Underarm bracing for adolescent idiopathic scoliosis leads to flatback – the role of sagittal spino-pelvic parameters

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Author contributions:

JPYC: Study conception and design, data collection, statistical analysis, supervision, manuscript writing, editing, final approval and submission.

CHWC: Data collection, statistical analysis, manuscript writing.

PWHC: Data collection, statistical analysis, manuscript writing.

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Abstract

Aims: To determine the influence of pelvic parameters on tendency of patients with adolescent idiopathic scoliosis (AIS) to develop flatback (thoracic hypokyphosis and lumbar hypolordosis) and its effect on quality of life outcomes.

Patients and Methods: This was a radiographic study of 265 subjects recruited for Boston bracing between December 2008 and 2013. Posteroanterior and lateral radiographs were obtained before and after completion of bracing. Measurements of coronal and sagittal Cobb angles, coronal balance, sagittal vertical axis and pelvic parameters were made. Refined 22-item Scoliosis Research Society (SRS-22r) questionnaire was recorded. Association between independent factors and outcomes of post-bracing ≥6° kyphotic changes in the thoracic spine and ≥6° lordotic changes in the lumbar spine were tested using likelihood ratio chi-square test and univariable logistic regression. Multivariate logistic regression models were then generated for both outcomes with odds ratios (ORs), and with SRS-22r scores.

Results: Reduced T5-12 kyphosis (-4.3° ± 8.2; $p<0.001$), maximum thoracic kyphosis (-4.3° ± 9.3; $p<0.001$), and lumbar lordosis (-5.6° ± 12.0; $p<0.001$) were observed after bracing treatment. Increasing pre-brace maximum kyphosis (OR: 1.133) and lumbar lordosis (OR: 0.92) was associated with post-bracing hypokyphotic change. Pre-brace sagittal vertical axis (OR: 0.975), pre-brace sacral slope (OR: 1.127), pre-brace pelvic tilt (OR: 0.940), and change in maximum thoracic kyphosis (OR: 0.878) were predictors for lumbar hypolordotic changes.

There were no relationships between coronal deformity, thoracic kyphosis or lumbar lordosis with SRS-22r scores.

Conclusions: Brace treatment leads to flatback deformity with thoracic hypokyphosis and lumbar hypolordosis. Changes in the thoracic spine are associated with similar changes in the lumbar spine. Increased sacral slope, reduced pelvic tilt and pelvic incidence are associated with reduced lordosis in the lumbar spine after bracing. Nevertheless, these sagittal parameter changes do not appear to be associated with worse quality of life.

Level of Evidence: level II, prognostic study

Introduction

Adolescent idiopathic scoliosis (AIS) is the most common pediatric spinal deformity[1] and is characterized by a 3-dimensional rotational deformity. For moderate-sized curves, bracing is indicated to prevent curve progression and to reduce the overall surgical risk.[2] Despite the well-established benefits of bracing for the coronal deformity, purely monitoring the Cobb angle is not sufficient. The Spinal Deformity Study Group has previously reported that the coronal Cobb angle may not describe all the necessary characteristics of AIS.[3] Some have since studied the sagittal and transverse planes of spinal deformities in addition to the frontal plane.[4,5]

The sagittal profile in particular should be addressed in the bracing population. It seems from clinical observation that patients develop flatbacks with prolonged bracing. Although not well studied in the pediatric population, thoracic hypokyphosis is an important outcome in adults as it is associated with discomfort, pain in standing upright and increased risk of disc degeneration.[6] The sagittal plane has been shown to be a major contributor for poor health-related quality of life outcomes.[7] Hence, sagittal malalignment may benefit from early interventions.

Currently, there is only limited evidence regarding the impact of sagittal profiles in the AIS population. Most only compared the features of scoliotic patients with the normal population[8,9] or its relationship with cervical alignment changes.[10,11] Yet, the spino-pelvic sagittal parameters, especially changes with bracing, is unknown in the AIS population. The effect of bracing on the sagittal alignment, needs to be addressed as these features may influence the effectiveness of bracing and relevant patient-perceived outcomes. Therefore the objectives of this study are to determine the change in sagittal spino-pelvic parameters with bracing, the predictors for sagittal alignment changes after brace treatment, and whether these changes lead to worse health-related quality of life outcomes.

Patients and Methods

Subjects

This was a retrospective study of all AIS patients who consecutively underwent underarm (Boston) bracing between December 2008 to 2013. Patients were referred for bracing following the criteria suggested by the Scoliosis Research Society[3]: initial chronological age between 10-14 years, major curve magnitude of 25-40 degrees, less than 1 year post-menarche status, Risser staging 0-2, and no prior treatment history. A total of 653 patients were identified during the study period but 206 subjects without any lateral radiographs before or after completing bracing were excluded. Those with lateral radiographs not including the femoral heads, precluding pelvic parameter measurements were also excluded. After exclusion, 265 patients remained for study (**Figure 1**). The demographic information of these patients are illustrated in **table 1**. All subjects completed the bracing regimen without dropout. The mean brace duration was 3.9 years ± 1.3.

Study parameters

Baseline demographic parameters including patient gender, age at brace initiation, number of months post-menarche, Risser stage, and curve type according to the Lenke classification[12] were recorded. Radiographic measurements were made on both posteroanterior (PA) and lateral radiographs. Each set of PA and lateral radiographs were obtained pre-bracing, first in-brace and immediately after completion of bracing. Supine anteroposterior radiographs were obtained to assess curve flexibility and expected alignment for brace fabrication[13]. The immediate in-brace PA radiographs were also studied to assess the initial curve correction. The images obtained after completion of bracing were obtained with the patients who completed brace treatment for 6 months. Follow-up radiographs were obtained at 2-years post-weaning to identify any rebound in alignment. One reader blinded to clinical information performed all measurements.

