Review of current technologies and methods supplementing brace treatment in adolescent idiopathic scoliosis

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Abstract

Purpose To report on the current technologies and methods supplementing brace treatment in adolescent idiopathic scoliosis.

Methods A comprehensive literature review was performed to determine the effectiveness of bracing, to report on imaging techniques that can assist in the assessment of bracing, to understand the roles of the biomechanical treatment concepts on bracing and to address the importance of the quality of life of the brace wearers.

Results The effectiveness of bracing still remains controversial. Many technologies are still in development to improve the bracing process and quantify the effects of bracing. Imaging techniques with decreased or no radiation are promising in providing more frequent data on curve progression for patients. Computer-assisted design models have been used for both fitting and manufacturing the brace to patient contours. Ultrasound has been developed as a new means of diagnosing scoliosis and determining the effects of a brace on a patient's spine in real time. The brace treatment outcomes are correlated to the quantity and the quality of brace usage. Compliance monitors and force sensors have been developed to track the quality of brace

usage. Improvements to brace wear also require consideration of patient quality of life. Surveys have been developed to describe the effects of family influence and self-image on bracing effectiveness of patient quality of life.

Conclusions Bracing remains a highly qualitative process, relying on the empirical judgment of the physicians and orthotists, along with buy-in with the patient. The suggested improvements will help to push bracing into a more evidence-based practice.

Keywords Adolescent idiopathic scoliosis · Bracing · Compliance monitors · Scoliosis imaging · Quality of life

Introduction

Scoliosis is a 3d spinal deformity involving lateral deviation of the vertebrae and axial rotation [1]. The most common form is adolescent idiopathic scoliosis (AIS), usually diagnosed or detected during the pubertal growth spurt at ages 10–14 years without an identifiable cause affecting 2–3 % of adolescents [2, 3]. While mild scoliosis is often asymptomatic, the spinal curvature may increase, resulting in back pain, reduced mobility and decreased pulmonary function [4].

The International Scientific Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT) recommends brace treatment for curves that are likely to progress [5]. The Scoliosis Research Society (SRS) also recommends bracing for a certain severity of curves but continues to study bracing intensely and has produced guidelines on inclusion and evaluation criteria for bracing studies [6]. The Boston brace also has guidelines for the prescription and sizing of braces [7]. Brace effectiveness remains controversial and is an important area of study for

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both organisations. In spite of decades of research, only two trials have been completed that were deemed acceptable by The Cochrane Collaboration for producing the best evidence for health care [8]. One showed low-quality evidence that bracing alters the natural history of scoliosis and another study showed that rigid braces have slightly better efficacy over soft braces [9, 10]. Still, while no definitive randomised control trials have been done on brace treatment, myriads of other studies with lower quality of evidence have demonstrated that bracing alters the natural history of scoliotic progression.

The central goal of brace treatment is to prevent curve progression during the high-risk period of the adolescent growth spurt [11]. With less curve progression, spinal pain syndromes can be treated and the patient's torso aesthetics may be improved [12]. Because physically detrimental effects of scoliosis involving pulmonary disease usually only occur with extremely severe scoliosis, aesthetics is considered to be the main objective of preventing curve progression with a brace [12].

While bracing has been shown to have efficacy in minimising curve progression, little is known about how a brace actually works. The current literature postulates that, by applying forces on the torso, correction may be achieved via two mechanisms: a passive component where forces physically push the apex of the curve back into position and an active component with the patient pulling their body away from pressure pads in the brace [13]. Patient compliance and quality of life also remain major hindrances to effective treatment. The purpose of this review article is to discuss the methods and technologies currently being developed that may help clarify these issues and improve the brace treatment process.

Bracing for scoliosis

The brace management of scoliosis usually involves three stages: diagnosis, brace fitting and follow-up assessment. Scoliosis is diagnosed with a Cobb angle of greater than 10° on a postero-anterior or antero-posterior radiograph of the patient's spine. Typically, a curve with a larger Cobb angle is more likely to progress and treatment is more strongly indicated [14]. A brace is typically considered when there is demonstrated progression of the curve to beyond 20° Cobb angle in an adolescent who has considerable growth remaining. Fitting involves prescription by a spinal surgeon, construction by an orthotist and an iterative checking/correcting and follow-up process to maximise in-brace correction [15]. After proper fitting, follow-up occurring every 3–6 months to monitor patient growth, curve correction and compliance is recommended [15]. The main purposes of follow-up are to monitor and address

compliance issues, ensure the brace is continuing to be effective and to determine if brace modifications are necessary in this critical time period of rapid spinal growth. Weaning is usually recommended at skeletal maturity, which is determined with a Risser sign of 4 and more than 12 months post-menarche or no documented growth height [16]. Skeletal maturity is considered to be achieved when there is a change in standing height in 6 months of less than 1 cm. Patients are recommended to be followed up for at least 1–2 years after the completion of treatment [17].

