

# Treatment of early adolescent idiopathic scoliosis using the SpineCor System

Coillard Christine MD, Circo Alin MD, Charles H. Rivard MD.  
*Ste-Justine Hospital, Montreal, Canada*

## Abstract

The purpose of this prospective observational study was to evaluate the effectiveness of the Dynamic SpineCor System for adolescent idiopathic scoliosis in accordance with the standardized outcome criteria proposed by the Scoliosis Research Society Committee on Bracing and Nonoperative Management. The SpineCor System is the first and only truly dynamic brace, which provides a progressive correction of Idiopathic Scoliosis from 15° Cobb angle and above. The new therapeutic approach is based on a new concept upon the etiology and pathogenesis of idiopathic scoliosis; a pathology of the neuro-musculoskeletal system in growth and maturation. This prospective observational study was carried out on a group of 639 patients (92.3% females) having idiopathic scoliosis treated with the SpineCor brace.

Five hundred and eighty three patients met the criteria for inclusion, and 234 patients were still actively being treated. Overall, 349 patients have a definitive outcome. All girls were premenarchal or less than 1 year postmenarchal. Assessment of brace effectiveness included (1) percentage of patients who have 5 degrees or less curve progression, and percentage of patients who have 6 degrees or more progression; (2) percentage of patients who have been recommended/undergone surgery before skeletal maturity; (3) percentage of patients with curves exceeding 45 degrees at maturity (end of treatment); and (4) Two-year follow-up beyond maturity to determine the percentage of patients who subsequently underwent surgery. Successful treatment (correction, >5 degrees, or stabilization, ±5 degrees) was achieved in 259 (74.2%) of the 349 patients from the time of the fitting of the SpineCor brace to the point in which it was discontinued (or at the time of the surgery). Fifty one immature patients (14.6%) required surgical fusion while receiving treatment. Eight mature patients out of 298 (2.7%) required surgery within 2 years of follow-up beyond skeletal maturity. The conclusion drawn from these findings is that the SpineCor brace is effective for the treatment of adolescent idiopathic scoliosis. Moreover, positive outcomes are maintained after 2 years because 151 (93.2%) of 162 patients stabilized or corrected their end of bracing Cobb angle up to 2 years after bracing.

**Key Words:** adolescent idiopathic scoliosis, conservative treatment effectiveness, SpineCor system, standardized outcome criteria

## **SpineCor System**

- THE FIRST AND ONLY TRULY DYNAMIC BRACE, WHICH PROVIDES A PROGRESSIVE CORRECTION OF IDIOPATHIC SCOLIOSIS FROM 15° COBB ANGLE AND ABOVE.
- PRESERVES NORMAL BODY MOVEMENT AND GROWTH AND ALLOWS NORMAL ACTIVITIES OF DAILY LIVING.
- IT IS WORN COMFORTABLY AND EASILY UNDER CLOTHING.
- INCREASES PATIENT'S TREATMENT ACCEPTANCE LEADING TO BETTER COMPLIANCE.

