is a condition where the spine is curved in three dimensions (from the back the spine appears to be shaped like an 's' and the trunk is deformed). It is often idiopathic, which means the cause is unknown. The most common type of scoliosis is generally discovered around 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 the 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 older people. Braces are one intervention that may stop further progression of the curve. They generally need to be worn full time, with treatment lasting until the end of growth (most frequently, from a minimum of two to four/five years). However, bracing for this condition is still controversial, and questions remain about how effective it is.

### **Study characteristics**

This review included seven studies, with a total of 662 adolescents of both genders. AIS from 15° to more than 45° curves were considered. Elastic, rigid (polyethylene), and very rigid (polycarbonate) braces were studied. The evidence is current to October 2013. Funding sources were not reported or external governmental or scientific agencies.

### **Key results**

We did not find any results on pulmonary disorders and disability. Quality of life was not affected during brace treatment (very low quality evidence); quality of life, back pain, and psychological and cosmetic issues did not change in the long term (very low quality evidence). Rigid bracing seems effective in 20° to 40° curves (low quality evidence), elastic bracing in 15° to 30° curves (low quality evidence), and very rigid bracing in high degree curves above 45° (very low quality evidence); rigid was more successful than an elastic bracing (low quality evidence), and a pad pressure control system did not increase results (very low quality evidence). No specific harms were reported.

Primary outcomes such as pulmonary disorders, disability, back pain, psychological and cosmetic issues, and quality of life should be better evaluated in the future. Side effects, as well as the usefulness of exercises and other adjunctive treatments to bracing should be studied too.

### **Quality of the evidence**

The evidence was moderate to very low quality. Reason for downgrading were evidence coming from few randomized trials with few participants and many lost at follow-up or from observational prospective controlled studies. An issue in the field of AIS is the high rate of failure of RCTs, since parents want to choose with physicians the preferred treatment for their children. Thus, it is challenging to obtain high quality evidence in this field.