

การเปรียบเทียบผลการถ่ายภาพรังสีทันทันที่ระหว่างการใส่กายอุปกรณ์เสริมลำตัวที่มีและไม่มี แผ่นบุภายในอุปกรณ์ชนิดไดนามิกที่ระดับอกสำหรับผู้ป่วยกระดูกสันหลังคด ชนิดไม่ทราบสาเหตุในวัยรุ่น: รายงานผู้ป่วยหลายราย

พิชญะ ระโยธี¹ สันติ อัสวพลังชัย² หทัยชนก อรุณแสงศิลป์¹ ศกสวรรณ ชัยวิรัตน์กุล¹ Syifa Fauziah¹

Selvia Suryadinata¹ ฉันทพร รักบางบุรณ์¹ Anna Ignas Mella¹ ภาพร โชคปิติกุล¹

¹โรงเรียนกายอุปกรณ์สิรินธร คณะแพทยศาสตร์ศิริราชพยาบาล มหาวิทยาลัยมหิดล

²ภาควิชาเวชศาสตร์ฟื้นฟู คณะแพทยศาสตร์ศิริราชพยาบาล มหาวิทยาลัยมหิดล

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บทคัดย่อ

โรคกระดูกสันหลังคดชนิดไม่ทราบสาเหตุในวัยรุ่นเป็นโรคที่พบบ่อย โดยกายอุปกรณ์เสริมลำตัวเป็นทางเลือกหนึ่งในการรักษา หากแบ่งลักษณะของแผ่นบุภายในอุปกรณ์ สามารถแบ่งได้ 3 กลุ่ม คือ ไม่มีแผ่นบุ มีแผ่นบุแบบคงที่ และมีแผ่นบุแบบไดนามิก อุปกรณ์ชนิดโรเซนเบอร์เกอร์เป็นอุปกรณ์ชนิดหนึ่งที่มีแผ่นบุแบบไดนามิก แต่การศึกษาวิจัยในอุปกรณ์น้อยมาก ดังนั้น การศึกษานี้ได้ประติษฐานอุปกรณ์ตามหลักการของบอสตันร่วมกับการประติษฐานแผ่นบุแบบไดนามิกตามหลักการของโรเซนเบอร์เกอร์ วัตถุประสงค์การศึกษา เพื่อเปรียบเทียบผลจากภาพรังสีทันทันที่ระหว่างใส่อุปกรณ์ชนิดที่มี (แบบที่ 2) และไม่มี (แบบที่ 1) แผ่นบุแบบไดนามิกที่ระดับอกในผู้ป่วยกระดูกสันหลังคดชนิดไม่ทราบสาเหตุในวัยรุ่น ในแง่การลดลงของมุมกระดูกสันหลังคด ระยะการเลื่อนของส่วนยอดกระดูกสันหลังคด และการชดเชยกระดูกสันหลังคดในระนาบหน้าหลัง การศึกษานี้เป็นการศึกษาแบบรายงานผู้ป่วยจำนวน 3 ราย ผู้ป่วยแต่ละรายถูกถ่ายภาพรังสีขณะใส่อุปกรณ์แบบที่ 1 และ 2 เพื่อวัดผลโดยทันที และนำไปเปรียบเทียบกับขณะที่ไม่ได้ใส่อุปกรณ์ ซึ่งผลลัพธ์แสดงให้เห็นว่า อุปกรณ์แบบที่ 2 ได้ผลดีกว่าแบบที่ 1 ในแง่การลดลงของมุมฯ สำหรับการลดลงของระยะการเลื่อนฯ พบว่าอุปกรณ์แบบที่ 2 ได้ผลดีกว่าแบบที่ 1 ในผู้ป่วยรายที่ 1 และ 3 ที่ระดับอก และรายที่ 1 และ 2 ที่ระดับเอว สำหรับการลดลงของการชดเชยฯ พบว่าอุปกรณ์แบบที่ 1 ได้ผลดีกว่าแบบที่ 2 ในผู้ป่วยรายที่ 1 และ 2 ในทางตรงกันข้าม อุปกรณ์แบบที่ 2 สามารถลดการชดเชยฯ ได้ดีกว่าในผู้ป่วยรายที่ 3 โดยรวมพบว่าอุปกรณ์ทั้ง 2 แบบสามารถลดภาวะกระดูกสันหลังคดได้ โดยอุปกรณ์แบบที่ 2 สามารถลดมุมฯ และระยะการเลื่อนฯ ได้ดีกว่าแบบที่ 1 ซึ่งแสดงให้เห็นว่าอุปกรณ์แบบที่ 2 มีแนวโน้มสูงที่สามารถใช้ในการรักษาผู้ป่วยได้ ในขั้นตอนต่อไปผู้วิจัยเสนอให้ทำการศึกษาระยะยาวในผู้ป่วยกลุ่มใหญ่ รวมไปถึงประเมินคุณภาพชีวิตและการยินยอมใช้อุปกรณ์ด้วย

