

Survival analysis of a group of 365 idiopathic scoliosis patients treated with the Dynamic SpineCor Brace

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Study Design. A prospective study was conducted on 365 patients with adolescent idiopathic scoliosis (AIS) treated with the Dynamic SpineCor Brace.

Objectives. To evaluate the effectiveness of the Dynamic SpineCor Brace for the treatment of adolescent idiopathic scoliosis among those with milder and more severe curves.

Summary of Background Data. Prior to this study, we did an exhaustive literature review on traditional rigid braces available on the market such as Boston, Wilmington, Milwaukee, Charleston and TLSO as well as the Dynamic SpineCor Brace (flexible and dynamic brace).

Methods. A group of 365 adolescents with AIS were followed during the course of their treatment with the SpineCor Brace. The cohort of patients was divided into two groups according to their initial Cobb angle: 1) milder group: having a curve between 15° and 29° and 2) a more severe group: having a curve of 30° or more. A survival analysis was performed to estimate the cumulative probability of success during treatment and at post-treatment follow-up period. To be qualified as a success, the patient must have either a stabilization ($\pm 5^\circ$) or a correction (more than 5°) of their initial Cobb angle. Failure was defined as a worsening of more than 5°.

Results. The survival analysis indicated a cumulative probability of success which is relatively stable for the patients in treatment with the SpineCor brace (Year 1: 1.00, 0.97; Year 2: 0.96, 0.89; Year 3: 0.85, 0.80; Year 4: 0.65, 0.70 for group 1 and 2 respectively) and which is maintained for the post-treatment follow-up period (Year 1: 0.97, 0.88; Year 2: 0.94, 0.88; Year 3: 0.91, 0.84; Year 4: 0.79, 0.84; Year 5: 0.67, 0.84 for group 1 and 2 respectively). Twenty-six patients were followed for 5 years after the end of the treatment by the Dynamic SpineCor Brace. Of these, 65.4% obtained a permanent correction of their initial Cobb angle, 30.8% stabilized their Cobb angle and only 3.8% worsened without having recourse to the surgery.

Conclusion. The SpineCor Brace is effective for the treatment of AIS. Moreover, the positive outcome appears to be maintained in the long turn.

Key words Adolescent idiopathic scoliosis - Orthopaedic treatment – Dynamic SpineCor Brace

Introduction

It is possible to alter the natural progression of AIS while wearing a brace [5,6,8,11,12,14,19] which helps to counter the negative impact of growth and biomechanic abnormalities. There are two types of braces: rigid braces and flexible braces. Although there is evidence that rigid brace treatment is effective [9,11,14,17], the flexible Dynamic SpineCor Brace, while being as efficient [3,4,5], offers multiple advantages by virtue of its flexibility. The Dynamic SpineCor Brace is hardly noticeable under clothing and is more comfortable than rigid braces, and as a result, adolescents may be more adherent to it than to rigid braces. Since successful brace treatment has been positively correlated with the total number of brace-wear hours per day [11,16,17] it may be possible to obtain better results (correction and stabilization of the Cobb angle) in the long term with the Dynamic SpineCor Brace. Furthermore, successful brace treatment may also be positively correlated with the ability of the brace to initiate significant positional exchanges [2,4,10]. This again may support the benefits of the SpineCor Brace since this new system employs a unique principle of Corrective Movement[®] specific to the type of scoliosis (Fig. 1) [3].

Corrective movement designed to open the scoliotic curve, decreases the spine deformation and corrects the postural disorganization. The specific movements for each type of scoliotic curve, which is maintained by a non-rigid brace SpineCor, have been designed based on kinematics of each spinal segment [3]. The moderate tension in the elastic bands allows the repetition and amplification of the corrective movement as the child undertakes everyday activities. This results in a progressive curve reduction [5]. The main objective of this study is to

evaluate the effectiveness of the Dynamic SpineCor Brace for the treatment of AIS by evaluating a group of 365 patients who are treated with this brace.

Methods

The studied population:

This prospective study was carried out on a group of 365 patients (92.1% female) having idiopathic scoliosis. The adolescents were recruited by an orthopedist specialized in scoliosis. This study was approved by the Research Ethics Committee of the Sainte-Justine Hospital and every patient signed informed consent.

