

## **Does Curve Regression Occur During Underarm Bracing in Patients with Adolescent Idiopathic Scoliosis?**

Running Title: Outcomes of Underarm Bracing for Adolescents with Idiopathic Scoliosis

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Each author certifies that his or her institution approved the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research.

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## 1 **Abstract**

2 *Background* Successful brace treatment entails good control of scoliosis with avoidance of  
3 surgery. However, achieving curve regression may be an even better radiological result than  
4 prevention of curve progression for patients with adolescent idiopathic scoliosis. Vertebral  
5 remodeling may occur with well-fitted braces. Better in-brace curve correction may influence the  
6 likelihood of vertebral remodeling and the chance of curve regression. Only a few reports have  
7 evaluated curve regression with brace treatment, and the factors associated with these events are  
8 unknown.

9 *Questions/purposes* (1) What changes in curvature are observed with brace treatment of  
10 adolescent idiopathic scoliosis? (2) What factors are associated with curve improvement? (3)  
11 What factors are associated with curve deterioration? (4) Is curve regression associated with  
12 improvements in patient-reported objective outcome scores?

13 *Methods* Between September 2008 and December 2013, 666 patients with adolescent idiopathic  
14 scoliosis underwent underarm brace treatment and were followed until skeletal maturity at 18  
15 years old. Among these patients, 80 were excluded because of early discontinuation of brace  
16 treatment (n=66) and loss to follow-up (n=14). Hence, 586 patients were included in this study,  
17 with a mean brace-wear duration of 3.8 years  $\pm$  1.5 years and post-weaning follow-up duration of  
18 2.0 years  $\pm$  1.1 years. The mean age at baseline was 12.6 years  $\pm$  1.2 years. Majority of the  
19 patients were female (87%, 507/586) and up to 53% (267/507) of females were post-menarche.  
20 Bracing outcomes were based on changes in the Cobb angle measured out of brace. These  
21 included curve regression, as indicated by at least 5° reduction in the Cobb angle, curve  
22 progression, as indicated by at least 5° increase in the Cobb angle, and unchanged, indicated by a

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23 change in the Cobb angle of less than 5°. We studied the pre-brace and supine Cobb angles,  
24 curve flexibility (pre-brace Cobb angle – supine Cobb angle / pre-brace Cobb angle x 100%),  
25 and correction rate (pre-brace Cobb angle – in-brace Cobb angle / pre-brace Cobb angle x  
26 100%), location of apical vertebrae, apical ratio (convex vertebral height / concave vertebral  
27 height), and change in the major curve Cobb angle and apical ratio post-bracing. The refined 22-  
28 item Scoliosis Research Society questionnaire was used for patient-reported outcomes and is  
29 composed of five domains (function, pain, appearance, mental health and satisfaction with  
30 treatment). Its minimum clinically important difference, based on a 5-point scale, has been  
31 quoted as 0.2 for pain, 0.08 for activity and 0.98 for appearance domains. Mental health has no  
32 quoted minimum clinically important difference for the adolescent idiopathic scoliosis  
33 population. Satisfaction with treatment is described based on improvement or deterioration in  
34 domain scores. Intergroup differences between bracing outcomes were evaluated with the  
35 Kruskal Wallis test. Univariate analyses of bracing outcomes were performed with a point-  
36 biserial correlation coefficient for continuous variables and Pearson’s chi-square test for  
37 categorical variables. Multivariate logistic regression models were created for improved and  
38 deteriorated outcomes. P values < 0.05 were considered significant.

39 *Results* Ninety-eight of 586 patients (17%) had an improved angle and 234 patients (40%) had  
40 curve deterioration. In those with improvement, the mean reduction in the Cobb angle was  $9^\circ \pm$   
41  $4^\circ$ , while in patients with deterioration, the mean increase in the Cobb angle was  $15^\circ \pm 9^\circ$ , and  
42 this maintained at the latest post-brace weaning follow-up. Despite a trend for patients with  
43 curve regression to have higher baseline flexibility and correction rate, after controlling for age,  
44 Risser staging, radius and ulnar grading, and Sanders staging, we found no clinically important

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45 differences with increased correction rate or flexibility. We did find that improvement in the  
46 Cobb angle after bracing was associated with reduced apical ratio (OR 0.84; 95% CI, 0.80-0.87;  
47  $p < 0.001$ ). Curve progression was associated by younger age (OR 0.71; 95% CI, 0.55-0.91;  $p =$   
48 0.008), pre-menarche status (OR 2.46; 95% CI, 1.31-4.62;  $p = 0.005$ ), and increased apical ratio  
49 (OR 1.24; 95% CI, 1.19-1.30;  $p < 0.001$ ) but no clinically important differences were observed  
50 with less flexible curves reduced correction rate. Improvements in scores of the refined 22-item  
51 Scoliosis Research Society domains of function (mean difference on 5-point scale: 0.2;  $p = 0.001$   
52 versus 0.1;  $p < 0.001$ ) and pain (mean difference on 5-point scale: 0.2;  $p = 0.020$  versus 0.0;  $p =$   
53 0.853) were greater in the post-brace improvement group than in the deterioration group and  
54 fulfilled the minimum clinically important difference threshold. Satisfaction with treatment  
55 domain score minimally improved with the curve regression group (mean difference on 5-point  
56 scale: 0.2) but deteriorated in the curve progression group (mean difference on 5-point scale: -  
57 0.4).

58 *Conclusions* Curve regression occurs after underarm bracing and is associated with superior  
59 patient-reported outcome scores. This possible change in Cobb angle should be explained to  
60 patients prior and during bracing. Whether this may help improve patients' duration of brace-  
61 wear should be addressed in future studies. Patients with well-fitting braces may experience  
62 curve improvement and possible vertebral remodeling. Those braced at younger age and with  
63 increased vertebral wedging are more likely to have curve progression.