คำสำคัญ: โรคกระดูกสันหลังคดชนิดไม่ทราบสาเหตุ; แผ่นบุแบบไดนามิกที่ระดับอก; มุมกระดูกสันหลังคด; ระยะการเลื่อนของส่วนยอดกระดูกสันหลังคด; การชดเชยกระดูกสันหลังคดในระนาบหน้าหลัง

ผู้สนับสนุนผลงาน:

สันติ อัสวพลังชัย

ภาควิชาเวชศาสตร์ฟื้นฟู คณะแพทยศาสตร์ศิริราชพยาบาล มหาวิทยาลัยมหิดล

2 ตึกศรีสังวาลย์ ชั้น 9 สำนักงานภาควิชาเวชศาสตร์ฟื้นฟู คณะแพทยศาสตร์ศิริราชพยาบาล

ถนนวังหลัง แขวงศิริราช เขตบางกอกน้อย กรุงเทพมหานคร 10700

อีเมล: drjai@yahoo.com

Comparisons of the immediate radiographic results between wearing a custom-made thoracolumbosacral orthosis with and without a dynamic thoracic pad for adolescent idiopathic scoliosis patients: A case series study

Pitchaya Rayothee¹, Santi Assawapalangchai², Hathaichanok Arunsaengsin¹, Sakolwan Chaiviratnukul¹, Syifa Fauziah¹, Selvia Suryadinata¹, Thanyaporn Rakbangboon¹, Anna Ignas Mella¹, Paporn Chokpitiboon¹

¹Sirindhorn School of Prosthetics and Orthotics, Faculty of Medicine, Siriraj Hospital, Mahidol University

²Department of Rehabilitation Medicine, Faculty of Medicine, Siriraj Hospital, Mahidol University

Abstract

One of the most common pathologies in adolescents is adolescent idiopathic scoliosis (AIS). Spinal orthosis is a treatment option for delaying the progression of the curve. Based on the characteristics of the padding inside the orthosis, it can be divided into three groups: no padding, static padding, and dynamic padding. The Rosenberger brace is one type of spinal orthosis with a movable or dynamic pad; however, very few studies have been done on this design. The study fabricated a custom-made thoracolumbosacral orthosis (TLSO) based on the Boston principle concept with a movable thoracic pad following the Rosenberger brace concept. Therefore, the objective of the study was to compare the immediate radiographic results between wearing a custom-made TLSO with a dynamic thoracic pad (design 2) and without a dynamic thoracic pad (design 1) in AIS patients in terms of the Cobb angle, apical translation, and coronal decompensation reduction. This was a case-series study involving three AIS patients who were fitted with custom-made TLSO designs 1 and 2, and with an in-brace X-ray immediately taken for both interventions. The Cobb angle, apical translation, and coronal decompensation were measured and compared with the most recent out-of-brace X-ray. The results illustrated that the TLSO design 2 showed better results in terms of the Cobb angle reduction at both the thoracic and lumbar curves. For the apical translation reduction of TLSO design 2, it presented better results for participants 1 and 3 at the thoracic curve and at the lumbar curve for participants 1 and 2. In terms of coronal decompensation reduction, TLSO design 1 performed better than design 2 among participants 1 and 2. However, TLSO design 2 performed better in participant 3. Overall, both designs showed improvements in the Cobb angle, apical translation, and coronal decompensation. TLSO design 2 showed better results in reducing the Cobb angle and apical translation compared to TLSO design 1. The result of TLSO design 2 shows the high potential effectiveness of brace treatment. In the next step, a long-term study with a large group of scoliosis patients would be recommended, which would include assessing the quality of life of patients, as well as patient compliance.