Guidelines for bracing studies

The SRS has defined guidelines for any study attempting to determine the effectiveness of brace treatment [6]. Inclusion criteria include patient age 10 years or older when prescribed a brace, Risser sign 0–2, primary curvature 25–40°, no prior treatment for scoliosis and, if female, either pre-menarcheal or less than 1 year post-menarcheal. All patients need a minimum of 2 years follow-up after skeletal maturity, noting whether surgery was recommended or required for these patients [6]. The assessment of brace effectiveness needs to include a comparison of the progressive group with non-progressive groups and to set threshold levels defining progression:

- Non-progressive: patients who have 5° or less of progression
- Progressive: patients with 6° or more of progression, patients progressed beyond 45° and patients recommended for surgery.

Guidelines for brace management in terms of efficacy as well as inclusion criteria, diagnosis and follow-up regimes have also been outlined by Canavese and Kaelin [16] and Schiller et al. [17]. Overviews of different types of braces and their effectiveness have also been discussed by Spon-seller [18] and Heary et al. [19]. Still, few articles have undertaken a review of the new technologies that are available to improve brace management of scoliosis. A review by Romine and Talwalkar discussed two of the new soft braces available for usage, computer-aided manufacturing of orthoses, as well as psychosocial effects of bracing [20].

A variety of tools have been developed to supplement brace treatment to improve the efficiency and safety of the bracing process, as well as to evaluate the effectiveness of bracing. In diagnosis, imaging techniques that use lower doses or no ionising radiation have been evaluated as a potential supplement or even replacement to the current standard of postero-anterior radiographs [21, 22]. Brace manufacturing has been transformed by computer-assisted modelling and manufacture by using 3D laser scanners to

obtain patient torso data and directly carve out a mould for a brace [23, 24]. For fitting braces, finite element computer models have been developed that may analytically test multiple types of braces to determine the optimal amount of force and pad placement within the brace [25–33]. Ultrasound has also been used to evaluate curve correction while patients are in a brace to check the efficacy of a brace in real time [34, 35]. Objective compliance monitors have been developed for measuring temperatures or in-brace forces to monitor how often patients are wearing their braces in between follow-ups [36–44]. Force logging systems can measure in-brace forces to record the fluctuations of in-brace forces in a patient's daily routine and relate forces to brace effectiveness [45–47]. Lastly, multiple quality of life and patient cosmesis surveys have been developed to assess brace treatment as a patient-centred process, aiming for adequate compliance and positive patient outcomes [48–50]. Questionnaires have been developed to identify common sources of stress that may help to inform patients and parents of potential conflicts that may arise from brace treatment [51–55].

Supplementing brace treatment with these tools will help brace treatment evolve from a largely qualitative process to a more standardised and quantitatively assessed treatment regime.

Scoliotic imaging

Imaging is essential for proper diagnosis, fitting and continued follow-up for the brace treatment of scoliosis to quantify the extent of each patient's deformity and detect possible progression. While X-rays continue to be the standard for scoliotic imaging due to its good contrast power in differentiating bone and soft tissue, radiographs involve high levels of ionising radiation, related to a higher incidence of breast cancer [56]. The EOS Imaging System appears to be a promising method of obtaining spinal images with decreased radiation. Using dual X-ray slot scanners, the radiation dose has been shown to be decreased by 6–9 times, while the image quality is improved over regular X-rays [21].

Magnetic resonance imaging (MRI) scanners have also been used to determine the mechanisms and amount of curve correction within a brace, showing that braces apply a laterodorsal force to the spine to push the spine forward and straighten it in the coronal and sagittal planes [57]. Most MRI imaging is performed with the patient in the supine position, which reduces the apparent curve severity, but radiographs are taken with the patient standing. A device designed by Adam et al. was used to evaluate spinal flexibility by physically compressing a patient's spine

while carrying out an MRI scan. The change in Cobb angle was measured from these compressive forces to determine spinal flexibility in scoliosis [58].

