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Effect of Preoperative SpineCor® Treatment on Surgical Outcome in Idiopathic Scoliosis: An Observational Study

Authors' Contribution:

Study Design A

Data Collection B

Statistical Analysis C

Data Interpretation D

Manuscript Preparation E

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Background: Idiopathic scoliosis is a three-dimensional deformity of the spine. We investigated the effect of preoperative treatment with SpineCor® dynamic brace on the efficiency of surgical correction from a posterior approach in adolescent idiopathic scoliosis.

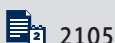
Material/Methods: This was a retrospective observational study. Participants were 53 girls who underwent surgery from posterior approach due to idiopathic adolescent scoliosis, divided into a study group (Group A, 27 girls) and a control group (Group B, 26 girls). Girls in the study group had previously undergone treatment with the SpineCor® brace. Outcome measures were amount of correction and coronal balance based on anteroposterior plain radiographs obtained prior to surgery, at 1 week after surgery, and at 12 months after surgery.

Results: In both groups, satisfactory deformity correction was achieved after surgery (Group A, 73%±12 vs. Group B, 68%±16) and at 12-month follow-up (75%±12 vs. 68%±12, respectively), with no statistically significant differences identified. Directly after surgery, patients preoperatively treated with the SpineCor® brace displayed smaller coronal balance deviation compared with the preoperative measurement, with significant differences in the outcome achieved at 1 week after surgery in Group B. At 12-month follow-up, both groups had significant coronal balance improvement.

Conclusions: This is the first study assessing the effect of dynamic brace treatment on scoliosis surgery. The study shows that a history of preoperative treatment with the SpineCor® dynamic brace does not affect the amount of the achieved correction of AIS directly after surgery or at 12-month follow-up, but it does facilitate faster restoration of normal coronal balance.

MeSH Keywords: Braces • Orthopedics • Postural Balance • Scoliosis

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Background

Adolescent idiopathic scoliosis (AIS), diagnosed based on the presence of a three-dimensional deformity of the spine, leads to changes in trunk, chest, and pelvic geometry. The observed posture and balance dysfunctions are “attributed to a sensory rearrangement of the motor system on the representation of body in space” [1]. The primary aim of surgical correction of scoliosis, regardless of the advancements in the methods and technologies used, remains the same: achieving maximum safe correction of the deformity in the coronal, sagittal, and transverse plane with minimum spinal fusion, while maintaining optimum axial and coronal balance (CB) [2,3]. Winter et al. stressed that the analysis of the efficiency of surgical treatment must not be limited to considering the amount of correction achieved after surgery, as it not only depends on the surgeon and the applied surgical technique, but also on the natural rigidity of the curve [4]. Hence, the latter must be accounted for in the evaluation of the final outcome of surgical correction warranted by failed conservative treatment. There have been some reports on the effect of preoperative bracing treatment on the amount of correction achieved after surgery, but the effect of preoperative dynamic bracing on other parameters is yet to be investigated [5–8], and sagittal and coronal balance especially warrant study. According to Dalleau et al., assessment of the body center of mass (COM) offset is useful in assessing postural imbalance prior to bracing or planned surgical intervention [1]. The research question of this study was: Is there any influence of preoperative treatment with SpineCor® dynamic brace on the efficiency of surgical correction from a posterior approach in adolescent idiopathic scoliosis, considering the amount of achieved correction and the restoration of coronal balance (CB)?

Material and Methods

The study was approved by the relevant Bioethics Committee, and it covered patients treated surgically for idiopathic scoliosis at a single orthopedic center over the period of 2013–2016. The study group (Group A) comprised patients who met the following eligibility criteria: preoperative conservative treatment with the SpineCor® brace for a minimum period of 18 months, female, age >10 years at the time of surgery, Cobb angle $\geq 45^\circ$ at the time of surgery, and scoliosis surgery performed from the posterior approach. The control group (Group B) was formed by patients without a history of preoperative dynamic bracing. The remaining eligibility criteria for Group B were the same as in Group A. Surgery was performed by the same medical team for all patients. This was a retrospective study, so recruitment for the study was simple: consecutive patients who met inclusion criteria, chosen from the hospital database.

