Targeting Journal: SPINE

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Title: The Intelligent Automated Pressure-Adjustable Orthosis for Patients with Adolescent Idiopathic Scoliosis (AIS): A Bi-Center Randomized Controlled Trial

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Device Statement:

The device that is the subject of this manuscript is not FDA-approved for this indication and is not commercially available in the United States.

The following publication Lin, Y., Lou, E., Lam, T. P., Cheng, J. C. Y., Sin, S. W., Kwok, W. K., & Wong, M. S. (2020). The Intelligent Automated Pressure-Adjustable Orthosis for Patients With Adolescent Idiopathic Scoliosis: A Bi-Center Randomized Controlled Trial. Spine, 45(20), 1395-1402 is available at https://doi.org/10.1097/BRS.0000000000003559

ABSTRACT

Study Design. Randomized controlled trial.

Objective. To compare the effectiveness of the automated pressure-adjustable orthosis (PO) and conventional orthosis (CO) for treatment of adolescent idiopathic scoliosis (AIS).

Summary of Background Data. Orthosis wearing quality may influence its effectiveness for AIS. An automated PO aimed to provide a more optimized and consistent biomechanical environment. Clinical evaluation was conducted to study the effectiveness of this innovative orthosis.

Methods. Patients with AIS who met the criteria (Age 10-14, Cobb 20°-40°, and Risser sign 0-2) were recruited from 2 clinics and randomly assigned to the PO and CO groups. Compliance sensors were embedded in both groups, while the PO group was set to adjust the interfacial pressure as prescribed automatically. Clinical assessments (radiology and quality of life, QoL) were conducted at the baseline, immediate after orthosis fitting and 1-year follow-up. Orthosis wearing compliance was tracked using thermo and pressure sensors.

Results. Twenty-four patients were enrolled with one drop-out (PO, n=11; CO, n=12). Significant immediate in-orthosis correction was observed in the PO (11.0°±6.5°, 42.0%, p<0.001) and CO (10.3°±5.3°, 37.6%, p<0.001) groups. After 1 year, no subject with PO progressed while 2 with CO had progression >5°. The mean daily wearing duration was 1.1 hours longer in the PO group as compared with the CO group (15.4±4.5 vs 14.3±3.8 hours). Moreover, the wearing quality within the targeted pressure was 33.9% higher in the PO group (56.5±16.5% vs 23.1±12.1%, p<0.001). No significant difference in the QoL results was observed between two groups nor within both groups during the study period.

Conclusion. This study showed that the automated PO could enhance wearing quality when compared with the CO, thus offering a better biomechanical corrective effect in the study period without adverse effect on the patients' wearing quantity and QoL.

Keywords: adolescent idiopathic scoliosis, automated pressure-adjustable orthotic treatment, compliance, electronic sensor, wearing quantity, wearing quality, interfacial pressure, Cobb angle, quality of life, mental health

Level of Evidence: 1

KEY POINTS

- In-orthosis correction, wearing quality and wearing quantity are important factors to the treatment outcome of AIS.
- Orthoses with and without the pressure-adjustable function have similar immediate in-orthosis correction.
- The pressure-adjustable orthosis could provide better wearing quality.
- Orthosis with pressure-adjustable function has the potential to offer better curve control.

MINI ABSTRACTS

A bi-center randomized controlled trial was conducted to compare the treatment effectiveness of the pressure-adjustable orthosis and conventional orthosis to the patients with adolescent idiopathic scoliosis . The pressure-adjustable orthosis could offer better curve control by providing a more consistent biomechanical environment at the prescribed level.

INTRODUCTION

Adolescent idiopathic scoliosis (AIS) is a complex three-dimensional spinal deformity with unclear cause and 1-4% of prevalence.[1-3] Orthotic treatment is commonly prescribed to patients with moderate AIS (Cobb 25°-40°) to control the progression of spinal curvatures.[4, 5] However, its treatment effectiveness can be influenced by many factors,[6-9] among which, patient's compliance is one of the crucial factors.[10-12] It refers to how the patient follows the prescription of the treatment protocol. Moreover, it should include both wearing quantity and quality.[13]

A considerable in-orthosis correction represents the ability to provide effective passive biomechanical correction,[14] and this is highly correlated to the orthosis tightness and strap tension.[15, 16] Under the ideal circumstance, the patient should tighten the straps as prescribed to yield consistent biomechanical correction, and thus to achieve treatment success. However, due to the wear and tear of straps in daily usage and physical exercises, the interfacial pressure has been reported to decline, which could impact the likelihood of successful treatment.[13, 17] Due to its long-term usage, few objective approaches to enhance the wearing quality could be found.

