Healthcare Improvement Scotland | SHTG Advice on health technologies

SHTG Assessment
January 2023

Orthotic bracing for the treatment of idiopathic scoliosis in children and young people (<18 years)

What were we asked to look at?

SHTG was asked to review the published literature on the clinical effectiveness, cost effectiveness and safety of orthotic bracing for the treatment of children and young people (<18 years) who have been diagnosed with idiopathic scoliosis. The Scottish National Spine Service (SNSS) is a national designated specialist service and this work was requested by NHS National Services Scotland (NSS) to inform future service delivery by the SNSS.

Why is this important?

The SNSS cares for children and young people diagnosed with disorders of the spine, including scoliosis. Orthotic bracing is one treatment option for patients with idiopathic scoliosis who are skeletally immature (they are still growing). Bracing may be able to slow down progression of the abnormal curvature of the spine and postpone or eliminate the need for major surgeries to fuse and realign the spine. Repeated surgery for scoliosis in young children can have negative effects on their mental health and wellbeing, which could be mitigated by postponing or eliminating the need for surgery.

What was our approach?

We conducted a comprehensive review of the published literature on the clinical effectiveness, cost effectiveness, safety and patient aspects of corrective orthotic bracing to treat children and young people diagnosed with idiopathic scoliosis. More information about SHTG Assessments can be found on our website.

What next?

Our Assessment will be used by NSS and SNSS to inform the use of bracing to treat idiopathic scoliosis in children and young people.

Key findings

1. A methodologically robust meta-analysis of seven studies (n=751) found that adolescents with idiopathic scoliosis receiving orthotic bracing had a higher rate of successful outcomes: odds ratio (OR) 3.58, 95% confidence interval (CI) 1.92 to 6.68. Patients treated with bracing also had a significantly better quality of life (mean difference 2.13, 95% CI 0.51 to 3.75), and a higher adverse event rate (OR 5.31, 95% CI 2.42 to 11.66) than patients who did not undergo bracing.

2. A Cochrane systematic review that did not include a meta-analysis due to high heterogeneity between studies considered the evidence to be of low or very low quality and had low confidence in the review findings. The review authors reported significantly higher success rates (curve remaining below 50°) with bracing compared with observation in three studies (n=415) in adolescent patients with idiopathic scoliosis. Two studies (n=347) in the review found no statistically significant differences in quality of life between the two groups. One study (n=242) found no significant differences in adverse events between bracing and observation.

3. One meta-analysis and two low quality systematic reviews compared night-time bracing with fulltime bracing in adolescent patients with idiopathic scoliosis. The low quality of the primary studies and substantial heterogeneity meant it was not possible to reach any conclusions on whether night-time bracing is as effective as fulltime bracing in this patient population.

4. Back pain was the most commonly reported adverse event in patients undergoing orthotic bracing for scoliosis. Results presented in the literature were variable, therefore it is uncertain what effect bracing has on back pain prevalence or severity in patients with adolescent idiopathic scoliosis.

5. A systematic review with methodological limitations identified three main risk factors associated with the failure of orthotic bracing in adolescents with idiopathic scoliosis: lower adherence to the prescribed bracing regimen, low levels of skeletal maturity at the time of bracing (patients are younger and still growing), and spinal curvature (Cobb angle) >30° at initial bracing.

6. The duration of brace wearing per day affects the effectiveness of the treatment. In a low quality literature review, rates of adherence to prescribed bracing regimens were affected by patient age, the type and fit of the brace, the

appearance of the brace, and whether the patient wore the brace at night only or during the day.

7. In one systematic review, nine observational studies of unclear quality suggested that overall levels of stress, anxiety and depression were low to moderate amongst adolescents with idiopathic scoliosis treated using bracing, surgery or physiotherapy.

8. Twenty-four studies in a systematic review consistently reported negative effects on perceived body image among patients with adolescent idiopathic scoliosis.

9. Based on a single study from the United States (US), bracing in patients with adolescent idiopathic scoliosis may be a cost-effective treatment option, generating more quality adjusted life years (+0.22 QALYs) at a lower cost (-$24,903 [approximately £21,057]) compared with observation. The high cost of surgery is a significant driver of the results; the cost effectiveness of bracing is based on an assumed reduction in the need for surgery in patients treated with bracing.
    - A comprehensive cost-effectiveness analysis for Scotland is not available so the results from the US study should be treated with caution.
    - Scotland-specific costings indicate that the cost of bracing and surgery account for a similar fraction of the costs as described in the US study and thus may not alter the estimated life-time incremental costs in the published economic model.
    - The approximate annual cost of the custom-made bracing pathway in NHSScotland is £2,814 (range £1,190 to £6,169) per patient with idiopathic scoliosis.

Contents

Definitions

Body schema: a collection of processes that registers the posture of the body and limbs in space. The schema updates during body movement and is normally an unconscious process.[1]

Cobb angle: the most widely used measurement to quantify the magnitude of a spinal curve on x-rays. The Cobb angle is measured by drawing lines along the endplates of the vertebrae at each end of the curve. The angle between the two lines, where they intersect, is the Cobb angle.[2]

Idiopathic: a disease or medical condition that has no known cause.[3]

Risser classification: the Risser classification is used to grade skeletal maturity based on levels of ossification and fusion in the iliac crest or long bones. Risser grades 0 to 5 indicate increasing levels of ossification and fusion (level 5 would indicate skeletal maturity).[4]

Introduction

Scoliosis is the abnormal twisting and curvature of the human spine.[5] A Cobb angle >10° is generally accepted as indicating the presence of scoliosis.[2] Typical signs of scoliosis include a visibly curved spine, one shoulder higher than the other, one shoulder more prominent than the other, a prominent ribcage and a difference in leg length.[5] Scoliosis can develop at any age, but is most common in children aged 10 to 15 years. In rare cases, severe scoliosis can result in physical harm, if for example, significant curvature of the spine puts increased pressure on the heart and lungs.

There are four main types of scoliosis: congenital, neuromuscular, idiopathic and adult de novo scoliosis.[6] Adolescent idiopathic scoliosis (AIS) is the most common form of scoliosis, accounting for approximately 80% of recorded cases. The Scientific Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT) have suggested classifying idiopathic scoliosis chronologically or by angle of the spinal curve (*Table 1*).[7]

Table 1: SOSORT classification of idiopathic scoliosis[7]

Chronological (age at diagnosis)	Angle of curve (Cobb degrees)
Infantile: age 0 to 2 years	Low: up to 20°
Juvenile: age 3 to 9 years	Moderate: 21° to 35°
Adolescent (young people): age 10 to 17 years	Moderate to severe: 36° to 40°
Adult: age 18+ years	Severe: 41° to 50°

	Severe to very severe: 51° to 55°
	Very severe: 56° or more

The most appropriate treatment option for scoliosis depends on the patient's age, the severity of the spinal curve and whether the curve is expected to worsen over time.[5] After initial observation, the main treatment options for scoliosis are orthotic bracing and spinal surgery. Orthotic bracing can be used in skeletally immature children and young people with scoliosis in order to slow down the progression of the spinal curve and minimise the Cobb angle at skeletal maturity. Treatment with bracing generally commences when an individual's spinal curve reaches a predefined threshold (normally a Cobb angle >20°) or is diagnosed as being progressive.[8] Bracing does not always sufficiently correct the scoliosis curve, and some children and young people, particularly those with severe scoliosis curves, may require surgery to realign their spine when they are older. People with a scoliosis curve with a Cobb angle >40° at diagnosis are usually treated with surgery instead of bracing.[9]

Research question

What is the clinical effectiveness, cost effectiveness, safety and patient experience of orthotic bracing for the treatment of idiopathic scoliosis in children and young people (<18 years)?

Literature search

A systematic search of the secondary literature was carried out between 30 May and 6 June 2022 to identify systematic reviews, health technology assessments and other evidence based reports. Medline, Embase, Cinahl and Web of Science databases were also searched for systematic reviews and meta-analyses.

To identify qualitative and patient issues literature, the primary literature was systematically searched on 6 June 2022 using the Medline and PsycInfo databases.

Key websites were searched for guidelines, policy documents, clinical summaries and relevant reports. Websites of organisations related to this topic, for example The British Orthopaedic Association, were also searched.

Concepts used in all searches include scoliosis, brace and bracing. A full list of resources searched and terms used is available on request.

All search results were limited to studies published from 2012 onwards in the English language. Results were also limited using the following PICO criteria:

Population	Children and young people (aged <18 years) with idiopathic scoliosis
Intervention	Any orthotic bracing
Comparator	No treatment, observation, surgery, different types of brace, fulltime versus night-time bracing, other treatments (eg scoliosis specific exercises)
Outcomes	Progression or correction of scoliosis curve, pulmonary disorders, disability, back pain, quality of life, mental health, psychological and cosmetic issues, safety, cost effectiveness, patient views, preferences and experiences

Health technology description

Orthotic braces used to treat patients with scoliosis are designed to slow down or stop the progression of the spinal curve.[9] Several kinds of orthotic brace are available. Some braces are rigid and put pressure on the spine to help prevent further curving. Other braces are more elastic, slowing curve progression by retraining the body into maintaining a corrective posture. The following braces are the most commonly used in studies on the treatment of scoliosis:[9-11]

- Boston rigid, fulltime brace made of lightweight plastic
- Wilmington rigid, fulltime brace made of lightweight plastic
- Charleston bending brace; a rigid, custom-made, night-time brace
- Providence night-time brace that applies a hypercorrective force on the spine while the patient is sleeping
- Rigo Cheneau fulltime, custom-made rigid plastic brace, and
- SpineCor fulltime, flexible bracing method using bands and a cotton vest.

In NHSScotland, the only orthotic brace used is a custom-made, rigid plastic Boston brace that is designed to be worn fulltime. An ongoing randomised controlled trial (BASIS) is currently recruiting patients with idiopathic scoliosis at 20 UK sites (estimated trial completion date February 2025). Participants are randomised to either the Boston fulltime brace or the Providence night-time brace.