## **Concept**

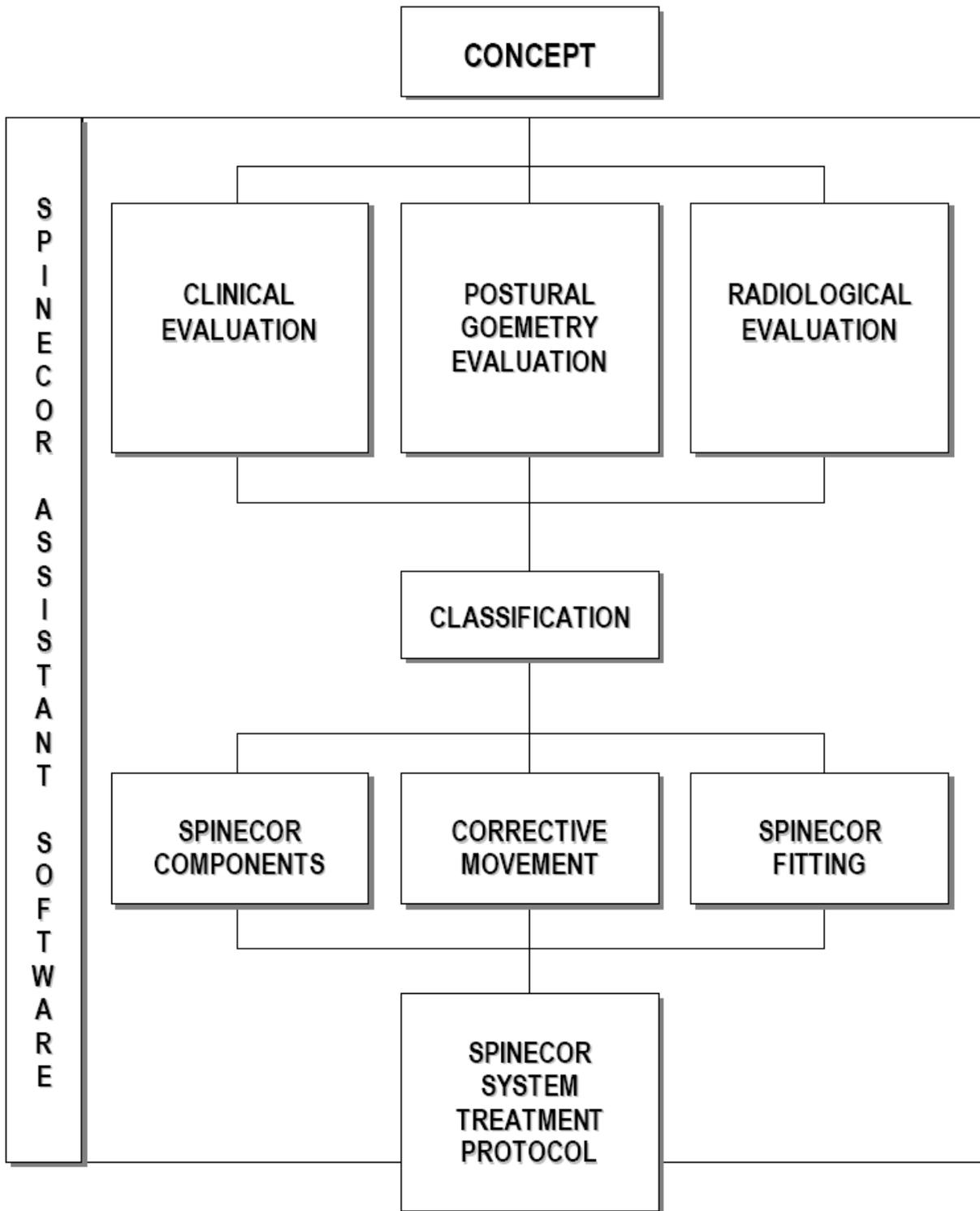
The new therapeutic approach is based on a new concept upon the etiology and pathogenesis of idiopathic scoliosis; a pathology of the neuro-musculoskeletal system in growth and maturation.

In order to obtain an accurate diagnosis, that would specify a particular class and subclass for the patient, the evaluation combines a clinical exam, radiological and postural evaluation.

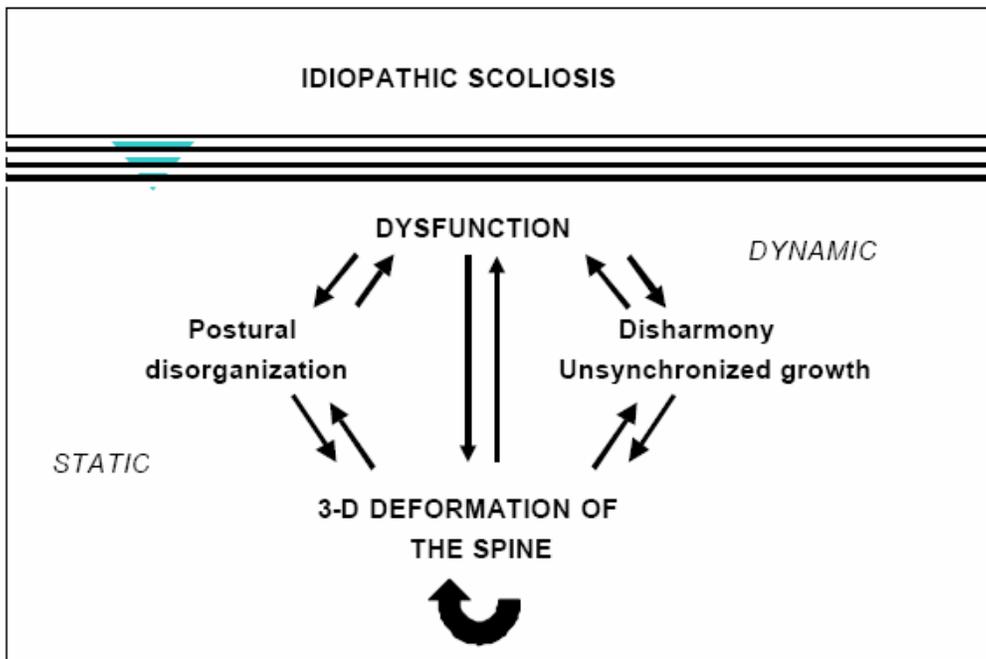
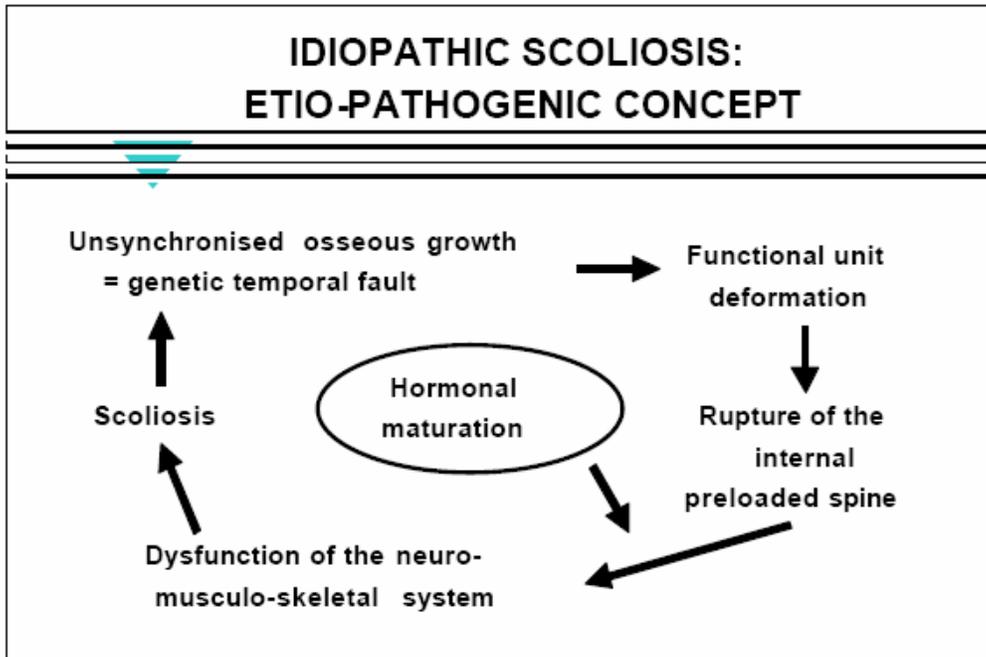
A specific corrective movement is performed, and the brace is applied according to the SpineCor Assistant Software instructions. The moderate tension in the elastic bands allows the repetition and amplification of the corrective movements as the child undertakes everyday activities. This results in a progressive curve reduction. To obtain a neuro-muscular integration of the new strategy of movement, the minimum duration of treatment is 24 months. Because of the progressive changes, absence of external support during the treatment and intact muscles, there is no loss of correction after the brace discontinuation.

