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Braces Optimized With Computer-Assisted Design and Simulations Are Lighter, More Comfortable, and More Efficient Than Plaster-Cast Braces for the Treatment of Adolescent Idiopathic Scoliosis

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Abstract

Study Design: Feasibility study to compare the effectiveness of 2 brace design and fabrication methods for treatment of adolescent idiopathic scoliosis: a standard plaster-cast method and a computational method combining computer-aided design and fabrication and finite element simulation.
Objectives: To improve brace design using a new brace design method.
Summary of Background Data: Initial in-brace correction and patient's compliance to treatment are important factors for brace efficiency. Negative cosmetic appearance and functional discomfort resulting from pressure points, humidity, and restriction of movement can cause poor compliance with the prescribed wearing schedule.
Methods: A total of 15 consecutive patients with brace prescription were recruited. Two braces were designed and fabricated for each patient: a standard thoracolumbo-sacral orthosis brace fabricated using plaster-cast method and an improved brace for comfort (NewBrace) fabricated using a computational method combining computer-aided design and fabrication software (Rodin4D) and a simulation platform. Three-dimensional reconstructions of the torso and the trunk skeleton were used to create a personalized finite element model, which was used for brace design and predict correction. Simulated pressures on the torso and distance between the brace and patient's skin were used to remove ineffective brace material situated at more than 6 mm from the patient's skin. Biplanar radiographs of the patient wearing each brace were taken to compare their effectiveness. Patients filled out a questionnaire to compare their comfort.
Results: NewBraces were 61% thinner and had 32% less material than standard braces with equivalent correction. NewBraces were more comfortable (11 of 15 patients) or equivalent to (4 of 15 cases) standard braces. Simulated correction was simulated within 5° compared with in-brace results.

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Conclusions: This study demonstrates the feasibility of designing lighter and more comfortable braces with correction equivalent to standard braces. This design platform has the potential to further improve brace correction efficiency and its compliance.

Keywords: Scoliosis; Thoracolumbo-sacral orthosis; Brace simulation; CAD/CAM; Comfort

Introduction

Adolescent idiopathic scoliosis (AIS) is a complex deformity of the spine and ribcage. For moderate spinal curvatures (Cobb angle 20° to 40°), an orthopedic brace treatment is generally prescribed to control curve progression. For thoracolumbar and lumbar curves, a common brace prescribed is a thoraco-lumbo-sacral orthosis (TLSO) [1]. Bracing has been the mainstay regarding nonoperative treatment for AIS but has not gained complete acceptance; the treatment's long-term effectiveness is still questioned [2,3]. Other studies demonstrated bracing as an effective nonsurgical treatment to prevent curve progression compared with no bracing [4-8]. A correlation was found between immediate in-brace correction and brace treatment's long-term effectiveness [9,10]. Final results of treatment depend on multiple factors: timing with adolescent growth curve acceleration phase, initial brace correction, patient's flexibility, brace wear time, and patient compliance with treatment [1,11-13].

A negative cosmetic appearance, physical and functional discomfort resulting from pressure points, humidity, and restriction of movement can cause poor compliance with prescribed wearing schedules [14-18]. Groups have studied brace wear time by embedding small temperature or pressure sensors to the brace to record average wear time [1,19-21]. Compliance ranged around 33% to 82% of prescribed wear time and 80% of patients had a tendency to overestimate their compliance [20,22,23]. Studies suggest that brace efficiency is related to brace wear time. The more patients complied with brace treatment, the better their chances were of obtaining a positive outcome [23-25].

Brace comfort is evaluated qualitatively by the patient during brace installation and at follow-up visits. The comfort notion has a triple origin: psychological, physical, and functional [26]. Pressure and friction ulcers are frequent in braces that exert excessive pressure. To the authors' knowledge, no published studies describe optimal pressure distribution and maximal pressures that can be applied by braces with regard to patients' comfort. Studies defining pressure pain thresholds for different anatomical regions indicate that all body regions are not equally sensitive [27-31]. These data do not consider AIS patient characteristics and brace design. Visser et al. [32] studied brace discomfort using a visual analog scale and pressure sensors. Results showed that discomfort increased with corrective pad height. Pham et al. [33] used pressure sensors to investigate daily activity pressure variations at different locations in the brace. Comfort was not evaluated and tolerable pressure thresholds remained unknown.

Finite element models (FEM) were developed to analyze brace biomechanics [34-37] and rationalize brace design [38,39]. Combined with a computer-aided design and computer-aided manufacturing (CAD/CAM) system, FEM allows the simulation of brace correction, as well as computation of pressures applied [40]. A clinical evaluation of in-brace predicted correction using FEM was performed on scoliotic patients [40]. That work did not include brace design optimization to improve comfort and compliance.

The goal of this study was to improve the design of braces by integrating physical and functional comfort criteria in this new brace design method.

Materials and Methods

Experimental study design

A total of 15 female patients aged 11 to 14 years were consecutively recruited over a 6-month period. All participants received an AIS diagnosis, had a Cobb angle between 20° and 45°, had an immature skeleton presenting a Risser sign of 0 or 1, and received a standard full-time TLSO prescription. The study was approved by the researchers' institutional ethical committee, and participants and their parents each gave written consent.

To compare brace effectiveness, 2 braces were designed and fabricated for each participating patient: a standard TLSO Boston brace-type (StdBrace) and a TLSO brace computationally improved for comfort (NewBrace). The same orthotist installed both braces for the patient. The StdBrace was fabricated using a plaster-cast method. A mold of the patient's body was formed for brace fabrication. A 5-mm foam layer and a heated copolymer sheet were molded on the plaster to create the brace shell. Then 15-mm corrective pads were added toward the trochanter, thoracic, and lumbar regions. The NewBrace was fabricated using a CAD/CAM and simulation brace design method linked to a carving machine. A polyurethane foam block was carved according to the CAD model for brace fabrication. A heated copolymer sheet was employed for brace shell thermoforming. No foam layer and no corrective pads were added because the brace included corrective regions in its shape. The orthotist knew the study purpose but did not participate in the NewBrace design and intervened only during installation (cutting edges and openings). Using the brace simulator, it was possible to choose between horizontal and oblique tightening straps. The final strap orientation was the result of brace optimization showing the best spinal correction.