Standing radiographs were obtained with the patient standing upright in a relaxed position with the arms raised and slightly fisted hands resting on clavicles. For the supine radiographs, patients were lying comfortably on a radiolucent table for the image. Supine radiographs were used as they are not effort dependent and provide reliable and reproducible assessment of flexibility. The posture is also identical to what patients are during the brace fabrication process. These radiographs are obtained on the day of brace casting and are obtained within 2-4 weeks of the pre-brace radiograph. Brace fabrication is performed with negative casting in the supine position with traction and counter-traction along the long axis of the curve to try and achieve similar correction as the supine radiograph. The moulded cast is then used to manufacture the underarm brace. After the brace fitting is complete, the patient wears the brace for two weeks before the first in-brace radiograph is obtained.

The major curve coronal Cobb angle was measured on PA radiographs. Change in Cobb angle was calculated by the difference in Cobb angle on the latest radiograph from the pre-brace radiograph. Correction rate was the relative change of Cobb angle on first in-brace radiograph from the pre-brace radiograph. Supine flexibility was the relative change of Cobb angle on supine radiograph from the pre-brace radiograph. Thoracic kyphosis, maximum thoracic kyphosis, lumbar lordosis, sagittal vertical axis, sacral slope, pelvic tilt and pelvic incidence were measured on the lateral radiographs. Thoracic kyphosis was measured by the angle from upper endplate of T5 to lower endplate of T12. Maximum thoracic kyphosis was defined as the largest thoracic sagittal angle. Lumbar lordosis was defined as the angle from the upper endplate of L1 to the upper endplate of S1. Sagittal vertical axis was the distance between C7 plumb line and the posterior-superior corner of the sacral end-plate.

The refined 22-item Scoliosis Research Society (SRS-22r) questionnaire[14] was used for assessment of health-related quality of life scores. These were obtained pre-bracing and after completion of bracing.

Statistical analysis

Descriptive statistics were reported as mean values ± standard deviation (SD). Normality of data was confirmed with Shapiro-Wilk test. Bivariate analysis was performed to compare pre- and post-bracing sagittal profiles and pelvic parameters using paired samples t-test. First in-brace and out of brace radiographic parameters were also compared as well as immediate and final out of brace parameters using the Wilcoxon signed rank test. Associations between independent factors and the kyphotic and lordotic outcomes post-bracing were tested by likelihood ratio chi-square test and univariate logistic regression. There were no missing data or loss to follow-up for the patients included in the study.

Clinically significant changes were considered when an angle changes by ≥6° after bracing. The two main outcomes of interest were: a) ≥6° post-bracing hypokyphotic versus hyperkyphotic change with maximum thoracic kyphosis and b) ≥6° post-bracing hypolordotic versus hyperlordotic changes with lumbar lordosis. All independent factors with $p<0.20$ on the univariate analysis were selected for the multivariate logistic regression model. This facilitated retention of any important confounding variables or variables of known clinical importance.[15-17] All of these parameters were entered into the model simultaneously. In order to avoid any potential issue of multicollinearity, correlation between independent factors were examined and the regression model would only include one of the two or more parameters in case of high correlation (correlation coefficient >0.5).[18] The effect of the parameters was ascertained, and their respective odds ratio (OR) of the likelihood of the outcome of interest was derived with 95% confidence interval (CI).

Investigations were performed to assess whether these post-bracing coronal deformity, and sagittal kyphotic and lordotic changes were associated with SRS-22r scores. Pre- and post-bracing SRS-22r domain and total scores were compared using Wilcoxon signed-rank test. From available literature, there was no direct minimal clinically important difference (MCID) reference for AIS patients after bracing. Therefore, this study utilized the MCID reported in adult spinal deformity[19] literature as the benchmark, which concluded +0.4 as an appropriate MCID for pain and activity (i.e. function) subscores, and total score. The appearance (i.e. self-image) and mental health domains were 'inconclusive', but the reported scores were 0.46 and 0.42 respectively. The satisfaction with management domain was not studied. Hence, we assumed a MCID of 0.4 for these three domains. A score of +0.4 was adopted as the benchmark for improvement in each domain score and the total score. As described by Crawford *et al*[19], this grossly equates to improvement in at least 2 out of 5 questions in each domain. Univariate analysis of the association of clinically significant thoracic kyphosis and lumbar lordosis changes with SRS-22r scores were performed using univariate logistic regression. Multivariate regression models were performed by including any independent variables that reached statistical significance.

Data analysis was performed using the SPSS software version 24.0 (IBM®, Armonk, NY, US). P-value of <0.05 was considered statistically significant. 95% CIs were reported where appropriate.