Physical therapy is not a necessity in the SpineCor program. However, when the patient is willing to undergo a physio program or a faster consolidation of the curve is desired, the specific SpineCor physiotherapy program is considered. For the patients at the beginning of the treatment, the physio is carried out with the brace on; for the patients in the weaning period the exercises are done without the brace, to reinforce the muscles responsible for each corrective movement; which are specific for each type of curve.

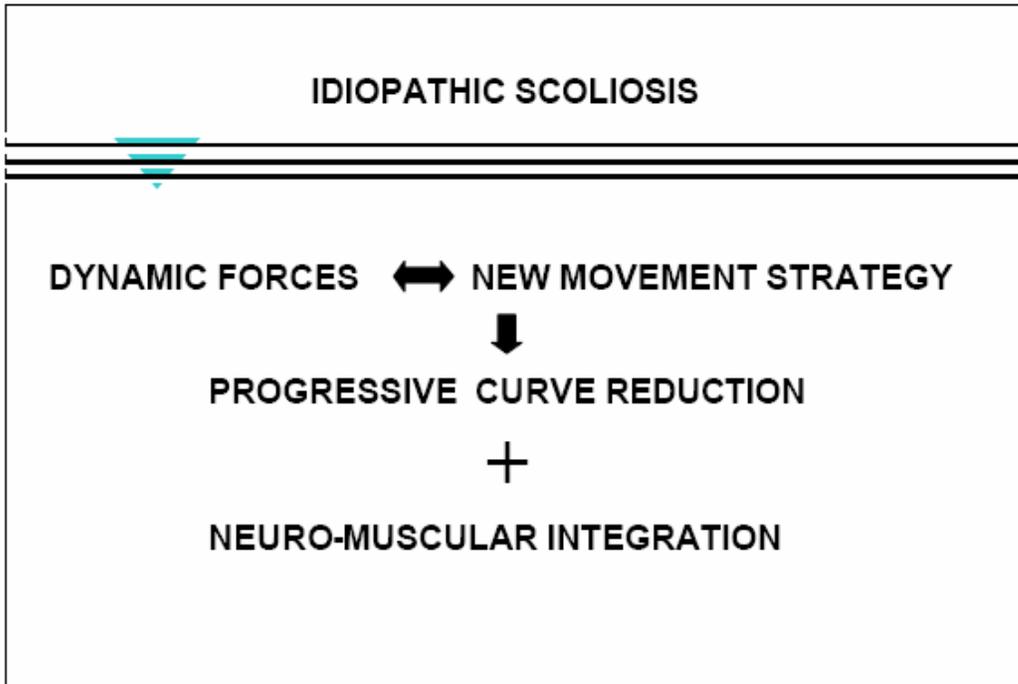
The SpineCor system approach



Ethiopatogenic hypothesis



**Therapeutic approach and treatment strategy**



**IDIOPATHIC SCOLIOSIS**

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**SPINECOR DYNAMIC BRACE TREATMENT**

