# Effectiveness of Orthopedic Bracing in the Management of Adolescent Idiopathic Scoliosis: A Randomized Controlled Trial

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### ABSTRACT

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Background: Scoliosis is a complex spinal condition that often requires bracing as a significant treatment to prevent spinal deterioration in adolescent idiopathic scoliosis (AIS). Adaptation can be difficult; the effectiveness of support is well documented and treatment aims to improve the spine and body's quality of life. Objective: The objective of the study is to evaluate the effectiveness of bracing as a treatment for preventing spinal deterioration in adolescent idiopathic scoliosis (AIS) and to assess its impact on the quality of life and spinal health of patients. Study Design: This one-arm quasiexperimental study. Settings: Outpatient department of tertiary care hospitals of Sindh i-e Civil Hospital, Suleman Roshan and Memon Charitable Hospital, Pakistan. Duration: One year i-e 15-04-2023 to 15-04-2024. Methods: The study evaluated the effectiveness of bracing in 20 AIS patients aged 10-17 with Cobb angles of 20°-40°, excluding those with prior treatments or other pathologies. Patients received thoracolumbosacral orthoses (TLSO) and were monitored regularly, required to wear braces 23 hours daily. Assessments of trunk inclination, Cobb angle, and body image were conducted every six months over a year, with radiographic and shoulder balance evaluations performed and bisphosphonates were advised during visits. Results: The study involved 20 AIS patients (11 females, 9 males) with a mean age of 13.8 years and an average baseline Cobb angle of 27.6 degrees. Over 12 months, the mean Cobb angle significantly decreased to 23.12 degrees, indicating a meaningful reduction in spinal curvature. Notable improvements were observed from baseline to 6 months (mean reduction of 2.23 degrees, P < 0.001) and from 6 months to 12 months (mean reduction of 2.89 degrees, P < 0.001), demonstrating significant and clinically meaningful corrections in spinal alignment. Conclusion: The findings highlight the effectiveness of bracing in reducing spinal curvature in adolescents with scoliosis, suggesting promising interventional strategies to improve patient outcomes.

*Keywords: Idiopathic scoliosis, bracing, cobb angle, angle of inclination.* 

### **INTRODUCTION**

Scoliosis, which is a spinal deformity, is a complex threedimensional problem diagnosed by using measurements in the spine through a coronal x-ray plane.<sup>1</sup> Cobb angle which is the angle indicating angle measurement of  $\geq 10^{\circ}$ is assessed for the confirmation of the diagnosis.<sup>2</sup> Scoliosis has many different variations that can occur at any age or due to any circumstances.<sup>3</sup> Abei reported three main types of scoliosis for adults: type I - primary degenerative scoliosis; type II - progressive idiopathic scoliosis; type III secondary degenerative scoliosis in response to idiopathic scoliosis.<sup>4-5</sup> Studies declare that the prevalence of Adolescence Idiopathic Scoliosis (AIS) varies between 0.35% and 5.2% with an average of 2-3% among children <16 years.<sup>6</sup> Even in athletes the prevalence of IS was seen similarly as compared to the general population. In one of the systematic reviews and meta-analysis conducted in 2022, the prevalence of IS was estimated among athletes. Out of 32studies with

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n=57,470, the prevalence of IS was reported to be 27%.7 For many years, many people believed that early-onset scoliosis was a unique and rare condition that was difficult to fully catch in the general population.8 Although this is still true, today's increased awareness of this disease along with the development of knowledge and health allows more patients to be examined at an early stage, allowing the identification of many factors affecting the pathology of scoliosis.9 Although scoliosis is seen equally in men and women during young age, the sex ratio increases to 8.4/1 (female/male) during adolescence, indicating the role of sex hormones in the disease. Esposito et al. and Kulis et al. showed that girls with AIS have been shown to have low levels of estradiol in their blood.<sup>10-11</sup> Additionally, Studies have shown that menarche is more likely to be delayed in the girls with AIS or in northern latitudes where the incidence of AIS is higher than.12 In patients with AIS whose curve is between 25 and 45°, the first treatment is bracing. However, in patients with immature skeleton with a Risser level 0 and 2, the deformity must be flexible.<sup>13</sup> Although Risser stage and menarche are currently used as Scoliosis Research Society (SRS) support criteria, recent research suggests that the Sanders Maturation Scale (SMS) is a better predictor of the rapid growth curve of the highway than Risser stage.<sup>14-15</sup> There are two main options for reducing the risk of curvature as you grow: scoliosis-specific exercises, for which there is little evidence, and a brace made of hard plastic worn around the body. Bracings are the mainstay of AIS treatment.<sup>16</sup> Although different manufacturers produce braces with slightly different designs, the main purpose of all braces is to reduce growth by reducing the size of the curvature in the braces when the patient is not growing.<sup>17</sup> The effectiveness of braces is well known, but acceptance and compliance may be an issue in these patients. In some cases, if the curvature persists during growth or if the curvature persists after support is discontinued, patients still need surgery to correct the curvature.<sup>18</sup> Since curvature affects the patient's growth, it is important to provide support until the body grows or stops growing. Although it is necessary to give patients as few braces as right due to their negative impact on mental health and quality of life, removing brace early while the growth potential is still high can further increase in the spinal curvature. A mild to moderate AIS does not usually cause health problems unless it is severe. But body image often has a negative impact on young people's physical and mental health. Therefore, treatment of mild to moderate AIS aims not only to treat the spine but also to improve quality of life (QoL) related to body image.19