Results

There was a general trend of developing flatback after brace treatment (**Table 2**). Reduced T5-12 kyphosis (-4.3° ± 8.2; $p<0.001$), maximum thoracic kyphosis (-4.3° ± 9.3; $p<0.001$), and lumbar lordosis (-5.6° ± 12.0; $p<0.001$) were observed after bracing treatment. Up to 25.7% (68/265) of patients had a decrease of ≥10° in maximum thoracic kyphosis, while 4.2% (11/265) had ≥20° decrease. Up to 34.7% (92/265) of patients had a decrease of ≥10° in lumbar lordosis, while 10.6% (28/265) had ≥20° decrease. Concurrent reductions in thoracic kyphosis and lumbar lordosis was observed in 26.8% (71/265) of patients. In patients who had a decrease of ≥10° in maximum thoracic kyphosis, there was also a concurrent mean decrease of 11.5° in lumbar lordosis. The sagittal vertical axis returned closer to the center of the body trunk (**Figure 2**) with changes from average of -21.0 mm ± 23.1 prior to bracing to -2.3 mm ± 25.0 after bracing. Minor changes in coronal balance and pelvic parameters were observed after brace treatment. The sacral slope reduced by an average of -2.0° ± 14.5 ($p=0.028$), while pelvic tilt and pelvic incidence increased by average of 3.8° ± 13.6 ($p<0.001$) and 1.9° ± 20.1 ($p=0.134$), respectively. There was no obvious differences with baseline and first in-brace parameters (Tables 2 and 3). Flatback changes were thus also observed between the first in-brace and out of brace sagittal parameters (Table 3). These changes were consistent between the initial out of brace and final follow-up out of brace measurements.

Several factors were associated with ≥6° change in maximum thoracic kyphosis and lumbar lordosis (**Table 4**). Pre-brace maximum kyphosis (ß=0.132, p<0.001) coronal curve flexibility (ß=0.027, p=0.035) and change of lumbar lordosis post-bracing (ß=-0.079, p<0.001) correlated with change in thoracic kyphosis. Pre-brace sagittal vertical axis (ß=-0.026, p=0.001), sacral slope (ß=0.089, p<0.001), pelvic tilt (ß=-0.043, p=0.014), and maximum thoracic kyphosis pre-brace (ß=0.058, p=0.008) and post-brace (ß=-0.095, p<0.001) were correlated with lumbar lordosis change. No associations were observed for age, Risser stage, coronal Cobb angle and balance or brace duration. Logistic regression analysis revealed that increasing pre-brace maximum kyphosis was associated with the likelihood of post-bracing hypokyphotic change (β: 0.125, OR: 1.133, 95% CI: 1.06-1.21), and every degree increase of lumbar lordosis (β: -0.081, OR: 0.92, 95% CI: 0.88-0.97) after bracing would result in 7.8% reduced likelihood of having thoracic hypokyphotic change (**Table 5**). For post-bracing lumbar hypolordotic change, pre-brace sagittal vertical axis (β: -0.026, OR: 0.975, p=0.013, 95% CI: 0.955-0.995), pre-brace sacral slope (β: 0.120, OR: 1.127, p<0.001, 95% CI: 1.072-1.185), pre-brace pelvic tilt (β: -0.062, OR: 0.940, p=0.017, 95% CI: 0.894-0.989), and change in maximum thoracic kyphosis (β: -0.130, OR: 0.878, p<0.001, 95% CI: 0.824-0.937) were predictors for lumbar hypolordotic changes (**Table 6**).

Improvements in function (0.17 ± 0.65, p<0.001), self-image (0.33 ± 0.83, p<0.001) and mental health (0.17 ± 0.94, p=0.007) domains were observed after bracing (**Table 7**). The overall score increased by 0.15 ± 0.48, from 4.12 ± 0.44 before bracing to 4.27 ± 0.45 after bracing (p<0.001). Before bracing, the function domain score was highest at 4.53 ± 0.46 while the self-image domain score was lowest at 3.39 ± 0.71. After bracing, the function domain was still the highest rated at 4.68 ± 0.46 while self-image improved the most to 3.71 ± 0.74. Logistic regression analysis did not find any association between ≥6° thoracic kyphosis and lumbar lordosis changes with post-bracing changes in SRS-22r scores (**Table 8**). No relationship was observed between the severity of the spinal deformity and SRS-22r scores (**Table 9**).

Discussion

The sagittal profile has been shown to be an important parameter influencing quality of life outcomes.[6] However, this relationship has only been shown in the adult population. The changes in sagittal profile for patients in AIS undergoing brace treatment and their impact on patient-perceived outcomes is not well understood. Our study findings suggest that brace treatment lead to flatback deformity and this may be influenced by a more vertical pelvis.[20] These changes are persistent even at 2-year post-bracing follow-up. Despite these changes in sagittal spino-pelvic parameters however, there appears to be no association with changes in SRS-22r scores.

It is evident that underarm bracing shown in this study reduces thoracic kyphosis and lumbar lordosis in most patients. The maximum thoracic kyphosis which may be more reflective of the actual thoracic curvature also showed the same trend. Based on a clinically relevant angle change of ≥6°, almost half of the patients (43%; 114/265) showed decrease in the maximum thoracic kyphosis while only 13.6% (36/265) showed increase in the kyphotic angle. The magnitude of change in many subjects were not modest either. Many (25.7%; 68/265) had ≥10° reductions and up to 4.2% (11/265) had ≥20° reductions in kyphosis. These changes lead to the threshold of hypokyphosis which is associated with more back pain and even potential pulmonary compromise.[21] Even more patients had reductions in lumbar lordosis, which is not unexpected as the changes in the thoracic spine usually mirrors that of the lumbar spine.[22] Hence, flatback deformity is a common occurrence after underarm bracing. Lebel *et al*[23] previously observed in a small series of patients treated with Boston and Chêneau braces that there were mean reductions of -1° and -3.2° in kyphosis. In this study, T1-12 was used to measure the thoracic kyphosis, which may underestimate actual changes. Our study verifies the postulation that flatback changes occur with brace treatment, which persists after brace weaning. Although progression of AIS may be related to flatback, our data presented in tables 4-6 suggests that progression in the coronal Cobb angle does not influence thoracic hypokyphosis or lumbar hypolordosis. In addition, coronal balance parameters showed no significant changes through brace treatment and hence does not influence our sagittal alignment outcomes. Different brace-types and fabrication methods may influence the outcomes of the sagittal parameters. Fang *et al*[24] showed that the reduction in thoracic kyphosis and lumbar lordosis may reach 7.1° with Chêneau bracing. Hence, braces should not only be fabricated according to the coronal deformity but by a 3-dimensional assessment of the spinal deformity. Molding the brace with reference to the sagittal contour should also be considered. It appears that the global alignment measured by the sagittal vertical axis shifted closer to the central axis of the trunk after bracing. At baseline, most subjects were in negative balance but returns to positive balance after bracing (**Figure 2**). It is not certain whether this is a compensatory change due to reduced lumbar lordosis as this is a maneuver to maintain a stable posture to minimize energy expenditure.[25] Further evidence for this compensatory mechanism can be observed via pelvic rotation which can regulate sagittal balance.[20] The mean pelvic tilt increased by 3.8° which suggests that after bracing, subjects exhibited pelvic retroversion or reduced anteversion.[20] Our practice entails placing the brace in pelvic retroversion to attempt better lumbar scoliosis correction. The data reinforces this with the change from baseline mean 6.2° pelvic tilt to 10.6° in-brace. This is consistent with the findings at the completion of bracing suggesting that the position after brace moulding strongly influences the post-brace outcomes of the spino-pelvic parameters.