An automated pressure-adjustable orthosis (PO) has been developed aiming to maintain a more consistent interfacial corrective effect at the prescribed level.[18-20] In a pilot study, PO tended to have better curve control capacity than that of the conventional orthosis (CO).[21] However, the results were only confined to a small subject group, and the accumulated effect of both the PO and CO. Besides, the influence on compliance or quality of life (QoL) were not studied. In addition, the pressure-adjustable device has recently been upgraded to a smaller dimension with less power consumption and its clinical effect should be evaluated.

With the automatically pressure-adjustable function, the wearing quality of spinal orthosis may be enhanced, and thus to further improve the treatment outcome. Based on these premises, this study aimed to investigate the wearing quality as well as to compare the treatment effect of the PO and CO to patients with AIS.

MATERIALS AND METHODS

Study Design

This is a bi-center randomized controlled trial (RCT) to compare the effectiveness of the PO versus the CO for patients with AIS. Ethical approval was obtained before the study began (Reference No. Pro00003495 & No. 2015.088-T).

Subjects

Females with moderate AIS who met the inclusion criteria as referenced from the recommendations by Scoliosis Research Society (SRS)[22] and International Scientific Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT)[23] were enrolled: age 10 to 14,

Risser sign 0-2, Cobb 20°-40°, and pre-menarche or within 24 months after menarche. Patients who had received surgery or any conservative treatments before baseline were excluded. Sealed envelopes with group assignment information were used and an equal number of subjects were randomly assigned to the PO and CO groups.

Devices and Sensors

Pressure-adjustable devices were embedded in the PO group, while compliance sensors were installed in the CO group. Both were covered by purpose-design 3-dimensional printed shells to protect against compression and collision. Waterproof soft paddings were placed between the skin and the device/sensor to prevent electric shock and damage from sweating.

The new automated pressure-adjustable device[18] weighted 35g with the dimension of 61×44×22 mm. The interfacial pressure can be regulated by inflation and deflation of the air bladder (131×50mm). The interfacial pressure regulation was disabled during the evening (23:00-7:00) to avoid disturbance by the noise from the pump. Subjects were allowed to turn off the pressure regulation if there was any over inflation. No over inflation was found in the study. Subjects and their parents in the PO group were instructed to charge the device for 1 hour per week. The dimension and weight of the compliance sensors[24] were 48×32×8mm and 8g respectively. The compliance sensor collected temperature and pressure data. No additional attention was needed for patients in the CO group.

