Introduce of NEWbrace for Adolescent Idiopathic Scoliosis

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ABSTRACT

Adolescent Idiopathic Scoliosis (AIS) affects 2–4% of adolescents. Therapy for AIS patients depends on curve size and skeletal maturity. The use of braces is one of the treatments recommended for subjects with scoliosis. The aim of this study was to introduce a novel brace design for scoliosis curve correction. The proposed brace consists of two external rigid shells, three adjustable pneumatic rod-based pumps, and two corrective pads. The new brace was designed with forces that decreased scoliotic curves and with low stress on the bone and disc. An adolescent idiopathic scoliosis patient aged 12 years old, who had conservative treatment, was enrolled in the study. 3D scans were taken of the patient to prepare the new brace. In-brace radiographs were taken after the subject wore the brace for 2 hours. The rate of in-brace correction was then calculated.

The patient's primary curvature was 37° and 26.7° in thoracic and lumbar, with sagittal profiles of 43.72 and 42.02 degrees in thoracic kyphosis and lumbar lordosis. After utilizing the Newbrace, her spines were completely straightened, and her kyphosis and lordosis were 37.51 and 36.8 degrees, respectively. The results of this study demonstrated that the newly designed brace was highly effective in correcting scoliotic curves. Further evaluation of its effectiveness in a larger group of scoliosis patients is strongly recommended.

Keywords

Scoliosis; Braces; Spine; Device Design

Introduction

Scoliosis in children is one of the most common deformities of the spine and a complex 3D structural disorder. Adolescent Idiopathic Scoliosis (AIS) is the most prevalent type of this deformity, which affects 2-4% of adolescents [1]. The pathophysiology of AIS is unknown, but some studies suggest a genetic aspect [2].

Therapy for AIS patients depends on curve size and skeletal maturity [3]. The Scoliosis Research Society (SRS) recommends that the primary treatment be for AIS with curves from 25 to 45° and Risser stage between 0 and 2 [4]. Many braces have been designed for scoliosis patients, such as Boston, Charleston, Lyon, Milwaukee, Providence, Wilmington, Rosenberger, Sforzesco, Cheneau, but her effect is indeterminacy on curve correction [5-9]. Initial rate in-brace curve correction is one of the indexes to measure the effect of braces on curve correction and is mostly used to evaluate the efficacy of new braces [10, 11]. Yen et al. evaluated the initial in-brace curve correction of the

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Rosenberger Thoracic-Lumbar-Sacral Orthosis (TLSO) brace and indicated that the in-brace correction in 48% of patients was less than 15%, 28% was between 15-30% correction, 16% with 30-50% correction, and 8% had over 50% correction [12]. This index has been investigated in other braces as well. the initial rates of in-brace correction with the Milwaukee, Boston, Charleston, and SpineCor braces are 17.4%, 35.6%, 62.2%, and 21.3% respectively [13, 14].

Most of the aforementioned braces are based on the use of transverse force (Boston, Milwaukee) [15, 16]. Meanwhile, another study indicate that the effectiveness of corrective forces varies according to the magnitude of the spinal curvature. Specifically, transverse forces tend to be more effective in smaller curves, whereas vertical forces demonstrate greater efficacy in larger curves [17]. Therefore, the vertical force is as effective as the transverse force in correcting the curvature and preventing its progression [17]. Therefore, based on this assumption, a new type of brace was developed, which used a combination of vertical and transverse forces. The present article describes the design and application techniques of a newly developed brace, as well as the preliminary outcomes in a patient treated with it. This brace combines a novel application of vertical corrective forces with transverse forces to achieve coronal curve correction while maintaining sagittal alignment.

Material and Methods

After testing various force configurations on the patient's spinal model, the combination that reduced the scoliotic curves without significantly affecting thoracic kyphosis or lumbar lordosis and produced lower bone and disc stress was selected for the new brace design, as reported in our previous study [16].