Inclusion criteria were as follows:

- Diagnosed and confirmed idiopathic scoliosis (normal neuro-muscular examination, absence of significant pathological malformation of the spine as per radiographic examination)
- Scoliosis with suspected high risk of progression (such as family history) or proven to be progressive (Cobb angle increase of 5° or more confirmed by two X-rays at 6 month intervals)
- Idiopathic scoliosis of any type (thoracic, thoracolumbar, lumbar or double)
- Girls or boys from 6 to 14 years of age
- Initial Cobb angle $\geq 15^{\circ}$ and $\leq 50^{\circ}$
- Risser sign 0, 1, 2 or 3

Exclusion criteria were as follows:

- Postural scoliosis : when a supine posteroanterior radiograph shows an almost complete reduction and there is a leg length discrepancy, the diagnosis should be revised because this could be a postural scoliosis and not a real idiopathic scoliosis [7]
- Patient inability to follow all the treatment instructions
- Patient having a significant pathological malformative spinal anomaly (vertebral malformation) or presence of a congenital malformation
- Neuromuscular scoliosis
- Patients who have had a prior surgery

The Dynamic SpineCor Brace (Fig. 2), developed in 1992-93, is made of two principal components. The first section consists of the pelvic base which is a belt that includes three pieces of soft thermodeformable plastic stabilized by two bands among legs and two bands of thighs. Its role is to offer a base of anchoring for the action of the elastic bands. When the pelvic base is stable, the vector of action of the bands is stable. The second section consists of the bolero and the corrective elastic bands. The various sizes available of the corrective elastic bands offer multiple possibilities in the adjustment of the brace for an optimal correction. Its function is directly connected to the induced Corrective Movement[©] specific to the class of scoliosis selected. The flexible nature of the System authorizes the redirection of the movements between the shoulders, the thorax and the pelvis. There are four principal ways to adjust the elastic bands corresponding to the four basic curves classified by Ponseti and Friedman [15]: thoracic (n = 144), thoracolumbar (with or without pelvic obliqueness, n = 139), lumbar (n = 23) and double (n = 59). A Corrective Movement[©] specific to the type of scoliosis is applied in order to allow

the fitting of the brace [3]. The moderate tension applied to the bands amplifies the Corrective Movement[©] during daily and sport activities of the patient; the postural geometry is thus actively and passively modified inducing the modification of the curves. In order to be effective and to obtain a neuromuscular integration of the new strategy of movement through active bio-feedback, the brace must be worn 20 hours a day for a minimum of 24 months of treatment. As an example, the Corrective Movement[©] for the Right Thoracic type 1 curve consists of a detorsion between the thorax and the shoulder girdle in the horizontal plane, facilitated by the left lateral shift of the trunk.

The effectiveness of the Dynamic SpineCor Brace was assessed by comparing the Cobb angles at the initial visit, during the treatment with the brace and during the post-treatment follow-up period. All of the patients were followed by the same clinician, and collection of data was standardized as follows. Throughout visits, the same vertebrae limits were preserved except if those limits changed two levels or more. In that case, a second measurement was also taken and both measurements were noted. Each time a posteroanterior and lateral X-ray was required; it was carried out on a revolving plate [18] to avoid any movement of the child between the two X-rays. The reported results relate only to the measurement of the posteroanterior Cobb angle, although it is also possible to appreciate the results on clinical criteria, postural and lateral radiographs.

The initial evaluation which was used as a reference included a posteroanterior and lateral X-ray without brace within a maximum of one month before the brace was fitted. During the treatment, X-rays were always required with the SpineCor brace and a shoe lift if needed

following the same schedule: the first X-ray on the day of the fitting, one month after the fitting of the brace, then every five months on average, until weaning. At the end of the treatment with the brace, the X-ray was performed once every six months for the first year and once per annum thereafter up to 5 years post-bracing. These post-treatment evaluations were performed without the brace and shoe lift on the patient. The lateral X-rays were obtained once every two visits during the treatment period.

