# Prospective interventional cohort of 254 patients treated by the SpineCor brace, following the Scoliosis Research Society Criteria

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## ABSTRACT

**Background:** To verify the effectiveness of the Dynamic SpineCor brace for adolescent idiopathic scoliosis and to confirm the stability of the results two years after the end of the treatment.

**Study design:** From 1993 to 2009, 840 patients were treated using the SpineCor brace. 413 patients fitted the criteria for inclusion recommended by the SRS committee and 159 patients were still in brace. After all, **254** patients have a definitive outcome. Assessment of brace effectiveness included; 1) percentage of patients who have 5° or less curve progression and the percentage of patients who have 6° or more progression, 2) percentage of patients who have been recommended/undergone surgery before skeletal maturity, 3) percentage of patients with curves exceeding 45° at maturity (end of treatment) and 4) 2-years follow-up beyond maturity to determine the percentage of patients who subsequently underwent surgery.

**Results:** Successful treatment (correction >5° or stabilization ±5°) was achieved in 165 patients of the 254 patients (64.9 %) from the time of the fitting of the SpineCor brace to the point in which it was discontinued. 46 immature patients (18.1 %) required surgical fusion whilst receiving treatment.

**Conclusions:** The SpineCor brace is effective for the treatment of adolescent idiopathic scoliosis. Positive outcomes are maintained after the weaning of the brace since 99 patients out of 106 (93.3%) stabilized or corrected their Cobb angle. Moreover, out of the 93.3%, 12.3 % of the patients still corrected their Cobb angle 2 years after the end of the treatment.

**Level of evidence:** Level 1 Prognostic study

## INTRODUCTION

Many conservative treatments are available for adolescents with idiopathic scoliosis (AIS). The mainstay of the conservative treatment still remains the brace which was demonstrated to provide a reduction of curve progression, a decrease in the need for surgery and sometimes a correction of the existing deformity. Other methods of passive correction such as Cotrel traction [1] and electro-spinal stimulation [2] as well as alternative medicine have been attempted but not yet demonstrated to be effective. Although there are numerous studies in literature which have tried to summarize the results of treatment,[3,4,5,6,7,8,9,10] the evidence for their accepted use is still unclear[11]. In addition, the lack of consistency for both inclusion criteria and the definition of brace effectiveness[12] make many clinicians skeptical about the efficacy of conservative treatments[13,14].

Conventional recommendation for brace treatment, as well as the braces themselves, has changed over time. In patients who still have growth remaining, watchful waiting (observation), followed by bracing if the curve progresses to grater than 25°, is the general course of care accepted in North America[15,16]. The Scoliosis Research Society (SRS) thought it was necessary to establish parameters for all future AIS bracing studies[12] in order to be able to make comparison amongst more valid and reliable studies. Such guidelines will allow promotion of the effectiveness of different braces using different approaches, for instance the three point pressure principle used by most of the rigid braces and the Corrective Movement© used by the Dynamic SpineCor brace. Unfortunately, since the publication of these guidelines, even though numerous articles regarding the effectiveness on various braces have been published, very few authors seemed to be following them[3,17]. Although in these previous retrospective studies the

natural history of the disease seemed to be altered, the definition of the success and more importantly the inclusion and exclusion criteria, have never been agreed on.

Several types of braces have been used with varying degrees of success. Roughly we can divide all the braces in two big categories depending on their mechanism of action: on one side we have the rigid braces (following the three point pressure system with or without derotation) and on the other side the SpineCor bracing system using the Corrective Movement© principle.

The effectiveness of the SpineCor brace compared with the natural history of the disease has already been shown for milder and moderate curves[3,4]. Moreover, the positive outcomes are maintained after skeletal maturity. The purpose of the present review is to provide confirmation on the demonstrated effectiveness of the SpineCor brace for AIS following the standardized criteria proposed by the SRS Committee on Bracing and Nonoperative Management[12].

## METHODS

### The studied population

The purpose of this prospective interventional study was to evaluate the effectiveness of the Dynamic SpineCor brace for adolescent idiopathic scoliosis and to evaluate the stability of the spine at 2 years after the weaning point. This study was carried out on a group of 840 patients (91.5% females) having idiopathic scoliosis treated with the SpineCor brace.