The brace included two external rigid shells, three rods (pneumatic pumps), and two pads. Additionally, it was predicted that the initial rate of in-brace correction of the newly designed brace must be between 45%-65% [16]. After the approval of the ethical code, an AIS patient, who had been scheduled for conservative treatment, was enrolled in the study. Oral consent of the patient and her parents was obtained for her to participate in the study and for her photos. The exclusion criteria were 1) using other types of braces or conservative treatment, and 2) other types of spine deformity.

Brace preparation:

At first, a 3D scan was taken of the patient. Three-dimensional body scanning was carried out by using a Vitus Smart three-dimensional (3D) body scanner (Human Solutions GmbH. The device was then fabricated following standard clinical procedures [18]. The external torso geometry was modified by an orthotist using Materialise 3-matic software, including adding material over bony prominences and trimming the required relief areas. A brace blueprint was subsequently generated. The final brace was manufactured using a numerically controlled carver (Model C, Rodin 4D, Bordeaux, France) integrated with the Computer-Aided Design and Computer-Aided Manufacturing (CAD/CAM) system. A polyurethane foam block was carved according to the CAD model, and the brace shell was thermoformed using a 4-mm heated copolymer sheet. After that, the NewBrace was trimmed by the orthotist and divided into two pieces, upper and lower baskets, and the location of lateral pads was determined based on the location of the curvature (Figure 1). In the design of this brace, three prefabricated pneumatic pumps (two pumps in the posterior and one in the anterior) were used to create vertical force. The forces of the anterior and posterior pneumatic pumps were 100N and 50N, respectively. The force of the pumps was determined based

a b

Figure 1: View of brace in anterior (**a**) and lateral (**b**)

on the previous study [17]. Two lateral belts were integrated into the brace. When the brace is donned and the belts are released, the pneumatic pumps apply vertical corrective forces to the torso. Anteroposterior radiographs were obtained before brace application, and in-brace radiographs were taken after the patient had worn the brace for 2 hours (Figure 1). Cobb angles were measured on both sets of radiographs, and the in-brace correction rate was subsequently calculated.

Results

A 12-year old AIS patient participated in this study. Primary and in-brace curvature data of the patient were collected (Table 1).

The primary curvature of the patient was 37° and 26.7° in thoracic and lumbar respectively. After utilizing the Newbrace, her spine was completely straightened, which is evident in her radiology pictures (Figure 2).

Table 1 illustrates the amount of sagittal profile in primary curvature and in-brace conditions. The Thoracic Kyphosis (TK) and Lumbar Lordosis (LL) were 43.72° and 42.02° before wearing any appliance, 37.51, and 36.8 after wearing Newbrace (Figure 2).

Table 1: Amount of spinal curvature in primary curvature and in-brace conditions

Index		Without brace	With brace
Scoliosis	Thoracic	37	0
	Lumbar	26.7	0
Kyphosis		43.72	37.51
Lordosis		42.02	36.8

Discussion

Various treatment approaches are used for subjects with scoliosis, in which the use of a brace is one of the effective interactions [14]. Based on the available literature, the braces are prescribed mostly for the curve between 20 and 45 degrees [4]. Various force configurations are used in the design of the available braces. However, it seems that a combination of vertical and transverse forces is more effective in decreasing scoliotic curve [17]. The effects of the use of various force