64 *Level of Evidence* Level III, therapeutic study.

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## 65 **Introduction**

66 Bracing is the only commonly accepted treatment option with potential to stop curve progression  
67 in patients with adolescent idiopathic scoliosis [47]. However, patients frequently have a poorer  
68 quality of life during brace treatment. Prolonged bracing can reduce spinal mobility, leading to  
69 poor body image and self-esteem and worse self-perceived function, pain, appearance, and  
70 mental health [13, 34, 35, 44, 46]. The Scoliosis Research Society proposed that bracing should  
71 only be considered in order to avoid progression and not to reduce the curve's magnitude [38],  
72 Similarly, most studies only discussed the use brace treatment to avoid curve progression [16,  
73 17, 22, 23, 28, 29]. However, recent Society on Scoliosis Orthopaedic and Rehabilitation  
74 guidelines suggested that bracing is both effective for preventing progression and improving  
75 curves at skeletal maturity [31]. Only a few studies with small study populations have suggested  
76 curve improvement during brace treatment of large curves [27, 32]. The prevalence of curve  
77 improvement with brace treatment and its determinants are currently unknown.

78 Spinal flexibility is a key factor for planning the treatment of adolescent idiopathic scoliosis. It  
79 provides useful information regarding the surgical strategy and outcome prediction [37, 40, 48].  
80 Flexibility assessments can also help predict in-brace correction [12, 18]. Spines with higher  
81 flexibility are likely to have better correction with orthotic treatment. Better in-brace curve  
82 correction may influence the end-of-treatment Cobb angle [45] and the Cobb angle at long-term  
83 follow-up [14]. However, this relationship and factors associated with changes after brace  
84 treatment are not well understood. Well-fitting braces may induce vertebral remodeling, as  
85 evidenced by changes in the curve pattern [49]. Based on Hueter-Volkman's law [42], we  
86 suspect that patients with good in-brace correction may have improved curvature.

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87 Thus, we asked, (1) What changes in curvature are observed with brace treatment of adolescent  
88 idiopathic scoliosis? (2) What factors are associated with curve improvement? (3) What factors  
89 are associated with curve deterioration? (4) Is curve regression associated with improvements in  
90 patient-reported objective outcome scores?

## 91 **Patients and Methods**

### 92 *Study Design*

93 Between September 2008 and December 2013, 666 patients with adolescent idiopathic scoliosis  
94 underwent custom molded underarm thoraco-lumbo-sacral orthosis (underarm brace) treatment  
95 and were followed until skeletal maturity at 18 years old. The study was approved by our  
96 institutional review board. All patients were referred for bracing according to the Scoliosis  
97 Research Society criteria: age between 10 years and 14 years, major curve magnitude of 25° to  
98 40°, Risser Stage 0 to 2, less than 1 year post-menarche, and patients who previously did not  
99 undergo treatment. Among 666 patients with a brace during this period, 80 were excluded (Fig.1)  
100 because of early discontinuation of the brace (n=66) and loss to follow-up (n=14). Of these 80  
101 patients, 44 had thoracic major curves and 36 had thoracolumbar/lumbar major curves. After  
102 exclusion, 586 patients were included for analysis, with a mean  $\pm$  standard deviation brace-wear  
103 duration of 3.8 years  $\pm$  1.5 years and post-weaning follow-up duration of 2.0 years  $\pm$  1.1 years.

### 104 *Study Parameters*

105 Baseline demographic data included chronological age, sex, and age at the time of menarche  
106 (Table 1). The mean age at baseline was 12.6 years  $\pm$  1.2 years. Majority of the patients were  
107 female (87%, 507/586) and up to 53% (267/507) of females were post-menarche. At baseline,

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108 before brace wear, we obtained the following radiographs: a pre-brace standing whole-spine  
109 posteroanterior radiograph, supine whole-spine radiograph, and immediate in-brace standing  
110 whole-spine posteroanterior radiograph. On the pre-brace standing radiograph, the Risser stage,  
111 major curve Cobb angle, major curve apex, and the curve type were identified. Left hand  
112 radiographs were also obtained at baseline to determine the skeletal age parameters of distal  
113 radius and ulna classification and Sanders staging. The distal radius and ulna classification are  
114 graded from radius grades 1-11 and ulnar grades 1-9 with increasing maturity status as the grades  
115 increase [6, 7]. Sanders staging is graded from 1-8 with increasing maturity status [39]. The  
116 curve type was classified as thoracic major curve (apex from T6-11) and thoracolumbar/lumbar  
117 major curve (apex from T12-L3). The major curve Cobb angle was also measured on supine  
118 whole-spine radiographs to assess curve flexibility (pre-brace Cobb angle – supine Cobb angle /  
119 pre-brace Cobb angle x 100%). This angle was also measured on the first in-brace radiograph to  
120 calculate the correction rate (pre-brace Cobb angle – in-brace Cobb angle / pre-brace Cobb angle  
121 x 100%). In addition, to represent curve remodeling, the convex and concave apical vertebral  
122 body heights were measured, and the apical ratio (convex height / concave height) was  
123 calculated. An increased ratio suggested more wedging between the convex and concave sides of  
124 the apical vertebra. The vertebral body height and the major curve Cobb angle were also  
125 measured on the final radiographs to determine any changes that occurred during bracing. Two  
126 post-brace weaning radiographs were analyzed, one at 6 months post-brace weaning and the final  
127 radiograph was a standing posteroanterior radiograph obtained at the time of skeletal maturity  
128 (age of 18 years or Risser Stage 4, no growth in body height for the past 6 months, and 2 years  
129 post-menarche) or immediately before surgery in patients with curve deterioration of 50° or more