Skeletal maturity is considered achieved when Risser 4 or more is reached and, in females, when the patient is 2 years after menarche. The United States grading system for Risser sign was used in this study[18].

Between 1993-2008, **840** patients accepted the treatment with the SpineCor brace, 333 patients where still actively being treated at the time of the analysis and 490 patients had a definite outcome. Because one condition imposed by SRS for the assessment of brace effectiveness was that a minimum 2-year follow-up beyond skeletal maturity should be included for each patient who was "successfully" treated with a brace, then for this study we will discuss only the patients with 2 years follow-up.

Taking into account the SRS criteria mentioned above, we needed to exclude some patients from the actual study. Out of the 490 patients, 39 patients were under the age of 10 years and 15 over the age of 15 years at the initial visit, 49 patients had a Risser sign 3 and 4 or were more than 1 year postmenarchal, 110 had an initial Cobb angle below 25° and 12 patients had a curvature above 40°. Overall, **254** patients respected all the inclusion, exclusion and outcome criteria proposed by the Scoliosis Research Society

Committee on Bracing and Nonoperative Management. All patients regardless of the treatment compliance have been included in the study.

**Radiographic analysis**

The initial pre-therapeutic radiograph used a digital technique where the irradiation is half as much as that of a standard radiographs. The initial evaluation included a postero-anterior and lateral X-ray without brace within a maximum of one month prior to brace fitting. Control X-rays (erect PA) with the SpineCor brace (and shoe lift when prescribed) were taken on the day of the fitting, at 4-6 weeks and then every 5 months until weaning ( Figure 1). Lateral X-rays were taken 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.

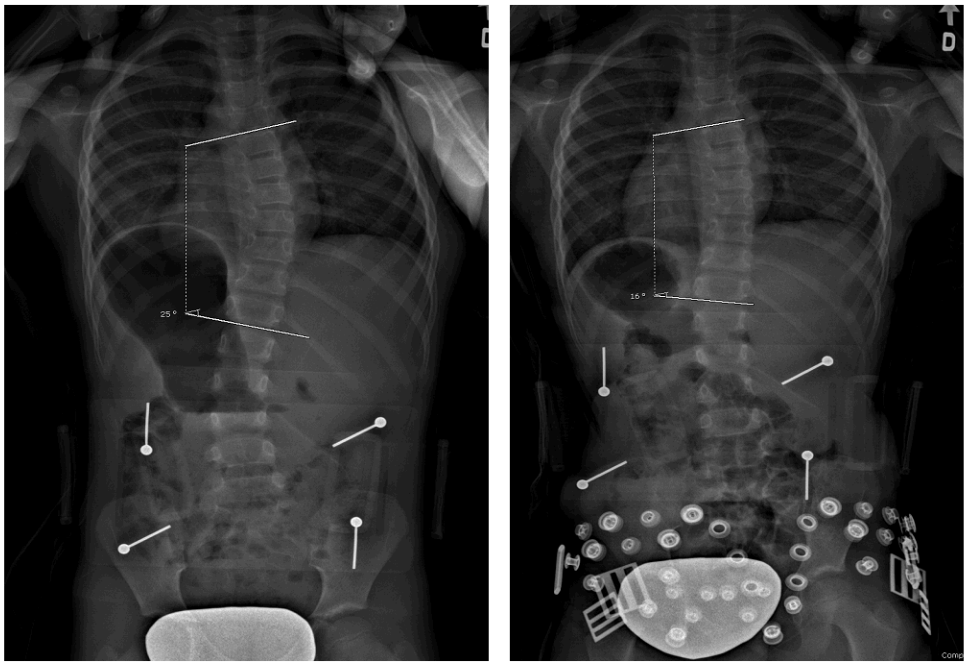

**Figure 1: x-Ray of a scoliotic patient before and immediately after the fitting of the SpineCor Brace (Right thoracic type 1)**

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

The Dynamic SpineCor brace, developed in 1992-93, uses a specific Corrective Movement© dependant of the type of the curve. Curve classification was based on the classification of Leroux and Coillard[19]. The curve specific Corrective Movement© is performed and the brace is applied according to definitions contained in the SpineCor Assistant Software. In order to be effective and to obtain a neuromuscular integration the brace must maintain and amplify the corrective movement over time. The brace must be worn 20 hours a day for a minimum of 18 months to create a neuromuscular integration of the Corrective Movement© through active bio-feedback (Figure 2). Generally, the brace is stopped at skeletal maturity (at least Risser 4).

