EUR J PHYS REHABIL MED 2014;50:479-87

A Prospective Randomized Controlled Trial of the Natural History of Idiopathic Scoliosis *versus* treatment with the Spinecor brace

Sosort Award 2011 Winner

C. COILLARD, A. B. CIRCO, C. H. RIVARD

Sainte Justine Hospital, Montréal, QC, Canada

Aim. **The purpose of this randomized controlled trial was to evaluate the efficacy of the Dynamic SpineCor brace for early idiopathic scoliosis (15°-30°) compared to the natural evolution of the disease. 68 patients participated in this study (32 treated and 36 controls) with at least 5 years follow-up.**

Methods. **The inclusion criteria were: 1) high risk of evolution: family history and/or proven progressive; 2) no significant pathological malformation of the spine; 3) initial Cobb angle between 15° and 30°; 4) risser 0, 1 or 2. Assessment of brace efficacy included the percentage of patients who have 5° or less curve progression and the percentage of patients who have 6° or more progression at skeletal maturity.**

Results. **At five-year follow-up a correction was achieved in 50% of treated patient and only in 9.5% of controls, stabilization in 42.3% treated and 47.7% in controls and progression in 26.9% for the treated group and 42.8% for controls. For the control patients we considered as a failure if the Cobb angle worsened by more then 5° from the original angle and the patient then received treatment.**

Conclusion. **The results 5 years after the treatment suggested that the SpineCor brace reduced the probability of the progression of early idiopathic scoliosis comparing with its natural history. Moreover, the positive outcome appears to be maintained in the long term.**

KEY WORDS: Scoliosis - Braces - Spine.

Still today 80% of the scoliosis are known as idiopathic. Although our understanding of the natural history of adolescent idiopathic scoliosis has increased and many breakthroughs regarding its aetiology are made, the true cause is still unknown and consequently the treatment can only be based on symptoms. There is much to learn regarding the basic mechanism responsible for the progression of a scoliotic curve and of the treatment possibilities.[1]

Currently two controversial treatment exist: on one side there is a strong emphasis placed on early detection and treatment of idiopathic scoliosis [2-5] opposed to watchful waiting and treatment only for curves over 25-30°.[6] Duval-Beaupere [7] pointed out that the progression of adolescent idiopathic scoliosis occurs most frequently during the adolescent growth spurt although the incidence of progression varies greatly in different reported publications. Lonstein and Carlson [2] found that curves between 20-30° progressed in 68% of patients. Clarisse [8] reviewed 110 untreated patients with curves between 10-29° reported a progression of 35% while Bunnell,[9] for a group of 326 patients with Cobb angles between 20-29° reported only a 28% of progression.

Many conservative or more invasive treatments are available for adolescent idiopathic scoliosis. Observation, exercises, casting, orthoses and surgical treatment are different options for the management. Unfortunately the majorities of the studies published are retrospective, without a control group or are focused on comparing different types of treatment. Although the principle that bracing is effective in the treatment of adolescent idiopathic scoliosis re-

Corresponding author: C. H. Rivard, Sainte Justine Hospital, 3175, Chemin de la Côte-Sainte-Catherine, H3T 1C5 Montréal, QC, Canada. E-mail: chrivard@gmail.com

mains unsubstantiated by the lack of randomized controlled trials.[10] Several retrospective and prospective reviews [5, 11-18] suggest that bracing is more effective for treatment of scoliosis than observation only. Miller *et al.*[5] reviewed 255 patients with initial curves measuring 15-30°. These patients were divided in two groups (144 treated and 111 without active treatment). The results, at a mean of 1.9 years later suggested that bracing reduced the probability of progression compared with the untreated group. Only one prospective study was published [19] and the authors concluded that bracing is effective compared to observation only. In this study the randomization was made by centers and not by patients and without follow-up.

Several authors stated that a randomized controlled trial on the efficacy of orthotic treatment that is compared to a control group (observation only) should be conducted.[20-22] Unfortunately such trial is not always easy to do. Recently, in a randomized study, Bunge *et al.*[23] failed to include enough patients even though they performed a pilot study to evaluate the willingness to participate with positive results. The same outcome was obtained by the researchers conducting the BrAIST study. Although BrAIST began as a randomized trial, the majority of families declined participation in order to pursue their own treatment preferences.[24]

The main objective of an orthotic treatment is to stop the progression of the disease in order to avoid surgical fusion. Because of a permanent vertebral deformation that seems to appear with Cobb angles of 30° and more, we consider that an early therapeutic approach, for patients with high risk of progression, will provide a better correction and that the stability of the spine will be permanent.[15, 16, 25]

In our previous publications [15, 16, 26] we already demonstrated the efficacy of the Dynamic SpineCor brace for the treatment of idiopathic scoliosis. The objective of this randomized controlled trial was to demonstrate the efficacy of the SpineCor System in the treatment of early adolescent idiopathic scoliosis (15°-30°) compared to the natural evolution of the disease and to evaluate the stability of the spine at 3 and 5 years after the randomization.