From the target population, all eligible patients agreed to take part in this study and were treated with the Dynamic SpineCor Brace. The patient cohort was divided into two distinct groups according to their initial Cobb angle before bracing: the first group having a curve from 15 to 29 degrees (n=195) and the second group having a curve of 30 degrees or more (n=170).

A survival analysis was carried out in order to evaluate:

1. Cumulative probability of success of 327 patients with at least 1 to 4 years of follow-up who were still under treatment with the brace comparing the Cobb angle at the beginning of the treatment and the last evaluation available during the treatment with the brace (X-ray in brace).
2. Cumulative probability of success of 120 patients with at least 1 to 5 years of follow-up for the period ranging between the end of bracing and the last available post-treatment follow-up (X-ray without brace).

To be qualified as a success, the Cobb angle of the current visit must have stabilized (± 5 degrees) or undergone a correction (of more than 5 degrees) compared to the initial Cobb angle.

Failure will thus be characterized by an aggravation of the initial Cobb angle of more than 5 degrees.

Results

In total, 365 adolescents took part in this study. The average age at the initial visit was 12.2 years (SD 2.3 year) and 67% of the studied population were skeletally immature with a Risser score of 0. The average duration of treatment was 2.2 years (SD 1.2 year). The initial cohort characteristics by curve amplitude and curve type are presented in Table 1.

Since 38 patients did not have any radiological evaluation in brace with at least 1 year follow-up, these subjects were excluded from the analysis. A survival analysis was performed on 327 adolescents with at least 1 to 4 years of follow-up between the fitting of the brace and the last available visit in brace (X-ray in brace). The cumulative probability of success at 1, 2, 3 and 4 years was 1.0, 0.96, 0.85 and 0.65 for group 1 (Cobb angle 15-29°) and 0.97, 0.89, 0.80 and 0.70 for group 2 (Cobb angle >29°) respectively (see Table 2 and Fig. 3). At 4 years there was a considerable decrease, most likely due to the limited number of patients available for the analysis during this time period. There was no significant difference in probability of success between the two groups ($p=0.24$) and median success time was similar in both groups (62.1 months (CI95%: 31.8-92.4) for group 1 and 64.2 months (CI95%: 55.3-73.1) for group 2).

Among the 171 adolescents who ended the bracing at the time of the data acquisition, 120 of them had a minimum post-treatment follow-up of one year. A survival analysis was carried

out on this cohort of patients for the period ranging between the end of bracing and the last post-treatment follow-up available. The cumulative probability of success at 1, 2, 3, 4 and 5 years was 0.97, 0.94, 0.91, 0.79, 0.67 for group 1 and 0.88, 0.88, 0.84, 0.84 and 0.84 for group 2 (Table 3 and Fig. 4). At 5 years there was a considerable decrease, most likely due to the limited number of patients available for the analysis during this time period. There was no significant difference between the patients of group 1 and those of group 2 ($p=0.81$) and survival (probability of improvement between the suspension of the brace and the last post-treatment follow-up) was similar for the two groups. The SpineCor Brace was a success for 84.55% of these patients.

By subdividing these 120 patients according to their initial Cobb angle, one can note that the percentage of correction and stabilization is the same for group 1 ($n=74$) and for group 2 ($n=46$). Indeed, 86.5 % ($n=64$) of the patients having an initial Cobb angle lower than 30° corrected or stabilized their curve. With regard to those having an initial Cobb angle greater than or equal to 30° , 82.6% improved (Fig. 5).

Twenty six patients (25 girls and 1 boy) were followed during 5 years after the end of the treatment with the brace. 65.4% of these patients ($n=17$) obtained a permanent correction of their initial Cobb angle, 30.8% ($n=8$) stabilized their Cobb angle and only 3.8% ($n=1$) worsened but did not require surgery.