Keywords: idiopathic scoliosis; dynamic thoracic pad; Cobb angle; apical translation; coronal decompensation

Corresponding Author:

Santi Assawapalangchai

Department of Rehabilitation Medicine, Faculty of Medicine, Siriraj Hospital, Mahidol University

2 Srisangwan Building, Siriraj Hospital, Wang Lang Road, Bangkoknoi, Bangkok 10700, Thailand.

E-mail: drjaii@yahoo.com

Introduction

Scoliosis is an abnormal lateral curvature of the spine with more than 10° and rotation of the vertebrae.^{1,2} The most common cause is still unknown (i.e., idiopathic), with 80% of cases presenting as adolescent idiopathic scoliosis (AIS), with a predominance toward affecting girls more than boys.^{1,2} The radiographic image is a standard measurement technique for measuring spinal deformity.³ Scoliosis can be treated by either conservative treatment or surgical treatment.¹ Spinal orthosis is the most common treatment to prevent curve progression⁴ and is an indication when the curve is between 25° - 40° and the Risser sign is between 0 - 2.3. There are many different types of spinal orthosis for AIS treatment and the classification varies depending on the time used, biomechanical principle, fabrication materials, and padding system. Regarding the padding system, the study is typically divided into three groups based on the characteristic and adjustability of the padding: no padding, static padding, and dynamic padding. The application of each design depends on the features and their objectives. The Wilmington brace⁵, Providence brace⁶⁻⁸, and Charleston Bending brace⁶ are three common braces that do not come with padding and are considered as none-padded braces. The Boston brace⁹ usually requires a static pad to apply the corrective force. The Rosenberger brace¹⁰ comes with a moveable strap and is considered to be a dynamic padding brace.

Experience of pressure discomfort, limitation of movement, the external appearance, and side effects from long-term use can significantly impact patients' compliance and thus the treatment outcome. Consequently, the research goal is to invent a new orthotic design with a dynamic pad that would still provide good spinal in-brace correction but with better comfort and improved patient compliance while wearing the device. However, a new brace design has never been used before, so this study only focused on the immediate in-brace results. A previous investigation mentioned that the location of the correcting force plays an important role in determining the level of curve reduction;¹¹ however, making such a pad is more time consuming in terms of both the manufacturing and fitting processes. To minimize this problem, the dynamic pad was prescriptive, and the clinician or patient could easily adjust the straps to ensure optimal in-brace correction, better comfort, and more convenience. The Rosenberger brace is the most commonly used dynamic brace pad. It is a low-profile prefabricated TLSO with moveable straps at the thoracic or lumbar. Theoretically, it has a better appearance and causes less restriction than the Milwaukee brace. A previous study by Spoonamore et al. (2004) showed that the failure rates of using the Rosenberger brace were lower in their subgroups of patients;¹⁰ however, the overall failure rate in the treated group was similar to that in the untreated group. The study also

suggested further research to clarify the indication for using this orthosis. Unfortunately, very few studies have been done on the Rosenberger brace or even on other dynamic pads and so we still do not have enough evidence to support the treatment result.