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130 during brace treatment. All patients were suggested a gradual weaning protocol over 6 months  
131 from the day of brace weaning. The mean pre-brace Cobb angle was  $31^\circ \pm 4^\circ$ , mean supine Cobb  
132 angle was  $22^\circ \pm 6^\circ$ , mean in-brace Cobb angle was  $18^\circ \pm 6^\circ$ . The mean flexibility was  $30\% \pm$   
133  $17\%$  and mean correction rate was  $41\% \pm 19\%$ . All radiographs were taken without the brace on  
134 for at least 24 hours except for the in-brace radiograph. The refined 22-item Scoliosis Research  
135 Society questionnaire was used to determine patient-reported quality of life outcomes and is  
136 comprised of five domains (function, pain, appearance, mental health and satisfaction with  
137 treatment). Its minimum clinically important difference, based on a 5-point scale, has been  
138 quoted as 0.2 for pain, 0.08 for activity and 0.98 for appearance domains [4]. Mental health has  
139 no quoted minimum clinically important difference for the adolescent idiopathic scoliosis  
140 population. Satisfaction with treatment is described and based on improvement or deterioration  
141 in domain scores. These scores were obtained immediately prior to seeing the clinician at the  
142 consultation room.

#### 143 *Arrangement of Brace Fabrication and Fitting*

144 Supine radiographs were obtained on the day of brace casting, within 1 month of the pre-brace  
145 radiograph. Patients underwent negative casting in the supine position with traction and counter-  
146 traction along the long axis of the curve. The amount of traction depended on the patient's  
147 tolerance. A molded cast was used to manufacture the underarm brace. After the brace was fitted,  
148 the patient wore the brace for 2 weeks before an in-brace radiograph was obtained. Patients were  
149 advised to wear the brace for 20 hours per day and were followed up regularly at our scoliosis  
150 clinic every 4 months to 6 months. Simultaneously, patients were monitored by an orthotist for  
151 any need to change or revise the brace as well as a clinical psychologist for regular counseling.

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152 Patients also had a designated physiotherapist to provide postural training and maintenance  
153 exercises.

#### 154 *Imaging Method and Measurements*

155 Radiographs were obtained with the patient standing upright in a relaxed position with the arms  
156 raised and slightly fistled hands resting on the clavicle. For the supine radiographs, patients lay  
157 comfortably on a radiolucent table. The film focus distance was 180 cm and the exposure factors  
158 were 77 kilovoltage peak and 20 miliamperage seconds. Two 35 cm x 35 cm cassettes were used  
159 to capture C7 to the hip joints. For in-brace radiographs, the images were taken at least 2 hours  
160 after the patient donned the brace to reflect the true correction achieved [24]. All parameters  
161 were collected on radiographs using the DICOM-based Radworks 5.1 computer software  
162 program (Appicare Medical Imaging BV, Zeist, the Netherlands). All radiographs were  
163 measured by two independent observers (JPYC, PWHC) who were blinded to the patients'  
164 details. When the difference in the measurements between the two assessors was less than 5° and  
165 1 mm, the mean of the two measurements was reported. When the discrepancy was more than 5°  
166 or 1 mm, a consensus between the assessors was determined.

#### 167 *Statistical Analysis*

168 Data are presented as the mean  $\pm$  SD. All analyses were performed with SPSS version 24.0 (IBM  
169 SPSS Inc, Chicago, IL, USA). Outcomes were based on changes in the Cobb angle. These  
170 included “improvement” or curve regression, as indicated by at least 5° reduction in the Cobb  
171 angle; “deterioration” or curve progression, as indicated by at least 5° increase in the Cobb angle;  
172 and “unchanged,” indicated by a change in the Cobb angle of less than 5°. Normality tests were  
173 performed using Shapiro-Wilk’s test with Q-Q probability plots. Intergroup comparisons of any  
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174 differences between the study parameters and bracing outcomes were made with the Kruskal  
175 Wallis test. The studied parameters were the pre-brace and supine Cobb angles, flexibility and  
176 correction rates, apical vertebrae, apical ratio, and change in the major curve Cobb angle and  
177 apical ratio post-bracing. A univariate analysis for associations between these variables and  
178 bracing outcomes was performed using a point-biserial correlation coefficient for continuous  
179 variables (age, Risser stage, apical ratio, curve flexibility, and correction rate), and Pearson's chi-  
180 square test was used to determine any association between the outcomes and categorical  
181 variables (sex, whether the patient had a brace post-menarche, Lenke curve type, and location of  
182 apical vertebrae).

183 Multivariate logistic regression models were created for improved and deteriorated outcomes  
184 based on statistically significant factors in the univariate analyses. P values < 0.05 were  
185 considered significant. Odds ratios are reported for statistically significant parameters. The 95%  
186 confidence intervals are listed, where applicable.

## 187 **Results**

188 Ninety-eight of 586 patients (17%) had curve regression (Fig. 2) and 234 patients (40%) had  
189 curve deterioration (Table 2). Among patients with improvement, the mean  $\pm$  SD reduction in the  
190 Cobb angle was  $9^\circ \pm 4^\circ$  while in those with deterioration, the mean  $\pm$  SD increase in the Cobb  
191 angle was  $15^\circ \pm 9^\circ$ , which fulfilled our criteria of  $5^\circ$  change in Cobb angle. At the final follow-  
192 up, there were no further changes as compared to brace-weaning. The mean change in Cobb  
193 angle was  $0^\circ \pm 4^\circ$  at mean 2 years  $\pm$  1 year post-brace weaning follow-up for the curve  
194 regression group. The mean change in Cobb angle was  $1^\circ \pm 3^\circ$  at mean 2 years  $\pm$  1 year post-  
195 brace weaning follow-up for the unchanged group. The mean change in Cobb angle was  $1^\circ \pm 4^\circ$

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196 at mean 2 years  $\pm$  1 year post-brace weaning follow-up for the curve progression group. There  
197 were no differences in the pre-brace Cobb angle between patients with an improved angle and  
198 those with a deteriorated angle. However, patients with improvement had a smaller supine Cobb  
199 angle ( $19^\circ \pm 5^\circ$  versus  $24^\circ \pm 6^\circ$ ;  $p < 0.001$ ) and higher flexibility ( $80\% \pm 76\%$  versus  $38\% \pm$   
200  $43\%$ ;  $p < 0.001$ ) and correction rate ( $54\% \pm 21\%$  versus  $34\% \pm 18\%$ ;  $p < 0.001$ ) than those in the  
201 deterioration group. There was an increased apical ratio in the deteriorated group ( $0.1 \pm 0.1$ ).