START TREATMENT	PRINCIPAL OBJECTIVE	QUALITY OF RESULT
BEFORE MAIN GROWTH SPURT →	CORRECTION →	HIGH
DURING OR AFTER MAIN GROWTH SPURT →	STABILISATION →	MODERATE

## Radiological classification

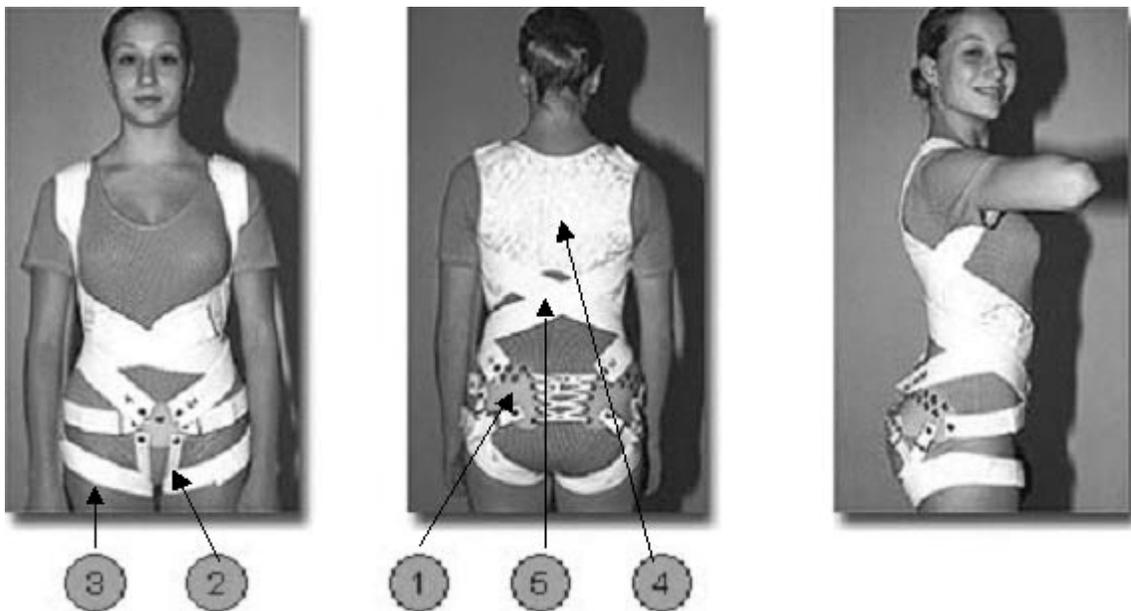
The conventional classification of idiopathic scoliosis is based on a radiological evaluation in the P/A view and different types are identified according to the position of the apex without any consideration of the sagittal view. This classification provides only partial information even though scoliosis is known as a three-dimensional deformation of the spine associated with postural disorganization. When comparing x-rays among patients classified as the same, several differences in the morphological aspect of the curvature and other characteristics may be noted. Clinically, the differences in posture for these patients are obvious enough to reconsider if they are indeed of the same type of scoliosis. This has led to the development of subclasses of the conventional classification of scoliosis patients. A classification that reflects the three-dimensional deformation of the spine and the associated postural disorganization is therefore essential. Observation of specific parameters, by combining frontal and sagittal x-rays, in order to get the maximum 3D information is involved.

- Tilt / rotation / version for each vertebra
- Tilt / rotation / version for the shoulder girdle / thorax / pelvic girdle
- P/A and lateral shift
- Modifications in the sagittal plane of the thoracic, thoracolumbar and lumbar segments
- Anteversion / retroversion / antepulsion / retropulsion

## Indications

The SpineCor System was designed for the treatment of Idiopathic Scoliosis only (from 15° and above). Its efficacy for treating neuromuscular, neurological or other types of scoliosis is unknown and generally non Idiopathic Scoliosis is contraindicated.

## SpineCor Components



The SpineCor Dynamic Corrective Brace is made up of two sections:

- The first section consists of **the pelvic base (1)**, **the crotch bands (2)** and **the thigh bands (3)**. Its role is to act as an anchoring point and support for the actions applied to the patient's trunk by the corrective elastic bands.
- The second section consists of **the bolero (4)** and **the corrective elastic bands (5)**. This is the part designed to make the correction of the scoliosis curve. The fitting of the corrective bands is specific for each patient and depends on the type of curve.