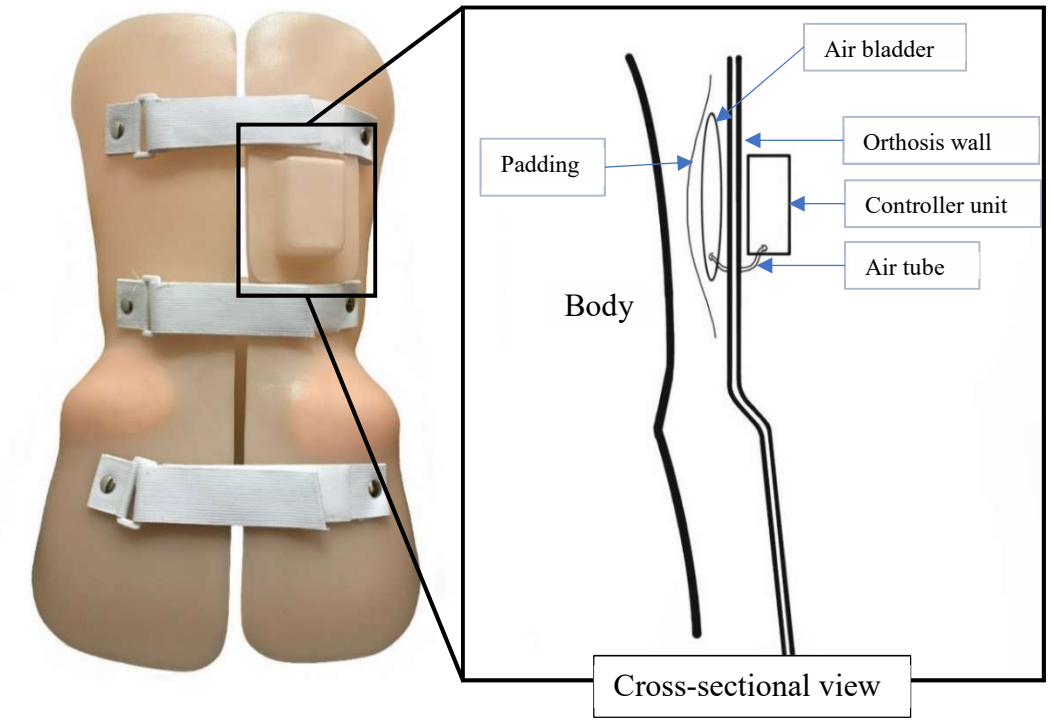

Figure 1. The pressure-adjustable orthosis and its placement (cross-sectional view)

Treatment Protocol

All subjects were prescribed with fulltime (23 hours/day) orthotic treatment.[25] To eliminate the confounding factors caused by device/sensor installation, orthotists in each center followed the same protocol to design and fabricate the orthoses for both groups. The device/sensor was installed after the adjustments of orthosis fitting. The device/sensor of both groups was installed at the

corresponding apical area of the primary curve to collect the data of temperature and pressure (Figure 1). The device in the PO group was set to automatically regulate the interfacial pressure within the range from 80% to 120% of the prescribed level.

Outcome Measures

Posterior-anterior (PA) radiographs of the spine in standing posture were taken at the baseline, immediate after fitting and one year of orthotic treatment. Cobb angle was used for evaluation of spinal curvature.[26]

Collection of temperature and pressure data was set with a 2-minute interval. A threshold determined the daily wearing quantity as the maximum air temperature of the corresponding day reported by the Government Observatory. Wearing quantity was presented in daily wearing hours which was calculated as:

$Wearing\ quantity = 24\ \times (\frac{Number\ of\ temperature\ data\ higher\ than\ the\ threshold\ at\ each\ day}{720})$.

And wearing quality was the percentage of the duration with the prescribed interfacial pressure range over the wearing quantity calculated as:

$Wearing\ quality = 100\% \times (\frac{\text{duration with prescribed interfacial pressure range}}{\text{wearing quantity}})$. Both the pressure-adjustable device and the compliance sensor utilized the same wearing quantity and quality calculation algorithm.

The SRS-22r questionnaire (Chinese version) was used to assess the QoL (score range from 0 to 5).[27] The trunk appearance was assessed using the Scoliosis Appearance Questionnaire (SAQ in Chinese version, including three main aspects and nine specific domains with different score ranges).[28] The Brace Questionnaire (BrQ) was applied to assess the perception towards orthotic treatment (Chinese version, score range from 0 to 100).[29, 30] The SRS-22r and SAQ were assessed at the baseline and after one year, while the BrQ was assessed at the 1-year follow-up. The higher the score of the SRS-22r and BrQ indicates a better QoL or perception. In contrast, the lower the score indicates the better perception of the SAQ.

Statistical Methods

Statistic analyses were conducted in the software of IBM SPSS Statistics (version 21.0, IBM Corp., US) at a significant level of 0.05. Descriptive statistics were used to demonstrate the quantitative features, including mean, standard deviation (SD), and range. After normality tests, the continuous intra-group changes of Cobb angles were analyzed by repeated-measures analysis of variance (ANOVA). The Wilcoxon Signed-Rank Test was utilized for the intra-group analysis of the results of the questionnaire, including SRS-22r and SAQ. Post-hoc tests were conducted using the Bonferroni correction. For the inter-group comparisons, differences in Cobb angles, wearing quantity and quality were examined by the independent Student's t-test. Differences in questionnaire results were examined by the Mann-Whitney U-Test (on the assumptions for the parametric test being inappropriate).

RESULTS

A total of 24 patients out of 93 eligible patients were recruited. Eleven patients in the PO group and 12 subjects in the CO group have finished 1-year of orthotic treatment (Figure 2). The initial

demographic parameters (PO: 8 out of 11 had primary thoracic curve vs CO: 7 out of 12 had primary thoracic curve, shown in TABLE 1) were comparable between the two groups.