202 After controlling for potential confounders including age, Risser staging, radius and ulnar  
203 grading, Sanders staging, curve type, and curve apex, improvement in the Cobb angle after  
204 bracing was found to be associated with reduced apical ratio of 1:1 (OR 0.84; 95% CI, 0.80-0.87;  
205  $p < 0.001$ ), and increased correction rate (OR 1.03; 95% CI, 1.02-1.05;  $p < 0.001$ ) (Table 3).  
206 However, this association with correction rate was not clinically significant. There was no  
207 association with flexibility.

208 Deterioration in the Cobb angle after bracing was associated with younger age, pre-menarche  
209 status at baseline, and increased apical ratio, correction rate, and flexibility (Table 4). For every  
210 year of increase in chronological age, there was a reduced likelihood of curve progression (OR  
211 0.71; 95% CI, 0.55-0.91;  $p = 0.008$ ). Patients who were pre-menarche had a higher likelihood of  
212 deterioration than those who were post-menarche (OR 2.46; 95% CI, 1.31-4.62;  $p = 0.005$ ). The  
213 association of curve deterioration with less flexible curves (OR 0.99; 95% CI, 0.99-1.00;  $p =$   
214  $0.030$ ) and a reduced correction rate during bracing (OR 0.98; 95% CI, 0.97-1.00;  $p = 0.042$ )  
215 were not clinically significant. An increased apical ratio was also associated with curve  
216 progression (OR 1.24; 95% CI, 1.19-1.30;  $p < 0.001$ ). The curve type and location were not  
217 associated with curve progression.

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218 The refined 22-item Scoliosis Research Society questionnaire scores generally improved in all  
219 domains, regardless of the outcome of Cobb angle (Table 5). Importantly, the scores for function  
220 (mean difference on 5-point scale: 0.2;  $p = 0.001$  versus 0.1;  $p < 0.001$ ) and pain (mean  
221 difference on 5-point scale: 0.2;  $p = 0.020$  versus 0.0;  $p = 0.853$ ) fulfilled the minimum clinically  
222 important difference and were better in the post-brace improvement group than in the  
223 deterioration group. There were no clinically meaningful differences in appearance (mean  
224 difference on 5-point scale: 0.3;  $p = 0.001$  versus 0.2;  $p < 0.001$ ). Patients in the improved group  
225 appeared to have minimal increase in satisfaction with treatment (mean difference on 5-point  
226 scale: 0.2), while those in the deteriorated group had worse satisfaction scores (mean difference  
227 on 5-point scale: -0.4).

## 228 **Discussion**

229 Bracing has well-accepted benefits of potentially stopping curve progression in patients with  
230 adolescent idiopathic scoliosis and avoiding surgery [47]. However, some patients may have  
231 curve regression with brace treatment [27, 32]. The prevalence of such phenomena and their  
232 associated factors are unknown. In this study, 17% (98/586) of individuals had an improved  
233 Cobb angle after bracing. Curve regression was associated with less vertebral wedging while  
234 curve progression was associated with younger age. Patients with curve regression had greater  
235 refined 22-item Scoliosis Research Society scores as compared to patients with curve  
236 progression, especially in the domains of pain, appearance, and satisfaction with treatment.

237 There are several limitations to this study. This was a retrospective radiographic study; hence, it  
238 was not possible to consistently report the duration of brace wear. Compliance data were based  
239 on patient self-reporting only, rather than an objective measure such as thermal sensors, which

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240 have not been available in our unit until recently. Patients with stiffer curves may also have  
241 poorer compliance. Hence, this may introduce bias into the study. The influence of the time the  
242 patient wore the brace may influence the likelihood of remodeling observed in vertebral bodies.  
243 This suggests that we underestimated the true prevalence of curve regression because the  
244 information regarding the in-brace duration further supports the chance of curve regression.  
245 Conversely, there is also potential overestimation of curve regression due to the selection and  
246 transfer bias of excluding 80 patients from the analysis. Early discontinuation of the brace  
247 treatment may have been related to curve deterioration and discomfort with the brace. Those loss  
248 to follow-up may also have had poor results with the brace and lost faith in our management.  
249 This group may have inherently stiffer curves which do not respond well to bracing. Hence, the  
250 actual prevalence of patients with curve progression may be higher than reported. Nevertheless,  
251 it is interesting to note that our noncompliance and drop-out rate (12%; 88/666) is far below what  
252 has been reported by Katz et al. [22] (only 17% were compliant). There were also similar  
253 numbers of thoracic and thoracolumbar/lumbar curves so curve type related stiffness is unlikely  
254 a factor resulting in noncompliance. Our unit also provides regular clinical psychologist visits as  
255 required and this may have improved overall compliance. Karol et al. [21] showed that with  
256 counseling, there was only a 14% rate of inadequate brace-wear or refusal. There may also be  
257 cultural issues at play that should be explored in future multiethnic multicultural studies. Despite  
258 blinded assessment of the imaging by two independent investigators, introducing a consensus  
259 approach for large data variances is inherently biased. Another limitation is the lack of a three-  
260 dimensional assessment; we only assessed changes in the coronal plane. Whether changes occur  
261 in the sagittal and axial planes requires further study. The apical ratio was determined based on