### **SpineCor Treatment**

- The SpineCor® brace is worn for 20 hours per day. The 4-hour out of the brace period should be taken in two or more intervals during the least active part of the day. The brace must be worn while sleeping.
- The length of treatment will depend on the severity of the curve, age at start of treatment and its evolution, but it is always a minimum of 24 months for adolescent scoliosis. Juvenile cases requires much longer treatment times.
- To optimise the dynamic effect of the brace, patients are encouraged to perform any type of sport wearing the brace (except for swimming).
- Patients may be suggested to undergo a specific SpineCor Physiotherapy Program in order to complement the action of the SpineCor brace.
- A shoe lift may be also prescribed at the time of brace supply. All shoe lifts should be sole and heel, not just heel, and must be worn during all activities

### **Prognosis**

To really change the natural progression of idiopathic scoliosis, it is essential to reduce the curvature enough to eliminate the negative impacts of abnormal biomechanics and growth.

Therefore it is possible to achieve a complete or almost complete correction of moderate curves, if the treatment is started before the main growth spurt (before Risser 1 and menarche). In curves over 30° of Cobb angle, or when the treatment started during or after the main growth spurt, the goal is a stabilization of the deformity. The therapeutic success is possible in more than 80 % (stabilization or correction of the curve) of cases.

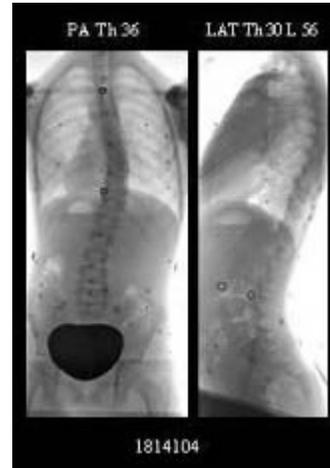
## Case study

### Before treatment

This case study follows the treatment of an adolescent female patient with idiopathic scoliosis whose initial presentation at 9.5 years and Risser 0 was with a 36° right thoracic curve.



Patient - 9 ½ years old - 36°  
Clinical Aspect before treatment



Patient - 9 ½ years old - 36°  
Radiological aspect before treatment

After evaluation of the patient's radiological, clinical and postural data, she was classified as a Right Thoracic Type 1 according to the SpineCor classification.

Each SpineCor classification has a specific corrective movement strategy for progressive curve reduction. In the case of Right Thoracic Type I, the corrective movement is counter clockwise rotation of the thorax and clockwise rotation of the shoulder girdle.



Corrective Movement  
Right Thoracic Type 1

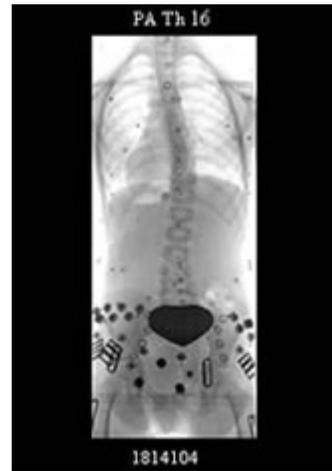


Wearing SpineCor Brace Set-up for Right  
Thoracic Type 1

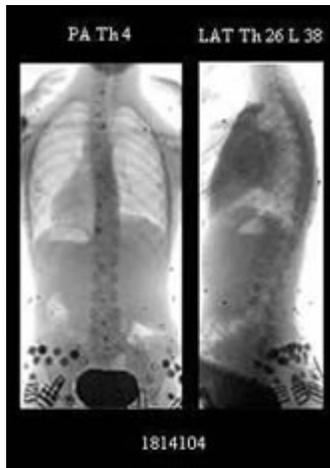
**Treatment review**



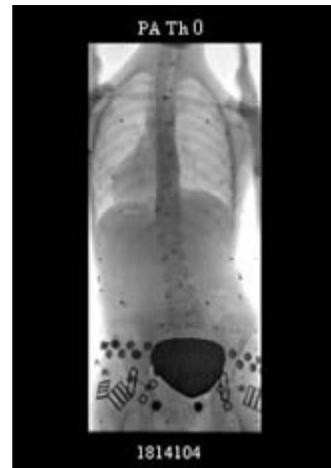
Day of Brace Fitting - 21°



One Month in Brace - 16°



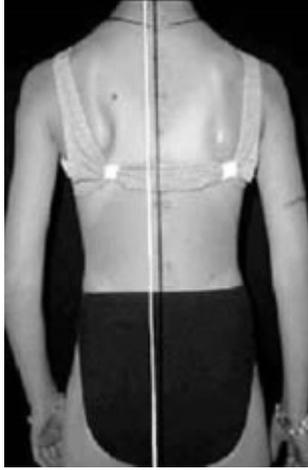
6 Months in Brace - 4°



13 Months in Brace - 0°

## After treatment

Patient's postural correction and Cobb angle reduction have been maintained three years post bracing.