Discussion

A survival analysis was carried out on adolescents with an idiopathic scoliosis having agreed to be treated by the Dynamic SpineCor Brace. A previous study was published in 2003 in European Spine Journal on the first 195 patients from the same data bank used for this present study [5]. The present study expands upon this by including more patients and a post-treatment follow-up of 5 years. The preliminary study revealed that on the 29 patients who had a minimum post-treatment follow-up of 2 years, 55% obtained a correction of their initial Cobb angle, 38% stabilized their Cobb angle and only 7% worsened by more than 5°. The recent results go in a similar direction. Indeed, this study reveals that the orthopaedic treatment was a success for 84.55 % of the 120 patients having a minimal post-treatment follow-up of 1 year and a failure for 15.45% of them. The results are even more encouraging if one looks at the 26 patients who now have 5 years post-treatment follow-up: permanent correction in 65.4% of the cases, stabilization in 30.8% and only 3.8% progression of the curve. With time, we noticed that the majority of curve progressions leading to surgical operations occurred during the period in brace and may explain the low percentage of aggravation in post-treatment follow-up period.

The SpineCor Brace uses a unique principle of Corrective Movement[®] designed to open the scoliotic curve, decreasing the spine deformation and correcting the postural disorganization. These specific movements are induced and amplified by the moderate tensions applied to the corrective bands while the child is active. Thus it results in a progressive reduction of the curvature. The brace is readjusted by the clinician in order to follow the obtained correction and according to the growth of the child. Corrective bands are equipped with velcro at one end, to

allow their adjustment to the velcro patches of the bolero and with a snap at the other end to be connected with the pelvic base. On the other hand, rigid braces use a system with three points of pressure and restrict the child's movement. In the study of Vijvermans and collaborators [19], on 151 patients who wore the Boston brace, 41.7% (n=63) of the patients corrected their initial Cobb angle by more than 5°, 32.5% (n=49) of the patients stabilized their curvature while 25.8% (n=39) worsened by more than 5°. 12.6% of their studied population [19] required surgery. These results are similar to those of Lonstein and Winter [12] on the Milwaukee brace, where 22% of their population ended up requiring a surgical operation. A prospective study by Nachemson and Peterson [14] had followed 111 patients wearing a TLSO brace for their thoracic or thoracolumbar curves. The treatment by TLSO was a success for 74% of these patients at 4 years. This study excluded lumbar and double curves which may have affected the results. Finally, the treatment by the Charleston bending brace [16] succeeded in preventing the progression of the spinal curvature in 66% of 98 patients who had completed the treatment with the brace. It should be noted that this kind of brace was worn only during the night and may be less effective than wearing a brace 23 hours out of 24 [17]. Table 4 summarizes these studies with the various types of braces.

Several authors [1,8,9,13] concluded that the average effect expected in the long run by the rigid braces was to stabilize the curve to pretreatment levels. However, our results show that it is possible to obtain a correction of the pretreatment Cobb angle and this correction can be maintained 5 years after the end of the treatment by SpineCor Brace. Also there is no component of collapse after the end of bracing, as noted for rigid braces, which, by not supporting an effective musculature, may encourage the progressive collapse of the curves [4]. However, a

limitation of the present study is that the results are based on patients treated with the SpineCor brace and are not compared with a non-treated control group or those treated by another type of brace (e.g. a rigid brace system). A more direct comparison with these two groups would provide a stronger basis for evaluating the efficacy of the SpineCor brace. Others limitations have to be considered: 1) this is not a randomized study, 2) adolescents with idiopathic scoliosis only were included in the present study, 3) patients with Risser sign 4 or 5 were not included in this study.

Conclusion

This prospective study shows that SpineCor Brace is effective for the treatment of adolescent idiopathic scoliosis and reveals a positive treatment outcome in the long run. The brace appears to be effective for milder curves (15-30 degrees) as well as moderate curves (30-50 degrees). Among those who completed the course of treatment with the brace, the correction appears to be maintained.