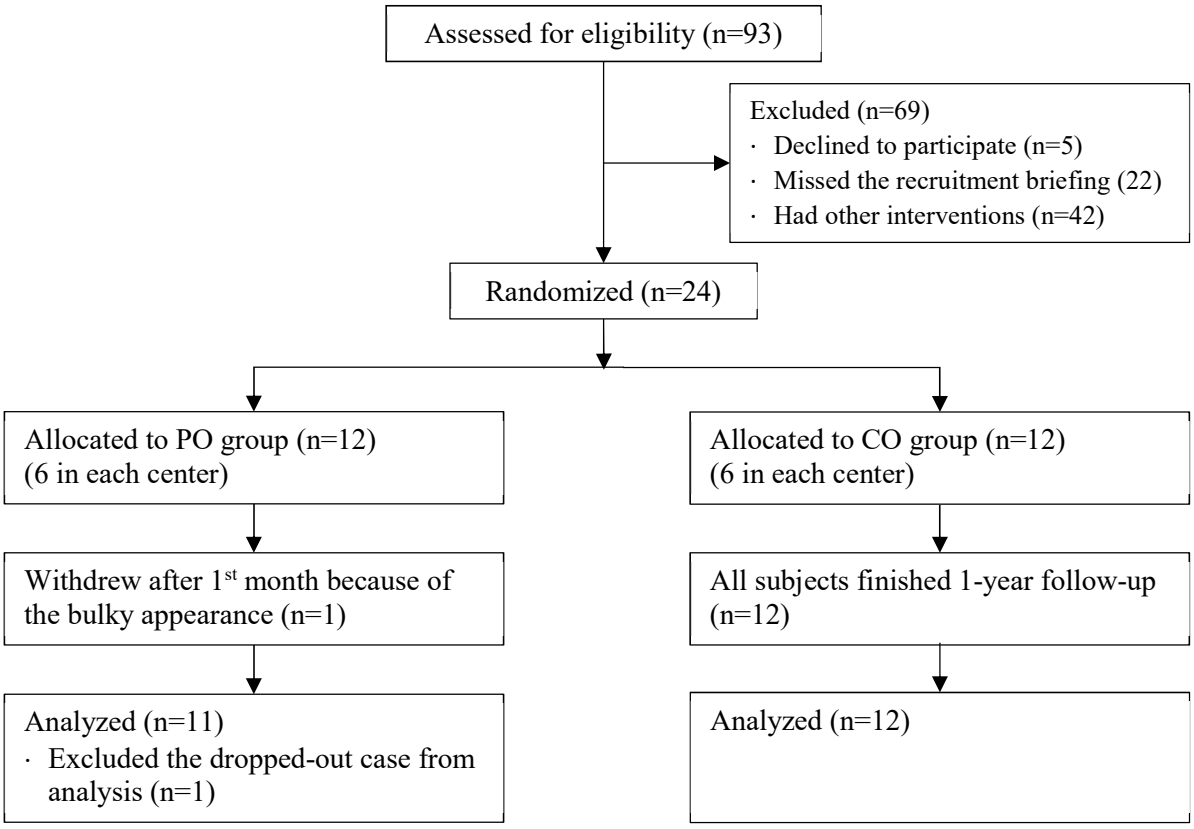

Figure 2. Patient Flow Diagram.

TABLE 1. Comparisons of initial demographic data and Cobb angle between the PO and CO groups

	PO Group (n=11)		CO Group (n=12)		*p*
	Mean ± SD	Range	Mean ± SD	Range	
Age (year)	12.4 ± 1.2	10.6-14.7	12.6 ± 0.9	11.3-14.1	0.579
Menarche (month since)	7.0 ± 7.8	0.0-20.0	5.0 ± 8.7	0.0-23.0	0.520
Risser sign (0-5 grade)	0.8 ± 0.9	0.0-2.0	0.4 ± 0.7	0.0-2.0	0.241
Height (cm)	156.6 ± 4.6	151.5-166.0	154.8 ± 3.6	150.7-160.6	0.303
Weight (kg)	41.2 ± 5.0	33.6-48.0	39.3 ± 5.2	34.6-49.4	0.323
BMI (kg/m^2)	16.8 ± 1.9	14.6-20.5	16.4 ± 2.6	14.2-21.8	0.322
Sitting Height (cm)	82.1 ± 2.1	80.0-85.0	82.0 ± 2.7	79.0-87.0	0.904
Cobb angle (°)	26.2 ± 4.7	20.0-34.0	27.4 ± 5.6	20.0-36.0	0.575

PO, pressure-adjustable orthosis; CO, conventional orthosis; SD, standard deviation; BMI, body mass index.