Photogrammetry is a non-radiographic method for determining the extent of scoliotic deformity. Spinous processes were palpated and marked, then photographed. The spinal deformity detected from the photographed image was shown to correlate closely to the Cobb angle [59].

Ultrasound was tested in three studies as a non-invasive method of imaging the spine. Vertebral rotation was evaluated using ultrasound and was found to correlate ($r^2 = 0.370$) with the Cobb angle, particularly in untreated cases [60]. However, spinal lordosis or kyphosis was found to change the rotation findings from ultrasound, making it difficult to determine a standardised spinal rotation magnitude. In another study, transverse processes and laminae were imaged using ultrasound and the vertebral angle was measured using the centre of pedicle method. The ultrasound vertebral angle corresponded closely with the Cobb angle, with a difference of only 1.6° on average [34].

While the above methods have focused on correlating new methods to the Cobb angle, which is the primary measure of scoliotic curve severity, other methods have been used to determine changes in patient cosmesis due to scoliosis. Surface topography has been one of the major methods for quantifying changes in cosmesis. In a study by Ajemba et al., two scans of a volunteer with no scoliosis were completed an hour apart. The difference in the dimensions between the two scans was $<4\%$, mostly due to patient sway [24]. Surface topography was also used to evaluate symmetry after surgical treatment and was found to correlate with both radiological measures and patient self-image [61].

New imaging methods are readily available for widespread usage. The EOS Imaging System has proven to be an effective low-dose replacement to conventional X-rays, while the methods for MRI and photogrammetry are available for further study, removing the risk of exposure to radiation altogether. Ultrasound methods still require further discussion but are promising in showing a 3D deformity with no radiation. Similarly, surface topography has been useful in defining torso asymmetry, but it may be difficult to quantitatively diagnose scoliosis without viewing the underlying spine. Still, in the ongoing follow-up of patients, the level of torso symmetry may be a helpful objective measure of curve improvement that is directly tangible and appreciable by the patient. This visible torso asymmetry is often the most troubling aspect of scoliosis for adolescents and has driven them to seek treatment, so the effectiveness of treatment should be evaluated for this feature.

Brace fitting

After the diagnosis of AIS, the right size and type of brace needs to be selected. Since the focus of this review article is to outline new technologies that can be used alongside brace treatment, the different brace types will not be discussed thoroughly here. After the brace type has been chosen, the proper size of brace as well as appropriate pad placement needs to be determined to ensure patient comfort while adequate forces at the appropriate locations and directions are applied to the spine.

The current method of construction of a custom brace involves using plaster to make a negative of the patient's body to produce the brace. This process is time-consuming, cumbersome and often involves high variability in fitting. Another issue in achieving proper brace fit involves selecting where to put pads in the brace. Pads are usually placed according to the orthotists' experience and they need to be rearranged multiple times before the desired curve correction is achieved. Pad placement is reassessed at each follow-up because the patient is growing rapidly and the brace may change the curve pattern, such as from a double to a single curve, during treatment.

New methods have been developed to streamline the brace manufacturing process. Magnetic resonance scans have been used to produce braces to within 3 % error for all dimensions when compared to a plaster cast, speeding up the process from 2 h to 15–20 min [62]. MRI and computed tomography (CT) imaging have been suggested as imaging methods that can be used to design a brace. However, as MRI is relatively expensive and CT exposes the growing adolescent to high levels of ionising radiation, these techniques may not be widely used.

Provel has developed a CAD method of producing braces, using inputs from a 3D laser scanner that can map the surface topography of a patient's spine. These 3D laser scanners, along with sculpting software, have been used to reconstruct torsos with low enough error to produce a custom brace [24].

In pad placement, finite element models have been created to test the progression of a curve based on spinal geometries and material properties, or to evaluate the effects of a lateral force from a brace on the spinal curvature. Finite element models were used to quantify and optimise the magnitude of force required for correcting spines of different stiffness [27]. In another study, finite element models of specific patients were made and their in-brace pressures were mapped on the spine. Correction of the modelled spines closely corresponded with actual patient correction [26]. Nie et al. used altered brace strap tension in their model to determine its effects on spinal curvature and in-brace forces [63]. In another study, finite element models were loaded at different orientations and

magnitudes and the amount of correction was evaluated [64]. Clin et al. tested 16 brace types on a patient's finite element model and changes in the curve were evaluated [32]. Berteau et al. modelled the specific locations and directions of forces and their effects on the frontal spinal deformity and minimising rib hump [65]. Overall, finite element models show great promise in testing a large number of different braces and pad placements to attain the best design for each individual patient.