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Figure Legends

- Fig. 1** Corrective Movement[®] for the right thoracic curve 1: detorsion in the horizontal way between the thorax and the shoulder girdle, inducing a slight left lateral shift of the trunk.
- Fig. 2** The SpineCor brace fitted on a patient to show the various components.
- Fig. 3** Survival analysis of 327 patients in treatment with the brace with at least 1 to 4 years of follow-up, for the period ranging between the fitting of the brace and the last available visit in brace. The probability of success ranges from 1.00 at 1 year to 0.65 at 4 years for group 1 and from 0.97 at 1 year to 0.70 at 4 years for group 2. Note: the results at 4 years are represented by a restricted number of patients as reflected by the size of the confidence interval.
- Fig. 4** Survival analysis of 120 weaning patients having a minimum post-treatment follow-up of 1 year, for the period ranging between the end of bracing and the last post-treatment follow-up available. The probability of success ranges from 0.97 at 1 year to 0.67 at 5 years for group 1 and from 0.88 at 1 year to 0.84 at 5 years for group 2. Note: the results at 5 years are represented by a restricted number of patients as reflected by the size of the confidence interval.
- Fig. 5** Visual comparison of the progression of mean Cobb angle at the initial visit, at the end of bracing and during the post-treatment follow-up period of group 1 (initial Cobb angle < 30°) (N = 74) and group 2 (initial Cobb angle ≥ 30°) (N = 46).

Table 1 Initial characteristic of the patients of the population being studied

		Group 1	Group 2	
		N=195	N=170	
		(15° - 29°)	(30° - 50°)	
		n (%)	n (%)	Total
Type of curvature	Lumbar	16 (8.2)	7 (4.1)	23
	Thoracic	59 (30.3)	85 (50)	144
	Thoraco-lumbar	96 (49.2)	43 (25.3)	139
	Double	24 (12.3)	35 (20.6)	59

Table 2 Cumulative probability of success of 327 patients with at least 1 to 4 years of follow-up who were still under treatment with the brace comparing the Cobb angle at the beginning of the treatment and the last evaluation available during the treatment.

Time	Probability (95% CI)*	
	Group 1	Group 2
1 year	1.00 (1.00-1.00)	0.97 (0.93-1.00)
2 years	0.96 (0.92-1.00)	0.89 (0.81-0.97)
3 years	0.85 (0.74-0.96)	0.80 (0.68-0.92)
4 years	0.65 (0.43-0.87)	0.70 (0.54-0.86)

* CI: Confidence interval

Table 3 Cumulative probability of success of 120 patients with at least 1 to 5 years of follow-up for the period ranging between the end of bracing and the last available post-treatment follow-up.

Time	Probability (95% CI)*	
	Group 1	Group 2
1 year	0.97 (0.93-1.00)	0.88 (0.86-1.00)
2 years	0.94 (0.88-1.00)	0.88 (0.78-0.98)
3 years	0.91 (0.84-0.98)	0.84 (0.72-0.96)
4 years	0.79 (0.65-0.93)	0.84 (0.72-0.96)
5 years	0.67 (0.45-0.90)	0.84 (0.72-1.00)

* CI: Confidence interval

Table 4 Comparison of raw data of the different studies

Study, Year of publication	Type of brace	Rate of success (Per cent)	No. of patients	Criterion for failure (Degrees of progression)	Daily Duration of brace wear (Hrs)
Coillard C et al, 2003	SpineCor	93 after 2 years post-brace	29	>5	20
Vachon V et al, 2005	SpineCor	84.5 after at least 1 year post- brace	120	>5	20
	SpineCor	96.2 after 5 years post-brace	26	>5	20
Vijvermans V et al, 2004	Boston	74.2 at the end of bracing	151	\geq 5	22
Nachemson AL & Peterson LE, 1995	TLSO	74 at the end of bracing	111	>5	16
Price CT et al, 1997	Charleston	66 after 1 year post-brace	98	\geq 5	Nighttime

