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Clinical Study

The effectiveness of the SpineCor brace for the conservative treatment of adolescent idiopathic scoliosis. Comparison with the Boston brace

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Abstract

BACKGROUND CONTEXT: The Boston brace (Bb) is the most widely used brace design to treat adolescent idiopathic scoliosis (AIS). The dynamic SpineCor (SC) brace is prescribed in several scoliosis clinics worldwide, but its effectiveness remains controversial.

PURPOSE: The study aimed to compare the treatment effectiveness of SC in patients with AIS treated by the developers of the brace with that of the Bb at a single institution.

STUDY DESIGN/SETTING: This is a retrospective comparison between a cohort of AIS patients treated using the SC brace and a cohort treated using the Bb.

PATIENT SAMPLE: We assessed 243 patients treated with either Bb or SC brace to prevent the progression of AIS.

OUTCOME MEASURES: The primary outcome was the progression in main Cobb angle when reaching one of the following end point criteria: (1) progression in Cobb angle of ≥6°, (2) main Cobb angle of ≥45°, (3) surgery undertaken, or (4) reaching skeletal maturity (Risser sign of 5 or growth of <1 cm in the previous 6 months).

METHODS: Patients were identified at a single institution between 2000 and 2012 following the Scoliosis Research Society criteria for brace treatment: (1) diagnosis of AIS, (2) Risser sign of ≤2, (3) curve magnitude between 25° and 40°, and (4) age ≥10 years. A total of 97 patients treated with SC by the developers of the brace and 146 patients treated with Bb were identified. Data collection and radiograph measurements were performed by a single experienced nurse not involved in the decision-making for brace treatment or in the data analysis. Age and Risser sign at onset of treatment, initial

FDA device/drug status: Approved (Boston Brace, SpineCor Brace).

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main Cobb angle, curve type, and duration of follow-up were similar in both cohorts. Statistical analysis was done using chi-square and logistic regression models, with a level of significance of .05.

RESULTS: The average progression was 14.7°±11.9° in the SC cohort compared with 9.6°±13.7° in the Bb cohort (p=.003). The average Cobb angle at the end point of the study reached 47°±13° in the SC cohort and 41.7°±14.2° in the Bb cohort (p=.005), whereas at the onset of bracing it was 32.2°±4.9° and 32.2°±4.4°, respectively, for the SC and Bb cohorts. The percentage of patients with a progression of ≥6° was 76% in the SC cohort and 55% in the Bb cohort (p=.001). The proportion of patients reaching 45° in the SC and Bb cohorts was, respectively, 51% and 37% (p=.03), whereas the proportion of patients referred to surgery was 39% and 30%, respectively, for the SC and Bb cohorts (p=.2). The odds of progressing ≥6° and of reaching ≥45° were 2.67 and 2.07 times greater, respectively, when using the SC brace.

CONCLUSIONS: The SC brace did not prevent curve progression as effectively as the Bb. Although it has the potential benefit of increasing mobility during brace wear, the SC brace was associated with increased curve progression in comparison with the Bb. There is also a trend for increased risk of requiring surgery when the SC brace is worn.

Keywords: Brace; Child; Orthopedics/methods; Scoliosis; Spinal deformity; Spine; Treatment outcome

Introduction

Brace treatment is widely used for the non-operative treatment of adolescent idiopathic scoliosis (AIS) and has been proven to be effective [1]. Rigid bracing with a thoracolumbosacral orthosis (TLSO) is most commonly used. It stabilizes the spine by exerting pressure or force in strategic areas to control the progression of the deformity [2]. On the other hand, it has the potential disadvantages of compliance, mobility, and cosmesis. The Boston brace (Bb) (© 2009–2015 Boston Brace. All Rights Reserved) is the most widely used type of TLSO. A non-rigid, more esthetic, and effective brace could, however, be a valuable alternative. With this concept in mind, the dynamic SpineCor (SC) (© The Spine Corporation Limited) brace has been developed using thoracic corrective elastic bands anchored to a pelvic base, and uses a specific corrective movement depending on the type of the curve. Appropriate tensioning of the bands induces a dynamic corrective strategy to prevent curve progression, also with the aim of achieving neuromuscular integration of the corrective movement through active biofeedback [3]. This corrective movement has the potential benefit of allowing some degree of controlled mobility, therefore providing the opportunity to re-educate and maintain the neuromuscular control of such spinal corrective movement.

Weinstein et al. [1] recently reported a 75% success rate in preventing progression of the main curve up to 50° or more of Cobb angle in patients wearing a rigid TLSO compared with 42% in patients under observation without bracing. The randomized trial was stopped prematurely because of the clear efficacy of bracing. Indications for bracing were the following: an age of 10 to 15 years, Risser sign of 0 to 2, and a primary Cobb angle of 20° to 40°.

Some studies suggest that the SC brace is very effective [3–5]. Unfortunately, these suggestions are mainly from clinicians involved in the development of the brace and an observer bias may not be excluded. In a 2007 descriptive study of 170 AIS patients without a control group, Coillard et al. [5] reported a failure rate of 33% (18 patients had more than 5° of main curve progression and 39 had surgery; 12 patients were withdrawn) with regard to curve progression of more than 5° using the SC brace. More recently, Coillard et al. [4] reported in a randomized control trial of 68 patients with mild idiopathic scoliosis (15°–30° of main Cobb angle) a progression of more than 5° in 27% of the treated patients with the SC in comparison with 43% in patients treated by observation. However, their study did not include patients according to the Scoliosis Research Society (SRS) indication criteria for bracing treatment and did not involve a comparison with patients treated with a rigid TLSO, which is usually considered as the gold standard for brace treatment.

Only a few studies compared the effectiveness of SC and TLSO, and their conclusions are debated because of limited sample sizes or non-standardized patient selection criteria. One study [6] reported no difference in the outcome between patients wearing the rigid TLSO or the SC. However, their sample size (35 TLSO vs. 32 SC) may not be sufficient to obtain adequate power, considering that the proportion of patients showing a progression of ≥6° or a final Cobb angle of >45° was increased in the SC cohort. On the contrary, Weiss et al. [7]. showed increased progression for patients using SC as compared with a matched cohort of patients using TLSO, but their study only included 12 and 15 patients in the SC and TLSO cohorts, respectively. Wong et al. [8] reported in their prospective randomized study a 32% failure rate in a cohort of 22 patients with moderate AIS (main Cobb angle of between 20° and 30°) wearing the SC brace compared with a 4.7% failure rate in a cohort of 21 patients wearing TLSO after a 45-month follow-up. To comply with the standardized criteria proposed by the SRS for the selection of patients for bracing, Guo et al. [9] conducted a randomized controlled trial in which they found that 35% of the 20 AIS patients