The Boston orthotic brace used in Scotland usually covers the thoracic spine (upper back) down to the sacral spine (buttocks). Every child's body and scoliosis curve are unique, so braces are often specially made for the individual patient.[10] As the child grows, the brace may need to be adjusted or replaced.

Treatment with braces usually lasts from 2 to 5 years, or until the completion of bone growth.[8] The number of hours per day a brace should be worn varies between 12 and 23 hours per day. Out with the hours of bracing, the patient can rest and engage in activities that are restricted when wearing the brace.

Epidemiology

In the UK, prevalence of idiopathic scoliosis is estimated at 2–3% of 10 to 16 year olds, with an estimated 3–4 children per 1,000 needing treatment.[5, 12]

If the Cobb angle at completion of growth exceeds a critical threshold (generally taken to be between 30° and 50°), there is a higher risk of health problems in adult life, decreased quality of life, cosmetic abnormality and visible disability, pain and functional limitations.[7]

Scoliosis curve progression requiring treatment is more common in female adolescents compared with male adolescents, with an estimated ratio of 7:1 or 8:1.[12] The ratio of females affected increases exponentially with the magnitude of the scoliosis curve, from a 1.3:1 female to male ratio when the Cobb angle in 10° to 20°, to 5.4:1 for Cobb angles between 20° and 30°, and 7:1 for angles greater than 30°.[7]

One study in the US (n=403) found that black patients with AIS had significantly greater Cobb angles on presentation compared with Hispanic patients (33° versus 27°, $p<0.05$) or white patients (33° versus 28°, $p<0.005$).[13] Black patients were also more likely to present with a Cobb angle in the range requiring surgical treatment compared with white patients: 34% versus 24%, $p<0.05$. Another study in the US (n=433) found no statistically significant differences in Cobb angle at presentation for Hispanic patients compared with white patients with AIS.[14]

Inequalities in scoliosis treatment

A study of patients presenting with AIS at one physician's practice in the US (n=403) found that all patients with a Cobb angle greater than 40° were recommended surgery as their initial treatment regardless of race.[13] Black patients were significantly more likely than white patients to be offered surgical treatment for scoliosis, likely as a result of more severe scoliosis curves in black patients at presentation.

In a second US study (n=443), there was no correlation between socioeconomic status (income level) or race and Cobb angle in patients with AIS.[14] In this study, referral delay (the time between referral and appointment) was not affected by patient age or household income.

Due to the differences in healthcare funding and service provision in the US and Scotland, the results of these studies may not be generalisable to the Scottish context.

Scottish organisational context

In Scotland, the SNSS provides specialist orthotic bracing for children and young people who have scoliosis.[15] The service is delivered through the Royal Hospital for Children and Young People in Edinburgh, the Royal Infirmary of Edinburgh and the Royal Hospital for Children in Glasgow.

Orthotic bracing prescriptions

The SNSS recommends that patients wear their Boston brace for 20 hours per day to achieve the best results. This leaves 4 hours per day which can be planned and used as desired by the patient.[15] Patients are recommended to exercise while not wearing the brace to prevent the muscles in their back and abdomen from weakening. Time out of the brace gives the skin a break and allows patients time for personal hygiene and eating.

Patients receiving their brace from the Glasgow-based orthotics team will be given a Boston brace that includes an iButton® which monitors the patient's average daily wear time.[15] If data from the iButton® indicate that the patient is not wearing the brace for the prescribed amount of time per day, an appointment can be made to discuss how the clinical team can support the patient to wear their brace more. An iButton® is not currently used in braces created by the Edinburgh-based orthotics team who use other methods, such as performing a visual check of the brace to note wear on the lining and straps. These visual checks along with feedback from the patient provides an indication of how often the patient is wearing their brace.

Patient care pathway

Figure 1 presents a simplified version of the referral pathway for children and young people with idiopathic scoliosis. Referrals to the SNSS come from consultants based in the patient's local health board.[15] Patients seen by the SNSS may proceed directly to surgery, require additional testing or undergo non-surgical management by bracing. *Figure 2* outlines the key steps for patients who are referred to the SNSS and are found to be best suited to non-surgical management of their condition.

Patients initially managed using bracing may eventually need corrective surgery or may be discharged from the service without needing or choosing to have surgery. Long delays in moving through the care pathway can have profound implications for the treatment options available to patients when they arrive at the SNSS. If there has been a long delay between

initial referral to orthopaedics through to an appointment with the SNSS, a patient's spinal curve may have progressed to the point where bracing is no longer a therapeutic option for them.

Spinal surgeries are performed at two SNSS sites in Edinburgh: the Royal Hospital for Children and Young People and the Royal Infirmary of Edinburgh.[15] Outpatient clinics are held at these hospitals and also at the Royal Hospital for Children, Glasgow.

Figure 1: a simplified diagram showing the normal referral pathway for patients with idiopathic scoliosis[15]

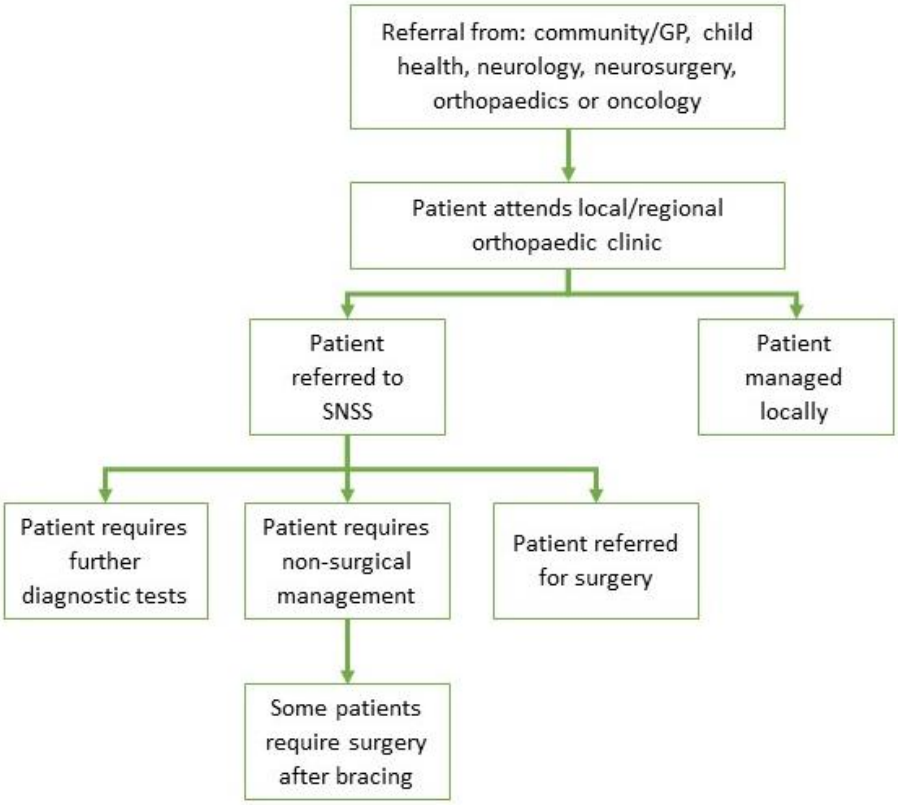

Figure 2: the normal care pathway followed by patients undergoing non-surgical management of idiopathic scoliosis at the SNSS[15]

Appointment 1: referral by consultant	In Glasgow: the patient is introduced to the department, bracing is discussed, their questions are answered and they are shown an example brace. An appointment date for casting is either given to the patient on the day or they are sent one at a later date. In Edinburgh: if an orthotist is available, they will discuss bracing, answer any questions and show the patient a sample brace. If this is not possible, the same will be offered via a telephone or video appointment. In either scenario the patient is given a leaflet about bracing by the Spinal Liaison Nurse. The patient is later contacted with a casting appointment date.
Within 4 weeks	
Appointment 2: orthotic casting	In Glasgow and Edinburgh: this appointment takes 45-90 minutes with two or three orthotists present. A plaster cast of the patient's body from shoulders to hips is taken using a Risser casting frame. This cast, along with the most recent x-ray, is used to make the brace.
Brace creation	In Glasgow and Edinburgh: the cast is modified by an orthotist based on x-rays of the patient. The brace is manufactured at an on-site workshop by an orthotic technician.
Within the next 4 weeks	
Appointment 3: orthotic fitting	In Glasgow and Edinburgh: this appointment lasts 1-2 hours. The orthotist completes adjustments to the brace to make sure the patient is comfortable. Advice on brace wearing and brace care will be provided to the patient at this appointment. Information leaflets and department contact details are given to the patient.
Within the next 6–8 weeks	
Appointment 4: orthotic review, consultant review and x-ray in-brace	In Glasgow and Edinburgh: the patient sees an orthotist for review, followed by an x-ray while wearing their brace. After the x-ray the patient is seen by the spinal consultant to discuss the x-ray. An orthotist will make any adjustments required to the brace following the x-ray.
Follow up	In Glasgow and Edinburgh: the consultant arranges for follow up x-ray appointments with the patient. The orthotist arranges to routinely review the patient's brace twice per year (including checking if they need a new one as a result of skeletal growth).

Clinical effectiveness

Comparing orthotic bracing with other treatment strategies

A meta-analysis and a Cochrane systematic review compared bracing with other treatment strategies in adolescents with idiopathic scoliosis.[8, 16] Despite being based on a similar research question, the meta-analysis and systematic review have only one primary study in common. This is likely a result of differences in the search strategies and inclusion criteria used.