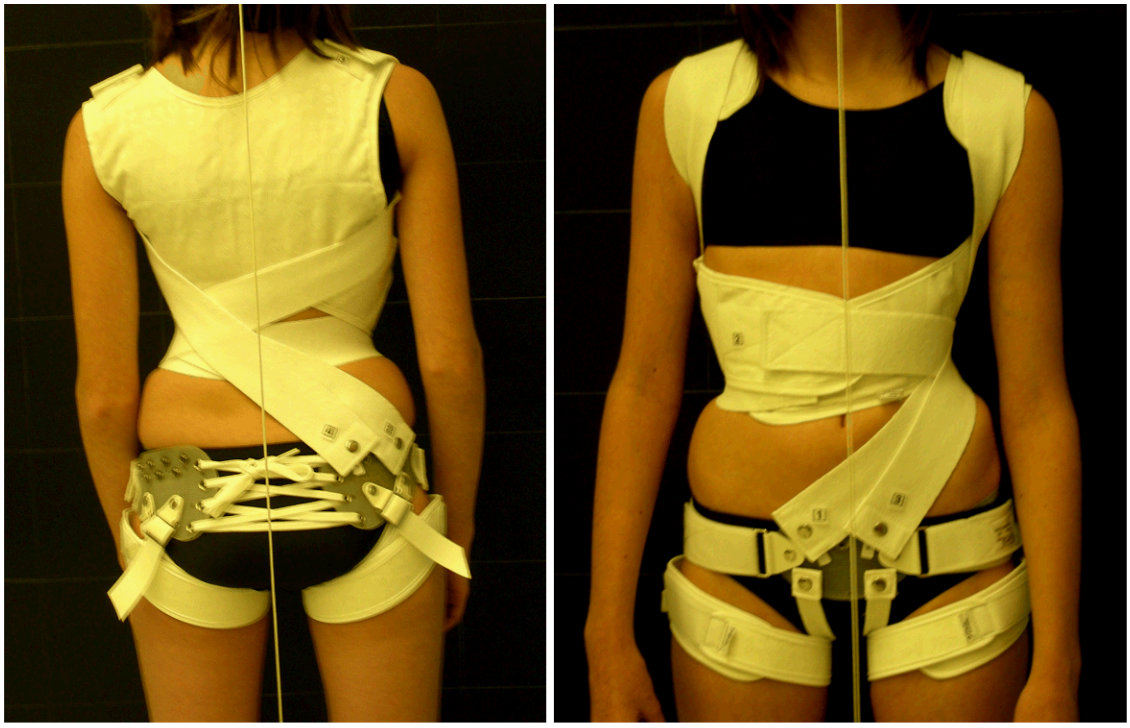

**Figure 2: The SpineCor brace fitted on a scoliotic patient (Double curve type 1)**

**Inclusion criteria were as follows:**

- Idiopathic scoliosis diagnosis and radiological confirmation of absence of significant pathological malformation of the spine
- Age over 10 years old and less than 15 when brace is prescribed
- Risser 0, 1 or 2
- If female, either premenarchal or less than 1 year postmenarchal.
- Initial Cobb angle equal to or above 25°
- 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

**Assessment of brace effectiveness**

Improvement of more than 5° or stabilization of ± 5° of the scoliosis curvature was defined as a positive outcome. An aggravation of the spinal curvature of more than 5°, the progression over 45°, the withdrawn and surgery was defined as a negative outcome. The data collected were analyzed in four outcomes as suggested by the SRS Committee on Bracing and Non-operative Management. In order to strengthen the ability to compare

and combine results across studies, we stratified our results by curve type, curve magnitude grouping, and skeletal maturity. Descriptive statistics were employed to analyze the population.

## RESULTS

All girls where premenarchal or less than one year postmenarchal. 106 patients out of 254, 99 girls and 7 males, all treated by the SpineCor brace respected all the inclusion criteria and had at lest 2 years of follow-up.

**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**

64.9 % of patients (165 out of 254) corrected or stabilized their initial Cobb angle, and 31 patients (12.2 %) had 6° or more progression of their initial Cobb angle (Table 1) (without surgery). From these 254 patients, 106 reached the 2 years follow up.