The basic hypothesis of this randomized controlled trial was that the treated group would see an average improvement compared with the control group at skeletal maturity and that this improvement will be maintained in the long-term follow-up.

Materials and methods

This study was carried out on a group of 68 patients (36 in the control group and 32 in the treated group) diagnosed with idiopathic scoliosis and with a Cobb angle between 15° and 30°.

The United States grading system for Risser sign was used in this study. Skeletal maturity is considered achieved when Risser 4 or more is reached.

The study protocol was approved by the Ethics Committee of Sainte-Justine Hospital, Montreal, Canada.

Randomization

The inclusion of a patient to the control or treated group was done on a random basis. An independent

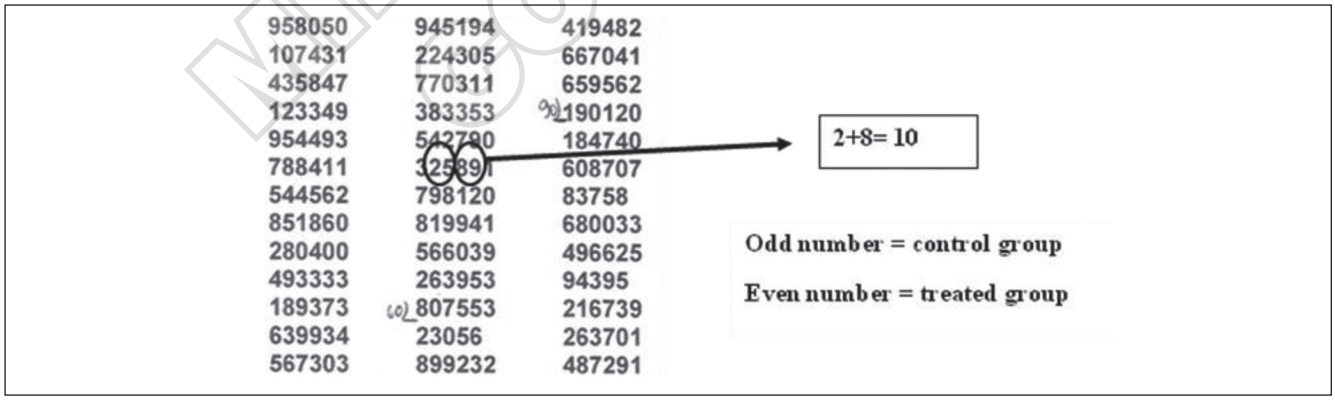

Figure 1.—Computer generated number table and the calculation method.

controller based in Sainte-Justine Hospital in Montreal assigned the patients to the control and treated group based on a random computer generated number table (Figure 1). Numbers were selected top down and columns from left to right and the independent controller used the following algorithm: The sum of the second and the forth digit was calculated. If the sum was an odd number the patients was assigned to the control group and if it came up an even number the patient was assigned to the treated group.

After the recruitment of 68 patients, the Ethics Committee, at their annual review, asked us to stop the recruitment, because the results at that time showed a 52% progression in the control group compared with 5% in the treated group. The study continued with the patients that already accepted the protocol.

Radiographic analysis

The initial pretreatment radiograph used a digital technique were the irradiation is half as much as that of a standard radiographs. The initial evaluation included standing postero-anterior and lateral radiographs without orthosis within a maximum of one month prior to the randomization.

For the treated group, control radiographs (standing PA) with the SpineCor orthosis (and shoe lift when prescribed) were taken on the day of the fitting, all the other radiographs at 4-6 weeks and then every 5-6 months until weaning were taken with the brace. Follow up radiographs were taken at the end of the treatment (patients usually took of their brace 3 days before) and at 6 months, one year and once every year for minimum 5 years. Standing lateral radiographs were taken once a year. These evaluations were performed without orthosis.

For the control group, radiographs were taken every 6 month for a minimum of 5 years post randomization using the same protocol as for the treated group every time.

All the X-rays were taken following the same protocol, in the same setting and were measured by the same orthopedic surgeons in order to minimize the measuring errors. Because of the nature of this study (brace *vs.* no brace), the measurements were done without being blinded to the treatment or control group status.

