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Clinical evaluation of the effectiveness of a new orthotic device for the non-operative treatment of scoliosis

Kap-Soo Han[a,1], Gi-Wook Kim[a,b,1], Seung-Rok Kang[a], Myoung-Hwan Ko[a,b,*] and Jeong-Hwan Seo[a,b,*]
[a]*Research Institute of Clinical Medicine of Chonbuk National University, Biomedical Research Institute of Chonbuk National University Hospital, Jeonju, Jeonbuk, Korea*
[b]*Department of Physical Medicine and Rehabilitation, Chonbuk National University Medical School, Jeonju, Jeonbuk, Korea*

Abstract.
BACKGROUND: Bracing is one of the oldest non-operative treatments for patients with scoliosis. However, a wide variety of braces is used, and some show no effect, while others show conflicting results.
OBJECTIVE: We aimed to evaluate the effectiveness of a new orthotic device for the treatment of adult scoliosis.
METHODS: Twenty adult patients who were diagnosed with scoliosis and qualified for the study were selected and all participants were treated for 12 hours/day for 12 weeks using a new orthotic device. Various efficacy assessments (Cobb's angle, spine length, pelvic angle, shoulder angle, thoracic angle, lumbar angle, pelvic sacral angle) were performed before and after the 12-week treatment. The values at each time point were compared.
RESULTS: There were significant treatment effects in a time-dependent manner on every efficacy assessment ($p < 0.05$) after 12 weeks of bracing.
CONCLUSION: In this clinical study, it was demonstrated that a new brace that is more comfortable for the wearer reduced scoliosis and may be a useful option for non-operative treatment of scoliosis.

Keywords: Scoliosis, orthotic device, non-operative treatment, spine, rehabilitation

1. Introduction

Normal human movement begins with maintaining proper posture. The human body may appear to be standing in a static state with no movement; however, in fact, the body itself is being finely controlled continuously to counteract gravity and to maintain the center of mass stable on the base of support. Therefore, imbalances create biomechanical compensation during postural activities [1]. In particular, pelvic obliquity that appears in the frontal plane due to imbalance may cause scoliosis by exerting asymmetrical pressure on the pelvis [2].

[1]Co-first authors.
*Corresponding authors: Myoung-Hwan Ko and Jeong-Hwan Seo, Research Institute of Clinical Medicine of Chonbuk National University, Biomedical Research Institute of Chonbuk National University Hospital, Jeonju, Jeonbuk, Korea. E-mails: vivaseo@jbnu.ac.kr and vivaseo@jbnu.ac.kr.

Generally, the spine is considered a uniquely unstable system that maintains posture with muscle-ligament structure, while providing movement at the same time [3–7]. Repetitive weight shift to one side of the pelvis or hip pressure being concentrated on one side [8] may lead to permanent deformities, including scoliosis and kyphosis [9]. Progression of scoliosis takes place during the development of young humans, and as a progressive disease that can have a major impact on function, scoliosis has a high incidence rate during this period and causes high socioeconomic costs owing to disease progression [10–12].

Treatment modalities for scoliosis include physiotherapy, use of orthopedic devices (braces), and surgery. Nevertheless, there remains debate as to the efficacy of these modalities [13]. With respect to physiotherapy [14–20], studies reported that there were no evidence-based results because of lack of reports of application of physiotherapy only that made observations until maturation of the musculoskeletal system [16,19]. Other studies compared physiotherapy and bracing, but reported that it is difficult to identify which modality was more effective for scoliosis due to lack of scientific evidence [17,20].

Surgical methods used include spinal fusion surgery [21–26] and use of interspinous spacers [8]. However, spinal fusion surgery is not an effective treatment modality because of the health issues that it may cause [21–24], including rib cysts and spinal herniation within 1 year after surgery [21,22]. Some studies also reported that surgery is questionable as a treatment modality for scoliosis because of recurrence of long-term complications [21,25,26].