Consequently in this study, a custom-made TLSO with a dynamic thoracic pad was designed based on the concept of a Rosenberger brace (moveable strap) and custom-made Boston brace (including the casting to fitting process). The uniqueness of this design was that it was a custom-made TLSO with an adjustable strap. As a custom-made TLSO with a dynamic thoracic pad has never been used in treatment before, as a first stage, this study aimed to investigate the immediate in-brace results and to observe its potential effectiveness before carrying out a study with a large group. Therefore, the objective of this study was to compare the immediate radiographic results between the custom-made TLSO with and without a dynamic thoracic pad in AIS patients as a case series study.

Case series

Participants were recruited from the outpatient at prosthetics and orthotics clinic, Siriraj Hospital. For the inclusion criteria, participants were diagnosed with AIS, male or female who is between 10 - 18 years old, Cobb angle is between 25° - 45°, all curve patterns with a flexible type, apical vertebra from T8 and below, and body mass index (BMI) is

between 18.5 - 24.9. The procedures utilized in this study involved minimal risk and were approved by the Siriraj Institutional Review Board of the Human Research Protection Unit as being in full compliance with international guidelines for human research protection (COA No. SI 818/2018). To minimize bias, all the participants were casted and had the device fitted by the same professional orthotist team. In addition, another professional orthotist was involved in measuring the outcomes from the X-ray images. The participants were firstly fitted with a custom-made TLSO without a dynamic thoracic pad, called Design 1 (Figure 1.a and 1.b), and subsequently with a custom-made TLSO with a dynamic thoracic pad, called Design 2 (Figures 1.c to 1.e) for comparison. The casting, rectification, and fabrication of design 1 was based on the custom-made Boston brace principles, whereas design 2 was modified from design 1 after adjustment following the first fitting for each participant. Therefore, the padding location, trimline, and the amount of force at the opening area could be controlled between the two brace designs. Three orthotists were required during the casting process to capture the spinal shape and correct the spinal deformity. During rectification, orthotists identified the padding location and reduced the plaster on a positive model; however, the soft padding was added if the curve did not sufficient corrected. The copolymer plastic sheet with a 4-millimeter thickness was used to fabricate the device. The device was

opened at the posterior side to allow donning and doffing, and a window was opened at the opposite side of a major curve to allow spinal shifting. For the suspension, orthotists tightened the straps to the maximum, and the participant could still tolerate them. Then, the marking line was drawn on the straps, and the orthotists must always fasten the straps to the

same marking line to maintain the tension. Moreover, the fittings of designs 1 and 2 and the taking of the X-ray images were done in a posteroanterior (PA) whole spine upright position on the same day to minimize any bias and to prevent any carry-over effect from each brace treatment.



Figure 1 a) frontal view and b) sagittal view of the custom-made TLSO design 1 c) frontal view, d) sagittal view, and e) top view of the custom-made TLSO design 2.

TLSO design 2 was based on the cutting area by covering the thoracic pad from design 1. Moreover, in the posterior side, there was some remaining material at the midline that could act as a connecting part between the brace and the cutting pad. The connecting part should be both flexible and should maintain the padding location. In the sagittal trimline, the plastic was cut along the midline of this plane following the shape of the pad. Then, the adjustable strap was attached to the outer side of the brace starting from the posterior side. After that, it was attached following the contouring of the cutting pad and finally went into the anterior slot.

Importantly, the direction of the strap should be oblique to push or apply anteromedial and upward rotating forces when the strap is tightened.

To acquire the required study data, radiographs were taken of each participant, including out-of-brace (no more than 3 months) and immediately when placed in the brace. All of the radiographs were assessed and measurements taken for the Cobb angle, apical translation, and coronal decompensation outcomes by one professional orthotist. All parameters were averaged from 3 times measurements. To calculate the percentage reduction of each outcome measurement, the

result was determined as the difference between the original values from the out-of-brace radiograph (OBR) and the new values from the in-brace radiograph (IBR) taken on the fitting day for both brace designs. Since this study design involved a case series, descriptive analysis was mainly used to report the results from each participant, including, age, gender, curve type, grade of Risser sign, degree of Cobb angle, apical translation, and coronal decompensation.