The meta-analysis was of high methodological quality and compared orthotic bracing with no specified intervention (observation) in adolescents with idiopathic scoliosis.[16] Seven randomised controlled trials (RCTs) or clinical controlled trials (CCTs), with a total of 751 participants, were included in the meta-analysis. Risk of bias, assessed by the meta-analysis authors using the Cochrane risk of bias tool, was judged to be low or unclear for all included studies. Mean age of trial participants ranged from 9.3 (standard deviation (SD) 1.7) to 15.58 (SD 3.4) years. The majority of participants (84.6%) were female. Duration of treatment and study follow up were not reported. Results from the meta-analysis are presented in *Table 2*. Statistically significant results favouring bracing over observation were reported for successful outcomes and quality of life. Successful outcomes were not defined in the meta-analysis. Based on the discussion section of the meta-analysis, successful outcomes appear to be the delay or prevention of spinal curvature progression and correcting the existing curvature.

Table 2: meta-analysis comparing bracing with observation in adolescents with idiopathic scoliosis[16]

Outcome	n participants (n studies)	Findings (95% CI)	p value	I^2
Successful outcomes (not defined)	751 (7)	OR 3.58 (1.92 to 6.68)	<0.0001	65%
Quality of life (PedsQL score)	751 (7)	MD 2.13 (0.51 to 3.75)	0.01	0%
Adverse events	751 (7)	OR 5.31 (2.42 to 11.66)	<0.0001	0%

OR = odds ratio, MD = mean difference

The Cochrane systematic review was of high methodological quality and compared bracing or bracing plus physiotherapeutic scoliosis specific exercises (PSSE) with observation, electrical stimulation or different types of brace in adolescents with idiopathic scoliosis.[8] A meta-analysis was not conducted because of heterogeneity in study design, comparators,

populations and braces applied. Study quality was assessed by the review authors using the Cochrane risk of bias tool for RCTs and the Newcastle Ottawa scale for observational studies. High or unclear risk of bias was found for most studies in relation to concealment of allocation and blinding of assessment for subjective outcomes.

Five RCTs and two prospective controlled trials (cohort studies) were included in the Cochrane review. One RCT failed completely when they were unable to recruit sufficient participants. One trial was continued as a cohort study when they could not recruit sufficient patients for randomisation, but reported both randomised and observational study results separately. The included studies incorporated a total of 662 adolescent participants. Mean age of study participants was approximately 12.5 years in all studies, except one that had a mean age greater than 14.0 years. In most studies the participants' Cobb angle was between 20° and 40°, apart from one study where Cobb angle ranged from 15° to 30° and another where the Cobb angle was greater than 45°. Duration of bracing and study follow up duration were not reported. Results from the systematic review are reported in *Table 3*. All outcomes were reported based on the results of single studies. GRADE (grading of recommendations, assessment, development and evaluations) strength of evidence was low or very low for all outcomes, meaning that the review authors had low confidence in the review findings and that results were deemed likely to change with the addition of future studies. All included studies consistently showed that bracing prevented curve progression. Two studies found that bracing did not change quality of life during treatment and did not change quality of life, back pain, and psychological or cosmetic issues in the long term (16 years follow up).

Table 3: results of a Cochrane systematic review comparing bracing or bracing plus PSSE with observation, electrical stimulation or different types of brace in adolescents with idiopathic scoliosis[8]

Outcome	n participants (n studies)	Findings (95% CI)	Quality of the evidence (GRADE)
Bracing versus observation (RCTs)			
Success rate (curves <50°; 2 years follow up)	116 (1)	RR 1.79 (1.29 to 2.5)	Low
Quality of life (PedsQL score; 2 years follow up)	111 (1)	MD -2.10 (-7.69 to 3.49)	Very low
Bracing versus observation (cohort studies)			
Success rate	242 (1)	RR 1.5 (1.19 to 1.89)	Very low

(curves <50°; 2 years follow up)			
Quality of life (PedsQL score; 2 years follow up)	236 (1)	MD 0.10 (-3.90 to 4.10)	Very low
Any adverse event (2 years follow up)	242 (1)	RR 1.27 (0.96 to 1.67)	Very low
Bracing plus PSSE versus observation in high degree curves (cohort studies)			
Success rate (no progression >50°, no fusion surgery, no waiting list for fusion)	57 (1)	RR 1.79 (1.04 to 3.07)	Very low
Rigid versus elastic brace (RCTs)			
Success rate (curves <50°; 4 years follow up)	43 (1)	RR 1.4 (1.03 to 1.89)	Low

MD = mean difference, RR = relative risk

Comparing fulltime and part-time bracing

Two systematic reviews and one systematic review with meta-analysis compared fulltime bracing with part-time or night-time bracing in adolescents with idiopathic scoliosis.[17-19] All three reviews have methodological limitations and incorporated observational studies of low methodological quality or high risk of bias. The results presented below should be interpreted with caution.

The systematic review with meta-analysis included 33 studies in the systematic review and 16 studies in the meta-analysis.[17] No studies were found that reported on part-time bracing other than night-time bracing. Patient characteristics other than the Cobb angle (mostly 25–40°) and Risser grade (range 0 to 4) were not presented in the review. Duration of treatment in the primary studies is unclear, with follow-up ranging from 1 to 10 years. The methodological quality of included studies was assessed by the review authors using the methodological index for non-randomised studies (MINORS) checklist and most studies were found to be of low quality and high risk of bias. The meta-analysis pooled the findings from studies that were rated as having a low risk of bias, many of which were non-comparative (*Table 4*). Heterogeneity in the meta-analyses was high which reduces confidence in the results. It is questionable whether it was methodologically appropriate to combine such heterogeneous studies in a meta-analyses or to compare brace success rates across non-comparative studies.

Table 4: pooled success rates for different bracing strategies in adolescents with idiopathic scoliosis[17]

Bracing strategy	n participants (n studies)	Success rate, % (95% CI)	I^2*
Fulltime rigid brace	779 (8)	73.2 (60.9 to 85.5)	90.1%
Night-time rigid brace	1,178 (7)	78.7 (72.4 to 85.0)	76.2%
Fulltime soft brace	349 (3)	62.4 (55.1 to 69.6)	79.1%

Success rate is defined in the meta-analysis as a Cobb angle progression ≤5° during follow up
*Heterogeneity in all analyses is high which reduces confidence in the results. It is questionable whether it was methodologically appropriate to combine such heterogeneous studies in a meta-analyses or to compare brace success rates across non-comparative studies.

Both systematic reviews included only comparative observational studies and presented the results for each study individually.[18, 19] There was little overlap of included studies between the two systematic reviews or between the reviews and the meta-analysis. The most recent systematic review included seven studies of low methodological quality.[19] No patient characteristics were presented in the review. Four studies examined the Charleston brace and three the Providence brace. Five studies found no differences in curve progression between fulltime and night-time bracing. Two studies found fulltime bracing to be superior for reducing curve progression. The review authors could not draw any conclusions based on these results because of the low methodological quality of the primary studies.

The second systematic review included nine comparative observational studies that were rated by the review authors as moderate to high quality using the Downs and Black criteria.[18] The primary study results were mixed and many studies referred to comparisons of specific brands of brace (three Charleston brace, three Providence brace and three other night-time braces). The authors concluded they could not definitively show that part-time bracing is as effective as fulltime bracing, but that part-time bracing could control curve progression and could potentially be used when patients stopped wearing their fulltime brace because of perceived negative effects of the fulltime brace on their quality of life and ability to engage in daily activities.

Ongoing trials

Seven ongoing RCTs in a population with AIS are exploring orthotic bracing as the intervention of interest. Details of the RCTs are presented in *Table 5*.

Table 5: ongoing RCTs on bracing in adolescents with idiopathic scoliosis

Trial ID	Population	Intervention and comparator(s)	Primary outcomes	Estimated completion date
NCT03825159	Age 10 to 17 with AIS	Brace v brace with an integrated system of electric surface stimulation and heat sensing	Change in Cobb angle; spine erectability; change in apical rotation	January 2023
NCT03978273	Age 9 to 16 with AIS	Night-time brace plus virtual brace v night-time brace only	Displacement of pressure centre	April 2023
NCT01761305	Age 9 to 17 with AIS	Hypercorrective night-time brace v scoliosis specific exercises v self mediated physical activity	Radiological progression of scoliosis; progression of Cobb angle >6°	December 2023
NCT04889339	Age 10 to 16 with AIS	Brace with growth modulation simulation v conventional brace	Change in Cobb angle	January 2024
NCT05001568	Age 10 to 16 with AIS	Optimised Providence brace v conventional Providence brace	Change in Cobb angle	January 2025
ISRCTN63247077	Age 10 to 15 with AIS	Boston fulltime brace v Providence night-time brace	Curve progression (Cobb angle)	February 2025
NCT04382638	Age 10 to 15 with AIS	Rigo Cheneau brace v Boston brace	Change in Cobb angle	September 2026
NCT04805437	Age 9 to 17 with AIS	3D printed Boston brace v standard Boston brace	Curve progression >6°	April 2037

Guideline recommendations

In 2016 SOSORT updated their guidelines on conservative treatments for scoliosis, including orthotic bracing.[7] The guidelines were updated to reflect the most recently published evidence based on a literature search in Medline, a manual search of conference abstracts and cross-checking reference lists of selected articles. The guidelines are aimed at health professionals, including specialty physicians and allied health professionals, as well as patients with scoliosis. Representatives from the relevant healthcare professions and

patients were involved in developing the guideline. A three round Delphi process was used to reach consensus on new or amended recommendations. The main limitation of the guideline is a lack of supporting tools for implementing the recommendations.

Recommendations in the guideline are assigned a 'strength of evidence' grade from level I to level VI. These strength of evidence levels appear to be based on the volume of published literature available, the study designs available to support the recommendation, or, in the case of levels V and VI, the degree of consensus among experts. Each recommendation was also assigned a 'strength of recommendation' grade from A to D:

A. Recommendation must be applied widely and to all patients with this specific need.
B. The recommendation is important, but does not have to be applied to all patients with this specific need.
C. The recommendation is less important and can be applied on a voluntary basis.
D. The recommendation is of very low importance.

In total, 26 recommendations on orthotic bracing were presented in the guideline (see *Appendix 2* for a complete list of recommendations). Seven recommendations were based on level I to II strength of evidence: published controlled trials (with or without randomisation) or systematic reviews and meta-analyses of these study types (*Table 6*).