With post-brace treatment follow-up observation (Table 2), the treatment success rate at 2 years was 93.4%, comparing the end of bracing Cobb angle to the one at 2 years post-bracing. 86 (81.1%) patients out of 106 stabilized their Cobb angle and 13 (12.3%) patients still improved from the time the brace was discontinued up to 2 years follow-up.

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

46 immature patients out of 254 (18.1 %) required surgical fusion while receiving treatment (Table 1). The average curve magnitude at bracing in this particular group was 34.3 ±5.3° (range: 25-40°). 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 with curves exceeding 45° at maturity**

In addition to patients referred for surgery before maturity, 10 patients out of 254 (3.9 %) progressed beyond 45° at maturity (end of bracing Cobb angle). (Table 1)

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

Five patients out of 106 (4.7%) had curves exceeding 45° at 2 years follow-up (Table 2) However, only two of them had a progression of their Cobb angle after the weaning point, the two others patients had a stabilization of their scoliosis. The Cobb angles of the progressive ones at the end of bracing were 38°, and 51° respectively. Their Cobb angles at 2 years follow-up post-bracing visit were 48°and 61°.

Regarding this particular sub-group of patients, after the weaning of the brace, surgery was recommended for two patients; surgical treatment was not an option for the other three patients.

5. **Results stratified by curve type, curve magnitude grouping, and skeletal maturity.**

The results were analyzed separately by curve type (thoracic, thoracolumbar, lumbar, and double curves), curve magnitude, and skeletal maturity (Table 1 and 2) and reported to the 254 patients. Bracing success depending on curve type (table 1) was achieved in

62.6% for thoracic [77/123], 41.4% for thoraco-lumbar [12/29], 59.3% for double [32/54] and 91.6% for lumbar curve [44/48] comparing the initial Cobb angle to the one at maturity. To study the effect of curve magnitude on outcome, the patients were divided into two groups. Group 1 consisted of 118 patients whose curves magnitude at bracing was 25° to 29°, and group 2 consisted of 136 patients with curve magnitude of 30° to 40°. Group 1 had 73.8 % [87/118] of success compared to 57.4 % [78/136] of success for group 2.

Comparison of brace success among initial Risser signs (table 1) 0, 1, and 2 and at skeletal maturity is as followed: 48.7% [79/148], 89.6 % [43/48] and 86.2 % [50/58] respectively.

**6. Follow-up results stratified by curve type and curve magnitude grouping.**

To quantify the success of treatment and the effectiveness of the brace we compared the results at the weaning point and at the 2 years follow-up. The results were analyzed again separately by curve type (thoracic, thoracolumbar, lumbar, and double curves), and curve magnitude (Table 2). Correction was achieved even after the treatment was stopped in 13.3% [6/45] for thoracic, 12.5% [4/32] for thoraco-lumbar, 10.5%[2/19] for double and 20% [2/10] for lumbar curve comparing the Cobb angle at the weaning point to the one at 2 years follow-up. To study the effect of curve magnitude on outcome, the patients were divided into two groups. Group 1 consisted of 56 patients whose curves magnitude at bracing was 25° to 29°, and group 2 consisted of 50 patients with curve magnitude of 30° to 40°. Group 1 had 91.1% [47/56] of success and still corrected in 7.2% [4/56] of patients compared to 96% [48/50] of success and 18% [9/50] of continuing correction for

group 2. Only two patients out of 106 (1.8%) underwent surgical treatment after the weaning of the brace.

**TABLE 1.** **Outcome for the 254 patients treated by the SpineCor brace comparing the initial Cobb angle to the one at the weaning point.**

| SpineCor Dynamic Corrective Bracing (n=254) | | | | | | | |
|---|---|---|---|---|---|---|---|
| | ≤ 5° | >5° | (>45°) | Patient weaned before skeletal maturity* | Withdraw | Surgery** | Total |
| **Patients** | 165 | 31 | (10) | 20 | 12 | 46 | 254 |
| **Type of Curve** | | | | | | | |
| Thoracic | 77 | 19 | (9) | 7 | 3 | 24 | 123 |
| Thoracolumbar | 12 | 2 | (0) | 8 | 5 | 10 | 29 |
| Double | 32 | 7 | (1) | 3 | 3 | 12 | 54 |
| Lumbar | 44 | 3 | (0) | 2 | 1 | 0 | 48 |
| **Initial Cobb Angle** | | | | | | | |
| [25-29 °] | 87 | 18 | (3) | 15 | 4 | 9 | 118 |
| [30-40°] | 78 | 13 | (7) | 5 | 8 | **37** | 136 |
| **Initial Risser Sign** | | | | | | | |
| 0 | 72 | 26 | (6) | 17 | 7 | **43** | 148 |
| 1 | 43 | 2 | (2) | 2 | 1 | 2 | 48 |
| 2 | 50 | 3 | (2) | 1 | 4 | 1 | 58 |