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262 only one image, which may not represent vertebral wedging because deformities occur in three  
263 dimensions. In addition, the differences are small and may be subjected to potential measurement  
264 errors due to the vertebral morphology. A ratio was used rather than absolute measurements to  
265 try and lessen the related bias. Our findings are also only relevant to underarm bracing, and the  
266 effect of different brace types should also be explored. The method for brace weaning should  
267 also be studied in future work. Although we adopted a gradual weaning protocol, there may be  
268 variations such as only nocturnal use for 6 months or a gradual step-wise reduction in brace-  
269 wear. This may not have a significant effect on the overall results with the large sample size but  
270 a dedicated study should be performed to verify this. Our brace weaning criteria of Risser stage  
271 4, no growth in body height for the past 6 months, and 2 years post-menarche may not be  
272 sufficient as curve progression after brace-weaning has been reported due to inadequacies of  
273 conventional maturity parameters [8].

274 We found that nearly 1 in 5 patients experienced curve regression with underarm bracing.  
275 However, most patients (43%) had an unchanged Cobb angle and more patients (40%) had curve  
276 deterioration. In all three outcome groups of curve regression, unchanged, and curve progression,  
277 the mean Cobb angle at baseline was similar. This suggests that factors other than the initial  
278 curve magnitude are responsible for the changes in post-bracing outcomes. One such factor is the  
279 location of the major curve. Patients with thoracolumbar/lumbar curves may have a better  
280 prognosis with a higher likelihood of an unchanged or improved Cobb angle, while those with  
281 thoracic curves are more likely to have a deteriorated angle. This was supported by Thompson et  
282 al. [43], who found that patients with thoracic curves had a higher risk of brace failure that  
283 ultimately led to surgery. This may be due to reduced effectiveness of the underarm brace to

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284 impart enough correction forces on the apex of the thoracic curve. As compared to other brace  
285 types, the underarm brace is unable to maintain an adequate longitudinal traction and mostly  
286 relies on transverse or bending forces for correction. Furthermore, additional padding posteriorly  
287 for pressure on the apical rib is less effective with the brace opening at the back. Similarly,  
288 flexibility is associated with bracing outcomes. In patients with curve regression, there is a clear  
289 trend of increasing stiffness during flexibility assessments with supine radiographs and less  
290 satisfactory in-brace correction than in those with curve deterioration. Curve flexibility and in-  
291 brace correction are inter-related. The flexibility of the curve has been shown to predict the  
292 immediate correction likely obtained with bracing [12, 36]. It is important to consider that our  
293 population especially that of the curve regression group are predominantly thoracolumbar/lumbar  
294 major curves which are inherently more flexible and fare better than thoracic curves [43]. This is  
295 different from other reports [22, 43, 47]. With this large study population, we were also able to  
296 test for male sex with 79 boys included in the analysis unlike other studies on bracing outcomes  
297 [22, 43, 47] with inadequate male sample sizes. However, sex is unlikely an important factor as  
298 we found no significant association with post-brace outcomes in our univariate analyses. The  
299 data appears to show trends in increased flexibility and correction rate with curve regression.

300 After controlling for multiple confounders like skeletal age, the main factor associated with  
301 curve regression was a reduced apical ratio of 1:1. Ample evidence suggests that the risk of  
302 curve progression is near or slightly above the peak height velocity [5, 9-11]; thus, a more  
303 skeletally mature patient may be less likely to have marked spine growth and the potential for  
304 curve progression. However, Risser staging has inherent limitations for predicting growth spurts  
305 in adolescents [3, 15, 19, 25, 41]. All children have a Risser Stage of 0 before the growth

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306 acceleration curve, which provides limited information about whether the patient has had a  
307 growth spurt. The baseline characteristics clearly illustrated the problem with using Risser  
308 staging for brace indications. Although patients fulfilled the brace criteria of Risser 0-2, there are  
309 some that reached the later skeletal maturity stages like radius grade 10, ulna grade 8 and  
310 Sanders stage 8. This mismatch [8, 10] between Risser staging and other more accurate maturity  
311 parameters may be associated with some unnecessary braces. Nevertheless, according to our  
312 results, changes in the curve pattern caused by vertebral remodeling occur with bracing  
313 independent of skeletal age. Change in the apical ratio is a good visual representation of vertebral  
314 remodeling. With a reduced apical ratio, the concave height becomes more closely matched with  
315 the convex height, indicating less vertebral wedging (Fig. 3). Similar to the concept of vertebral  
316 body stapling or tethering [2, 33], the brace may alter spinal growth with potential correction of a  
317 scoliosis deformity. Potential curve correction is supported by the initial rate of correction with  
318 the brace. Well-fitted braces which correct approximately 50% of the deformity and maintain a  
319 balanced spine have been shown to cause changes in the curve pattern, and this has been  
320 considered evidence of vertebral remodeling [49]. Better initial correction with the brace will  
321 more likely act according to Hueter-Volkman's law [42], and we suspect that these patients may  
322 have improvement in their curvature because of altered vertebral growth and remodeling. It is  
323 important to note that we utilize the supine radiograph to predict what is achievable with bracing.  
324 The supine radiograph has been shown to be predictive of in-brace correction [12] and has the  
325 benefits of being a passive modality which produces the similar alignment as is expected with  
326 the patient standing. Nevertheless, our custom molding technique relies on the orthotist's  
327 experience and is a factor not easily standardized or assessed objectively. Subtle technical

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328 determinants of a good brace-fit include patient tolerance to traction during molding and the  
329 degree of strap tightness.