Table 6: SOSORT guideline recommendations based on evidence strength levels I to III[7]

Recommendation	Strength of evidence	Strength of recommendation
'Bracing is recommended to treat AIS.'	I	B
'The use of bracing is recommended in patients with progressive idiopathic scoliosis above 25° during growth; in these cases PSSE alone (without bracing) should not be performed unless prescribed by a physician expert in scoliosis.'	I	B
'Bracing is recommended to treat patients with Cobb angles above 20° ± 5°, still growing (Risser 0 to 3), and with demonstrated progression of [curve] or elevated risk of treatment of spinal [curves].'	I	B
'It is recommended that braces are worn fulltime or no less than 18h per day at the beginning of treatment, unless otherwise justified in the opinion of a clinician specialised in conservative treatment of spinal [curves].'	II	B

'Since there is a "dose-response" to treatment, it is recommended that the hours of bracing per day are in proportion with the severity of [curve], the age of the patient, the stage, aim and overall results of treatment, and the achievable compliance.'	II	B
'It is recommended that daily brace wear is proportionate to the [curve] severity, age of patient, scoliosis stage, aim and overall results of treatment, and the expected compliance.'	II	B
'Bracing is recommended to treat juvenile and infantile idiopathic scoliosis as the first step in an attempt to avoid or at least postpone surgery to a more appropriate age.'	III	B

Strength of evidence: I = multiple RCTs or systematic reviews of such studies; II = one RCT; III = multiple controlled non-randomised studies or systematic reviews of such studies

Safety

Adverse events

The meta-analysis of seven controlled trials (n=751) described in the clinical effectiveness section included adverse events as an outcome (*Table 2*).[16] Adverse events were not defined by the meta-analysis authors. Based on the discussion section of the meta-analysis, adverse events associated with bracing appear to include pain, skin irritation, and lung and kidney dysfunction. Adverse events were statistically significantly more common in patients with AIS in the orthotic bracing group compared with patients under observation: OR 5.31, 95% CI 2.42 to 11.66, p<0.0001.

The Cochrane review described in the clinical effectiveness section reported adverse events from one cohort study comparing bracing with observation in patients with AIS (*Table 3*).[8] The relative risk (RR) of any adverse event at 2 years follow up was 1.27 (95% CI 0.96 to 1.67). The most commonly reported adverse event was back pain. The cohort study reported no statistically significant difference between the bracing and observation group: RR 0.72, 95% CI 0.47 to 1.10. The evidence quality for this outcome was assessed by the systematic review authors as being very low. One serious adverse event, hospitalisation for anxiety and depression, was reported in one patient who wore a brace. Adverse events involving the skin under the brace were reported for 12/146 (8%) of cohort study participants wearing a brace.

Back pain

Two primary studies, published after the literature search in the Cochrane systematic review described above, assessed back pain in patients with AIS and reached variable conclusions.[20, 21]

A cross-sectional study (n=987) explored the prevalence of back pain among adolescents with idiopathic scoliosis attending an outpatient clinic in Hong Kong (2016-2017).[21] Consecutive patients aged 10 to 18 years, who had a Cobb angle of at least 10° were invited to participate in the study. Duration of scoliosis treatment was not reported. Patients were asked to report back pain regardless of intensity or whether it occurred during activity or at rest. Participants filled in a series of questionnaires either on their own or with the help of their parent or guardian. The questionnaires covered back pain, depression, anxiety and stress, insomnia and daytime sleepiness. The study results may be affected by recall bias because patients reported on their experiences over the previous 12 months. Many of the questionnaires had not been validated in the study patient population. Medical and radiological information for each patient was extracted from their medical records by clinicians blinded to the results of the questionnaires.

Of the 1,116 patients approached, 88.4% (n=987, female=719, male=268) agreed to participate in the study. Participants had a mean age of 14.7 (SD 1.8) years and 90% of patients had a Cobb angle ≤40°. Female participants had a higher lifetime prevalence of back pain compared with male participants: OR 1.1, 95% CI 1.02 to 1.2, p=0.028. Twelve month prevalence of chronic thoracic pain was 6%, for low back pain it was 6%, and for any back pain it was 9%. After adjusting for confounding variables, factors associated with chronic back pain in patients with AIS included having a single scoliosis curve, wearing a brace, moderate depression, moderate to severe daytime sleepiness and older age (*Table 7*). After adjusting for confounders and using a categorical Cobb angle variable with a cutoff of 40°, risk factors for chronic back pain were thoracic Cobb angle >40°, moderate depression, moderate to severe daytime sleepiness, wearing a brace and being older (*Table 7*).

Table 7: risk factors associated with self reported chronic back pain in patients with AIS[21]

Factors	OR (95% CI)	p value
Unadjusted for Cobb angle		
Single scoliosis curve	3.85 (1.85 to 8.01)	<0.001
Wearing a brace	3.19 (1.56 to 6.52)	0.001
Moderate depression	2.49 (1.08 to 5.71)	0.032

Moderate to severe daytime sleepiness	2.17 (1.10 to 4.28)	0.025
Older age (per year)	1.24 (1.01 to 1.51)	0.036
Categorical Cobb angle variable with a cutoff at 40°		
Thoracic Cobb angle >40°	3.74 (1.45 to 9.66)	0.005
Moderate depression	3.74 (1.45 to 9.66)	0.004
Moderate-severe daytime sleepiness	2.39 (1.23 to 4.68)	0.011
Wearing a brace	3.00 (1.47 to 6.15)	0.003
Older age (per year)	1.25 (1.03 to 1.52)	0.025

OR = odds ratio; CI = confidence interval

Another cross-sectional study explored back pain prevalence and intensity among patients with AIS in Canada.[20] Consecutive patients aged 10 to 17 years, who had AIS, a Cobb angle of at least 10°, and attended an orthopaedic outpatient clinic in 2014–2015, were recruited for the study. Participants had a mean age of 14.2 (SD 1.8) years. No information is given about the type of brace worn or the duration of treatment. Participants completed the Brief Pain Inventory (BPI) and the Roland Morris Disability Questionnaire (RMDQ). The Cobb angle and the angle of trunk inclination were measured for each participant, and the history of bracing was determined through patient medical records. Age, gender, history of bracing and scoliosis severity were confounding factors adjusted for in the analyses. Five hundred patients agreed to participate in the study (74.6% of those invited). Approximately one third of participants had a history of bracing (n=181, 36.2%). Current back pain was reported by 68% of participants (n=340 of 500), most of whom described the pain intensity as mild. A history of bracing was associated with a statistically significant decrease in reported back pain intensity. For each scoliosis site, patients with a history of bracing reported less disability than patients who had not received bracing. Both back pain intensity and disability were positively associated with patient age and curve severity. Since the study was cross-sectional the authors were unable to determine if there were causal links between age, curve severity, bracing and back pain.

Risk factors for bracing failure

A systematic review with methodological limitations explored risk factors for bracing failure in patients with AIS.[22] Twenty-five studies were included in the systematic review. The authors did not provide any patient characteristics for the primary studies or assess the quality of the studies. Failure of orthotic bracing was defined as progression of the spinal curve, including progression to a Cobb angle >50° or to spinal surgery thresholds. Seven factors were repeatedly identified as being associated with failure of orthotic bracing (*Table*

8). The three risk factors most commonly cited were patients wearing the brace for less than 10 hours per day, low levels of skeletal maturity at the time of first bracing, and an initial Cobb angle >30°. The authors noted that there is still uncertainty about whether there is a cumulative effect if more than one risk factor applies to an individual.

Table 8: risk factors for failure of orthotic bracing (progression of the spinal curve)[22]

Risk factor	n studies
Wearing the brace for less than 10 hours per day	8
Low level of skeletal maturity at time of bracing	6
Cobb angle >30° at initial bracing	5
Vertebral rotation	4
Low levels of in-brace correction	3
Main thoracic curve	2
Osteopaenia	2
Pelvic tilt, spinopelvic inclination	1
BMI >85th percentile	1
Low BMI (underweight children)	1
Angle of the plane of maximal curvature, hypokyphosis, or torsion >5°	1
Vertebra wedging	1

BMI = body mass index; kyphosis = rounded upper back caused by spinal curve; vertebral wedging = the angle between the upper and lower endplates of a vertebra

Patient and social aspects

Factors leading to an unpleasant bracing experience

A primary study used quantitative and qualitative methods to explore factors contributing to an unpleasant bracing experience in a cohort of young people with AIS (n=17, aged 10 to 17).[23] Study participants completed three questionnaires: the SRS-22 quality of life questionnaire, the General Comfort Questionnaire (GCQ), and the Oswestry Disability Index (ODI). Fourteen study participants agreed to be interviewed with a series of open questions. One participant did not complete all of the study questionnaires.

Four participants were male, time since initiation of bracing therapy ranged from zero to 72 months and Cobb angle ranged from 12.8° to 47.8°. Participants scored lowest (that is, maximum discomfort) on the GCQ for the environmental and psychospiritual domains, suggesting that patients had concerns about external factors and circumstances, which affected their perception of their daily environment. On the SRS-22 questionnaire, patients scored lowest for satisfaction and self-image, suggesting that patients felt negatively about their appearance in the brace.

The two most commonly reported concerns among interviewees were appearance, and physical and psychological discomfort. Sixty-four percent of patients preferred wearing the brace at night rather than during the day, and 54% felt their body shape was 'bad, ugly, abnormal'. Wearing the brace at night was preferred because the patients were distressed by negative peer attitudes, there were difficulties with wearing the brace at school without help, and patients received critical comments about their physical shape during daytime wear. When asked about their primary concern about wearing a brace, 42% mentioned a negative perception of appearance, 33% cited inconvenience and 25% reported discomfort. The study authors concluded that the psychological burden associated with wearing a brace was the factor most likely to lead to a negative experience of bracing, not the corrective force of the brace or any associated physical discomfort.