Clinical aspect after treatment



15 Months of Brace Treatment - 2° Radiological aspect after treatment

## Material and Methods

The studied population:

This prospective observational study was carried out on a group of 639 patients (92.3% females) having idiopathic scoliosis treated with the SpineCor brace.

## Radiographic analysis

The initial pre-therapeutic radiograph uses a digital technique where the irradiation is half as much as that of a standard radiographs<sup>11</sup>. The initial evaluation included a postero-anterior and lateral X-ray without brace within a maximum of one month before the brace was fitted. The following X-ray controls were always administered with the SpineCor brace and shoe lift if prescribed following the same schedule: the first control on the day of the fitting and at 4-6 weeks, then every 5 months until weaning. The lateral X-rays were obtained once a year. At the end of the treatment, the controls were continued at 6 months, one year and once every year. These evaluations were performed without brace.

**Inclusion criteria were as follows:**

- Idiopathic scoliosis diagnosis and radiological confirmation of absence of significant pathological malformation of the spine
- Risser 0, 1, 2 or 3
- Initial Cobb angle equal to or above 15°
- Initial Cobb angle equal to or less than 40°
- No prior treatment for scoliosis

**Exclusion criteria were as follows:**

- Presence of a congenital malformation of the spine, spina bifida aperta or spondylolisthesis
- Neuromuscular scoliosis
- Postural scoliosis

Skeletal maturity is considered when Risser 4 or more is reached. The United States grading system<sup>14</sup> for Risser sign was used in this study. Respecting the criteria mentioned above, we needed to exclude some patients from the actual study. **583** patients respected the inclusion criteria, 234 (40.1%) did not completed the treatment by brace at the time of the analysis and 51 immature patients required surgical fusion while receiving treatment. Lead up to 298 patients who had reached skeletal maturity at the end of bracing. Out of this cohort of patients, 162 patients had 2 years and 69 patients had 5 years follow-up post-bracing.

**Description of the bracing system and treatment protocol**

The Dynamic SpineCor brace, developed in 1992-93, use a specific Corrective Movement<sup>®</sup> depending of the type of the curve<sup>2</sup>. Curve classification was based on the classification presented by Ponseti and Friedman<sup>13</sup>. The specific Corrective Movement<sup>®</sup> is performed, and the brace is applied according to the SpineCor Assistant Software instructions. In order to be effective and to obtain a neuromuscular integration of the movement through active biofeedback, the brace must be worn 20 hours a day for a minimum of 24 months. Generally, the brace is stopped at skeletal maturity (at least Risser 4) or after 2 years of regular menstruation.

**Statistical analysis**

Success was defined as either an improvement of more than 5° or stabilization of  $\pm 5^\circ$  of the scoliosis curvature. An aggravation of the spinal curvature of more than 5° was defined as worsening. The outcome data were analyzed in four ways as suggested by the SRS Committee on Bracing and Nonoperative Management<sup>10</sup>.

## Results

349 patients had a definite outcome, 51(14.6 %) required surgical fusion while receiving treatment and 298 finished the treatment by brace.

From the 298 patients, 279 girls and 19 males, had reached skeletal maturity at the end of bracing. The average age at initiation of brace (n=298) was  $12.8 \pm 1.9$  years (range 6.6-16.5). Patients wore the brace an average of  $2.4 \pm 1$  year with an average age at the time of brace discontinuation of 15.4 years. 162 patients had 2 years and 69 patients had 5 years follow-up post-bracing. The evolution of the mean Cobb angle of these patients is shown in Table 1.

**TABLE 1.** Average Cobb angles for all structural curves at various points during and after treatment by the SpineCor brace

	SpineCor brace				
	Beginning of treatment*	In brace*	End of treatment*	2 years post-bracing <sup>†</sup>	5 years post-bracing <sup>‡</sup>
Mean Cobb angle (°)	26.3 ± 6.8	19.2 ± 11.1	22.9 ± 11.5	21.4 ± 12.0	17.9 ± 10.4
Number of patients (n)	298	298	298	162	69

\*298 patients who had completed the treatment **by brace** at skeletal maturity

<sup>†</sup>162 patients who had 2 years follow-up after the end of bracing

<sup>‡</sup>69 patients who had 5 years follow-up after the end of bracing

### Assessment of brace effectiveness includes all of the following:

#### 1. Percentage of patients who have 5° or less curve progression and the percentage of patients who have 6° or more progression at skeletal maturity

137 patients (46.0%) out of 298 stabilized their Cobb angle ( $\pm 5^\circ$ ) at skeletal maturity at the end of bracing, 122 patients (40.9%) corrected their initial Cobb angle and 39 patients (13.1%) had 6° or more progression of their initial Cobb angle. Successful treatment, as defined above, was achieved in 86.9% of SpineCor brace patients.