No subjects progressed to surgical level during the 1-year orthotic treatment. The intra-group comparison of both groups was shown in TABLE 2. Significant immediate in-orthosis correction of the primary curve was observed in both groups ($p<0.001$). The immediate in-orthosis corrections of the PO and CO groups were 11.0°±6.5° (41.8%) and 10.3°±5.3° (37.9%) respectively. No statistically significant difference of Cobb angle was observed between the PO and CO groups at the three measurement points.

TABLE 2. Intra-group Cobb angle changes in the PO and CO groups

Cobb (°)	Baseline	IM in-orthosis	1-year	*p*		
	Mean ± SD	Mean ± SD	Mean ± SD	IM *vs.* BL	1y *vs.* BL	1y *vs.* IM
PO group	26.2 ± 4.7	15.2 ± 6.4	22.3 ± 5.3	0.001‡	0.120	0.041*
CO group	27.4 ± 5.6	17.1 ± 6.1	26.9 ± 8.8	0.001‡	1.000	0.001‡

*$p<0.05$
‡ $p<0.001$
X-ray at 1-year follow-up was taken without orthosis.
PO, pressure-adjustable orthosis; CO, conventional orthosis; IM, immediate; 1y, 1-year follow-up; BL, Baseline; SD, standard deviation.

The number of subjects who achieved 30% of in-orthosis correction (PO: n=8, 72.7% vs CO: n=8, 66.7%) and who achieved 35% of in-orthosis correction (PO: n=5, 45.5% vs CO: n=6, 50.0%) was similar. After 1-year orthotic treatment, the mean Cobb angle reduction in the PO group was 3.3° higher than the CO group. The Cobb angle examined without orthosis at 1-year follow-up showed that there were four subjects had curve reduction >5°, and two subjects had 1° of progression in the PO group; while there were two subjects had curve reduction >5°, and two subjects had curve progression >5° in the CO group ($X^2 \geq 2.008$, $p=0.156$).

The comparisons of orthosis wearing quantity and quality between the PO and CO groups were summarized in Table 3. The orthosis wearing quantity was similar between the two groups that the daily wearing quantity was 1.1 hours slightly longer in the PO group (Figure 3). The PO group had significantly longer daily wearing duration with interfacial pressure within the targeted range ($p<0.001$, 8.7 vs 3.3 hours) and had significantly better-wearing quality ($p<0.001$, 56.5 vs 23.1%) than the CO group.

TABLE 3. Comparisons of the orthosis wearing quantity and quality between the PO and CO groups

	PO Group (n=11)		CO Group (n=12)		*p*
	Mean ± SD	Range	Mean ± SD	Range	
Wearing quantity (hour)	15.4 ± 4.8	8.1-22.8	14.3 ± 4.0	8.7-19.4	0.550
Wearing with prescribed PR (hour)	8.7 ± 3.2	1.4-12.3	3.3 ± 2.2	0.4-6.6	0.001‡
Wearing quality (%)	56.2 ± 17.3	17.2-80.0	22.4 ± 12.7	5.1-43.5	0.001‡

‡ $p<0.001$
PO Group, pressure-adjustable orthosis group; CO Group, conventional orthosis group; SD, standard deviation; PR, pressure range