Thoracic hypokyphosis is more likely to occur when there is lumbar hypolordosis. Despite suggestions of curve flexibility as an important covariate with our univariate analysis, our multivariate analysis suggests only larger pre-brace thoracic kyphosis and post-brace reduction in lumbar lordosis will influence reduced post-brace thoracic kyphosis, while the pelvic parameters also influence the post-brace reduction in lumbar lordosis. The pelvic parameters namely larger sacral slope and smaller pelvic tilt are factors influencing reduced lumbar lordosis. A more vertical pelvis may influence the lumbar spine to reduce its lordosis as this places the position of the lumbar spine closer to the mid-axis, thereby modifying the entire sagittal spinal profile.[20] This close relationship between the lumbar lordosis and pelvic parameters is well-established.[26] Hence, the patients' pre-existing pelvic parameters may provide some indication to the likely post-brace sagittal profile. It is important to note that coronal Cobb changes are not associated with changes in the sagittal parameters. We observed flatback in patients (**Figures 3 and 4**) with and without coronal Cobb angle correction. Although the coronal and sagittal plane are coupled in 3-dimensional deformities[27], there was no correlation observed between coronal curve change and sagittal plane changes. The initial correction rate may also be associated with the intrinsic flexibility nature of the deformity.[13,28] Nevertheless, this too had no association with changes in sagittal parameters. As such, our findings suggest that these hard braces may be able to deform or remodel the sagittal contour independent of the coronal plane. These effects are likely to be influenced by the pressure contributed by the brace alone as no correlation was observed between change in sagittal parameters and maturity parameters like age, post-menarchal months and Risser staging, or with duration of brace-use.

Regardless of the radiological parameters and changes observed in the study, there are no obvious clinical implications in terms of worsened SRS-22r scores. Overall, patients have improved function and self-image, and total scores reaching MCID for improvement in SRS-22r after brace treatment and this is consistent with previous reports.[29] Analyses identified no associations between the severity of spinal deformity, specific kyphotic or lordotic outcomes and changes in domains and total scores of SRS-22r. This is unexpected considering the well-established association between sagittal malalignment and quality of life outcome scores.[19] It is possible that the SRS-22r does not adequately reflect the impact of sagittal plane deformities in pediatric patients or this is an entity unique to adult patients. Long-term follow-up of these patients is necessary to determine the outlook of sagittal plane deformities in young adulthood. Nevertheless, due to the effects observed in the adult population, early recognition is necessary. This does not retract from the importance of better brace molding not only for the coronal plane but also for the sagittal plane contouring.

There are a few limitations of note to this study. Firstly, this was a retrospective study and not all braced patients in the study period were included due to absence of some lateral radiographs. In addition, there was no objective compliance data such as the use of thermal sensors for earlier braced patients. This is an important factor to study in future prospective studies as brace duration and compliance complement each other and may indicate the likelihood of vertebral remodeling and curve pattern changes. Timing of brace weaning may also be of concern as growth and curve behavior may not overlap.[30] There is also no literature reporting the MCID of SRS-22r changes for patients with AIS undergoing bracing. Hence, the benchmark of MCID used in this study was for the adult population and may not be completely applicable to the adolescent population. The effect of cervical spine alignment was not studied due to unavailability of whole-body images. Cervical kyphosis may occur with thoracic hypokyphosis and this relationship should be elucidated. Finally, changes in the axial profile such as vertebral rotation and rib prominence should also be evaluated in future studies as the coronal and sagittal profiles are coupled to the axial plane.

This study provides an in-depth analysis of the radiological outcomes of patients with AIS undergoing underarm bracing. Flatback deformity occurs frequently and may be influenced by pre-brace pelvic parameters. Despite the lack of influence on SRS-22r, sagittal malalignment may have long-term concerns that may require closer attention when brace fabrication is performed. Prompt interventions including brace modifications or change to alternative brace-types should be considered when thoracic hypokyphosis and lumbar hypolordosis changes occur to prevent permanent sagittal malalignment. Further studies are necessary to determine whether brace modification do reverse these changes and also the long-term implications of sagittal alignment in patients who have weaned bracing.