**TABLE 2.** **Outcome for the 106 patients treated by the SpineCor brace comparing the Cobb angle at the weaning point to the one at 2 years follow-up post-bracing.**

| SpineCor Dynamic Corrective Bracing (n=106) | | | | |
|---|---|---|---|---|
| | **≤ 5°** | **>5°** | **>45°*** | **Surgery**** |
| **Patients (n)** | 99 | 7 | 5 | 2 |
| **Type of Curve** | | | | |
| Thoracic | 39 | 6 | 4 | - |
| Thoracolumbar | 32 | - | 0 | 1 |
| Double | 18 | 1 | 1 | 1 |
| Lumbar | 10 | - | - | - |
| **Initial Cobb Angle** | | | | |
| [25-29°] | 51 | 5 | 1 | 1 |
| [30-40°] | 48 | 2 | 4 | 1 |
| **Initial Risser Sign** | | | | |
| 0 | 53 | 5 | 3 | 2 |
| 1 | 22 | 1 | 1 | - |
| 2 | 24 | 1 | 1 | - |

* Measured at 2 years of follow-up
**Two patients undergone surgical treatment after the weaning of the brace

## DISCUSSION

The purpose of this prospective interventional study was to confirm the effectiveness of the Dynamic SpineCor brace for adolescent idiopathic scoliosis following the standardized criteria proposed by the SRS Committee on Bracing and Nonoperative Management. In addition, we wanted to compare the effectiveness of the SpineCor brace to rigid braces. We used reference articles as an alternative of bracing and we tried to find studies that used the inclusion, exclusion and outcome criteria proposed by the Scoliosis Research Society Committee on Bracing and Nonoperative Management[12] or at least authors that used very similar inclusion and exclusion criteria as our study. Even though in more than three years since the publication of these criteria, many articles regarding conservative treatments have been published, very few are respecting all the criteria. Following all the criteria for inclusion, exclusion and outcome has some drawbacks and maybe the most important is the fact that even the noncompliant patients are to be included in the study and it seems that this is one of the criteria that is most frequently "forgotten". In this situation we have the difficult task of comparing "apples with oranges" and try to have a valid discusion. Following this logic and trying to be as rigorous as possible, we wanted to compare the effectiveness of the SpineCor brace to rigid braces. We used these reference articles as an alternative of other since they used very similar inclusion and exclusion criteria as our study. (Table 3)

**Table 3: Comparable studies**

| Author/year/brace/population | Age (yrs) | Risser | Cobb (°) | Follow-up (yrs) | Reported progression at weaning | Reported progression at follow-up |
|---|---|---|---|---|---|---|
| Noonan[7]/1996/Milwaukee/69 | 8+ | 0-3 | 20-40+ | 6 | 67% | 33% |
| Price[20]/1997/Charleston/76 | 10-14 | 0-2 | 25-49 | 1.2 | 27% | 37% |
| Trivedi[10]/2001/Charleston/42 | 10-15.1 | 0-1 | 25-40 | 0.5-7 | 42.8% | ND |
| Katz[6]/2001/Boston/51 | 10+ | 0-2 | 36-45 | 2.7 | 39.2% | 55% |
| D'Amato[21]/2001/Providence/102 | 10+ | 0-2 | 20-42 | 2 | 26% | ND |
| Gepstein[22]/2002/Charleston/TLSO (85) (37) | 10-16 | 0-4 | <25-40< | 2 | 20%/19% | ND |
| Spoonamore[9]/2004/Rosemberg/71 | 9-16 | 0-3 | 15-44 | 2 | 61% | ND |
| Gabos[5]/204/Wilmington/55 | 10-15 | 0-1 | 20-45 | 14 | ND | 22% |
| Yrjonen[23]/2006/Providence/36 | 9.3-15 | 0-3 | 20-42 | 1.8 | ND | 27% |
| **Richards[12]/2005/ SRS criteria** | **10-15** | **0-2** | **25-40** | **2** | **yes** | **yes** |
| Yrjonen[24]/2007/Boston/102;51 male and 51 female | Mean 13.1 | 0-3 | 20-40 | 2.4 | 31.4% m 21.6% f | 18.8% m 27.2% f |
| Coillard[3]/2007/SpineCor/170 | 10-15 | 0-2 | 25-40 | 2 | 33.5% | 4.3% |
| Danielsson[25]/2007/Boston/41 | 10-16 | 0-4 | 14-37 | 16 | 45.7% | ND |
| Janicki[17]/2007/TLSO/Providence 48/35 | 10-17 | 0-2 | 25-40 | 2 | 85%/69% | ND |
| Bulthuis[26]/2008/TriaC/63 | Mean 11.3 | 0-1 | 20-40 | 6 | 24% | ND |
| De Mauroy[27]/2008/Lyon/1338 | Mean 13.9 | ND | <30-40< | 2 | 5% | 28% |
| Negrini[28]/2008/Sforzesco/50 | 9-15 | 0-4 | Mean 46.7 | ND | 6% | ND |