With post-brace treatment follow-up observation (Table 2), the treatment success rate at 2 years was 93.2% (n=162), comparing the end of bracing Cobb angle to the one at 2 years post-bracing. 133 patients out of 162 stabilized their Cobb angle and 18 patients still improved from the time the braces were discontinued up to 2 years follow-up. After 5 years post-bracing, success was achieved in 95.6% (n=69) of the time, comparing the Cobb angle at the end of bracing to the one after 5 years post-bracing (table 2).

#### 2. Percentage of patient who have had surgery recommendation/undergone before skeletal maturity

51 immature patients (14.6 %) out of 349 who respected the inclusion criteria and who had a definite outcome (298 + 51), required surgical fusion while receiving treatment. The average curve magnitude at bracing in this particular group was  $32.7^\circ \pm 6.1^\circ$  (range: 17-41°). General indication for fusion in all patients was progression of primary curve of more than 60° in thoracic region and 45° in thoracolumbar and lumbar region.

**3. Percentage of patients who progressed beyond 45° at maturity**

Seven patients out of the 298 patients who had a definite outcome (2.3 %) had documented progression of curve beyond 45° at maturity. Surgery was required for 3 of these patients.

**4. 2-years follow-up beyond maturity to determine the percentage of patients who subsequently undergo surgery**

Eight mature patients out of 298 (2.7%) require surgery after weaning of the brace.

**TABLE 2.** Treatment success in relation to scoliosis curvature

Success of treatment with brace	n	Percentage of success (%)
Beginning – End of treatment*	298	86.9
End of treatment- 2 years follow-up <sup>†</sup>	162	93.2
End of treatment- 5 years follow-up <sup>◊</sup>	69	95.65

\*298 patients who had completed the treatment by brace at skeletal maturity

<sup>†</sup>162 patients who had 2 years follow-up after the end of bracing

<sup>◊</sup>69 patients who had 5 years follow-up after the end of bracing

## Discussion

The primary objective of this study was to perform an evaluation of the long-term outcome results of the prospective cohort of patients who completed the treatment with the SpineCor brace. Moreover, we wanted to compare the effectiveness of the SpineCor brace to rigid braces, particularly; Boston brace<sup>3,4</sup>, Wilmington brace<sup>5</sup>, Milwaukee brace<sup>6</sup>, Charleston brace<sup>7,14</sup> and the Rosenberger brace<sup>8</sup>.

To assess the effectiveness of a nonsurgical treatment of scoliosis, it is important to evaluate efficacy of bracing in patients who are at greatest risk of progression. All types of curves were treated with the SpineCor brace as well as both genders.

A previous study was published in 2007 in Journal of Pediatric Orthopaedics<sup>1</sup> on the first 493 patients from the same data bank used for this present study. The actual study expands upon this by taking in consideration standardized outcome criteria published by the SRS Committee in 2005<sup>10</sup>. The preliminary study in 2007 revealed that on the 47 patients who had a minimum post-treatment follow-up of 2 years, 10.7% continued the correction of their initial Cobb angle even after the weaning of the brace, 85% stabilized their Cobb angle and only 4.3% worsened by more than 5° (that represents a total of 95.7% of success). The recent results go in a similar direction. Indeed, this study reveals that the orthopedic treatment was a success for 93.2 % of the 162 patients having a minimal post-bracing follow-up of 2 years, comparing the end of bracing Cobb angle to the one at 2 years post-bracing. Of these, 18 patients (11.1%) corrected their Cobb angle and 133 patients (82.1%) had stabilization. As reported by Montgomery and collaborators<sup>15</sup>, a follow-up of 2 years is sufficient to foresee progression after weaning from the brace. The results are even more encouraging if we look in the long term. There are 69 patients who now have 5 years post-treatment follow-up. Permanent correction was achieved in 28.9 % of the cases (20 patients), stabilization in 66.6% (46 patients) and only 4.4% (3 patients) progression of the curve, comparing the end of bracing Cobb angle to the one at 5 years post-bracing. Finally, success was achieved for 95.6% of the 69 patients having a post-bracing follow-up of 5 years, comparing the end of bracing Cobb angle to the one at 5 years post-bracing. These data suggest it is possible to maintain in long term, the correction or stabilization obtained during the treatment by brace.