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Figure legends

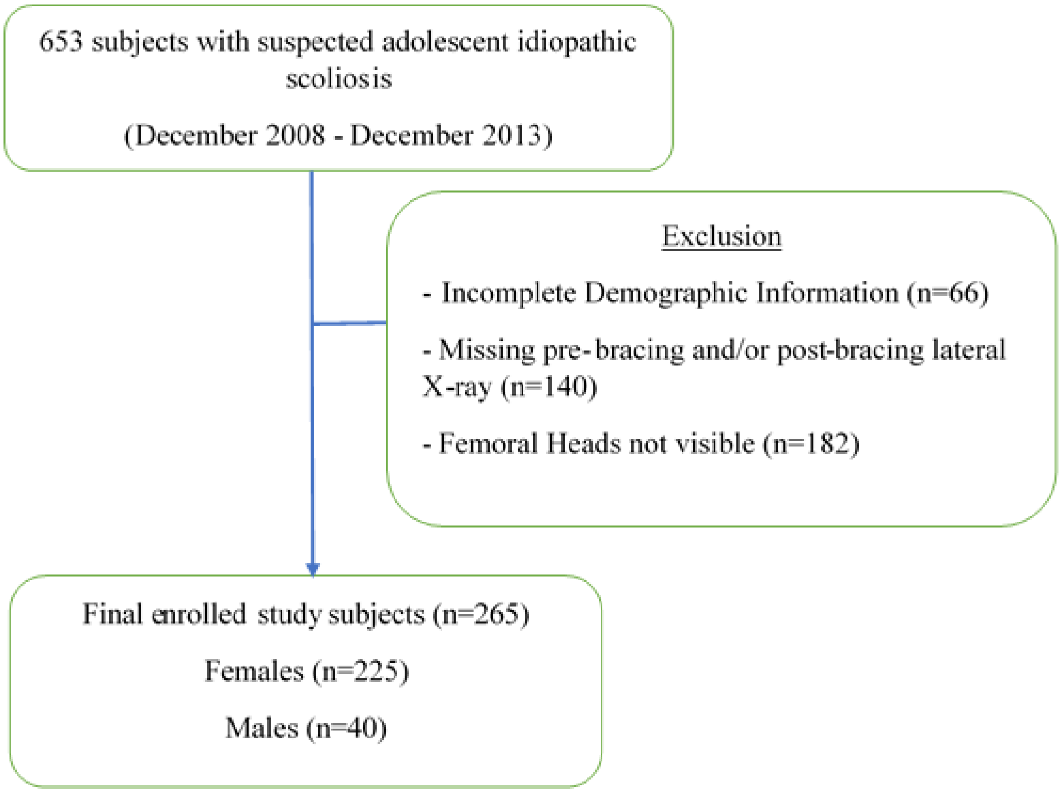


Figure 1: Flowchart for subject recruitment.

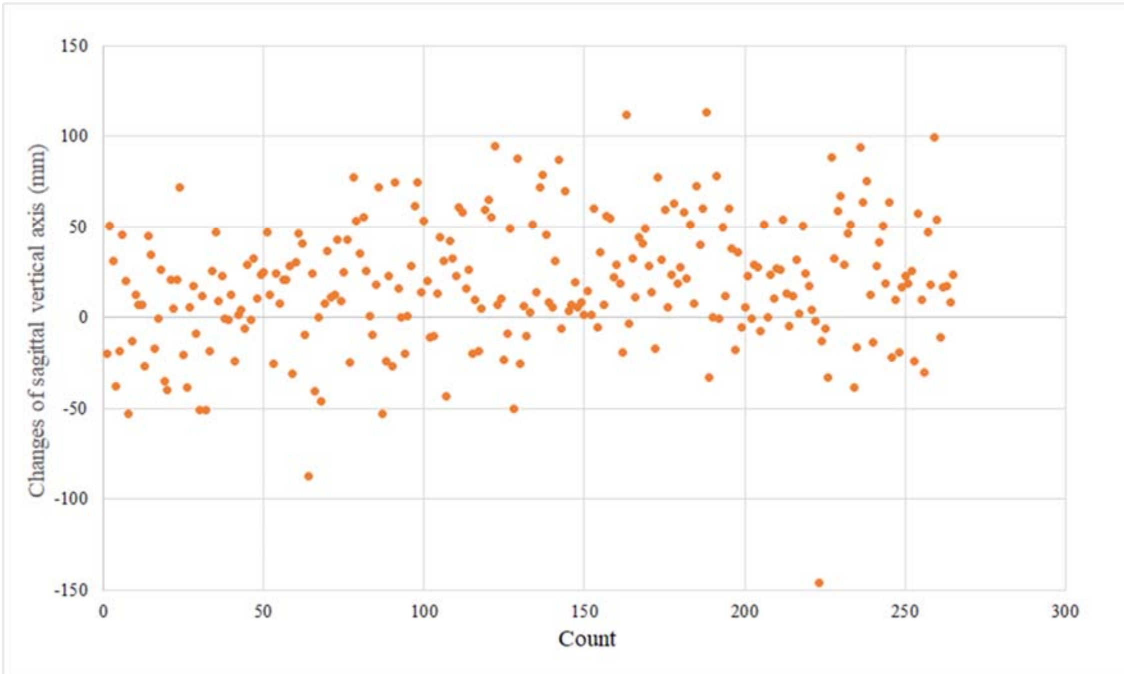
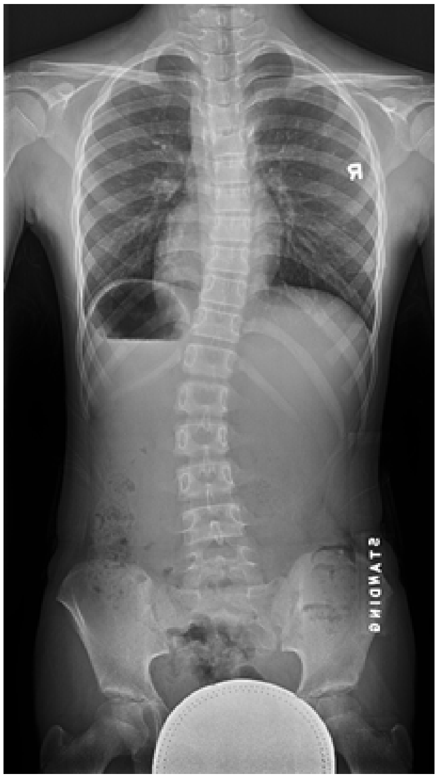