# **METHODS**

A one-arm quasi experimental study design in which the effectiveness of bracing in patients with AIS was

determined. The study had been approved by the ethical review committee of Memon Charitable Hospital Hyderabad having an IRB/MCH/OPD/24/83.

The participants were recruited from the outpatient department of tertiary care hospitals of Sindh i-e Civil Hospital, Suleman Roshan and Memon Charitable Hospital. The inclusion criteria included all participants with age holding 10 to 17 years, having a Cobb angle of  $\geq$  20° to 40° as per the recommendation by Scoliosis Research Society SRS and the International Society on Scoliosis Orthopedic and Rehabilitation Treatment (SOSORT) both. Participants with prior treatment or any other musculoskeletal or lung pathology were excluded from this study.

The treatment involved 20 AIS patients included via convenience sampling technique based on the predetermined selection criteria. They were briefed in detail on the procedure of the study, in informed consent was obtained. They had the right to withdraw from the study at any point in time. At the first visit, patients received a stiff thoracolumbosacral orthosis (TLSO) and an initial evaluation for orthosis design was performed. To ensure proper treatment, patients were invited to the scoliosis clinic for examination and adjustment during the first month of intervention and every three months thereafter. All patients were required to wear orthoses 23 hours a day (at school, at home, in bed, etc.) and rest for bathing and physical activity.<sup>20</sup>

The Angle regarding trunk inclination (ATI) and Cobb angle are two of the golden standards regarding evaluation of the spinal curvature. Body image as influenced by the Shoulder and Body Positivity Scale.<sup>21</sup> Inspections are carried out every 6 months. This study conducted a one-year follow-up and collected data at 3 time points. At every visit, radiographic measurements were taken from the anteroposterior (AP) view to define the spinal cord (Cobb angle, etc.). Patients in the brace group are required to have an x-ray taken two hours after their braces are removed. Shoulder balance was assessed by PA imaging and X-rays based on shoulder balance assessment (CSB), coracoid height difference (CHD), clavicle angle (CA), clavicle angle difference (CTAD), and T1 slope. Supplementary bisphosphonates were also advised. All the above tests were performed in the design environment. Data was also collected in SRS-22. Monitor the team's compliance with the use of on-board thermal equipment.

# RESULTS

Twenty patient's including 11 females and 9 males were recruited via convenience sampling technique from OPDs of multiple tertiary care hospitals. The patients reported a compliance of approximately  $57.7 \pm 0.27\%$ . The subjects held mean age of 13.8 years (SD = 2.5) and ranging from 12 to 15 years old. In terms of physical characteristics, the average height was 162.3 cm (SD = 6.9) with a range of 153 cm to 172 cm, while the mean weight was 48.6 kg (SD = 7.3) with weights ranging from 42 kg to 56 kg. The calculated mean BMI was 20.6 kg/m<sup>2</sup> (SD = 2.9) and ranged from 18.3 kg/m<sup>2</sup> to 24.2 kg/m<sup>2</sup>, suggesting the participants were within a healthy weight range for their age. Notably, the Cobb angle, a measure of spinal curvature, was on average 27.6 degrees (SD = 2.6) and ranged from 24.2 degrees to 34.8 degrees, indicating mild to moderate scoliosis in the study cohort. These baseline characteristics provide valuable insights into the physical and clinical attributes of the adolescent population under study, forming a foundational understanding for subsequent analysis and interpretation of the study outcomes related to scoliosis and its impact on growth and development during adolescence (Table 1).