Intervention

The SpineCor® dynamic brace is a unique form of conservative orthopedic treatment. Indications in idiopathic scoliosis are similar to other brace treatments, with curves over 25 (20 in progressive cases) degrees, due to high probability of curve progression. This is a brace therapy utilizing a curve-specific Correction Movement through the use of individually-fitted elastic bands [9–11]. It is made by a special medical team. The orthosis should be worn for 20 h per day. An individual program of kinesiotherapy in the SpineCor system can also be included to complement the brace treatment. Specific exercises enhance the effect of the brace in creating the neuromuscular integration (via active biofeedback) [10].

Outcome measures

The analyzed radiographic parameters included Cobb angle and CB defined as the alignment of a plumb line drawn from the center of the C7 vertebral body with the midline of the sacrum. For the analysis, AP plain radiographs obtained in a standing position were used. The measurements were performed prior to surgery (Measurement 1), at 1 week after surgery (Measurement 2), and at 12 months after surgery (Measurement 3). Following the analysis of the radiographs, the amount of correction achieved at 1 week and 12 months was calculated with the following formula:
(preoperative Cobb angle–postoperative Cobb angle)×100%
OVER (preoperative Cobb angle)

The obtained results were then compared between the groups and statistically analyzed. The *t* test for independent samples was used to compare 2 groups of independent data after meeting the assumptions of normal distribution and homogeneity of variances. Normal distribution was tested with the Lilliefors-corrected Kolmogorov-Smirnov test and Shapiro-Wilk test. Homogeneity of variance was tested with Levine's and Bartlett's tests. The Mann-Whitney U test was used to compare differences between 2 independent groups when the data were either ordinal or interval, but not normally distributed. For $N > 20$, the Z score was given, while for $N < 20$, the U value was used. Friedman's ANOVA test was used to compare multiple groups of related data when the data were either ordinal or interval, but not normally distributed. The studied variables were considered stochastically independent at $p = 0.05$.

Results

The study group (Group A) comprised 27 girls, whose mean age at the time of surgery was 14.3 ± 1.5 (11–18) years and mean preoperative Cobb angle was $73 \pm 13^\circ$ (47 – 102°). In this group, double primary curves were the most prevalent (67%),

Table 1. Basic data before and after surgery.

| | Group A | Group B | P value |
|---|----------|----------|---------|
| Age at surgery (year) | 14.3±1.5 | 15.0±1.5 | 0.162 |
| Pre-op main curve magnitude (°) | 73±13 | 70±13 | 0.442 |
| Post-op main curve magnitude (°) | 20±10 | 23±12 | 0.408 |
| Curve correction (%) | 73±12 | 68±16 | 0.155 |
| 1-year post-op main curve magnitude (°) | 19±11 | 22±10 | 0.250 |
| 1-year post-op curve correction (%) | 75±12 | 68±14 | 0.062 |

Values are shown in mean ±SD.

Table 2. Comparisons of the correction magnitude between subgroups of curve location.

| Subgroups of curve pattern | Curve correction (%) at 1 week | p Value | Curve correction (%) 1-year post-op | p Value |
|----------------------------|--------------------------------|---------|-------------------------------------|---------|
| Main Th | | | | |
| Braced (n=7) | 71±10 | | 78±12 | |
| Non-braced (n=5) | 69±8 | 0.726 | 70±8 | 0.207 |
| Main Th, L | | | | |
| Braced (n=18) | 76±12 | | 76±11 | |
| Non-braced (n=18) | 69±18 | 0.169 | 67±15 | 0.053 |
| Main Th-L and L | | | | |
| Braced (n=2) | 58±3 | – | 56±1 | |
| Non-braced (n=3) | 59±14 | | 72±20 | – |

Main Th – main thoracic, main double Th; L – main double thoracic and lumbar; main Th-L and L – main thoraco-lumbar and lumbar.