Participant 1 was a 15-year-old female, diagnosed as AIS when she was 13 years old and she had been post-menarche for 2 years. Her BMI was 18.67 and she had a flexible curve. Figure 2.a illustrates the participant 1's immediate results for the OBR and IBR measurements. The outcome measures showed that she had a double curve, right major thoracic curve at T8 (35°) and left minor lumbar curve at L2 (26°), and her Risser sign was grade 3. The apical translation at the thoracic and lumbar were 21.14 mm and 15.51 mm, and the coronal decompensation was 8.37 mm to the left side. Comparing between TLSO designs 1 and 2, as illustrated in Table 1, the degree of Cobb angle and reduction percentages were better in design 2 at both curves. The reduction percentages in design 1 and design 2 at the thoracic were 31.53% and 40% and at the lumbar were 23.08% and 30.77%, respectively. Similar results were also presented in the apical translation, which was decreased in design 2 at both curves. The reduction percentages in design 1 and design

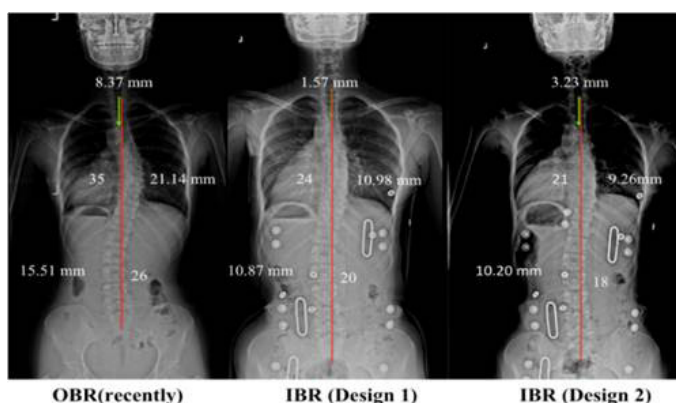
2 at the thoracic were 48.06% and 56.20% and at the lumbar were 29.9% and 34.24%, respectively. In contrast, the coronal decompensation reduction in design 2 was less than in design 1. The reduction percentages in design 1 and design 2 were 81.24% and 61.41%, respectively.

Participant 2 was an 11-year-old female, diagnosed as AIS in the same year of age and she had been post-menarche for 2 months. Her BMI was 18.81 and she had a flexible curve. Figure 2.b illustrates the participant 2's immediate radiographic results. The outcome measures showed that she had a double major curve with a right thoracic curve at T9 (32°) and left lumbar curve at L2 (33°), and her Risser sign was grade 3. The apical translation at the thoracic and lumbar were 8 mm and 12.5 mm, and coronal decompensation was 20 mm to the left side. Comparing between TLSO designs 1 and 2, as shown in Table 1, a Cobb angle reduction was obviously seen at both curves. The reduction percentages in design 1 and design 2 at the thoracic were 31.25% and 53.13% and at the lumbar were 51.52% and 72.73%, respectively. Similar results were presented in the apical translation, which was decreased in design 2 at the lumbar, but not at the thoracic. The reduction percentages in design 1 and design 2 at the thoracic were 75.75% and 61.75% and at the lumbar were 20.24% and 42.80%, respectively. Meanwhile, design 2 did not reduce coronal decompensation more than design 1. The reduction percentages in design

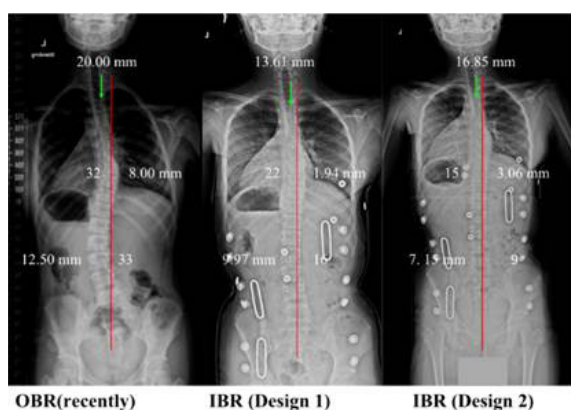
1 and design 2 were 31.95% and 15.75%, respectively. However, both designs were still better than the OBR results.