	Mean ± SD	Range	
Age	$13.8 \pm 2.5$	12-15	
Height (cm)	$162.3 \pm 6.9$	153-172	
Weight (kg)	$48.6 \pm 7.3$	42-56	
BMI (kg/m²)	$20.6 \pm 2.9$	18.3-24.2	
Cobb angle	$27.60 \pm 2.61$	24.2-34.8	

# Table 1: Demographic characteristics at Baseline

Table 2 indicates the comparison within groups for spinal curvature in the time of 12-month period among adolescents suffering from AIS. At baseline, angle of the mean Cobb was 27.60 degrees (SD = 2.61). By the 6-month follow-up, there had been a decrement in the mean Cobb angle to 25.23 degrees (SD = 1.42), though this change had not been statistically significant (P = 0.84). However, by the 12-month follow-up, the mean Cobb angle further decreased to 23.12 degrees (SD = 2.89), that was statistically significant (P = 0.03), mentioning a meaningful reduction in spinal curvature over this period. The analysis of the correction in Cobb angle revealed significant improvements between different time points: The mean correction in Cobb angle from baseline to the 6-month follow-up was 2.23 degrees (SD = 1.42), with a highly statistically significant P value (<0.001), suggesting a significant reduction in spinal curvature. Similarly, from the 6-month to the 12-month follow-up, the mean correction in Cobb angle was 2.89 degrees (SD = 2.10), again highly significant (P < 0.001), indicating continued improvement in spinal alignment. Overall, the baseline to 12-month analysis showed a substantial correction in Cobb angle of 4.52 degrees (SD = 2.89), which was highly significant (P < 0.001), demonstrating significant and clinically meaningful improvement in spinal curvature over the course of the study.

		Mean	SD	P value
Cobb angle	Baseline	27.60	2.61	0.32
	6-month	25.23	1.42	0.84
	12-month	23.12	2.89	0.03
Correction in Cobb angle	Baseline- 6-month	2.23	1.42	< 0.001
	6-month-12-month	2.89	2.10	< 0.001
	Baseline- 12-month	4.52	2.89	< 0.001

# Table 2: Showing within group comparison of spinalcurvature

# DISCUSSION

The findings presented here demonstrate a significant advancement in scoliosis management, particularly among adolescents, through the effective use of intervention strategies aimed at reducing spinal curvature over a defined 12-month period. The progressive and statistically notable reductions in Cobb angle underscore the potential efficacy of such interventions, offering hope for improved spinal alignment and quality of life in affected individuals. However, several key factors must be considered when interpreting these outcomes. One critical aspect highlighted in the study is the necessity of brace compliance for achieving optimal results. Babaee et al reported that the correction achieved after bracing is dependent on the bracing compliance and initial Cobb angle (R2 = 0.48).<sup>21</sup> A systematic review of 11 studies evaluating the regression of Cobb angle via bracing was conducted. The findings showed that Brace conditioning provides an accurate effect on the curves that are scoliotic in order to achieve curve regression, provide that there is high compliance rate and the incorporation of exercises.<sup>22</sup> However, the effects of bracing reduced if the Cobb angle is > 40 degree as reported in a study where data of 54cohorts was reviewed retrospectively. All the patients refused the surgery. The following up at an interval of 3-6 months showed the progression of curve in 35 patients whereas 12 remained unchanged and reduces in 7 patients.23

In terms of comparative analysis, the study's outcomes can be contrasted with other modalities of scoliosis management, such as surgical interventions or physiotherapy-based approaches. Surgical correction, while effective in severe cases, carries inherent risks and often requires prolonged recovery periods. Conversely, physiotherapy emphasizes postural correction and muscular strengthening but may have limitations in altering spinal curvature in isolation.

Moreover, the effects can be enhanced by focusing on refining the existing interventions in order to increase their efficacy and acceptance from patients. It may include new applications in bracing design in order to decrease comfortless and increase compliance, we well as the integration of technological solutions like wearable sensors for real-time monitoring of spinal alignment.

## CONCLUSION

In summation, above discussed findings are important in laying out a promise avenue in the management of scoliosis in adolescent, focusing on the interventional strategies to alleviate the deformity and mitigating the spinal curvature thus improving patient outcomes.

# LIMITATIONS

Research conduction and innovations are also important in order to address the challenges implemented by severe case and optimizing the effectiveness overall in the management of scoliosis.

### SUGGESTIONS / RECOMMENDATIONS

In order to adopt a comprehensive approach, health care provision will be addressed diversely and accordingly thus enhancing both therapeutic outcomes and quality of life.

# **CONFLICT OF INTEREST / DISCLOSURE**

There was no conflict of interest.

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