Previous studies have been published in 2003 in European Spine Journal on the first 195 patients and in 2007 in The Journal of Pediatric Orthopedics on a group of 493 patients from the same prospective cohort. The preliminary study in 2003 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 more recent results followed a similar trend. Comparing the end of bracing Cobb angle to the one at 2 years post-bracing, the second study[3] revealed in 47 patients, that the follow-up of orthopedic treatment was a success in 95.7 % of the patients with a mean correction of 8.6±1.7°.

In general most rigid brace studies show a slow loss of correction until the end of the treatment (when the curve is similar to the beginning of the treatment) and followed by an aggravation after the weaning point[5]. Many studies also identified a trend of decreasing brace efficacy with increasing curve size. As reported by Montgomery and collaborators[29], a follow-up of 2 years is sufficient to foresee progression after weaning from the brace. Contrary to the rigid braces, it seems possible with the SpineCor brace to have sustainable correction or stabilization of the scoliotic curves at 2 years after discontinuation of brace treatment. Other big issues resulting in failure of the treatment have been raised. Patient self image, non compliance and dissatisfaction with the cosmetic appearance of the brace can ultimately led to the failure of the bracing treatment[30,31]. Those patients who do not wear their braces (part time or full time) should be expected to have a result similar to the natural history of the disease. This association, between brace compliance and outcomes was reported by Rahman et al[32]. The results indicate that those patients who are compliant with the brace treatment have significantly

more favorable outcomes. Even if several authors have questioned the SRS recommendation for the inclusion in the study of the non compliant patients, we have to acknowledge the fact that, the compliance of the brace treatment may be one of the most important factors that influence the outcome. Again it seems that, because of the design of the SpineCor brace, this issue is less common and therefore a better compliance can lead to a more positive outcome.

Our results demonstrated variable positive outcome for patients having a lumbar (91.6%), thoracolumbar (41.4%), thoracic (62.6%) and double curves (59.3%). Thoracolumbar curves seemed to have a higher rate of surgery thus a less successful treatment[23]. Double curves were, as well, less successful compared to the other type of curves. This may be explained by the fact that we detected them later compare to the other types of curves because the posture is more often quite normal and they are more rigid. Positive outcome was also achieved for group 1 with 73.8% of success (initial curvature between 25° to 29°) compare to 57.4% for group 2 (initial curvature between 30° to 40°) comparing the beginning of bracing to the weaning point. Those results demonstrate the fact that it is possible to achieved higher rate of correction or stabilization when the conservative treatment is started in the early stage. In spite of this, it was surprising to find out that success was attained in 48.7 % of patients having an initial Risser sign of 0 compared to 89.6% and 86.2% for patients having a Risser sign of 1 and 2 respectively. These seem to confirm our previous results.

Although several studies appear to demonstrate superior results compared to those found here, sampling (inclusion and exclusion criteria), design and measurement issues could explain these differences (Table 3). The majority of outcome studies on orthotic

management of idiopathic scoliosis have focused on the in brace correction of the Cobb angle and on the correction calculated at the weaning point and few studies address the long term outcome.

