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Clinical assessment of the efficacy of SpineCor brace in the correction of postural deformities in the course of idiopathic scoliosis

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Summary

Background: The objective of the study was to perform a clinical, comparative assessment of the degree of postural deformities before and after the treatment of idiopathic scoliosis in patients treated with SpineCor brace compared to the control group.

Material/Methods: A group of 90 children with idiopathic scoliosis (including 74 girls) at the average age of 12.2 was subject to prospective observation. Average pre-treatment Cobb angle was 24.9° in the thoracic spine and 25.8° in the lumbar spine. The group actively treated with the SpineCor brace consisted of 45 children, while the control group consisted of the remaining 45 children with the natural course of the disease.

Results: Both groups did not differ significantly in terms of age, gender, height, body weight, Risser sign of skeletal maturity and baseline clinical and radiological parameters of scoliosis. Significant reduction of rib hump was observed upon 2-year SpineCor brace treatment (P=0.04) compared to the group treated by physiotherapy only (P=0.91). Similarly, improvement in lumbar prominence was observed in the actively treated group (P=0.009), with a trend towards worse results in the control group (P=0.07) In the group treated with the SpineCor brace, significant reduction in pectoral and hamstring muscle contractures as well as reduction in shoulder asymmetry and reduction in anterior and posterior vertical deviation were observed.

Conclusions: Treatment using the SpineCor dynamic brace leads to a clinical improvement in posture, particularly to reduction in rib hump, lumbar prominence and muscular contractures.

key words: **idiopathic scoliosis • SpineCor • conservative treatments • results • postural deformities**

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Background

The most important goal of conservative treatment of scolioses is prevention of curvature progression or even the correction of curvature [1]. However, from the standpoint of patients (i.e. mostly pubertal girls), aesthetic improvement is very important. For these children, the main argument to use the brace is the improvement of looks and cosmetic reasons. Since the literature available on the subject is scant [2–6], we decided to evaluate the impact of dynamic brace use on various postural aspects in children with scoliosis. The use of SpineCor dynamic braces has gained many supporters over recent years and is widely propagated [2,7–10].

The objective of the study was to perform a clinical, comparative assessment of the degree of postural deformities before and after the treatment of idiopathic scoliosis in patients treated with SpineCor brace compared to the control group.

Material and Methods

The entire group of 90 children with idiopathic scoliosis (including 74 girls) was subject to prospective observation. The mean age of the children was 12.2±2.4 years (ranging from 7 to 16 years). SpineCor dynamic braces have been routinely used in the treatment of scoliosis at site since 2006. The study was conducted as part of routine hospitalization associated with scoliosis treatment. In all cases analyzed in this study, the examination, qualification, placement of the brace and brace position corrections were performed by a SpineCor LTD (BP)-certified rehabilitation specialist. Included in the study were patients with Cobb angle of 15–40°, with Risser sign of skeletal maturity of 0–3. Girls were at most one year after first menstruation. Children with neurogenic scoliosis, scoliosis due to congenital defects, or children previously treated with other conservative and surgical techniques were excluded from the study. Pre-treatment Cobb angle [11] was 24.9±7.6° (range between 15° and 40°) in the thoracic segment and 25.8±6.3° (range between 15° and 40°) in the lumbar segment. Individual clinical parameters are listed in Table 1. Types of scolioses represented in individual groups are presented in Figure 1.

The group actively treated with the SpineCor brace consisted of 45 children. The control group consisted of the remaining 45 children, potentially qualifying for brace treatment, with the natural course of the disease, subjected to systematic observation and physiotherapy program. The control group consisted of children whose parents did not agree for the treatment or in whom the treatment was not possible due to social reasons.

The schedule of visits and the treatment procedure were consistent with the SpineCor treatment protocol [12]. Patients were advised to wear the brace 20 hours a day while engaging in their normal lifestyle, including physical activities while wearing the brace. Four hours of not wearing the brace were allowed, albeit not as a single four-hour streak. The break period had to be divided into at least to shorter periods of less daytime activities. The need to wear the brace while sleeping was underscored.

Frontal examination included asymmetry in the position of head and shoulders, the depth of the waist and the protuberance of hips. Range of motion was assessed in the limbs. The contracture of pectoral muscles was assessed while standing by a vertical plane by the measurement of the angle of anteflexion of an extended upper limb at the moment of mobilization of other pectoral muscles compensating for the limb movement. The contracture of hamstring muscles was assessed in forward bend with extended, connected lower limbs, as the distance between the fingers and the surface, expressed in centimeters.

Patient's back was assessed in standing and bent positions. The posterior rib hump and the lumbar prominence were measured in degrees using a scoliometer in Adams test. The examination consisted in viewing the back from the perspective of the lower limbs. Trunk asymmetry consisting in unilateral elevation of the paraspinal dorsal region due to the spinal rotation at the particular level. Next, the angle between the slope of the hump and the line parallel to the surface crossing the hump apex was determined using the scoliometer. The scoliometer was used in a similar manner to measure the deformation in the lumbar segment known as the lumbar prominence. Rotation and incline

Table 1. Clinical characteristics of patients at baseline and after 24 months in the brace treatment group and in the control group.