Participant 3 was a 14-year-old female, diagnosed as AIS since she was 11 years old and she had been post-menarche for 1 year. Her BMI was 20.44 Kg/m² and she had a flexible curve. Figure 2.c illustrates the participant 3's immediate radiographic results. The outcome

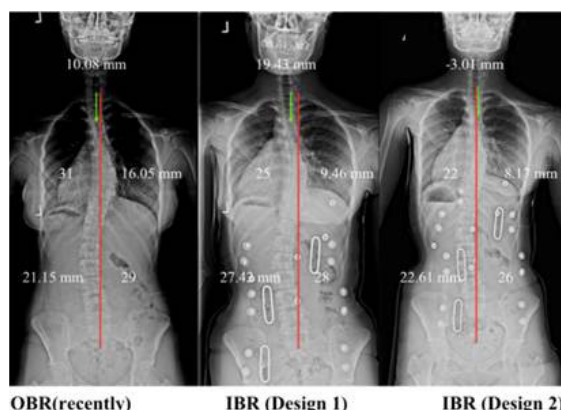
measures showed that she had a double major curve. The right thoracic and left lumbar curve were at T8 (31°) and L1 (29°), respectively, and her Risser sign was grade 3. The apical translation at the thoracic and lumbar were 16.05 mm and 21.15 mm, and coronal decompensation was 10.08 mm to the left side. Similar to participants 1 and 2, while wearing TLSO design.



a)



b)



c)

Figure 2 a) participant 1, b) participant 2, and c) participant 3's immediate radiographic for the out-of-brace result (OBR) and in-brace result (IBR)

Table 1 Results of participant 1, 2, and 3

	Participant 1						Participant 2						Participant 3					
	OBR	IBR ₁	IBR ₁ %	IBR ₂	IBR ₂ %	OBR	IBR ₁	IBR ₁ %	IBR ₂	IBR ₂ %	OBR	IBR ₁	IBR ₁ %	IBR ₂	IBR ₂ %	OBR	IBR ₁	IBR ₁ %
Cobb angle at the thoracic (degree)	35.00	24.00	31.53	21.00	40.00	32.00	22.00	31.25	15.00	53.13	31.00	25.00	19.35	22.00	29.03			
Cobb angle at the lumbar (degree)	26.00	20.00	23.08	18.00	30.77	33.00	16.00	51.52	9.00	72.73	29.00	28.00	3.45	26.00	10.34			
Apical translation at the thoracic (mm)	21.14	10.98	48.06	9.26	56.20	8.00	1.94	75.75	3.06	61.75	16.05	9.46	41.06	8.17	49.10			
Apical translation at the lumbar (mm)	15.51	10.87	29.90	10.20	34.24	12.50	9.97	20.24	7.15	42.80	21.15	27.42	-29.65	22.61	-6.90			
Coronal decompensation (mm)	8.37	1.57	81.24	3.23	61.41	20.00	13.61	31.95	16.85	15.75	10.08	19.43	-92.76	3.01	70.14			

Note: OBR = Out-of-brace radiographic; IBR₁ = In-brace radiographic design 1; IBR₁% = Reduction percentage of In-brace radiographic design 1; IBR₂ = In-brace radiographic design 2; IBR₂% = Reduction percentage of In-brace radiographic design 2; mm = millimeter