Figure 2: Spread of changes in sagittal vertical axis post-bracing showed most proceed in the positive direction and remained within +5cm and -5cm.

Figure 3: Illustrative case of a patient who developed coronal curve correction and flatback after brace treatment.



(A) Pre-brace posteroanterior radiograph showed a Cobb angle of 29° from T11-L3 and

(B) lateral radiograph showed T5-12 thoracic kyphosis of 27.9°, maximum kyphosis of 31.8° and lumbar lordosis of 57.6°. After brace treatment,

the (C) posteroanterior radiograph showed a Cobb angle of 14.3° from T11-L3 and

(D) lateral radiographs showed flattening of the thoracic kyphosis to 0.1°, maximum kyphosis to 5.1° and lumbar lordosis to 36.9°.

Figure 4: Illustrative case of a patient who developed flat back without coronal curve correction after brace treatment.

(A) Pre-brace posteroanterior radiograph showed Cobb angle of 30° from T11-L3 and

(B) lateral radiograph showed T5-12 thoracic kyphosis and maximum kyphosis of 35.5°, and lumbar lordosis of 70.7°. After bracing,

the (C) posteroanterior radiograph showed a Cobb angle of 27.2° from T11-L3 and

(D) lateral radiograph showed flattening of the thoracic kyphosis and maximum kyphosis to 11.2°, and lumbar lordosis to 40.6°.

Table 1. Demographic information

Parameters	Number (Total n = 265)	Percentage (%)
Sex		
Male	40	15
Female	225	85
Age (Years, mean ± SD)	12.53 ± 1.17 (Range 5.9)	
Lenke Curve Type		
1	84	32
2	11	4
3	17	6
4	5	2
5	108	41
6	40	15
Time post-menarche (Months, mean ± SD)	2.51 ± 3.62 (Range 11.0)	
Risser Staging		
0	141	53
1	79	30
2	45	17

n: number of subjects, SD: standard deviation

Table 2. Sagittal and coronal parameters before and immediately after bracing

	Change		p-value	95% CI	Before		95% CI	Immediately After		95% CI
	Mean	SD			Mean	SD		Mean	SD	
Thoracic kyphosis (°)	-4.3	8.2	<0.001*	-5.32 to -3.33	17.1	8.4	16.04 to 18.06	12.7	8.7	11.68 to 13.78
Maximum kyphosis (°)	-4.3	9.3	<0.001*	-5.43 to -3.18	20.3	9.3	19.15 to 21.39	16.0	9.6	14.79 to 17.12
Lumbar lordosis (°)	-5.6	12.0	<0.001*	-7.09 to -4.20	56.1	12.2	54.64 to 57.58	50.5	12.3	48.98 to 51.95
Sagittal vertical axis (mm)	+18.7	34.6	<0.001*	14.49 to 22.86	-21.0	23.1	-23.75 to -18.16	-2.3	25.0	-5.31 to 0.74
Sacral slope (°)	-2.0	14.5	0.028*	-3.73 to -0.22	42.2	10.1	41.03 to 43.47	40.3	11.1	38.93 to 41.61
Pelvic incidence (°)	+1.9	20.1	0.134	-0.57 to 4.28	48.5	14.4	46.71 to 50.20	50.3	14.0	48.61 to 52.00
Pelvic tilt (°)	+3.8	13.6	<0.001*	2.18 to 5.48	6.2	10.6	4.93 to 7.48	10.0	8.7	8.98 to 11.09
Truncal shift	+4.6	13.0	<0.001*	3.06 to 6.20	-1.2	11.1	-2.50 to 0.19	3.5	13.35	1.86 to 5.09
C7-CSVL (mm)	+2.3	13.9	0.008*	0.59 to 3.95	-6.6	12.2	-8.11 to -5.17	-4.4	11.39	-5.75 to -3.00

Distribution of Changes in Sagittal Profile
Number of Subjects (Percentage)

	Decreased	Unchanged (Absolute change <6°)	Increased
Thoracic kyphosis	112 (42.3)	124 (46.8)	29 (10.9)
Maximum kyphosis	114 (43.0)	115 (43.4)	36 (13.6)
Lumbar lordosis	135 (50.9)	86 (32.5)	44 (16.6)

* statistical significance at p<0.05

Table 3. Changes of sagittal and coronal parameters at first in brace, first out of brace and at final follow-up