Even if early reports indicated that the Milwaukee brace[34] 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 traditional rigid braces tended then to continually increased toward the pre-treatment angle[5,6,7,35]. In the study of Noonan and colleagues, 63% of the 88 patients wearing the Milwaukee brace were classified as a failure. Noonan *et al* showed that 27 patients (31%) had an arthrodesis[7]; 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. Similar loss of correction over-time was also observed with other braces such as Wilmington and Boston braces. In the study of Gabos and coworkers, 22% out of 55 patients demonstrated an increase in the curvature of $\geq 5^{\circ}$ between the end of bracing with the Wilmington brace to the time of final follow-up[4] (mean of 14.6 years after the completion of treatment). In addition, 13% demonstrated an increase in the curvature 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. Similar results where reported by Bulthuis et al in 2008 using the TriaC brace[26]. They demonstrated a progression for only 24% of the patients but even if a mean of 6 years follow up exist, the evolution post treatment is not reported. Olafsson and colleagues studied a population of AIS patients wearing the Boston brace but with smaller curves (22 to 44° curve magnitude)[8]. For this cohort of

patients, mean Cobb angle at treatment start was 32 ± 6°, after bracing this was 12.1 ± 7.6°, after weaning 25.4 ± 11.3° and at follow-up 29 ± 12°. More recently, Yrjõnen et al. demonstrated a curve progression in 31.4% of the male patients and 21.6% of female patients treated with the Boston brace. All the patients had single curves and 28 % of patient considered non compliant were eliminated from this study. Moreover, an increase in the curvature of ≥5° between the end of bracing and the time of final follow-up of 18.8% to 27.2% (male vs female) was found[24]. Janicki and colleagues published in 2007, at the same time that our previous publication[3,17], the first studies strictly respecting the SRS criteria. They demonstrated a treatment failure in 85% of patients treated with a TLSO and a 69% aggravation in patients treated with the Providence brace. A comparison of previously published clinical and radiological results between the TLSO, Providence and SpineCor is represented in the table 4.

**Table 4: Summary of clinical and radiological results: TLSO, Providence and SpineCor[3,17]**

| | **SpineCor[3]** | **Providence[17]** | **TLSO[17]** |
|---|---|---|---|
| No.patients | 170 | 35 | 48 |
| Correction/Stabilization (≤5 degrees) | 101 (59%) | 11 (31%) | 7 (15%) |
| Progression (≥ 6 degrees) | 57 (34%) | 24 (69%) | 41 (85%) |
| Progression (>45 degrees) | 2 (1.2%) | 15 (45%) | 30 (56%) |
| **Progression to surgery** | **39 (23%)** | **21 (60%)** | **38 (79%)** |
| Withdrawal from study / no follow-up | 12 (7.1%) | Not reported | Not reported |

Very good results were reported by De Mauroy[27] and colleagues for the Lyon brace and by Negrini[28] and colleagues for the Sforzesco brace. They reported a progression of only 5% and 6% respectively at the end of the bracing period and only for the Lyon brace a follow up progression of 28% was described. Nevertheless, for the Sforzesco brace, the SRS inclusion and exclusion criteria are not followed, the dropouts are not taken in study and only partial results are reported; short term results with no follow up yet.

However, comparing with the natural history of the disease and the already published literature, our latest results confirm that it is possible to obtain a correction or a stabilization of the pre-treatment Cobb angle (64.9%) and it seems possible to maintain the brace success for 2 years after the end of the treatment by SpineCor brace since only 7 patients out of 106 (6.6%) who have completed the 2 years follow up had a curve worsening during this follow-up period. These findings suggest that the SpineCor Bracing system can alter the natural history of the adolescent idiopathic scoliosis and its use in the conservative treatment of this disease is justified.

## CONCLUSION

The SpineCor Brace is effective for the treatment of AIS. Moreover, the positive outcomes are maintained 2-year follow-up beyond skeletal maturity. This particular feature of the SpineCor brace makes it very different to the already published literature on brace in which apparent correction obtained during treatment can be expected to be lost over time[5,6,7,17,35]. However, future studies that will support and reinforce this finding are necessary. Forthcoming studies using **the same standardized criteria for AIS brace studies** as used in this study will allow valid and reliable comparison between the SpineCor brace and any others rigid braces.

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