A spinal orthosis for scoliosis plays a major role in delaying spinal curve progression.¹² Beside compliance from the patient, the spinal orthotic design significantly affects the spinal treatment. Moreover, the design, location, and direction of any padding and the force applied on the padding directly affect the curve correction,¹¹ and these are based on the decision-making of the clinician. Regarding the dynamic pad, the role of the dynamic pad in this study was to enhance the corrective force applied upon the apical thoracic with easily loosening and tightening the strap. Each participant showed different reductions in Cobb angle, apical translation, and coronal decompensation. The study results for the Cobb angle reduction were consistent with those previously reported by Wong et al. (2000), where the pressure of padding and strap tension provided a highly correlated correlation with the anterior-posterior Cobb angle.¹³ This previous study suggested that the biomechanical function of spinal orthosis should concern the tightness of the strap, and the location and direction of padding, which was relevant for our study because we recognized that the dynamic strap could help to increase the tension and pressure correction for individual patients. Nevertheless, the direction of force in the adjustable strap still followed the optimal direction. Concerning the corrective force measurement in braces, Van den Hout et al. (2002) studied the interface corrective force in a Boston brace design.¹⁴ Their study reported that the corrective pressure at the lumbar was higher

than at the thoracic region. A following study by Hermus et al. (2009) focused on the interface corrective force in their new TLSO design with a dynamic thoracic pad incorporated.¹⁵ Interestingly, the corrective pressure at the thoracic was higher than at the lumbar region. Therefore, their study concluded that the thoracic brace pad was dynamic, or their dynamic thoracic pad could increase or decrease the corrective force, which was similar to our dynamic concept. However, their research did not study if there was a correlation between the corrective pressure from the dynamic pad and spinal curve correction. Landauer et al. (2003) reported that the spinal outcome could be significantly successful if the initial in-brace correction was more than 40% with good compliance.¹⁶ A similar suggestion by Weiss and Rigo (2011) was that there should be a more than 40% of in-brace correction; however, it was hard to correct in line with those percentages in all the curve patterns.¹⁷ In TLSO design 2, the percent reduction at the thoracic curve of participant 1 and both curves of participant 2 was higher than 40%. In contrast, both curves of participant 3 and the lumbar curve of participant 1 were less than the suggested value. However, the percent reduction of design 2 was still better than design 1.

Conclusion

Overall, both designs could reduce all outcomes, with TLSO design 2 performing slightly better than TLSO design 1 in terms of the Cobb angle and apical translation results.

To clarify further details, the Cobb angle reductions of both designs at the thoracic and lumbar were better in all participants. In addition, only the corrective force from the dynamic thoracic pad in design 2 affects the reduction of both thoracic and lumbar curves because the straps act as two main roles; a principal force for the thoracic curve correction and a superior counter-force for the lumbar curve correction. In terms of the apical translation reduction, in participants 1 and 2, both designs could reduce the translation, with design 2 slightly better than design 1, except for in the case of the thoracic curve of participant 2, where design 2 performed slightly worse than design 1. In participant 3, both designs could reduce the translation at the thoracic curve, but design 2 was slightly better than design 1. In contrast, the translation at the lumbar curve could not be reduced by both designs. On the other hand, the results were reported in minus values or the apical translation at this area actually increased when compared with the out-of-brace result. Focusing on the coronal decompensation reduction, in participants 1 and 2, both designs could reduce the decompensation, but design 1 was slightly better than design 2. For participant 3, the decompensation was increased in design 1 and decreased in design 2; however, the decompensation from design 2 was slightly shifted to the opposite side. Furthermore, there was no report related to the immediate complication in terms of pain and pressure sore from two brace designs in all participants. This study encountered many

challenges, such as the limitation of related articles and clinical evidence of TLSO with a dynamic pad. However, our research results showed a good tendency of this treatment and further research with a larger number of participants needs to be considered. Finally, the success of scoliotic treatment by using orthosis is time dependent. To prove the effectiveness of treatment, we recommend future research to study the long-term use and assess the patient quality of life such as treatment compliance, complication, and satisfaction.

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