With respect to bracing, various braces, including the Cheneau brace and the Boston brace, are used regardless of growth stage [27–33]. A recent review reported that the treatment modality with the application of a brace is an evidence-based modality and it was found to be effective even in follow-up observations after completed growth of the musculoskeletal system [13]. Nevertheless, because a wide variety of braces being used, some show no effect whatsoever, while others show conflicting results [27–34]. Braces made of soft material that were developed to overcome the disadvantages of braces made of hard material have been reported to not provide sufficient compliance, contrary to the claims of the manufacturers [35]. Bracing is one of the oldest non-operative treatment modalities; nevertheless, it continues to have problems while new methods of bracing are being introduced.

Currently, braces that have been used as non-operative treatment modalities have consisted mostly of devices that limited movement by wrapping the entire upper body where scoliosis is present with a hard material. Recent braces, by contrast, use a method of correction that allows flexibility by separating the upper parts (towards the shoulders) and lower parts (towards the pelvis) of scoliosis. Accordingly, the present study applied the newly introduced brace on adult patients with scoliosis as a non-operative treatment modality to identify its preliminary clinical effect.

2. Materials and methods

2.1. The principle of a new orthotic brace

When the pelvis becomes twisted, it generally shows three types of directionalities (elevation/deviation/rotation). Three-dimensional (3D) stabilization of the pelvis using an orthopedic brace is designed to achieve spinal stabilization, and having a positive effect on balancing the center of gravity during gait and movement. When the two ilium bones in the pelvis become twisted, space is created between the sacroiliac joint, the pubic symphysis, and the left and right hip joints, for which convergence and 3D-stabilization must be promoted together. The typical correction method is based on the principle of force in one or two directions being countered by force in opposite direction, meaning the three-point pressure principle of applying force that pushes in the direction opposite to incurvation (curved

Fig. 1. (L) Three point pressure method; (R) Counter compensation method: Two forces F_{u1} and F_{u2} in the upper area are applied to transverse direction of the ribs. F_{l1} and F_{l2} in the pelvis are reaction forces required to obtain equilibrium in the body. T_c is the counter compensation torque acting via the rib cage onto the spine.

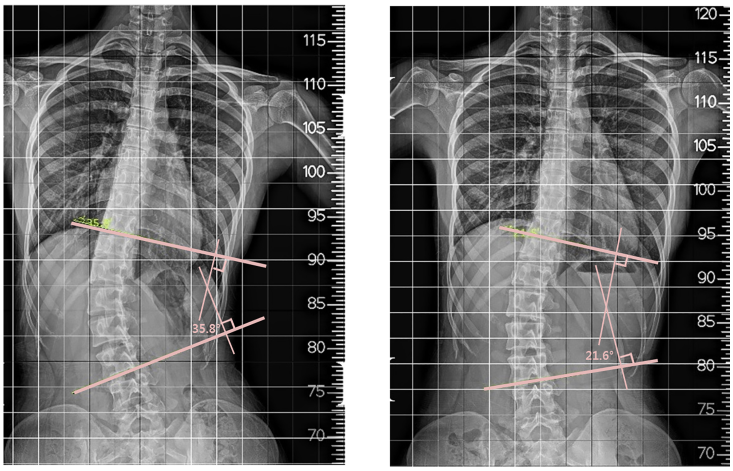

Fig. 2. Before (L) and after (R) treatment. X-ray images of a patient wearing the new brace.

spine) (Fig. 1(L)). The principle of correction mechanism of ALL LINE^{TM} brace (PHS, Seongnam-Si, Gaeonggi-Do, Korea) is based on applying counter compensation action using a top-bottom belt for proper correction because other parts of the body may become twisted due to compensation when trying to align the body to the gravity line (Fig. 1(R)). When wearing the brace, the elastic belt relays force to each skeletal pad to produce proper movement in the wearer. The present study was a clinical trial that applied the newly developed brace to 20 adults and assessed its effect on relieving scoliosis.