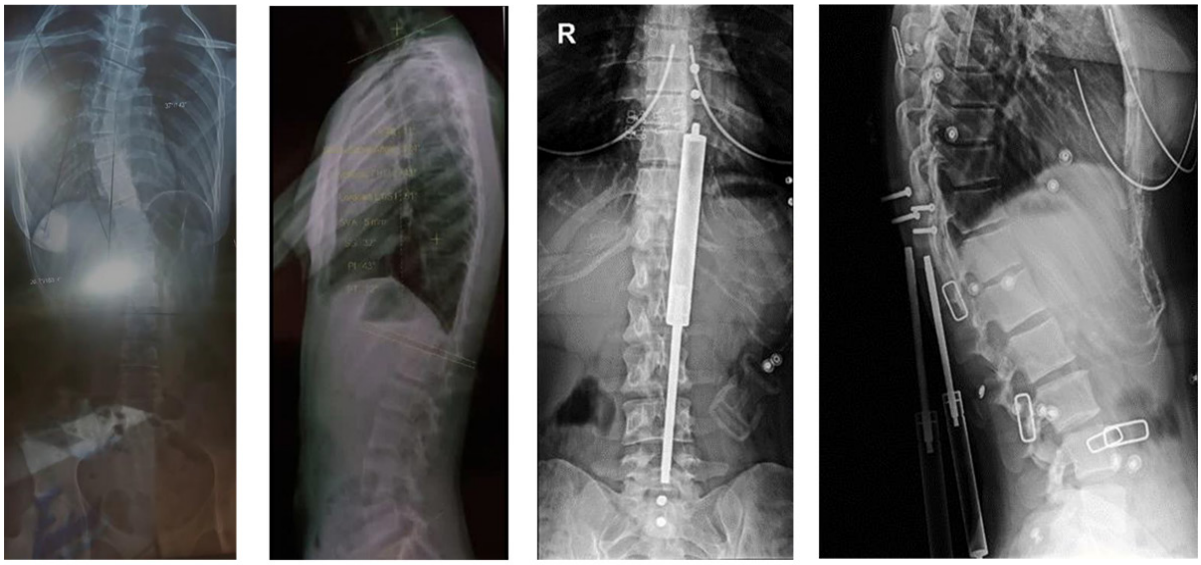

Figure 2: **a**: sagittal view of body patient without a brace, **b**: coronal view of body patient without a brace, **c**: sagittal view of body patient with a brace, **d**: coronal view of body patient with a brace.

configurations on the scoliotic curve were evaluated based on Finite Element Analysis (FEA) by the authors, and the best configuration was selected. In this part of the study, a new brace was developed based on the output of the FEA analysis and tested on a scoliotic subject.

The result of this study showed that the scoliotic curve of the lumbar and thoracic regions decreased by 100% compared to no brace conditions. The interesting point was that both scoliotic curves were corrected following the use of this approach. This brace is a new prototype of the braces that were used to correct scoliotic curves, which used a combination of transverse and vertical forces and also used pneumatic pumps to force the scoliotic curves upward. The use of lateral straps to control the upward directed force (the force of pneumatic pumps) helps to don and push the braces in a comfortable way. Moreover, it is possible to control the force of the pumps. It should be noted that this prototype is a low-profile orthosis and does not have a cervical pad, influencing the willingness of the subject to use orthosis.

It should be noted that this is a technical note to introduce a new design of brace for scoliotic subjects. It is recommended that the new design of this orthosis be tested on a large number of subjects in the near future. Therefore, the output of this study should be used with caution.

Conclusion

The output of this study showed a high efficiency of the new design of brace in scoliotic curve correction. It is highly recommended that the efficiency of the new design of the brace should be tested on more scoliotic subjects.

Authors' Contribution

M. Karimi conceived the idea. The introduction of the paper was written by A. Nadi and M. Rafiaee. M. Karimi and A. Nadi gather the images and the related literature, and also help with the writing of the related works. The method implementation was carried out by M. Karimi and A. Nadi. A. Nadi

and M. Karimi carried out the results and analysis. The research work was proofread and supervised by M. Karimi, A. Nadi and M. Rafiaee. All the authors read, modified, and approved the final version of the manuscript.

Ethical Approval

The Ethics Committee of Isfahan University of Medical Sciences approved the protocol of the study Ethic cod: IR.MUI.NUREMA.REC.1400.181.

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Conflict of Interest

None

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