Lastly, ultrasound has been used during bracing to obtain a real-time view of how the spinal curve responds to loading while being fitted in a brace [35]. Rather than visually inspecting the correction, ultrasound allows direct measurement of the spinal curvature while developing the brace. The ultrasound vertebral angle was found to correlate well with the Cobb angle. Because ultrasound emits no ionising radiation, this process can be repeated until the orthotist achieves the optimal curve correction.

While the feasibility of using personalised finite element models for patients continues to be explored, its potential as a clinical tool to guide brace fitting is immense. A major problem with brace treatment is that patients have varied curve patterns that respond differently to loading, making it difficult to use a standard brace design. With personalised modelling, the direct effects of applying forces on that particular patient's spine can be evaluated. Similarly, using ultrasound for fitting allows the brace customisation process to tangibly improve patient outcomes in a quantitative fashion. Because ultrasound emits no ionising radiation, the impact of numerous brace configurations can be tested.

Compliance monitors

Many bracing studies in the past have either disregarded compliance issues or only consider subjective views of compliance from patient surveys. However, compliance is very much akin to dosage when taking medication. Including poorly compliant patients skews results to make braces seem far less effective than if they were worn as prescribed. However, compliance is critical to record so as to ensure good patient outcomes. A study on patient-reported compliance showed that patients who had good compliance had a decrease in the Cobb angle of 5.2°, while those with poor compliance had an increase in Cobb angle of 5.1° [66]. However, patient-reported compliance is usually much higher than actual compliance. One study found that 96 % of patients reported at least 60 % compliance while the average compliance was actually 33 % [36].

Because of the subjective nature of patient-reported compliance, temperature sensors have been designed to indicate when a brace is being worn and when it is taken

off [38, 43]. In a study by Rahman et al., patients with non-progressive scoliosis usually had greater than 80 % compliance, while patients with progressing curves had 60 % compliance or less [44]. Another study showed that brace wear for more than 12 h per day had only 18 % progression, while wearing a brace less than 7 h per day had a 69 % progression rate [67]. Interestingly, one study showed that patients who were told that their compliance was being monitored had higher compliance (85 %) compared to a control group which was not told that they were being monitored (60 %) [68].

By implementing these low-cost and effective compliance monitors when treating patients with scoliosis, patient compliance will be more likely to increase and the dose-dependent nature of brace treatment can be recorded and studied further. Temperature-sensing compliance monitors are ready for universal usage in brace treatment. It is strongly recommended that these objective sensors be implemented, allowing physicians to have a clear view of the patient's dosage of brace treatment before drawing conclusions on its effectiveness.

In-brace forces

One of the major issues in bracing is the lack of knowledge of what forces are imposed on the body by the brace. Wearing a brace with adequate force and tightness is important for achieving proper curve correction. Furthermore, understanding the amount and location of forces generated by selected pad placements will help to improve brace effectiveness, making the treatment process more objective. Currently, the magnitude of in-brace forces is estimated indirectly from the amount of tension in the brace straps. It is common to place a mark on the strap that acts as a target to attain in tightening the strap. By tightening straps, it is hoped that the higher in-brace forces will result in better correction without causing the patient undue pain.

Some studies have involved mapping in-brace pressures while straps are being tightened. In a study by Wong and Evans, strap tension was increased from 23 to 52 N and the mean in-brace pad pressures were found to be positively correlated with the strap tension [69]. In another study, tightening straps was found to increase the in-brace pressure when they were made 2 cm tighter than what an orthotist thought was adequate strap tension [70]. Others have studied the effects of changing posture on in-brace pressures and strap tension. Pressures were found to increase when inspiring or walking (activity), while they would decrease when expiring, laying supine, prone or on the side [70, 71]. However, other studies showed that there was no statistically significant correlation between the

mean in-brace forces and curve correction [72]. There remains a need to standardise how in-brace forces are measured and what types of postures are tested during clinic visits so that there may be a pooling of data for meta-analysis studies.