Clinical parameter	Brace (n=45)			Control group (n=45)		
	Baseline	24 months	P	Baseline	24 months	P
Rib hump (degrees)	10.3±3.3	8.6±3.8	**0.04**	8.1±4.4	8.2±4.1	0.91
Lumbar prominence (degrees)	10.3±4.3	7.8±3.9	**0.009**	8.6±4.0	10.4±4.5	0.07
Shoulder asymmetry (cm)	0.90±0.28	0.59±0.46	**0.004**	0.78±0.35	0.80±0.35	0.77
Contracture of pectoral muscles (degrees)	21.4±9.6	9.8±8.5	**<0.001**	18.8±8.5	17.3±7.2	0.39
Contracture of hamstring muscles (degrees)	9.4±8.8	3.3±8.0	**0.02**	5.0±6.3	5.5±7.9	0.76
Anterior vertical deviation (cm)	0.98±0.48	0.53±0.48	**<0.001**	0.82±0.64	0.69±0.68	0.40
Posterior vertical deviation (cm)	0.84±0.50	0.27±0.40	**<0.001**	0.83±0.81	0.48±0.59	0.06
Kifosis (degrees)	23.1±10.1	20.8±9.7	0.37	23.5±9.3	22.9±11.1	0.82
Lordosis (degrees)	33.2±6.4	30.3±4.8	0.06	30.3±8.2	27.6±8.6	0.20

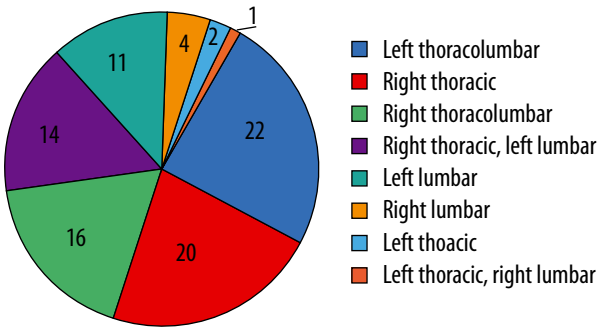

Figure 1. Types of scolioses represented in the study group of 90 children.

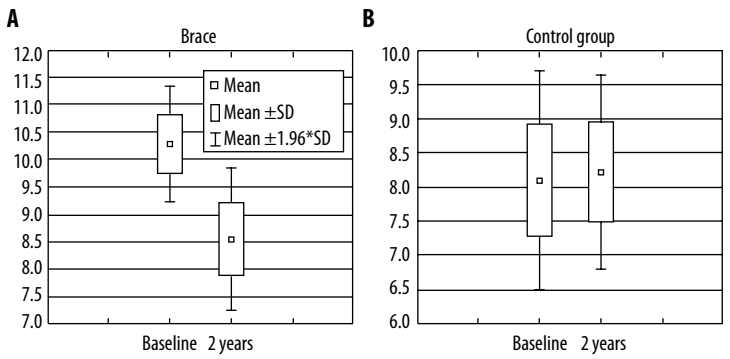

Figure 2. Rib hump angle at baseline and after 24 months in the brace treatment group (**A**) and in the control group (**B**).

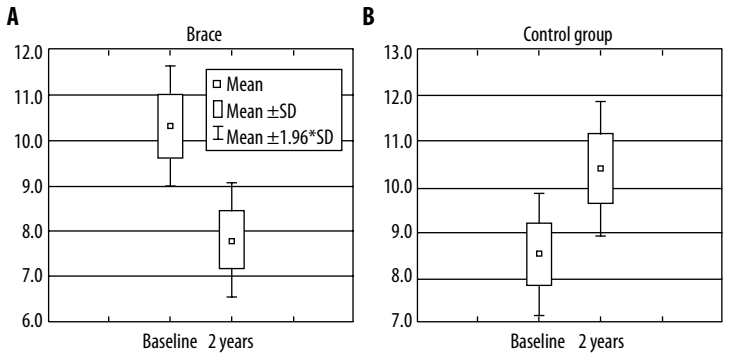

Figure 3. Lumbar prominence angle at baseline and after 24 months in the brace treatment group (**A**) and in the control group (**B**).

of trunk segments were assessed in two planes at shoulder girdle, chest and pelvis. Lateral dislocation was assessed using the Th1/S1 vertical line; the shift to the right or to the left was expressed in millimeters. The spinous processes of the vertebra were marked on the skin using a special pencil. Next, the type of scoliosis and the effect of correction applied were assessed.

The study was approved by the Bioethics Committee of the Medical University of Łódź.