Quality of life

A high quality meta-analysis of seven observational studies assessed quality of life in patients with AIS, treated with bracing or observation, using the SRS-22 questionnaire.[24] The review authors assessed the quality of the included studies using the Newcastle Ottawa scale and judged two studies to be moderate quality and five to be high quality. Participants in primary studies were mostly female (70–100% of participants). Age ranged from 10 to 18 years. The meta-analysis found there were statistically significant differences for SRS-22 scores in the domains of satisfaction with management and total score (*Table 9*). This suggests that patients with AIS undergoing bracing have a higher quality of life compared with AIS patients who are under observation or untreated. No statistically significant differences were found for any other domain in the SRS-22 questionnaire. These results

were consistent in sensitivity analyses that excluded one study at a time from the meta-analysis.

Table 9: quality of life scores in patients with AIS treated with bracing compared with observation[24]

SRS-22 domain	SMD in scores (95% CI)	p value	I^2 (%)
Pain	0.123 (-0.101 to 0.347)	0.282	53.40
Self-image and appearance	0.108 (-0.116 to 0.332)	0.334	29.30
Function and activity	0.202 (-0.022 to 0.425)	0.077	<0.01
Mental health	0.089 (-0.103 to 0.281)	0.365	3.90
Satisfaction with management	0.393 (0.127 to 0.659)	0.004	22.20
Total score without satisfaction	0.123 (-0.232 to 0.478)	0.497	<0.01
Total score	0.312 (0.04 to 0.571)	0.018	<0.01

SMD = standardised mean difference, CI = confidence interval

Psychological effects and body image

A moderate quality systematic review explored the association between AIS and mental health disorders.[25] The authors of the systematic review did not appraise the quality of the 30 included studies. Fifteen studies were cross-sectional, eight were prospective cohort studies, four were case control studies, one was a registered audit, one was a validation study and one was a clinical trial. The majority of primary study participants were female (0–41% male) and most participants had a Cobb angle between 20° and 40°. Age range of participants in primary studies was from 9 to 40 years. Nine studies reported on stress or anxiety, three studied depression, eight studied both anxiety and depression, four examined eating disorders, five studied personality disorders and two studied schizophrenia.

Nine studies indicated overall low to moderate stress levels amongst adolescents treated with bracing, surgery or physiotherapy. Three studies reported that bracing increased the level of stress compared with the stress caused by the scoliosis curve alone. One study showed a constant brace related anxiety among patients over a 12 month observation period. Another study examining both depression and anxiety, found 32% of patients with AIS exhibited significant psychological distress, regardless of treatment. A large epidemiological study found a 7% prevalence of mental health disorders in patients with AIS, the highest prevalence being for anxiety. Depressive symptoms were found to be more common amongst female patients than male patients in two studies. Severity of depression

was associated with duration of brace wear and severity of the main scoliosis curve. One cross-sectional study found that 7.3% of patients had probable major depressive disorder and 3.2% had severe anxiety. In the same study, 14.1% of parents of children with AIS had depression and anxiety, which may have an effect on their children's levels of distress.

Studies on eating disorders among patients with AIS reported variable results. One study found a significantly higher prevalence of eating disorders in patients with scoliosis compared with the general population. This study also reported a correlation between the severity of the scoliosis curve and the presence of anorexia nervosa. Another study found that more than half the patients studied had BMI scores within the range considered anorexic. In contrast, two studies found low prevalence of eating disorders in patients with AIS and that rates of anorexia were similar to the general population.

Two studies suggested higher neurotic personality traits were present in patients with AIS compared with the general population. In one study, bracing led to an increase in neurotic characteristics from 2% before bracing to 25% one month after starting treatment. The two studies evaluating an association between scoliosis and schizophrenia found a higher risk of schizophrenia among patients with idiopathic scoliosis compared with the general population (hazard ratio (HR) 1.52, 95% CI 1.03 to 2.23 in one study).

A moderate quality scoping review explored body image and body schema disorders in adolescents with idiopathic scoliosis.[26] The review examined whether AIS has an impact on body image and schema, whether body image and schema alterations are correlated with disease severity, and whether the mode of treatment affects body image and body schema. Participant age in the included primary studies ranged from 13.4 to 16.6 years. The review authors assessed study quality using six criteria they developed themselves. Two studies that failed to meet an arbitrarily set quality threshold score were excluded from the review. Twenty-seven studies were included in the review: 24 reported on altered body image perceptions and four reported alterations to body schema (one study reported both). Ten studies were cross-sectional, eight were prospective, four studies were retrospective, three were case control studies and two were RCTs. All of the included studies measured body image perception and body schema using questionnaires that were completed by the patients; it is likely that the results include subjectivity bias.

Alterations in self-perceptions of body image affecting patients with AIS were consistently reported in the primary literature that used the SRS-22 questionnaire. Three studies reported poorer body image in patients with severe scoliosis compared with patients with milder disease. Treatment effects on body image scores were variable. Two studies reported improved body image after surgery, one study found better body image scores in patients after surgery compared with bracing and physiotherapy, and five studies found no significant differences in scores among different treatment options. In one study, girls with

AIS and a BMI <18 had poorer body image compared with girls with AIS and a BMI >18 ($p<0.001$).

Body image assessed using other questionnaires found similar alterations in body image perception among patients with AIS. One study measuring body image perception using the Trunk Appearance Perception Scale (TAPS) questionnaire found that body image perceptions were better after physiotherapy alone than with bracing plus physiotherapy. Two other studies using different scoring systems found no significant differences in body image perceptions between patients receiving orthotic bracing compared with patients not undergoing bracing. Similarly, there were no significant differences in body image perceptions between patients who adhered to recommended brace wearing time compared with patients who wore their brace less often.

Fifteen studies assessed the correlation between perceived body image and disease severity or demographic characteristics. A negative correlation was found between curve severity and body image in seven out of ten studies. Of the eight studies assessing the correlation between age and body image perception, only one study found a significant difference that suggested body image perception worsened with age. One of two studies assessing the association between perceived body image and gender, found poorer body image perception in females. Finally, two studies found significant correlations between body image and trunk rotation angle or hump height.

Body schema alterations were measured indirectly in primary studies in the review by assessing perceptions of posture or verticality. One study found no significant differences in perception of verticality or posture between a group of patients with AIS and a healthy control group. In another study, there was a significant difference in perception of posture verticality compared with an age matched control group. Two studies assessed trunk misalignment awareness and general body perception. A significant difference was found between the subjective perception of trunk curvature and the objective measurement of trunk curvature, and an overall lower body awareness, in the AIS group compared with the age matched control group.

Adherence to prescribed bracing therapy

The potential for bracing therapy to be effective in the treatment of scoliosis is dependent on patients wearing the prescribed brace for the recommended period of time per day (adherence quantity) and at the recommended pressure (adherence quality).[27]

A multicenter trial (BRAIST, n=242), that included both a randomised and a preference cohort of patients, assessed the dose-response relationship between duration of daily brace wear and success of bracing therapy over a period of approximately 2 years.[28] Participants were aged 10 to 15 years, skeletally immature (Risser grade 0 to 2) and had a Cobb angle of

20° to 40°. The majority of participants (68%) assigned to the bracing arm of the trial were given a customised Boston brace. Temperature data (an indicator of brace wear) were available from 116 patients. The duration of brace wear was significantly positively associated with the rate of bracing success ($p<0.001$) as indicated by patients reaching skeletal maturity with a Cobb angle less than 50°. Wearing the brace for a mean of 0–6 hours per day was associated with a 41% success rate, whereas wearing the brace for an average of at least 12.9 hours per day was associated with success rates of 90–93%.

A low quality literature review explored factors that affected adherence to orthotic bracing therapy in adolescents with idiopathic scoliosis.[27] Seventeen studies (n=1,037) were grouped into six categories of factors affecting bracing adherence: type of brace (including structure and appearance); patient age; psychological aspects of brace wearing; night-time versus daytime wear; fulltime versus part-time wear, and the method of measuring adherence to bracing therapy (results from the primary studies are summarised in *Table 10*).

Involving patients in the design of braces may improve perceived appearance and increase their willingness to wear the brace. Patients in one study (n=10) reported that rigid braces made them feel hotter, were restrictive or made them feel ashamed. Other problems raised included heat rashes, rubbing on bony prominences (such as the hips) as a result of a poor fit, and braces limiting patients' choice of clothes. Younger patients generally wore their braces as prescribed compared with older patients. Adherence to brace wearing at night-time versus daytime was variable. Patients appeared to wear their brace more at night-time if they were concerned about the appearance of the brace during the day. Some patients were better at wearing their braces for the prescribed duration and at the prescribed pressure in family settings compared with when they were in social settings. Two studies found that providing advice to patients about their treatment, and how adherence to bracing therapy was measured, led to improvements in-brace wearing.

Table 10: primary study results from a systematic review on factors affecting adherence to orthotic bracing among patients with AIS[27]

n patients	Mean age (years)	Type of brace	Measure of adherence	Adherence (%)	Key findings
76	13	Milwaukee or Boston	Patients and family interview	65	Younger patients wore their braces as prescribed more than older patients. Adherence was greater at night-time than in daytime.
10	15	TLSO	Temperature monitor	65	Cosmetic appearance of the brace plays a major role in increasing patient adherence to treatment. Adherence was greater at night-time than daytime.
61	12	Wilmington	Temperature monitor	85 subjective 75 objective	Younger patients wore their braces as prescribed more than older patients. No significant difference in bracing adherence was found between fulltime and part-time brace wearing.
12	14.1	Boston	Pressure monitor	70	No significant difference between brace wear time and brace wear at prescribed pressure.
5	12.6	Boston	Smart orthosis	-	Smart orthosis increased patients' ability to wear the brace at the prescribed range of pressure levels.
9	14.2	Cheneau	Temperature monitor	67.5	Patients wore their brace for the recommended duration more at night-time. During the day, patients wore their brace at the correct pressure more often.
20	13.6	Boston	Pressure monitor	-	Adherence in daytime is more than at night-time.
12	13	SpineCor	Temperature monitor	54	Younger patients wore their braces as prescribed more than older patients.