A force-logging system has been developed that can record in-brace forces for weeks at a time during a patient's daily activities [46]. The low-profile, battery-powered system lasted 4 months and recorded data to evaluate compliance and ensure that the in-brace force levels were similar to the prescribed levels. Strap tension sensors were also included in the system to correlate in-brace forces with strap tension [47]. Pneumatic force-logging systems have also been designed to apply forces within a brace via air pressure. The amount of force can be logged by measuring the pressure within the pockets [73]. Another system uses active control of a pump/valve system to regulate air pocket pressures to keep in-brace forces at a certain level [74, 75].

While the usage of pressure mats and force sensors for patients in the clinic has yielded useful information on force distributions within a brace, they only give a snapshot at a point in time of how forces may change in a brace. Furthermore, bracing conditions in an artificially induced environment such as a clinic are likely to be very different from the daily activities of a patient. However, continuous data logging force sensors have been tested clinically and can be tested in a wider range of scoliosis centres to better understand the changing in-brace forces. Conducting in-brace force studies with standardised force or pressure transducers, as well as a set criteria for postures, will improve the understanding of applied in-brace forces.

Quality of life in brace wearers

While technology is useful in helping patients have better outcomes, quality of life remains one of the most important areas that need to be considered when undergoing brace treatment. Adolescence is a critical time for the development of self-identity and self-confidence [76]. Having a chronic illness that attracts unwanted attention only makes the development process more challenging.

Quality of life surveys have been developed by a wide range of scoliosis clinics. Some of these include the Bad Sobernheim Stress Questionnaire, the Scoliosis Research Society SRS-22 Questionnaire, the SF-36 Survey, and the Brace Questionnaire [77, 78]. While these surveys have different focuses and questions, the objective is similar: to quantify quality of life measures for scoliotic patients. Familial relations, pain, cosmesis and activity levels were the major issues related to quality of life that were found to be of particular importance in brace treatment.

As dependents, children with scoliosis are usually heavily influenced by parents in their views of brace treatment. One study found that a mother's views on scoliosis correlated closely with the child's views of morbidity and efficacy of brace treatment [54]. A survey of patients and their parents showed that parents would often decide on the treatment for their children, but were dependent on the doctor's recommendation that bracing is an effective non-invasive treatment [51]. Support from both parents and friends were very important in order to relieve stress or fear in bracing [79].

Because adolescent idiopathic scoliosis usually arises alongside puberty, children are starting to struggle with the issues of self-image and making friends to a greater extent than in childhood. As a result, cosmesis is one of the biggest factors in determining the quality of life in these patients. Rib prominence was found to be the most significant cosmetic feature, as an asymmetry in the rib hump would be far more noticeable by peers [80]. Scoliosis patients tended to score higher than controls in psychological and emotional well-being in some studies, but others showed minimal difference between braced and unbraced patients [48, 81]. Other studies found that bracing lowered physical activity by 20 % in all braced patients [82]. In contrast to this study, patients were found to have minimal changes in gait cycles and activity whether in a brace or not [83]. From these mixed results, it is clear that further studies need to be done in evaluating effects on both the psychological well-being and the physical activity of patients.

From these surveys, useful information about a clinic's population in terms of the patient's stress levels and anxiety over bracing can be found. It will be helpful to clinicians to use these surveys to monitor their patients and pay special attention to certain patients that may be having more difficulty coping with brace treatment.

Conclusions

The technologies that have been described in this review are part of a broader picture of improved brace treatment. Bracing remains a highly qualitative process, relying on the empirical judgment of the physicians and orthotists, along with buy-in with the patient. The suggested improvements will help to push bracing into a more evidence-based practice, using these technologies to show when bracing is the most effective and how to improve patient outcomes, as well as quality of life. This review article has focused on five major areas of study:

1. Improving diagnostic and follow-up imaging to minimise radiation.
2. Optimising brace fit to determine pad placement and brace contour for efficacy.
3. Tracking compliance of brace wear to identify weak points in brace treatment.
4. Mapping and adjusting forces within a brace in the clinic and during daily activities.
5. Determining quality of life issues related to the brace treatment of scoliosis.

Keeping in mind that these areas of research need to be integrated and streamlined, the direction of brace treatment needs to be not only the invention of new types of braces and larger randomised control trials, but also the development of technologies to supplement these braces.

While technology in temperature and force sensors as well as imaging and manufacturing techniques has progressed immensely, bracing has not taken advantage of this innovation. Widespread adoption of these technologies will go a long way to improving patient outcomes from bracing for adolescent idiopathic scoliosis (AIS).

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Conflict of interest None.

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