2.2. *Evaluation of effectiveness of a new brace*

Anteroposterior (AP) and lateral view radiographs of the thoracolumbar spine in the standing posture were obtained from patients aged 19–40 years. Patients who were diagnosed with scoliosis with a Cobb's angle of 10°–40° on the X-ray and wished to participate in the present study were recruited ($n = 20$). The participants wore the ALL LINE^{TM} brace from PHS for 12 hours a day for a total of 12 weeks and changes in the Cobb's angle before and after wearing the brace were examined. This sponsor-initiated clinical trial study was conducted after obtaining approval from the Institutional Review Board (IRB) of Chonbuk National University Hospital (IRB no. CUH 2017-02-030-001).

2.3. Measurement methods

2.3.1. Measurement of changes in Cobb's angle

Cobb's angle is a diagnostic measure of scoliosis. After locating T2, where spinal curvature begins, and T8, where the lowest structural curve is found, T5 representing the apex at the midline of T2–T8 is defined. After drawing a line along the top of the vertebral body (T3) with a large slope above T5 and a line along the bottom of the vertebral body (T7) with a large slope below T5, lines perpendicular to the top and bottom lines are drawn and the angle formed where the two lines intersect represents Cobb's angle [37]. This is the most reliable and accurate method for measuring spinal curvature. In the present study, patients with Cobb's angle $\geqslant 10^\circ$ were diagnosed with scoliosis.

2.3.2. Measurement of other changes

Other bodily changes were measured as described below.

Change in height

The difference of the length from the bottom of the feet to the top of the head when a person stands upright before and after the brace.

Spine length

Spine length is from the top of the seventh cervical vertebra to the bottom of the fifth lumbar vertebra.

Pelvic angle

In the pelvic area, the angles were measured relative to the apex of left and right iliac crest.

Shoulder angle

In the shoulder area, angle of the location of the left and right acromioclavicular joints.

Deviation of scoliotic spine from the midline

Definition of endpoint: measure deviation of scoliotic apex relative to the midline passing through the first sacral vertebra.

2.4. Data analysis

Spine length, pelvic angle, shoulder angle, and deviation of scoliotic spine from the midline measured before and 12 weeks after wearing the brace were compared. Data satisfying normality were analyzed using paired t-tests, while data not satisfying normality were analyzed using Wilcoxon signed rank tests.

3. Results

Normality test for comparison of spine length, pelvic angle, shoulder angle, and deviation of scoliotic spine from the midline measured before and 12 weeks after wearing the brace showed that shoulder

Table 1
Patients' demographic information

	Mean ± SD (min-max)
Age (years)	24.33 ± 4.47 (19–34)
Height (cm)	163.13 ± 3.02 (157.2–167.6)

Table 2
Treatment results of the group with the brace

	Before wearing the brace	12 weeks after wearing the brace	Before – After	p-value
	Mean ± SE	Mean ± SE	Mean ± SE	
Cobb's angle	29.34	23.99	5.35 ± 0.83	0.000
Spine length	41.41 ± 0.62	42.21 ± 0.51	−0.80 ± 0.24	0.000
Pelvic angle	2.32 ± 0.64	1.04 ± 0.21	1.28 ± 0.55	0.001
Shoulder angle	2.27 ± 0.37	1.19 ± 0.18	1.08 ± 0.37	0.010
Thoracic angle	4.22 ± 0.35	3.46 ± 0.28	0.75 ± 0.20	0.001
Lumbar angle	4.36 ± 0.31	3.80 ± 0.30	0.56 ± 0.15	0.002
Pelvic sacral angle	0.53 ± 0.08	0.36 ± 0.07	0.17 ± 0.06	0.002

angle, deviation of scoliotic spine from the midline (thoracic angle), and deviation of scoliotic spine from the midline (lumbar angle) satisfied normality; therefore, they were analyzed using paired t-tests. Spine length, pelvic angle, and deviation of scoliotic spine from the midline (pelvic sacral angle) did not satisfy normality; therefore, they were analyzed using the Wilcoxon signed rank test.