					Adherence in daytime is more than at night-time.
10	11.6	TLSO	Wireless monitor (force transducer and wireless data)	60	Adherence in daytime is more than at night-time. As treatment progressed, patients wore their braces less often for the prescribed daily time but wore their braces at the correct pressure more often.
7	14.1	TLSO	Temperature monitor	65	Objective measurement of bracing adherence was underestimated compared with a subjective method.
21	12.4	TLSO	Temperature monitor	-	Providing knowledge about the treatment protocol and adherence monitoring increased bracing adherence.
45	12.6	TLSO	Log sheet and pressure monitor	-	Patients were less likely to wear their brace in social situations.
522	10.8	Milwaukee, Lyon or PASB	Patient and family interviews	61.1	The PASB group wore their braces as prescribed more than the other two bracing groups.
7	-	-	Pressure and temperature monitor	-	Adherence at night-time is more than in daytime.
171	12.3	TLSO	Temperature monitor	-	Providing knowledge about the treatment protocol and adherence monitoring increased adherence.
39	13	Boston	Patients interview	-	Patients were more likely to wear their brace as prescribed in family situations compared with social situations.
10	16.3	-	-	-	Appearance of the brace and cooperation with patients in the brace design process could increase adherence.

TLSO = thoracolumbar sacral orthosis, PASB = progressive action short brace

Other patient and social aspects

A cross-sectional study assessed the prevalence of bullying among children who attended an orthopaedic outpatient clinic in the US.[29] Children attending the clinic completed the Child-Adolescent Bullying Scale (CABS-9) questionnaire and answered questions about what orthopaedic devices they used, and what they thought about their condition and the devices they used. The children's parents completed a different questionnaire that included whether they felt their child was bullied.

The study recruited 198 patients aged 10 to 17 years. Thirty-six percent (n=72) of recruited patients reported experiencing moderate bullying and 3% (n=5) reported severe bullying. Of those with scoliosis, 33% percent reported moderate to severe bullying. Race and ethnicity were the only demographic characteristics that significantly correlated with bullying. Hispanic patients reported the highest rates of bullying, followed by white patients and Asian patients. Thirteen percent of patients who reported moderate or severe bullying stated that they were bullied specifically because of their condition. Twenty-three percent of children who reported bullying and used an orthopaedic device reported they were bullied because of the device. Moderate to severe bullying was significantly more common among children who felt they were made fun of because of their orthopaedic condition (p=0.0003), who felt other people noticed and commented on the way they moved or walked (p=0.004), and who said they were made fun of because of their orthopaedic devices (p=0.003). Moderate to severe bullying was reported by 40% of patients wearing a brace or orthotic. Parental concern was highly correlated with their child's bullying score (p=0.0002); 12% of parents reported their child being bullied because of their orthopaedic condition compared with 6% of the children.

Another study explored the information needs of adolescents with idiopathic scoliosis and their parents or carers using a national survey in the UK.[30] The survey consisted of 18 questions and was posted for 6 months on the Scoliosis Association UK and NHS Choices websites. Results were received from 44 different postcode areas around the UK. Eighty-three people completed the survey: 48 (58%) patients with AIS and 35 (42%) parents or carers of patients with AIS. Seven patients were male. Mean age of respondents with scoliosis was 13.3 ± 1.9 years and time since first referral to a hospital clinic ranged from 0–6 months to 3 years.

The most frequently reported information needs related to treatment options, what would happen next and the effect of the condition on the child in later life. Free text responses centred around the effects of scoliosis on the child's current activities. Sixty-five percent of respondents had received some information about scoliosis and 67% of them reported being satisfied or very satisfied with the information they received. All of the patients who reported they were unsatisfied with the information they received sought additional information from the internet, as did 77% of respondents who were satisfied with the

information they had received. Respondents' views on how useful information on the internet was varied from finding it helpful to worrying, frightening or confusing. Some respondents felt there was not enough information provided by the NHS about the full range of treatment options available to them or their children, and some parents felt they were left with the responsibility to explain the information to their child. There was an overall sense among respondents that more patient information was needed. Suggestions included providing information tailored to a child's particular stage of scoliosis or age, providing information about all possible treatment options and producing written information that could be taken away.

Cost effectiveness

One study from the US assessed the cost effectiveness of bracing compared with observation in adolescent skeletally immature patients with scoliosis.[31] The analysis incorporated a life-time horizon decision tree (69 years). Baseline characteristics of the patient cohort were: age 10 years; Risser grade 0; Sanders class 3 (intra-articular calcaneal fractures classification); Lenke class 1 (classification system for scoliosis type) and a 35° Cobb angle. All costs and effects were discounted at a 3% annual rate.

The clinical efficacy estimates for the model came from a US clinical trial (BRAIST)[28] that comprised a randomised and a preference based cohort, where treatment success was defined as reaching skeletal maturity without spine curvature progressing to or exceeding 50° (the cutoff point for surgery). The success rates for the treatment strategies (72% for bracing and 48% for observation) were applied at the start of the model. A successful treatment strategy is one that does not require surgery in adolescence but may require surgery in adulthood. The rate of adult surgery (3% for bracing and 13% for observation) came from a longitudinal observational study with a minimum of 20 years follow up.[32] Patients who undergo surgery are at risk of infection (1.5% adolescents and 5.2% adults), neurologic complications (0.32% adolescents and 7.5% adults) or revision surgery (8% adolescents and 19.3% adults). No differences in surgical complication rates between comparators was assumed. Only postoperative mortality was included in the model (0.3% adolescents and 0.4% adults). Non-operative treatment was also associated with complications such as chronic back pain (19% for bracing and 15% for observation).

For the purpose of calculating costs and effects associated with long term events, a specific point in time was selected for these events to occur. Patients who experienced the event were assumed to develop chronic back pain at age 46 years, undergo adult surgery at age 56 years, experience infection 12 months following surgery and receive revision surgery 2 years after initial surgery.

The costs in the analysis included: custom design bracing, maintenance and professional provider fees ($8,000 [approximately £6,758]); non-operative treatment such as physical consultations, physiotherapy and radiography ($950 [approximately £803] annually); surgical intervention ($68,900 [approximately £58,204]); treatment of infections ($33,705 [approximately £28,473]); the annual cost of chronic incomplete thoracic spinal cord injury for patients who develop neurologic complications ($16,792 [approximately £14,185]); and the cost of chronic back pain treatment ($950 [approximately £803] annually).

Health-related quality of life data in the model were obtained from several sources. Non-complicated treatments during adolescence were associated with general population age-dependent utility norms, based on the SF-6D UK value set. Utility weights associated with adult surgery (0.606), chronic back pain (0.658) and postoperative complications (0.68 to 0.73) were sourced from the published literature by the study authors.

Base case results were derived from a Monte Carlo simulation with 1,000 iterations. The total lifetime costs associated with observation were $85,279 [approximately £72,040] (± $4,543 [approximately £3,838]) and $60,377 [approximately £51,004] (± $5340 [approximately £4,511]) for bracing. Total QALYs in the observation arm were 23.9 (± 1.8) and 24.1 (± 2.0) in the bracing arm. These results suggest that bracing is the dominant treatment strategy. In other words, bracing was found to be more effective (+0.22 QALYs) and cost less (-$24,903 [approximately £21,037]) compared with observation in adolescent patients with thoracic scoliosis.

Base case results are driven by the high cost of spinal fusion surgery, which is more prevalent in the observation arm (52%), whereas only approximately a third of patients (28%) in the bracing arm were modelled to undergo adolescent surgery. The associated cost of bracing ($8,000 [approximately £6,758]) is relatively low when compared with the cost of surgery and is not considered a major driver.

Costs in Scotland

The cost of complex, instrumented correction of spinal curvature (surgery) in the UK, reported in the NHS England reference costs, ranges between £18,974 and £32,528 depending on the level of complexity and comorbidity.[33] The majority of surgeries have low complexity and comorbidity scores, and the likely cost of the procedure is approximately £19,000 (healthcare resource group (HRG) code: HC51 (A-E)). This is substantially lower (-67%) than the cost of surgery in the US, reported in the economic analysis as $68,900 (£58,204).

The annual cost of bracing in the US economic analysis was $8,000 (£6,758) and included custom design, maintenance and professional provider fees. The cost of each custom-made Boston brace at the Edinburgh specialist centre in Scotland is approximately £820 (£659 to

£1,012), including materials (£132 (16%)) and staff time (hospital Agenda for Change band 4 and band 6[34] for brace manufacture, revision and repair £688 (84%)). Additional annual healthcare resource use includes two consultant led appointments, two x-rays and one magnetic resonance imaging (MRI) scan at an annual cost of approximately £531 per brace.

A fitted brace can last between 3 and 12 months which equates to an average of 2.1 (ranging 1 to 4) braces annually per patient. This makes the approximate annual cost of braces in NHSScotland £1,708 (£659 to £4,046), which is lower (-75%) than the cost in the US. Including the additional healthcare resource use, the approximate annual cost of the bracing pathway in NHSScotland is £2,814 (ranging £1,190 to £6,169) per patient (Ms R Adam and Ms K Sutters, Orthotists, NHS Lothian. Personal communication 14 October 2022). The custom-made braces at the Glasgow specialist centre also include a thermal sensor (iButton®) at an approximate cost of £101 per unit. This sensor has a 10 year life span and can be used multiple times, yielding a negligible cost per brace (Mr M Dixon, Paediatric Orthotic Service Lead, NHS Greater Glasgow and Clyde. Personal communication 17 October 2022).

The effects of bracing on quality of life in adolescents was not included in the US economic analysis. Factors such as appearance, configuration and mental health have been previously reported to affect the quality of life of brace wearers (see patient aspects section of this report).[35] Conditional on the relative efficacy of bracing in the US clinical study being observed in Scottish clinical practice, bracing is likely to be a cost effective treatment for adolescents with scoliosis as a result of its potential to avoid or postpone expensive surgical interventions.