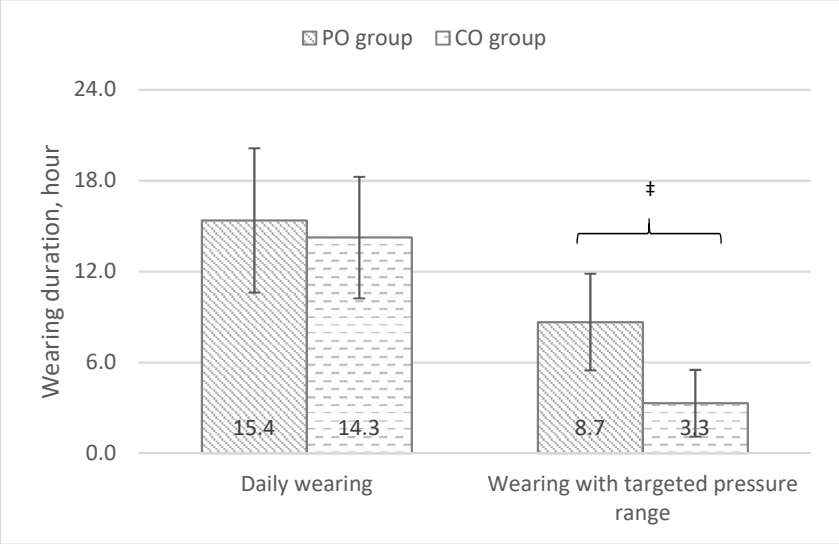

Figure 3. Comparison of the average daily wearing quantity (duration) and the wearing duration with a targeted pressure range between the PO and CO groups. (‡ $p<0.001$)

Furthermore, no statistical difference of the SRS-22r and SAQ results was observed in the intra-group comparisons. From the inter-group comparisons of the SRS-22r, SAQ and BrQ, no statistical differences were found at the baseline (not applicable for BrQ) and at the 1-year follow-up, as summarized in Table 4.

TABLE 4. Comparisons of the SRS-22r, SAQ and BrQ results between the PO and CO groups

	PO Group (n=11)	CO Group (n=12)	*p*
	Mean ± SD	Mean ± SD	
SRS-22r Mean (score range 1 – 5)			
Baseline	4.3 ± 0.2	4.3 ± 0.4	0.644
1-year follow-up	4.1 ± 0.2	4.2 ± 0.3	0.405
SRS-22r Function (score range 1 – 5)			
Baseline	4.8 ± 0.2	4.7 ± 0.3	0.698
1-year follow-up	4.7 ± 0.4	4.5 ± 0.4	0.573
SRS-22r Pain (score range 1 – 5)			
Baseline	4.9 ± 0.3	4.4 ± 0.7	0.159
1-year follow-up	4.6 ± 0.3	4.4 ± 0.5	0.711
SRS-22r Self-image (score range 1 – 5)			
Baseline	3.7 ± 0.2	3.9 ± 0.6	0.916
1-year follow-up	3.6 ± 0.3	3.7 ± 0.4	0.509
SRS-22r Mental Health (score range 1 – 5)			
Baseline	4.2 ± 0.3	4.2 ± 0.8	0.514
1-year follow-up	4.1 ± 0.2	4.2 ± 0.3	0.638
SRS-22r Satisfaction (score range 1 – 5)			
Baseline	3.7 ± 0.8	4.3 ± 0.8	0.260
1-year follow-up	3.5 ± 0.6	4.2 ± 0.5	0.082
SAQ Total (score range 16 – 80)			
Baseline	41.2 ± 13.0	50.3 ± 5.8	0.169
1-year follow-up	46.6 ± 9.5	47.3 ± 5.8	0.714
BrQ at 1-year follow-up (score range 20 – 100)			
Total	80.4 ± 9.4	76.0 ± 10.1	0.584
General health	70.0 ± 7.1	66.7 ± 12.1	0.253
Physical functioning	69.2 ± 17.3	70.0 ± 7.2	0.189
Emotional functioning	73.6 ± 15.6	727. ± 11.7	0.852
Self-esteem aethetics	64.0 ± 15.2	56.7 ± 16.3	0.851
Vitality	72.0 ± 16.4	58.3 ± 14.7	0.780
School activity	92.0 ± 11.0	74.5 ± 20.0	0.641
Bodily pain	92.7 ± 8.9	92.8 ± 11.6	0.690
Social functioning	87.4 ± 11.7	85.3 ± 14.3	0.925

PO Group, pressure-adjustable orthosis group; CO Group, conventional orthosis group; SD, standard deviation

DISCUSSION

The study suggested that applying the PO could significantly improve the wearing quality and achieve better control against curve progression than the CO in this short-term study.