followed by primary thoracic curves (26%). The control group (Group B) consisted of 26 girls, whose mean age at the time of surgery was 15±1.5 (11–18) years and mean preoperative Cobb angle was 70±13° (45–101°). In this group, double primary curves were also the most prevalent (69%), followed by primary thoracic curves (19%). The 2 groups were comparable in terms of age, sex, curve pattern, and preoperative Cobb angle (Tables 1, 2). In both groups, satisfactory correction was achieved after surgery (73%±12 vs. 68%±16 for Group A and Group B, respectively) and at 12-month follow-up (75%±12 vs. 68%±12 for Group A and Group B, respectively). No statistically significant differences were identified between the 2 groups in terms of the achieved correction. Also, the comparison of the 2 groups showed no statistically significant differences between mean Cobb angle values at 1 week after surgery (p=0.408) and at 12 months (p=0.250) (Table 1). In primary curve pattern, no statistically significant differences were found between the groups among primary thoracic curve patients in terms of the achieved correction at 1 week and at 12 months after surgery. A trend for maintaining greater correction in a 12-month follow-up was noted in double primary curve patients who had a history of preoperative SpineCor®

treatment (p=0.053). Due to the low prevalence of a typical lumbar curve in both groups, it was impossible to apply adequate statistical analysis (Tables 2, 3).

Comparable coronal balance (CB) deviation was noted preoperatively in both groups – at 17.8±7.2 mm for Group A and 17.5±10.5 mm for Group B. Friedman’s test showed a statistically significant difference between the mean CB values both in the study group and in Group B, at p<0.001. At 1 week after surgery, patients preoperatively treated with the SpineCor® dynamic brace showed smaller coronal deviation compared to preoperative measurements (p=0.019), with the results also showing statistically significant differences from the results noted at 1 week after surgery in Group B (p=0.002). In Group B, CB measured at 1 week after surgery showed a statistically non-significant increase compared to Measurement 1 (p=0.33). In a 12-month follow-up, CB improvement was noted in both groups. In both groups, the results obtained in Measurement 3 showed a statistically significant improvement compared to Measurement 1: at p<0.001 for Group A and p=0.004 for Group B (Table 4).

Table 3. Comparisons of the magnitude between subgroups of curve location.

| Subgroups of curve pattern | Before surgery | p Value | One week after surgery | p Value | One year after surgery | p Value |
|----------------------------|-----------------------|---------|------------------------|---------|------------------------|---------|
| Main Th | | | | | | |
| Braced (n=7) | 78±17 77 (47–102) | | 23±10 21 (11–38) | | 18±12 19 (0–35) | |
| Non-braced (n=5) | 78±8 77 (68–88) | 0.949 | 24±7 24 (15–35) | 0.812 | 24±7 26 (12–32) | 0.323 |
| Main Th-L | | | | | | |
| Braced (n=18) | 70±10 70.5 (49–87) | | 18±9 18 (1–30) | | 17±9 19 (1–32) | |
| Non-braced (n=18) | 65±11 63 (45–80) | 0.140 | 20±12 18.5 (1–41) | 0.484 | 21±11 20.5 (6–47) | 0.227 |
| Main Th-L and L | | | | | | |
| Braced (n=2) | 81±20 81 (67–95) | | 34±11 34.5 (27–42) | | 36±9 35.5 (29–42) | |
| Non-braced (n=3) | 89±12 89 (76–101) | – | 37±16 42 (19–51) | – | 23±17 28 (5–38) | – |

Main Th – main thoracic, main double Th; L – main double thoracic and lumbar; main Th-L and L – main thoraco-lumbar and lumbar.

Table 4. Coronal balance before and after surgery.

| [mm] | Group A | Group B | P value |
|---|-----------------------|------------------------|---------|
| Before surgery | 17.8±7.2 21 (0–27) | 17.5±10.5 17 (0–39) | 0.55 |
| After surgery | 11.3±14.1 | 20.6±12.5 | 0.002* |
| One year after surgery | 9 (0–53) 3.7±6.4 | 20 (0–53) 8.7±10.5 | 0.072 |
| Levels of significance between measurements | 0 (0–20) p<0.001 | 0 (0–34) p<0.001 | |

Values are shown in mean ± SD. * Significant difference between Group A and Group B.

The mean duration of preoperative bracing in Group A was 25.3±7.9 months (median 24 months, minimum duration 15 months, maximum duration 48 months). No statistically significant correlations between the length of bracing treatment and the achieved correction were found (p=0.37). The mean interval between the completion of brace treatment and surgery was 7.5±4.9 months (median 6 months, range 1–24 months), and did not have a statistically significant effect on the ultimate outcome of surgical correction (p=0.42).