	First in brace		95% CI	First out of brace		95% CI	Final follow-up		95% CI
	Mean	SD		Mean	SD		Mean	SD	
Thoracic kyphosis (°)	16.0	8.4	14.92 to 17.03	12.7	8.7	11.68 to 13.78	12.8	8.8	11.72 to 13.84
Maximum kyphosis (°)	21.4	10.7	20.09 to 22.78	16.0	9.6	14.79 to 17.12	16.0	9.8	14.85 to 17.23
Lumbar lordosis (°)	53.9	10.4	52.59 to 55.20	50.5	12.3	48.98 to 51.95	50.3	12.2	48.81 to 51.75
Sagittal vertical axis (mm)	-25.4	25.5	-28.64 to -22.24	-2.3	25.0	-5.31 to 0.74	-4.1	24.5	-7.01 to -1.09
Sacral slope (°)	39.5	8.6	38.46 to 40.61	40.3	11.1	38.93 to 41.61	39.8	9.9	38.59 to 40.99
Pelvic incidence (°)	50.2	12.7	48.58 to 51.77	50.3	14.0	48.61 to 52.00	50.0	13.6	48.33 to 51.63
Pelvic tilt (°)	10.6	9.5	9.45 to 11.83	10.0	8.7	8.98 to 11.09	10.2	10.1	8.97 to 11.41
Truncal shift	-4.3	10.0	-5.52 to -3.06	3.5	13.35	1.86 to 5.09	4.1	13.1	2.48 to 5.64
C7-CSVL (mm)	-8.5	12.6	-9.90 to -6.82	-4.4	11.39	-5.75 to -3.00	-4.3	11.3	-5.64 to -2.91

	Between out of brace and first in brace		95% CI	p-value^	Between final follow-up and first out of brace		95% CI	p-value^
	Mean changes	SD			Mean changes	SD		
Thoracic kyphosis (°)	-3.4	7.6	-4.39 to -2.50	<0.001*	0.1	2.5	-0.25 to 0.35	0.991
Maximum kyphosis (°)	-5.5	10.0	-6.73 to -4.23	<0.001*	0.1	2.6	-0.24 to 0.40	0.015*
Lumbar lordosis (°)	-3.8	11.2	-5.19 to -2.39	<0.001*	-0.2	3.2	-0.57 to 0.20	0.099
Sagittal vertical axis (mm)	+23.1	34.9	18.75 to 27.50	<0.001*	-1.8	34.7	-5.97 to 2.43	0.317
Sacral slope (°)	+0.9	13.8	-0.83 to 2.63	0.386	-0.5	13.5	-2.12 to 1.16	0.561
Pelvic incidence (°)	+0.4	18.5	1.18 to -1.92	0.867	-0.3	19.1	-2.63 to 1.98	0.734
Pelvic tilt (°)	-0.5	12.6	0.80 to -2.1	0.531	0.2	13.2	-1.45 to 1.75	0.956
Truncal shift	+4.6	13.0	3.06 to 6.20	<0.001*	0.6	5.8	-0.12 to 1.28	0.418
C7-CSVL (mm)	+2.3	13.9	0.59 to 3.95	0.002*	0.1	3.5	-0.33 to 0.52	0.654

* Statistical significance at p<0.05

^ Wilcoxon signed rank test

Table 4. Univariate analysis for post-bracing outcomes: a) maximum kyphotic change and b) lumbar lordotic change

Commented [U1]: (add in inbrace MK for thoracic, and inbrace Lordosis for LL, prebrace coronal for both)

Outcome a) Hypokyphotic versus hyperkyphotic change in subjects with maximum kyphotic change ≥ 6° (n=150, ≥-6° n=114; ≥+6° n= 36)		
Factors	Likelihood ratio chi-square statistic (G^2)^	p-value
Sex	1.285	0.257
Risser Stage	1.392	0.499
Lenke Type (1,2,3 vs 5,6 vs 4)	3.607	0.165
	Estimated regression coefficient (β)^	p-value
Age	-0.275	0.103
Months post-menarche	0.018	0.743
Pre-brace Cobb Angle	-0.070	0.181
Pre-brace truncal shift	-0.029	0.102
Pre-brace C7-CSVL	-0.020	0.209
Pre-brace Maximum Kyphosis	0.132	<0.001*
First in brace Maximum Kyphosis	-0.007	0.693
Correction Rate	0.015	0.142
Flexibility	0.027	0.035*
Brace duration	0.053	0.732
Change of Cobb angle Post-bracing	-0.022	0.207
Change of lumbar lordosis Post-bracing	-0.079	<0.001*
Outcome b) Lumbar lordotic change (n=179, ≥-6° n=135; ≥+6° n=44)		
Factors	Likelihood ratio chi-square statistic (G^2)^	p-value
Sex	1.905	0.168
Risser Stage	0.891	0.641
Lenke Type (1,2,3 vs 5,6 vs 4)	0.729	0.694
	Estimated regression coefficient (β)^	p-value
Age	-0.287	0.059
Months post-menarche	0.010	0.830
Pre-brace Cobb Angle	0.022	0.633
Pre-brace truncal shift	0.002	0.906
Pre-brace C7-CSVL	0.002	0.891
Pre-brace Sagittal Vertical Axis	-0.026	0.001*
Pre-brace Sacral Slope	0.089	<0.001*
Pre-brace Pelvic Incidence	0.019	0.130
Pre-brace Pelvic Tilt	-0.043	0.014*
Pre-brace Maximum Kyphosis	0.058	0.008*
First in brace Lumbar Lordosis	0.030	0.091
Correction Rate	0.000	0.959

Flexibility	-0.008	0.478
Brace duration	0.053	0.683
Change in Cobb angle Post-bracing	-0.007	0.636
Change of Maximum Kyphosis Post-bracing	-0.095	<0.001*

^ For categorical variables, likelihood ratio chi-square test was used; for continuous variables, univariable logistic regression model was used