Conclusion

Based on a meta-analysis and a Cochrane systematic review, orthotic bracing appears to be more effective than observation in reducing spinal curve progression in patients with AIS. Quality of life results were variable: two meta-analyses found quality of life to be better in patients undergoing bracing for AIS compared with observation, but two studies in the Cochrane systematic review found no statistically significant differences in quality of life between these two interventions. No secondary evidence was identified that compared bracing with any other active intervention.

A systematic review that did not present patient characteristics or assess study quality, described three main risk factors associated with failure of bracing: patients not wearing their brace for the prescribed time and pressure, low levels of skeletal maturity at time of first bracing, and a Cobb angle >30° at initial bracing. This suggests efforts to support patients to wear their brace as prescribed may improve the effectiveness of bracing therapy. Treatment adherence rates were affected by patient age, the type and fit of the

brace, patient perceptions of the appearance of the brace and whether the patient wore the brace at night-time or during the day. Using temperature or pressure monitoring could aid clinicians in determining patient adherence to brace wearing, allowing them to provide additional support for patients who are not wearing their brace as prescribed. Other patient aspects reported in the literature include the negative impact of AIS and bracing on patients' mental health (stress, anxiety and depression), a poor view of self-image and negative alterations to body schema.

The most common adverse event reported in relation to bracing was back pain. Two studies reported no statistically significant differences in back pain in patients with AIS treated with bracing compared with observation. One study found that bracing increased the prevalence of back pain in patients with AIS. Another study found a protective effect of bracing in patients with AIS, who had lower back pain intensity and less disability compared with patients not treated with bracing. It is therefore uncertain what effect bracing has on back pain in patients with AIS.

Based on a single study from the US, bracing in patients with AIS appears to be a cost-effective treatment option, generating more QALYs at a lower cost compared with observation. The high cost of spinal surgery is a significant factor affecting the cost effectiveness of bracing, which is based on an assumed reduction in the need for surgery in patients treated with bracing.

Scotland-specific bracing and surgery costs are suitably similar in proportion to the costs described in the US study and local analysis may not change the estimated life-time incremental costs presented in the published economic model. The approximate annual cost of the custom-made bracing pathway in NHSScotland is £2,814 (range £1,190 to £6,169) per patient with idiopathic scoliosis.

There are a number of limitations to the evidence available on orthotic bracing in patients with AIS. Firstly, there are only a small number of RCTs which is partly a result of parents refusing to allow random treatment allocation of their children. Secondly, there is considerable heterogeneity between studies caused by variation in populations, brace types and wear patterns, comparators, outcomes, and duration of treatment and follow up. This heterogeneity prevents the use of meta-analysis to address some of the questions on bracing for treating AIS.

Identified research gaps

Further studies, particularly randomised controlled or controlled clinical trials, comparing bracing with other active interventions would be beneficial. For example, studies comparing different types of brace, comparing bracing with PSSE or comparing bracing with surgery. These studies should clearly define and preferably standardise their outcome measures.

Economic evaluations comparing bracing with other treatments, that take an NHS perspective, would also be helpful in determining cost effectiveness of bracing in patients with AIS in Scotland.

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Appendix 1: Abbreviations

AIS	adolescent idiopathic scoliosis
BMI	body mass index
BPI	brief pain inventory
CABS	child-adolescent bullying scale
CCT	controlled clinical trials
CI	confidence interval
GCQ	general comfort questionnaire
GRADE	grading of recommendations, assessment, development and evaluations
HR	hazard ratio
HRG	healthcare resource group
MD	mean difference
MINORS	methodological index for non-randomised studies
MRI	magnetic resonance imaging
ODI	Oswestry disability index
OR	odds ratio
PASB	progressive action short brace
PSSE	physiotherapy scoliosis specific exercises
QALY	quality adjusted life years
RCT	randomised controlled trial
RMDQ	Roland Morris disability questionnaire
RR	relative risk
SF	short form
SHTG	Scottish Health Technologies Group
SMD	standardised mean difference
SNSS	Scottish National Spine Service
SOSORT	Scientific Society on Scoliosis Orthopaedic and Rehabilitation Treatment
SRS	Scoliosis Research Society
TAPS	trunk appearance perception scale

TLSO	thoracolumbar sacral orthosis
UK	United Kingdom
US	United States

Appendix 2: SOSORT guideline recommendations

The table below lists the full set of 26 recommendations relating to orthotic bracing in the 2016 SOSORT guidelines.[7]

Recommendation	Strength of evidence	Strength of recommendation
'Bracing is recommended to treat adolescent idiopathic scoliosis.'	I	B
'The use of bracing is recommended in patients with progressive idiopathic scoliosis above 25° during growth; in these cases PSSE alone (without bracing) should not be performed unless prescribed by a physician expert in scoliosis.'	I	B
'Bracing is recommended to treat patients with Cobb angles above 20° ± 5°, still growing (Risser 0 to 3), and with demonstrated progression of [curvature] or elevated risk of treatment of spinal curves.'	I	B
'It is recommended that braces are worn fulltime or no less than 18h per day at the beginning of treatment, unless otherwise justified in the opinion of a clinician specialised in conservative treatment of [scoliosis].'	II	B
'Since there is a "dose-response" to treatment, it is recommended that the hours of bracing per day are in proportion with the severity of [curve], the age of the patient, the stage, aim and overall results of treatment, and the achievable compliance.'	II	B
'It is recommended that daily brace wear is proportionate to the [curve] severity, age of patient, scoliosis stage, aim and overall results of treatment, and the expected compliance.'	II	B
'Bracing is recommended to treat juvenile and infantile idiopathic scoliosis as the first step in an attempt to avoid or at least postpone surgery to a more appropriate age.'	III	B
'Casting (or rigid bracing) is recommended to treat infantile idiopathic scoliosis to try stabilising the curve.'	IV	B

‘Very hard rigid bracing (casting) is recommended to treat patients with curve between 45° and 60° to try avoiding surgery.’	IV	C
‘It is recommended that each treating team provide the brace that they know best, which means the brace they are more experienced and with perceived outcomes. This is due to the actual knowledge; there is no brace that can be recommended over the others.’	IV	C
‘It is recommended that the wearing time of the brace is gradually reduced, while performing stabilising exercises, to allow adaptation of the postural system and maintain results.’	IV	B
‘It is recommended that any mean is used to encourage compliance, including a careful adherence to the recommendations defined in the SOSORT Guidelines for Bracing Management.’	IV	B
‘It is recommended that quality of the brace is checked through an in-brace x-ray.’	IV	B
‘It is recommended not to apply bracing to treat patients with curves below Cobb angle 15° ± 5°, unless otherwise justified in the opinion of a clinician specialised in conservative treatment of [scoliosis].’	V	B
‘It is recommended that braces are worn until the end of vertebral bone growth and then the wearing time is gradually reduced, unless otherwise justified in the opinion of a clinician specialised in conservative treatment of [scoliosis].’	V	B
‘It is recommended that compliance to bracing is regularly checked through compliance monitor devices.’	V	B
‘It is recommended that bracing is applied by a well-trained therapeutic team, including a physician, an orthotist and a therapist, according to the criteria defined in the SOSORT Guidelines for Bracing Management.’	V	B
‘It is recommended that all the phases of brace construction (prescription, construction, check, correction, follow up) are carefully followed for each	V	B

single brace according to the criteria defined in the SOSORT Guidelines for Bracing Management.'		
'It is recommended that the brace is specifically designed for the type of the curve to be treated.'	V	B
'It is recommended that the brace proposed for treating a scoliotic [curve] on the frontal and horizontal planes should take into account the sagittal plane as much as possible.'	V	A
'It is recommended to use the least invasive brace in relation to the clinical situation, provided the same effectiveness, to reduce the psychological impact and to ensure better patient compliance.'	V	A
'It is recommended that braces do not so restrict thorax excursion in a way that reduces respiratory function.'	V	B
'It is recommended that braces are prescribed, constructed and fitted in an outpatient setting.'	V	B
'It is recommended that braces are regularly changed according to growth and/or specific pathological needs as judged by a scoliosis expert physician.'	V	B
'It is recommended that out of brace x-rays are regularly performed to check the effectiveness of bracing treatment: the number of hours out of brace before x-ray taking should correspond to the daily weaning time.'	V	B
'It is recommended that the prescribing physician and the constructing orthotist are experts according to the criteria defined in the SOSORT Guidelines for Bracing Management.'	VI	C

Strength of evidence: I = multiple RCTs or systematic reviews of such studies; II = one RCT; III = multiple controlled non-randomised studies or systematic reviews of such studies; IV = other studies; V = SOSORT consensus with more than 90% of agreement; VI = SOSORT consensus with 70 to 89% of agreement

Strength of recommendation: A = it must be applied widely and to all patients with this specific need; B = it is important, but does not have to be applied to all patients with this specific need; C = less important, it can be applied on a voluntary basis; D = very low importance.