330 The parameters associated with curve progression were younger age (pre-menarche patients and  
331 younger chronological age) and increased apical ratio. Younger patients, especially those who  
332 are pre-menarche, are expected to have larger growth potential and risk of curve progression  
333 [26]. No clinically significant differences were observed with reduced curve flexibility nor  
334 reduced correction rate. Poor brace outcomes are expected if the brace cannot correct the  
335 deformity, and difficulties with brace-fitting may be owing to an inherently stiff curve [43]. Our  
336 results on the contrary do not support this. Even patients with less-flexible curves may not  
337 behave poorly. Besides growth potential, another factor associated with curve progression is  
338 increased vertebral wedging as seen by an increased apical ratio (Fig. 4). Our brace may be  
339 unable to alter vertebral growth adequately to prevent increased wedging. Vertebral wedging and  
340 increased rotational deformity have been suggested to be risk factors of curve progression [30].  
341 These are early prognostic factors for poor bracing outcomes.

342 Beyond the radiologic findings, curve regression has an additional benefit of better patient-  
343 reported quality of life outcome scores. Our reported scores for the overall population are similar  
344 to those reported in other studies [1, 20]. However, greater improvements in all domains,  
345 particularly the domains of function and pain, were observed with intergroup comparisons  
346 between patients in the improved group and those in the deteriorated group fulfilling the  
347 minimum clinically important differences as reported by Carreon et al. [4]. Although there was a  
348 difference in the appearance domain scores between the groups, this did not reach clinical  
349 significance. Interestingly, patients in the curve regression group reported having mildly

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350 improved satisfaction with treatment while patients with curve deterioration group had a worse  
351 satisfaction of treatment after bracing. As our scores were obtained prior to the consultation,  
352 there are likely improved external features apparent to the patient prior to seeing the radiograph.  
353 Our findings further stress the importance of achieving these outcomes because there are obvious  
354 benefits in terms of patient-reported outcome measures.

355 Curve regression occurs in patients undergoing brace treatment and the Cobb angle is maintained  
356 even after brace weaning. Vertebral remodeling may also occur with less vertebral wedging at  
357 weaning as compared to brace initiation. Curve regression is likely a better outcome for patients  
358 undergoing brace treatment as the deformity is less severe. This is also reflected by better  
359 patient-perceived quality of life scores. Although we perceive no deterioration of the deformity  
360 and avoiding surgery as success with brace treatment, we should push the boundaries further as  
361 achieving curve regression is more impactful. This study has shown that 17% of patients may  
362 experience curve regression with satisfactory duration of brace-wear. The possible improvement  
363 in Cobb angle should be disclosed to patients prior and during bracing. Positive information may  
364 encourage patients and their families to be more compliant with bracing protocols. This  
365 perceived effect along with the influence of using better skeletal maturity parameters than Risser  
366 staging for initiating bracing, and using more objective compliance data should be verified in  
367 future prospective studies. Physicians should also advocate for braces to be made with the curve  
368 reduced as much as possible, and often the molded brace can achieve similar correction to that  
369 predicted with pre-bracing supine radiographs. A well-fitting brace provides the best chance of a  
370 positive outcome and the potential of vertebral remodeling to a more normal spine.

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## Acknowledgements

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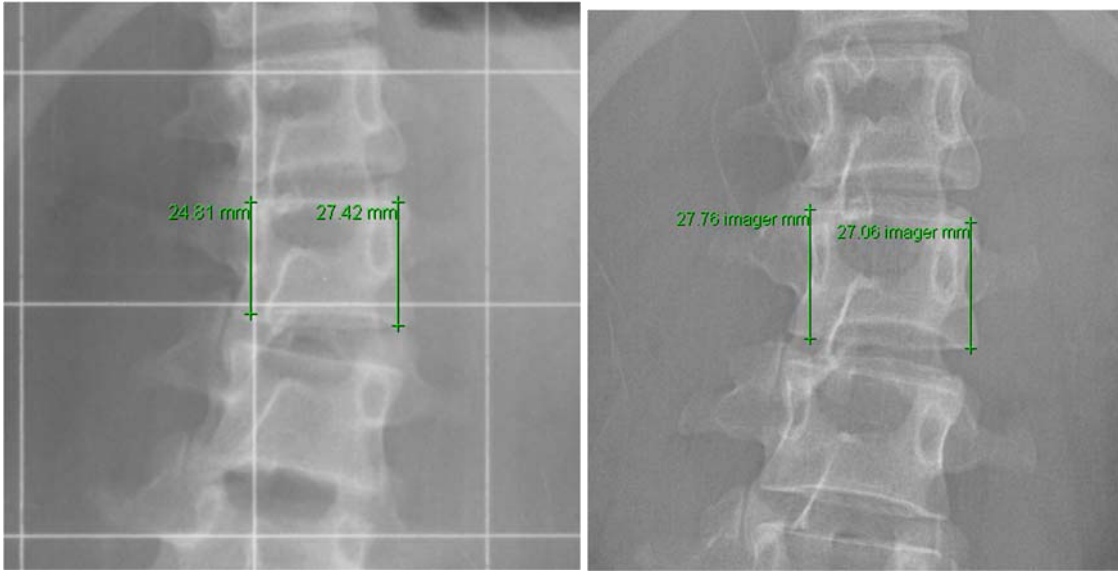
## Legends