Though orthotic treatment is generally considered as a standard treatment modality for immature patients with moderate scoliosis,[5] its effectiveness could be influenced by many factors, such as the initial maturity level,[31] curvature,[8, 31] in-orthosis correction,[9, 14] and wearing quantity.[32-34] In this study, the initial demographic parameters and primary curve were comparable between the two groups. Both the PO and CO groups achieved effective in-orthosis correction (41.8% *vs* 37.9%) superior to the 25% of correction threshold in the previous study.[8] Besides, the wearing quantity was similar between the PO and CO groups. Therefore, the short-term Cobb angle examined without orthosis were assumed to be similar between the two groups. However, with 33.4% significantly better wearing quality ($p<0.001$), the PO group showed 16.7% better results on curve control. None of the subjects in the PO group had curve progression while 2 out of 12 subjects in the CO group progressed at one year of orthotic treatment ($X^2 \geq 2.008$, $p=0.156$). Wong's team provided the same type of orthosis to AIS with a smaller initial Cobb (24.8°) as the current study.[35] Comparing the survival rate at 1-year follow-up of the previous study[35] to the current one, it was slightly superior to the CO group (95.0 vs 83.3%) while slightly less than the PO group (95.0 vs 100%).

In current clinical practice, putting markings on the straps of spinal orthosis are commonly used by clinicians to indicate to the patients the proper strap tension level in order to maintain interfacial correcting pressure. However, it is still a subjective method, and the patient's compliance to maintain adequate wearing quantity and quality could be an issue. The PO was designed to automatically offset the inappropriate interfacial pressure out of inadequate or excessive strapping tension which could lead to pressure sore.[36] The results of the current study suggested the PO can provide a more consistent in-orthosis biomechanical correcting environment and improve the treatment outcome within the study period.

The biomechanical corrective effect on scoliotic spine has been suggested to be generated by passive correction from spinal orthosis and active correction from spinal muscle contractions.[37, 38] Galante's team proposed the correction of spinal deformity was mainly derived from passive correction.[39] This study also demonstrated the importance of maintaining the consistency of passive biomechanical corrective effect.

While a recent meta-analysis on 20 studies with 1910 patients suggested that there was a significantly higher success rate in the patients with longer wearing quantity,[40] other studies suggested that part-time orthotic treatment were equally effective when compared with full-time wearing.[41-44] A recent study suggested wearing quality could contribute to orthotic treatment effectiveness in addition to wearing quantity.[13] In the current study, better curve control performance was observed with better wearing quality that revealed putting an orthosis on without considering the appropriate corrective pressure may not be able to achieve sufficient corrective effect. Furthermore, lacking information on orthosis wearing quality may partially explain a significant variation of treatment outcomes and controversy of the importance of sufficient wearing quantity.

Despite the potential of better treatment effectiveness of the PO by improving the wearing quality, its bulkiness may require extra attention that could result in reduction of wearing quantity and

negative impact on the QoL. The rejection rate of this study was 17.2%, and the drop-out rate in the PO group was 8.3%. The self-reported reason of rejection was (1) unacceptance of the bulky appearance of the pressure-adjustable device; (2) doubt of the effectiveness of the PO and even orthotic treatment; (3) concern of convenience and safety issued of electronic components. Besides, special care is required for the PO that the battery needs to be charged weekly. However, no statistical significant difference of QoL nor the perception towards orthotic treatment was found between the PO and CO groups. The wearing quantity was slightly longer in the PO group than the CO group. Besides, no decreasing trend of QoL was observed in both groups. These results suggested that the pressure-adjustable device would not result in a deduction of QoL nor wearing quantity. The possible reason was that the appearance of the PO covered by clothes showed no visible difference comparing to the CO (Figure 4). Besides, 8 out of 11 subjects in the PO group verbally reported comfortable at the corresponding corrective area because the corrective pressure was provided via inflatable air bladder with soft texture instead of the foam padding material.

Figure 4. A subject with the pressure-adjustable spinal orthosis before (left) and after (right) covering by a white school uniform.

For future studies, it is suggested to enlarge the sample size and study duration with adjusted recruitment criteria at a lower Cobb angle threshold as recommended by the SRS (25-40°)[22] and SOSORT (20±5°)[23]. Moreover, technical improvements of the PO devices such as the dimension of the device and its battery capacity can be considered.

CONCLUSION

The pressure-adjustable orthosis could provide a longer duration of consistent interfacial biomechanical corrective pressure compared to the conventional one. With this function, it showed a relatively better trend of curve control during the studied period without harming the quality of life nor the wearing quantity. A study for monitoring the corrective pressure for the whole treatment period is warranted to confirm the actual benefit of this pressure-adjustable orthosis for the management of AIS.

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