Appendix 3: Summary evidence tables

Systematic review evidence table

Study	Population	Intervention	Comparator	Findings from study abstract
Bertuccelli (2022)[26]	n=1,876 (27 studies) AIS; mean age range 13.4 to 16.6	Body image and schema measurement tools eg SRS-22.		Body image disorders were reported, with more severe scoliosis cases showing higher body image dissatisfaction. Studies did not reveal clear associations between clinical measures of scoliosis severity and body image. Disorders of body schema have been reported in four studies.
Costa (2021)[17]	33 studies (16 in meta-analysis) AIS; Cobb angle 24–40°	Rigid fulltime bracing, rigid night-time bracing, soft fulltime bracing.	Rigid fulltime bracing, rigid night-time bracing, soft fulltime bracing.	In the meta-analysis, the rigid fulltime brace had on average a success rate of 73.2% (95% CI 61% to 86%), night-time of 78.7% (95% CI 72% to 85%), soft braces of 62.4% (95% CI 55% to 70%), observation only of 50% (95% CI 44% to 56%). [Observational data taken from two historical cohort studies] There was insufficient evidence on part-time wear for a meta-analysis. No significant difference in outcomes between the night-time or fulltime concepts could be identified. Soft braces have a lower success rate compared to rigid braces.
El Hawary (2019)[22]	25 studies AIS			Seven risk factors for bracing failure were identified: poor brace compliance, lack of skeletal maturity, Cobb angle over a certain threshold, poor in-brace correction, vertebral rotation, osteopaenia and thoracic curve type. Three risk factors were highly repeated in the literature as having a much higher risk to fail brace treatment and to progress to surgery. This data demonstrates that 60% to 70% of the patients referred to bracing are Risser 0 and 30% to 70% of this group will not wear the brace enough to ensure treatment efficacy. Furthermore, Risser 0

				patients who reach the accelerated growth phase with a curve ≥40° are at 70% to 100% risk of curve progression to the surgical threshold despite proper brace wear.
Karimi (2019)[18]	n=526 (9 studies) AIS; Risser grade 0–2	Part-time or night-time bracing (Providence or Charleston).	Fulltime bracing.	Part-time bracing is recommended mostly for single curves with severity less than 35°. It cannot be concluded definitely that the effectiveness of part-time bracing is the same as that of fulltime bracing. However, it seems that part-time braces can be used to control the progression of scoliosis curves and can be used instead of fulltime braces if fulltime brace wear is stopped.
Meng (2017)[24]	n=640 (7 studies) AIS; 70–100% female; age 10–18 years.	Bracing. [May be in patients who then had surgery.]	Observation or no treatment.	There was no significant difference in pain (SMD 0.123, 95% CI -0.101 to 0.347, p=0.282), self image and appearance (SMD 0.108, 95% CI -0.116 to 0.332, p=0.334), mental health (SMD 0.031, 95% CI -0.130 to 0.201, p=0.365), function and activity (SMD 0.202, 95% CI -0.022 to 0.425, p=0.077), and total score without satisfaction (SMD 0.123, 95% CI -0.232 to 0.478, p=0.497) between the untreated (observation) and brace treated AIS patients, whereas a significant difference was observed in satisfaction with management (SMD 0.393, 95% CI 0.127 to 0.659, p=0.004) and total score (SMD 0.312, 95% CI 0.054 to 0.571, p=0.018) between the two groups.
Mitsiaki (2022)[25]	30 studies Idiopathic scoliosis; 0–41% male; overall Cobb angle 20–40°	Any treatment plus assessment of mental health.	Control group; surgery; observation.	Studies highlighted the association of brace treatment with elevated anxiety. In addition, mental health conditions and traits (eg anxiety and depressive symptoms, neuroticism) were detected more frequently amongst AIS patients compared to healthy controls.
Negrini (2015)[8]	n=662 (7 studies)	Orthotic braces including elastic	Observation, observation or	There was very low quality evidence from one small RCT (n=111) that quality of life during treatment did not differ significantly

	AIS; mean age approx. 12.5 years; Cobb angle mostly 20-40°	banding, rigid (polyethylene) braces, and very rigid (polycarbonate) thoraco-lumbosacral orthosis. Bracing plus PSSE.	electrical stimulation, different type of braces.	between rigid bracing and observation (MD -2.10, 95% 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 quality of life, 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, n=116; 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, n=47; 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, n=242; RR 1.50, 95% CI 1.19 to 1.89) and at three years' follow up (one study, n=240; RR 1.75, 95% CI 1.42 to 2.16). There was very low quality evidence from a prospective cohort study (n=57) 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°) (RR 1.79, 95% CI 1.04 to 3.07 in the intention to treat 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 (n=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 (n=12) 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 (n=236) 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).
Rahimi (2020)[27]	n=1,033 (17 studies) AIS; mean age range 10.8 to 16.3	Bracing.		The results demonstrated that the type of braces determines structure and appearance, and affects compliance. Psychological aspects, age, brace wear pattern (daytime or night-time or part-time versus fulltime) and the assessment method (using temperature versus pressure sensors) can affect recorded compliance.
Ruffilli (2021)[19]	n=850 (7 studies) AIS; >10 years old	Night-time bracing (Charleston or Providence).	Fulltime TLSO bracing.	Five out of seven studies reported no differences in curve progression between traditional fulltime bracing and night-time braces and the remaining two studies reported fulltime bracing to be superior. The authors concluded that they could not draw conclusions about night-time braces because of the low methodological quality of included studies.
Zhang (2019)[16]	n=751 (7 studies) AIS; mean age range 9.3 ± 1.7 to 15.58 ± 3.4. Majority of patients were female.	Bracing.	Observation.	The results of the meta-analysis suggested significant differences between bracing and observation groups in successful outcomes (OR 3.58, 95% CI 1.92 to 6.68, p<0.0001, I^2=65%), quality of life (MD 2.13, 95% CI 0.51 to 3.75, p=0.01, I^2=0%), and adverse events (OR 5.31, 95% CI 2.42 to 11.66, p<0.0001, I^2=0%).

Observational studies data table

Short Title	Population	Intervention	Comparator	Findings
Carrillo (2021)[29]	n=198 Age 10–17 and parents; attended an outpatient orthopaedic clinic in the US	Child-Adolescent Bullying Scale (CABS-9) and parent questionnaire.		61% (n=121) perceived no-to-minimal exposure to bullying, 36% (n=72) moderate exposure, and 3% (n=5) severe exposure. Children ages 10 to 13 (n=100) and children ages 14 to 17 (n=98) reported similar rates of bullying (p=0.97). Higher rates of moderate to severe bullying were reported by patients with foot deformity (80%), multiple orthopaedic diagnoses (55%), chronic pain (39%), fracture or acute injury (37%), and scoliosis (33%). Moderate to severe bullying was reported by 37% of patients who wore a cast, 40% who wore a brace or orthotic, and 52% who used multiple orthopaedic devices. Parental concern that their child was being bullied was highly correlated with their child's bullying score (p=0.0002).
Theroux (2017)[20]	n=500 AIS; mean age 14.17 ± 1.81; minimum Cobb angle 10°; attended an orthopaedic outpatient clinic in Canada	Brace.		Spinal pain prevalence was 68% (95% CI 64.5 to 72.4) with a mean intensity of 1.63 ± 1.89. Spinal pain intensity was positively associated with scoliosis severity in the main thoracic (p=0.003) and lumbar (p=0.001) regions. The mean disability score was 1.73 ± 2.98. Disability was positively associated with scoliosis severity in the proximal thoracic (p=0.035), main thoracic (p=0.000), and lumbar (p=0.000) regions.
Wang (2022)[23]	n=17	Rigid orthotic bracing, measurement of brace pressure		Our survey reveals that participants scored the lowest in the domains of environmental factors, psychospiritual factors, satisfaction and self image. Appearance anxiety, physical and psychological discomfort and inconvenience were the three

	AIS; age 10–17; treatment duration 0–72 months; Cobb angle 12.8° to 47.8°; Chinese			most frequently mentioned problems in the interviews on participants' daily bracing experiences. A significant, moderately positive relationship between corrective force and discomfort level was found only when participants were lying on their left side, but not in any of the other positions. No significant correlation between treatment length and perceived discomfort was found.
Wong (2019)[21]	n=987 AIS; mean age 14.7 ± 1.8; Cobb angle 11–20° (28%), 21-30° (44%), 31–40° (18%), 41° or above (10%); attended an outpatient scoliosis clinic in Hong Kong	Bracing.		Depending on the types of period prevalence, the prevalence of thoracic pain ranged from 6% (55 of 987) within 12 months to 14% (139 of 987) within 7 days, whereas that of low back pain ranged from 6% (54 of 987) to 29% (289 of 987). Specifically, chronic thoracic pain or low back pain had the lowest prevalence. Compared with the no pain group, patients with current back pain had more severe insomnia (OR 1.80, 95% CI 1.10 to 2.93, p=0.02) and daytime sleepiness (OR 2.41, 95% CI 1.43 to 4.07, p<0.001). Those with chronic back pain had the same problems along with moderate depression (OR 2.49, 95% CI 1.08 to 5.71, p=0.03). Older age (OR range 1.17 to 1.42; all p values <=0.030) and Cobb angle >40° (OR range 2.38 to 3.74; all p values <=0.015), daytime sleepiness (OR range 2.39 to 2.41, all p values <=0.011), and insomnia (OR range 1.76 to 2.31, all p values <=0.001) were associated with episodic and/or chronic back pain. Females were more likely to experience back pain in the last 12 months than males. Moderate depression (OR 3.29, 95% CI 1.45 to 7.47, p=0.004) and wearing a brace (OR 3.00, 1.47 to 6.15, p=0.003) were independently associated with chronic back pain.

AIS = adolescent idiopathic scoliosis, OR = odds ratio, CI = confidence interval

Cost effectiveness data table

Short Title	Population	Intervention	Comparator	Findings
Ikwuezunma (2021)[31]	AIS; skeletally immature (Risser 0); age 10, 35° main thoracic curve	Bracing	Observation	The decision-analysis model revealed that bracing was the dominant treatment choice over observation at $50,000 per QALY willingness to pay threshold. In simulation analysis of a hypothetical patient cohort, bracing was associated with lower net lifetime costs ($60,377 ± $5,340 with bracing vs. $85,279 ± $4,543 with observation) and higher net lifetime QALYs (24.1 ± 2.0 with bracing vs. 23.9 ± 1.8 with observation). Bracing was associated with an incremental net monetary benefit of $36,093 (95% CI $18,894 to $55,963) over observation over the patient's lifetime. The model was most sensitive to the impact of bracing versus observation on altering the probability of requiring surgery, either as an adolescent or an adult.

QALY = quality adjusted life-year, INMB = incremental net monetary benefit