Discussion

In difficult cases of rigid, progressive curves, failed brace treatment is usually followed by surgical intervention. The primary goal of surgical treatment is optimum safe correction of spine deformity in all its planes, improving respiratory function and

body posture. Another important aim is to prevent complications such as coronal imbalance, junctional kyphosis, and revision surgery [2]. The SpineCor® dynamic brace is a unique form of dynamic orthotic treatment [9–11]. Due to the lack of published reports regarding the effect of SpineCor® treatment on the outcome of AIS surgery, the topic remains controversial. Some authors have discussed the impact of other types of braces. In a study by Weigert et al., the final outcome of surgical correction in a group of patients preoperatively treated with the Boston brace and in a group who did not undergo Boston brace treatment preoperatively was similar [7]. Sun et al., on the other hand, demonstrated the achievement of satisfactory correction in patients treated conservatively with braces prior to surgery, while also stressing the adverse effects (lower flexibility and correctability) of such management on the final postoperative outcome [5].

In our study, similar satisfactory outcomes were achieved regarding the correction of deformity both at 1 week and 12 months after surgery. However, we found greater correction was maintained at 12 months after surgery in patients preoperatively treated with the SpineCor® brace. This correlation was primarily noted in patients with double primary curves. Primary thoracic curves, likely due to their natural rigidity, are less prone to preoperative conservative treatment. Neither the length of treatment nor the interval between the completion of bracing treatment and the surgical intervention showed a statistically significant effect on the achieved correction.

Coronal balance (CB) was considered as the distance between the plumb line drawn from the midpoint of C7 vertebra and the central sacral line, as defined by the Scoliosis Research Society (SRS) [12]. In terms of CB, patients with a history of preoperative dynamic brace treatment showed a significantly greater improvement after surgery. The trend was maintained in a 12-month follow-up, yet the difference from the control group (Group B) decreased in significance over time. At 1 week, the group of patients with no history of preoperative SpineCor® bracing treatment even showed an increase in coronal deviation compared to Measurement 1. This could be explained by factors such as a rapid change in biomechanics and body perception in space, as well as postoperative pain. The significant CB improvement noted directly after surgical correction of scoliosis points to the benefits of preoperative SpineCor® treatment. It is likely that the correction imposed by the dynamic brace once worn, and the sustained stimulation of deep sensation through integration on the nervous and musculoskeletal system occurring in the corrective movement strategy, result in improved CB after surgical intervention. Gauchard et al point to the curve pattern as a factor influencing balance control, as patients with double primary curves are more stable than those with lumbar curves [13]. In our study, double primary curves were the most prevalent curve pattern in both Group A and Group B. At 12-month follow-up, the double primary curve patients in Group A had greater correction, and the difference was close to statistical

significance. Wang et al. found that the correction factor is not CB-independent [14]. Miller et al. found that less correction was a risk factor for greater sagittal and coronal decompensation, with curve correction being significant in predicting coronal decompensation [15]. Hence, it seems essential to aim at the maximum amount of correction while fixing as few vertebrae as possible to maintain normal balance. In our study, satisfactory correction was achieved in both groups, with CB restored much better and faster in patients with a preoperative history of bracing. In both groups, patients were treated with posterior fusion, and in both groups the double primary curves were the most prevalent. Thus, our results show that preoperative SpineCor® treatment influences CB maintenance.

The strength of this study is the homogeneity of the studied group, primarily in terms of the surgical method employed, as well as the use of a control group with similar key characteristics. Its limitations include the relatively small sample size, preventing the application of all relevant statistical analyses, as well as a short follow-up period. Further research in a larger population with a follow-up period longer than 12 months is necessary, aimed at also evaluating other parameters, such as sagittal balance and the amount of kyphosis and lordosis.

Conclusions

This is a first study assessing the effect of dynamic brace treatment on scoliosis surgery. The study shows that a history of preoperative treatment with the SpineCor® dynamic brace does not affect the amount of the achieved correction of AIS directly after surgery or at 12-month follow-up, while facilitating faster restoration of normal coronal balance. Preoperative SpineCor® treatment results, however, in prompt restoration of normal coronal balance after surgery.

Conflict of interest.

None.

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