A total of 20 adults were enrolled in the present study; however, due to drop-out of two participants, the study was ultimately conducted with 18 participants (17 females and 1 male). The mean age of the participants was 24.33 years, ranging between 19 and 34 years (Table 1).

As shown in Table 2, the mean Cobb's angle changed from 29.34° before wearing the brace to 23.99° after 12 weeks of wearing the brace (measured without wearing the brace), showing a statistically significant corrective effect. The mean height changed from 163.13 cm before wearing the brace to 163.54 cm after 12 weeks of wearing the brace (measured without wearing the brace), showing a tendency of an overall increase between 0 and 1.1 cm, but with no statistically significant difference. The mean spine length changed from 41.41 cm before wearing the brace to 42.21 cm after 12 weeks of wearing the brace (measured without wearing the brace), showing a statistically significant difference. The mean pelvic angle changed from 2.32° at wearing the brace to 1.04° after 12 weeks of wearing the brace (measured without wearing the brace), showing a statistically significant difference. Mean shoulder angle changed from 2.27° before wearing the brace to 1.19° after 12 weeks of wearing the brace (measured without wearing the brace), showing a statistically significant difference. With respect to deviation of scoliotic spine from the midline, the mean thoracic angle changed from 4.22° before wearing the brace to 3.46° after 12 weeks of wearing the brace (measured without wearing the brace), showing a statistically significant difference; mean lumbar angle changed from 4.63° at before wearing the brace to 3.80° at 12 weeks after wearing the brace (measured without wearing the brace), showing a statistically significant difference; and mean pelvic sacral angle changed from 0.53° before wearing the brace to 0.36° after 12 weeks of wearing the brace (measured without wearing the brace), showing a statistically significant difference.

4. Discussion

We conducted a clinical trial which applied a newly introduced method of bracing for adult patients diagnosed with scoliosis. Applying the brace showed improvement in all parameters: Cobb's angle, spine length, pelvic angle, shoulder angle, and thoracic, lumbar, and pelvic sacral angles from the midline.

Currently, various braces (Cheneau, Boston, Spine Cor, Milwaukee, and CAD/CAM) are used, regardless of whether the patient is an adolescent or adult [27–34]. However, some braces are disliked by adolescent patients because of their outer appearance; for this reason, some people falsely participated in previous studies, claiming to have worn the brace when they actually did not [36]. As mentioned before, people feel uncomfortable about wearing braces in spite of the improvement of design and material compliance [27–35]. Therefore, despite its long history, there remains the need to develop braces that have few problems with appearance for use in long-term treatment, stability for therapeutic effect, assuring flexibility needed for movement during daily life, and being highly effective even when worn for a short time.

According to previous studies, there were no major differences of brace effect between wearing a brace part-time (12–16 hours) versus full time (23 hours) [6,9]. Kahanowitz reported that similar results were found when the pre-brace Cobb's angle was $< 35°$ [13]; however, when the angle was larger than that, over 50% of the patients advanced to the point of requiring surgery. In the present study, the mean pre-brace Cobb's angle was approximately 29° and the brace was worn part time (12 hours) for a short period (12 weeks). Nevertheless, the results between before and after the device showed statistically significant improvements (5.35° decrease in Cobb's angle) and improvement effect was similar as shown in other devices [6,9,13].

The limitations of the present study include the fact that the orthopedic brace was worn for a short period of only 12 weeks (3 months), which is shorter than observational periods in previous studies. Moreover, the study did not observe return of symptoms during the period when the orthopedic brace was no longer worn. The study also did not identify the efficacy and safety of the brace in patients with scoliosis who were in the growing stage. Nonetheless, this preliminary study could provide clinical evidence that wearing an appropriate orthopedic brace, even for a short period, sufficiently relieved scoliosis in adult patients with moderate scoliosis. Expanded clinical trials will be performed to address these limitations are needed in the future.

Acknowledgments

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Conflict of interest

None to report.

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