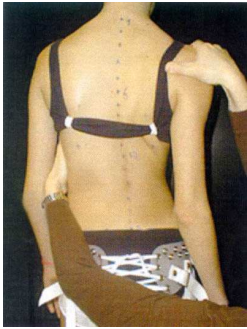


Fig. 1

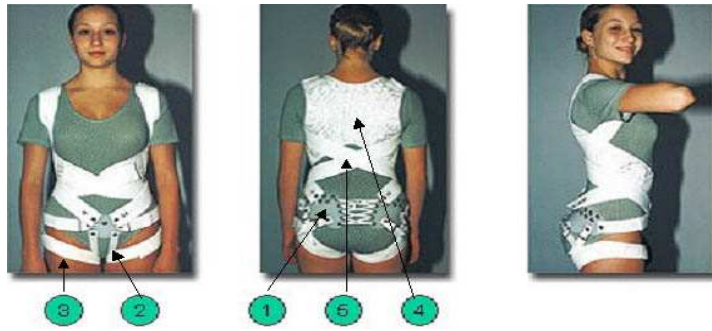
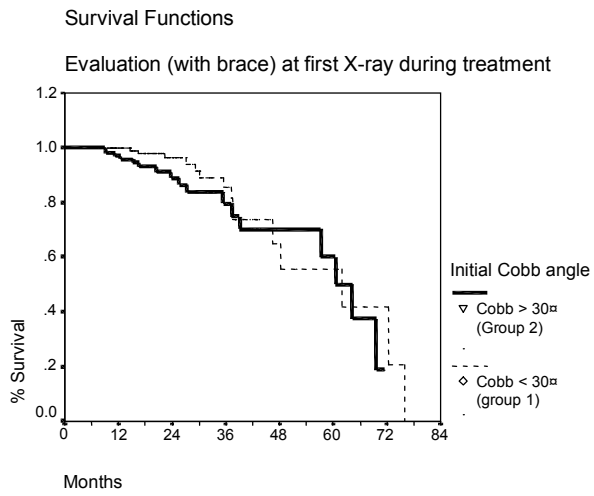


Fig. 2

- (1) Pelvic base
- (2) Crotch bands
- (3) Thigh bands
- (4) Bolero
- (5) Corrective elastic bands

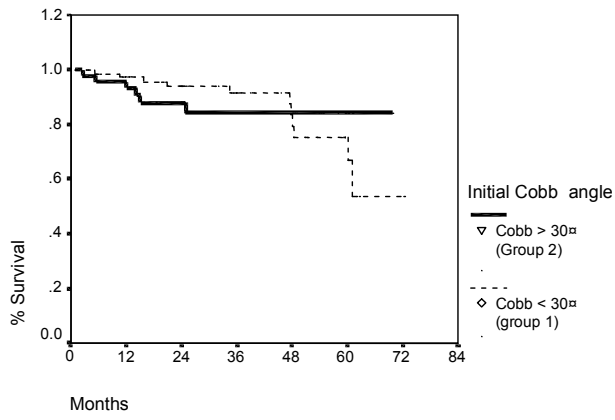


Survival median < 30° : 62.1 (31.8 – 92.4)
 Survival median > 30° : 64.2 (55.3 – 73.1) p = 0.24

Fig. 3

Survival Functions

Evaluation from the end of bracing to the last post-treatment follow-up



Survival median < 30° : 61.3 (55.8 - 66.8)
Survival median > 30° : 60.9 (54.3 - 67.4) p = .81

Fig. 4

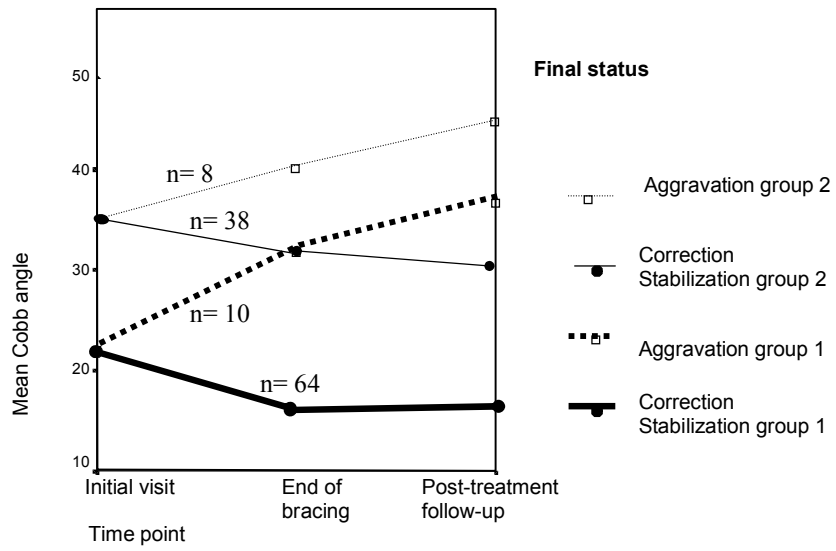


Fig. 5