* Significance at p-value <0.05

Table 5. Multivariate logistic regression model for ≥ 6° hypokyphotic change in maximum thoracic kyphosis

	Chi-square	df	p-value	Nagelkerke R^2	% Predicted Correctly
Model	49.907	8	<0.001*	0.424	81.3

Predictors	Regression Coefficient (β)	S.E.	Wald X^2	p-value	Odds Ratio	95% CI
Age	-0.348	0.224	2.426	0.119	0.706	0.456 – 1.094
Lenke curve types (Type 1, 2, 3 vs 4 vs 5,6)			0.477	0.788		
Pre-brace Cobb angle	-0.092	0.067	1.877	0.171	0.912	0.800 – 1.040
Pre-brace maximum kyphosis	0.125	0.033	14.313	<0.001*	1.133	1.062 – 1.209
Correction Rate	0.006	0.015	0.157	0.692	1.006	0.977 – 1.036
Flexibility	0.010	0.020	0.255	0.613	1.010	0.971 – 1.050
Change of lumbar lordosis post-bracing	-0.081	0.024	11.442	0.001*	0.922	0.880 – 0.966

* Significance at p-value <0.05
Note: S.E.: standard error, CI: confidence interval

Table 6. Multivariate logistic regression model for ≥ 6° hypolordotic change in lumbar lordosis

	Chi-square	df	p-value	Nagelkerke R^2	% Predicted Correctly
Model	68.979	7	<0.001*	0.476	84.9

Predictors	Regression Coefficient (β)	S.E.	Wald X^2	p-value	Odds Ratio	95% CI
Age	-0.222	0.210	1.117	0.291	0.801	0.531 – 1.209
Sex (reference group: males)	-0.122	0.655	0.035	0.852	0.885	0.245 – 3.194
Pre-brace maximum kyphosis	-0.004	0.028	0.024	0.876	0.996	0.943 – 1.051
Pre-brace SVA	-0.026	0.010	6.161	0.013*	0.975	0.955 – 0.995
Pre-brace SS	0.120	0.026	21.814	<0.001*	1.127	1.072 – 1.185
Pre-brace PT	-0.062	0.026	5.723	0.017*	0.940	0.894 – 0.989
Change of maximum kyphosis post-bracing	-0.130	0.033	15.535	<0.001*	0.878	0.824 – 0.937

* Significance at p-value <0.05
Note: S.E.: standard error, CI: confidence interval

Table 7: Changes of SRS-22r scores pre- and post-bracing

SRS-22r Domains	n#	Pre-brace	Post-bracing	Changes	Z^	p-value	95%CI for changes	Range
		Mean score ± SD						
Function	181	4.50 ± 0.57	4.68 ± 0.46	0.17 ± 0.65	-3.876	<0.001*	0.08 to 0.27	6.80
Pain	181	4.42 ± 0.75	4.51 ± 0.57	0.09 ± 0.73	-1.448	0.148	-0.01 to 0.20	7.20
Self-image	181	3.39 ± 0.71	3.71 ± 0.74	0.33 ± 0.83	-5.397	<0.001*	0.21 to 0.45	6.80
Mental Health	181	4.03 ± 0.87	4.20 ± 0.77	0.17 ± 0.94	-2.678	0.007*	0.03 to 0.31	8.60
Satisfaction with management	75	3.70 ± 0.86	3.60 ± 0.86	-0.10 ± 0.85	-0.815	0.415	-0.30 to 0.10	4.00
Total Score	181	4.12 ± 0.44	4.27 ± 0.45	0.15 ± 0.48	-3.970	<0.001*	0.08 to 0.22	2.81

^ Wilcoxon signed-rank test – total SRS-22r score and all domain scores were based on negative ranks except Satisfaction with management domain which was based on positive ranks
Note: SD: Standard deviation, SRS-22r: refined 22-item Scoliosis Research Society questionnaire
*statistical significance at p<0.05

Table 8: Bivariate analysis of post-bracing sagittal profile changes and SRS-22r scores

	Estimated regression coefficient (β)	p-value		Estimated regression coefficient (β)	p-value
Outcome: hypokyphotic vs hyperkyphotic changes			Outcome: hypolordotic vs hyperlordotic changes		
Changes in the domain scores of					
- Function	0.008	0.985	- Function	-0.534	0.145
- Pain	-0.144	0.706	- Pain	-0.191	0.543
- Self-image	-0.235	0.398	- Self-image	-0.334	0.159
- Mental Health	-0.085	0.723	- Mental Health	-0.001	0.997
- Satisfaction with management	-0.474	0.228	- Satisfaction with management	0.164	0.662
Changes of Total Score	-0.411	0.369	Changes of Total Score	-0.196	0.637

* Significance at p-value <0.05
Note: SRS-22r: refined 22-item Scoliosis Research Society questionnaire

Table 9: Relationship between spinal deformity and SRS-22r scores

First out of brace compared to prebrace parameters	Estimated regression coefficient (β)	p-value
Outcome: Worsening of QoL indicated by negative change of SRS scores (i.e. <0)		
Change of Cobb angle	0.012	0.378
Change of truncal shift	-0.001	0.951
Change of C7-CSVL	-0.006	0.613
Change of Thoracic kyphosis (°)	-0.005	0.777

Change of Maximum kyphosis (°)	0.006	0.740
Change of Lumbar lordosis (°)	-0.004	0.741
Change of Sagittal vertical axis (mm)	-0.006	0.218
Change of Sacral slope (°)	-0.009	0.408
Change of Pelvic incidence (°)	-0.003	0.676
Change of Pelvic tilt (°)	0.004	0.757