Although earlier report indicated that Milwaukee brace<sup>16</sup> could afford some lasting reduction in the degree of spinal curvature, subsequent studies with longer follow-up demonstrated that, following the cessation of brace treatment, curves that had demonstrated some correction at the end of bracing with classical rigid braces tended to continually increased toward the pre-treatment magnitude<sup>3,5,6,17</sup>. In the study of Noonan and colleagues<sup>6</sup>, 63% of the 88 patients wearing the Milwaukee brace were classified as a failure. They defined 3 types of failure: 1) increased 5° or more from initial bracing to the time that the patient stop wearing the brace, 2) underwent a surgery or had a structural curve of more than 50° at the time of the follow-up and 3) major curve progressed 10° or more from initial bracing to time to follow-up. Noonan et al shown that 27 patients (31%) had an arthrodesis; of these 18 patients (67%) had curve progression while they wore the brace, and 9 (33%) had progression of the curve after a trial of intentional weaning. We notice this lost of correction over-time with other braces such as Wilmington and Boston braces. In the study of Gabos et al<sup>5</sup>, 22% out of 55 patients demonstrated an increased in the curve of  $\geq 5^\circ$  between the end of bracing with the Wilmington brace and the time of final follow-up (mean of 14.6 years after the completion of treatment). Besides, 13% demonstrated an increase in the curve of  $\geq 5^\circ$  between the end of bracing and the time of final follow-up that resulted in a curve that was  $\geq 5^\circ$  greater than the deformity measured at the time of the initial treatment. Katz and Durrani<sup>3</sup> conducted a retrospective study on 51 patients with AIS treated with the Boston brace for curve ranging between 36° and 45°. At the time of brace discontinuation, 31 patients (61%) were judged treatment success. With follow-up observation, an additional 8 patients progressed beyond 5°, and a total of 16 patients (31%) required surgical correction. Olafsson et al<sup>4</sup> studied a population of AIS patients wearing the Boston but with smaller curves (22 to 44° curve magnitude). They used two types of Boston braces, first one with 0° lumbar profiles and the other one with 15° lumbar profile. 50 patients completed treatment with the 0° lumbar profile brace. For this cohort of patients, mean Cobb angle at treatment start was  $32 \pm 6^\circ$ , after bracing was  $12.1 \pm 7.6^\circ$ , after weaning  $25.4 \pm 11.3^\circ$  and at follow-up  $29 \pm 12^\circ$ . Regarding the 60 patients still in treatment wearing the Boston brace with 15° lumbar profile, in one third of the case, either it remained unchanged or it increased with bracing.

However, our results show that it is possible to obtain a correction of the pretreatment Cobb angle and this correction can be maintained 2 years, and even 5 years, after the end of the treatment by SpineCor brace. Actually, for the cohort of patients with 5 years post-bracing follow-up (69 patients), comparing the Cobb angle at the end of bracing to the one after 5 years follow-up, 20 patients (28.9%) still corrected their curvature, 46 patients stabilized their Cobb angle and their was only 4.4% of worsening (3 patients). With the Dynamic SpineCor brace there is no component of collapse after the end of bracing, as noted for rigid braces<sup>5,6,17</sup> which, by not supporting an effective musculature, may encourage the progressive collapse of the curves<sup>2</sup>.

The purpose of any conservative treatment for AIS is to alter the natural progression of the spinal deformity. It has been shown that patient with Risser 0 or 1 have 68% incidence of progression<sup>17</sup>. So if we compare our results of brace treatment with the natural history of AIS, we can assume that SpineCor is efficient to alter the natural history of this pathology. Effectively, the overall success rate of 86.9% with the brace indicates that the SpineCor brace does significantly modify the predicted natural history of the disorder. If we compare our results to the ones found in the literatures, we can appreciate the positive outcome of SpineCor patients. The first published study on the clinical effectiveness of the Rosenberger brace<sup>8</sup> demonstrated an overall failure rate similar to untreated rates from published natural history studies. 61% out of 71 patients worsened their Cobb angle. 40 curves (56%) progressed more than 5°, 22 patients (31%) either had the surgery or met surgical criteria, and 10 patients (14%) who did not have surgery progressed greater than 10°. Trivedi and Thomson<sup>7</sup> had an overall success rate of 60% with the Charleston brace. On the other hand, Gepstein et al<sup>14</sup> achieved 80% of success (population of 85 patients) with the Charleston brace. In this study, surgery was performed in 11.8% of patients. Trivedi and Thomson only included girls in their study creating an element of selection bias, since boy seems to have more severe curves then girls<sup>3,7</sup>. Surprisingly, they still got poorest result even if they excluded boys compared to the Gepstein and coworkers study<sup>13</sup>.

In summary, the SpineCor Brace is effective for the treatment of AIS. Moreover, the positive outcome appears to be maintained in the long turn. This particular finding about SpineCor brace, appears to makes him very different from the classical rigid braces in which any apparent correction obtain during treatment can be expected to be lost over time, that is after cessation of bracing<sup>5,17</sup>. However, futures studies that will support this finding are necessary. Upcoming studies respecting the same standardized **outcome** criteria for AIS brace studies as used in this actual study will allow valid and reliable comparison between the SpineCor brace and any others rigid braces.

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