**Fig. 1** Flowchart of patients included into the study.

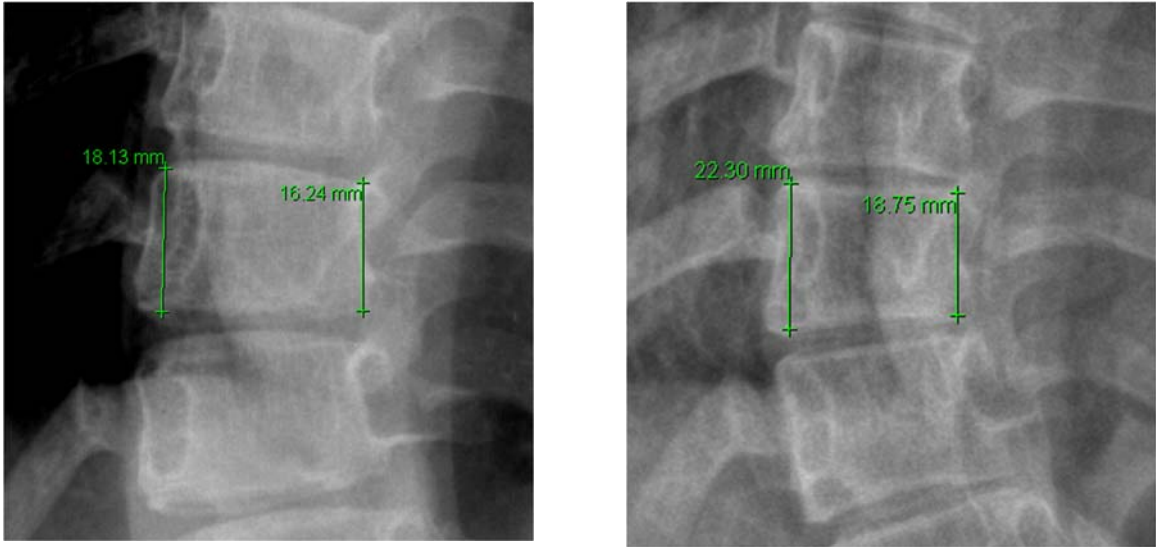
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**Fig. 2** These radiographs are of a patient with improved curve magnitude, with (A) a pre-brace standing radiograph showing a T10-L3 curve of 30° and (B) a post-brace standing radiograph showing curve regression of 15°.



**Fig. 3** These radiographs are of a patient with improved curve magnitude with remodeling as shown by (A) a pre-brace L2 apical ratio of 1.1 (convex height of 27 mm and concave height of 25 mm) and (B) a post-brace L2 apical ratio of 1.0 (convex height of 27 mm and concave height of 28 mm).



**Fig. 4** These radiographs are of a patient with curve progression and increased vertebral wedging as shown by (A) a pre-brace T10 apical ratio of 1.1 (convex height of 18 mm and concave height of 16 mm) and (B) a post-brace T10 apical ratio of 1.2 (convex height of 22 mm and concave height of 19 mm).

**Table 1.** Baseline characteristics

Parameter	n (%) <sup>a</sup>
Age (years, mean $\pm$ SD)	12.6 $\pm$ 1.2
Sex	
Male	79 (14)
Female	507 (86)
Risser stage	
0	304 (52)
1	175 (30)
2	108 (18)
Radius grade	
R5	23 (4)
R6	121 (21)
R7	241 (42)
R8	150 (26)
R9	37 (6)
R10	5 (1)
Ulnar grade	
U3	4 (1)
U4	53 (9)
U5	163 (28)
U6	215 (37)
U7	132 (23)
U8	9 (2)
Sanders staging	
SS1	7 (1)
SS2	58 (10)
SS3	189 (33)
SS4	106 (18)
SS5	89 (15)
SS6	47 (8)
SS7	76 (13)
SS8	5 (1)
Post-menarche	267 (53% of females)
Mean months post-menarche $\pm$ SD	5.6 $\pm$ 3.3
Curve type	
Thoracic major	251 (43)
Thoracolumbar/lumbar major	335 (57)
Apical vertebral wedging at baseline	
Concave apical vertebral height (millimeters, mean $\pm$ SD)	20 $\pm$ 3
Convex apical vertebral height (millimeters, mean $\pm$ SD)	22 $\pm$ 3
Apical ratio	1.1 $\pm$ 0.1
Apex	
T6	2 (1)

T7	34 (5)
T8	86 (15)
T9	76 (13)
T10	36 (6)
T11	15 (3)
T12	81 (14)
L1	154 (25)
L2	93 (16)
L3	9 (2)

<sup>a</sup>Unless otherwise stated



**Table 2.** Outcomes of bracing

Parameters	Improvement	Unchanged	Deterioration	Intergroup comparison
Frequency in percentage	17% (98/586)	43% (254/586)	40% (234/586)	
<b>Curvature</b>				
Pre-brace Cobb angle (°, mean ± SD)	31 ± 4	30 ± 4	31 ± 4	No clinically significant difference
Supine Cobb angle (°, mean ± SD)	19 ± 5	20 ± 5	24 ± 6	Improvement group more flexible than deterioration group (p < 0.001) <sup>b</sup>
Baseline flexibility (% , mean ± SD)	40 ± 15	33 ± 15	23 ± 16	Improvement group more flexible than unchanged and deterioration groups (p < 0.001) <sup>b</sup>
Baseline correction rate (% , mean ± SD)	55 ± 20	42 ± 17	34 ± 18	Improvement group with better brace correction than unchanged and deterioration groups (p < 0.001) <sup>b</sup>
Curve apex	78% T12-L3	66% T12-L3	60% T6-T11	
	Most prevalent: L1 (41%) L2 (20%) T12 (15%)	Most prevalent: L1 (28%) T12 (18%) L2 (17%)	Most prevalent: T8 (20%) T9 (18%) L1 (18%)	
Baseline apical ratio (mean ± SD)	1.1 ± 0.7	1.1 ± 0.1	1.1 ± 0.1	No clinically significant difference
<b>Post-bracing changes</b>				
Change in the coronal Cobb angle (°, mean ± SD)	-9 ± 4	0 ± 3	15 ± 9	Improvement and deterioration groups with significant changes in Cobb angle (p < 0.001) <sup>b</sup>
Rate of change (%)	-27 ± 18	1 ± 12	47 ± 32	p < 0.001 <sup>b</sup>
Change in the apical ratio (mean ± SD)	0.0 ± 0.0	0.0 ± 0.0	0.1 ± 0.1	p < 0.001 <sup>b</sup>