Statistical analyses

Statistical analyses were made using STATISTICA 10 software package (StatSoft, Inc. 2011). The numerical values were presented as arithmetic means with standard deviations. The statistical analysis was conducted using Student's t-test for normal distribution; in other cases, Mann-Whitney's U-test, Wilcoxon's test and Spearman's rank correlation test were used. The Shapiro-Wilk's test was used to assess the normality of distribution. Probability level corresponding to statistical significance was set at 0.05.

Results

Both group were not statistically different in terms of age (P=0.38), sex (P=0.28), height (P=0.19), body wight (P=0.32), Risser sign of skeletal maturity (P=0.67). The baseline thoracic Cobb angle was similar in the SpineCor group and in the control group (25.5±8.9 *vs.* 24.2±5.4, respectively; P=0.53), as was the lumbar Cobb angle 27.2±7.1 *vs.* 24.2±4.9, respectively; P=0.06). Also the baseline clinical examination parameters as listed in Table 1 did not differ between the study groups. The observation period was 2 years in all children.

Significant reduction in rib hump compared to baseline was demonstrated upon a 2-year use of the SpineCor brace (10.3±3.3 *vs.* 8.6±3.8; P=0.04) compared to the control group

treated by physiotherapy only, where improvement was not observed 8.1±4.4 *vs.* 8.2±4.1; *P*=0.91). Similarly, improvement in lumbar prominence was observed in the actively treated group (10.3±4.3 *vs.* 7.8±3.9, *P*=0.009), with a trend towards worse results in the control group (8.6±4.0 *vs.* 10.4±4.5, *P*=0.07). The results are presented in Figures 2 and 3.

The mean change in the hump angle upon 2-year observation period was –2.4±3.8 in the SpineCor group compared to 0.45±3.9 in the control group (p<0.001). Similarly, the mean change in the lumbar prominence angle upon 2-year observation period was –2.8±3.1 in the SpineCor group compared to 1.7±5.3 in the control group (p<0.001).

In addition, in the group treated with the SpineCor brace, significant reduction in pectoral and hamstring muscle contractures as well as posture improvement (reduction in shoulder asymmetry and reduction in anterior and posterior vertical deviation – see Table 1) were observed.

Discussion

This article presents the clinical effects of the treatment of idiopathic scoliosis using the SpineCor brace. According to current SRS criteria, therapeutic success is currently defined as lack of Cobb angle progression larger than 5 degrees or as a reduction in the curvature. These success criteria were met for the SpineCor treatment by 78% of children in the study group. In the control group, stabilization (without improvement) was achieved in 53% of patients, and progression of scoliosis was observed in 47% of patients.

Posture improvement as assessed in the clinical trial was achieved in the study group. Significant reductions in rib hump and lumbar prominence were observed upon the use of the SpineCor brace; no such effect was observed in the control group. Similarly, positive results were obtained with regard to postural verticalization. The studies conducted by the Coillard group showed that the reduction in the hump seize as measured by a scoliometer in children treated with SpineCor brace was correlated with the curvature angle determined from the radiological image by the Cobb method [8]. The authors suggest that this simple clinical measurement can be used for screening examinations as for estimation of treatment [2]. A similar linear relationship between the radiological measurements (Cobb angle, vertebral rotation) and the results of clinical examination using the scoliometer was observed in a study conducted in Poznań [13].

Misterska et al. observed that wearing the brace has no negative impact in the activity and mental health of girls. What;s more, the patients had much better perception of the shape of their chest [14]. Kinel et al. also observed that the use of braces has no negative effect on the quality of life of adolescents [4]. In another study, the same group reported that girls with curvatures larger than 45° treated by SpineCor braces had lower rotational deformity of the chest compared to non-treated children; however, no difference was observed in relation to the deformity in frontal and sagittal planes [5]. Several authors highlighted the discrepancy between the Cobb angle and the degree of thoracic deformity [3,6]. The thoracic deformity may be improved by using the brace despite a measured increase in the Cobb angle [6]. These observations suggest that not only attempts to reduce the scoliosis angle, but also cosmetic reasons are important arguments supporting the use of the brace. Forces exerted by the brace model the soft tissues and the rib hump, improving their appearance.

As shown by recent metaanalysis published by Sanders et al. in 2012, one may expect reduction in the scoliosis angle progression by ca. 6° when using the brace [15]. The number needed to treat (NNT), which is a parameter important from clinical and economical standpoints, shows that 9 individuals have to be treated using the brace to avoid orthopedic surgery in 1 patient. Better effects were observed in very well-compliant patients; in such cases, the NNT was 4 (1 surgery avoided per 4 braces worn). One should keep in mind that despite high efficacy, surgical treatment of scoliosis is associated with one of the highest percentages of complications. In a large American registry, the frequency of early complications per nearly 52,000 procedures included in the analysis was 15%, with peri-operational mortality of 0.17% [16].

Conclusions

Treatment using the SpineCor dynamic brace leads to a clinical improvement in posture, particularly to reduction in rib hump, lumbar prominence and muscular contractures.

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