<sup>b</sup> indicates clinically significant difference of >5 degrees

**Table 3.** Multivariate logistic regression model of post-bracing curve regression

Predictor	Regression coefficient (B)	Odds ratio	95% CI	p value
Age	0.16	1.17	0.89 – 1.55	0.26
Risser Stage (reference: Risser Stage 0)				0.52
Risser 1	0.40	1.49	0.68 – 3.24	0.32
Risser 2	0.46	1.59	0.65 – 3.87	0.31
Radius Grade (reference: R10)				0.60
R5	-1.60	0.20	0.00 – 18.74	0.49
R6	-1.44	0.24	0.01 – 9.18	0.44
R7	-2.06	0.13	0.00 – 4.22	0.25
R8	-1.51	0.22	0.01 – 6.14	0.37
R9	-0.69	0.50	0.02 – 10.64	0.66
Ulnar Grade (reference: U8)				0.30
U3	-0.84	0.43	0.00 – 68.51	0.75
U4	-0.47	0.63	0.02 – 24.93	0.80
U5	-1.57	0.21	0.01 – 4.36	0.31
U6	-0.44	0.65	0.04 – 11.06	0.76
U7	-0.67	0.51	0.04 – 6.65	0.61
Sanders Staging (reference: SS8)				0.51
SS1	1.03	2.81	0.03 – 277.01	0.66
SS2	-0.06	0.94	0.07 – 13.70	0.97
SS3	0.85	2.33	0.45 – 12.03	0.31
SS4	1.12	3.06	0.69 – 13.64	0.14
SS5	0.74	2.10	0.52 – 8.54	0.30
SS6	-0.33	0.72	0.18 – 2.87	0.64
SS7	-	-	-	-
Curve type (thoracic vs thoracolumbar/lumbar)	3.47	32.20	0.00 – 1621536.23	0.53
Apex (reference: T6-T9) T12-L3	-3.28	0.04	0.00 – 1879.93	0.55
Correction rate (in-brace from pre-brace)	0.04	1.03	1.02 – 1.05	< 0.01
Flexibility (supine from pre-brace)	0.01	1.01	0.98 – 1.03	0.69
Change in the apical ratio (in percentage)	-0.19	0.84	0.80 – 0.87	< 0.01

The model explained 48% (Nagelkerke's  $r^2$ ) of the variance in brace improvement and correctly classified 87% of cases.

**Table 4.** Multivariate logistic regression model for curve progression post-bracing

Predictor	Regression coefficient (B)	Odds ratio	95% CI	p-value
Age (years)	-0.35	0.71	0.55-0.91	0.01
Pre-menarche at baseline	0.90	2.46	1.31-4.62	0.01
Risser stage				0.44
Curve type (thoracic vs thoracolumbar/lumbar)				0.98
Apex (T6-T11 vs T12-L3)				1.00
Correction rate (in-brace from pre-brace)	-0.02	0.98	0.97-1.00	0.04
Flexibility (supine from pre-brace)	-0.01	0.99	0.99-1.00	0.03
Change in the apical ratio (deviation from 1)	0.22	1.24	1.19-1.30	<0.01

The model explained 57% (Nagelkerke's  $r^2$ ) of the variance in brace deterioration and correctly classified 82% of cases.

**Table 5.** Changes in baseline pre-brace and post-brace Scoliosis Research Society-22r domain and total scores

Domains	Entire study population		p value	Improvement		p value	Deterioration		p value
	Mean $\pm$ SD score			Mean $\pm$ SD score			Mean $\pm$ SD score		
	Pre-brace	Post-brace		Pre-brace	Post-brace		Pre-brace	Post-brace	
Function	4.5 $\pm$ 0.6	4.7 $\pm$ 0.4	< 0.001	4.6 $\pm$ 0.4	4.8 $\pm$ 0.4	0.001	4.5 $\pm$ 0.6	4.6 $\pm$ 0.5	< 0.001
Pain	4.5 $\pm$ 0.6	4.6 $\pm$ 0.6	0.002	4.5 $\pm$ 0.4	4.7 $\pm$ 0.6	0.020	4.4 $\pm$ 0.6	4.4 $\pm$ 0.6	0.853
Appearance	3.4 $\pm$ 0.7	3.8 $\pm$ 2.2	< 0.001	3.5 $\pm$ 0.5	3.8 $\pm$ 0.8	0.001	3.4 $\pm$ 0.7	3.7 $\pm$ 0.8	< 0.001
Mental health	4.0 $\pm$ 0.9	4.2 $\pm$ 0.8	< 0.001	4.0 $\pm$ 0.7	4.2 $\pm$ 0.9	0.091	4.0 $\pm$ 1.0	4.2 $\pm$ 0.7	0.001
Satisfaction with treatment	3.7 $\pm$ 0.8	3.8 $\pm$ 0.8	0.752	3.9 $\pm$ 0.8	4.1 $\pm$ 0.7	0.934	4.1 $\pm$ 0.5	3.7 $\pm$ 0.8	0.642
Total	4.1 $\pm$ 0.4	4.3 $\pm$ 0.4	< 0.001	4.1 $\pm$ 0.4	4.4 $\pm$ 0.4	< 0.001	3.7 $\pm$ 0.8	4.2 $\pm$ 0.5	< 0.001