Description of the bracing system and treatment protocol

The Dynamic SpineCor orthosis, developed in 1992-1993, uses a specific Corrective Movement© dependant of the type of the curve. Curve classification was based on the classification of Nguyen *et al.*[27] The curve specific Corrective Movement© is performed and the orthosis is applied according to definitions contained in the SpineCor Assistant Software. All the health providers need to complete a two-phase training course before fitting the SpineCor orthosis.

In order to obtain the neuromuscular integration the orthosis must maintain and amplify the corrective movement over time. The orthosis 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. Generally, the orthosis is stopped at skeletal maturity (at least Risser 4).

The trial protocols' algorithm is described in Figure 2.

The recruitment was performed by an orthopedic surgeon with a solid experience in the treatment of scoliosis. Before being accepted in the study, each patient received a recruitment examination including: 1) a regular and neuromuscular clinical examination; 2) a regular PA and lateral standing radiography; 3) an radiography to evaluate the bone age

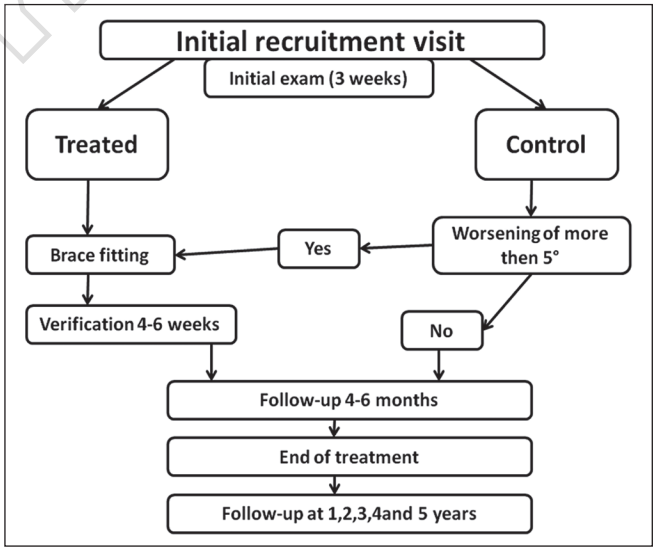

Figure 2.—Trial procedure.

(optional); 4) a supine PA radiography to establish the reducibility of the curve.

Each patient that conformed to the inclusion criteria and accepted to participate in this study was informed of the evaluation procedure and of all the advantages and disadvantages of participating in this study. Upon acceptance consent form was signed.

Inclusion criteria

All patients had a diagnosis of idiopathic scoliosis and had radiological confirmation of absence of significant pathological malformation of the spine, age over 8 years old and less than 15 when randomization is performed and a Risser sign of 0, 1 or 2. The initial Cobb angle was equal to or above 15° but not grater then 30°. All patients had no prior treatment for scoliosis. All patients had a suspected high risk of progression: 1) family history of scoliosis or other well known prognostic factors (Risser, Age, Menstruation status, etc.) and/or 2) proven progression (Cobb angle increase of 5° in the last 6 months). Even though we have no reference for family history as a risk factor progression, in our experience a patient with a family history of scoliosis is at a higher risk of progression.

Exclusion criteria

The presence of a congenital malformation of the spine, spina bifida aperta, spondylolisthesis, neuromuscular scoliosis or postural scoliosis was considered as non-eligible for this study. All patients or patients' parents that could not accepted all the protocol rules were not included in this trial. A last exclusion criterion was previous treatment: rigid brace, other treatments except physiotherapy or shoe lift. For the latter, the treatment must be interrupted if the patient is randomized as a control patient.

Study population

Between July 1998 and June 2002, 78 consecutive patients with Cobb angles between 15°-30° and that respected all the inclusion and exclusion criteria, were seen in our clinic. The protocol was proposed to all and 68 patients (87.2%) were recruited and accepted to participate in this randomized controlled trial. At that time we had no problem recruiting the patients. After the recruitment visit the patient with idiopathic scoliosis between 15°-30°, was assigned at the begging of the first visit, to one of the two groups. Thirty-six patients were assigned to the control group and 32 patients to the treated group. Forty-seven patients finished the study: 21 patients (18 females and 3 males) in the control group and 26 patients (22 females and 4 males) for the treated group. Twenty one (15 from the control group) patients were lost due to withdrawal from the study (patients and/or family could not accept the protocol anymore) or due to situational changes (moves and so on) (Figure 3). All the subjects were followed up post randomization for a minimum of 5 years in

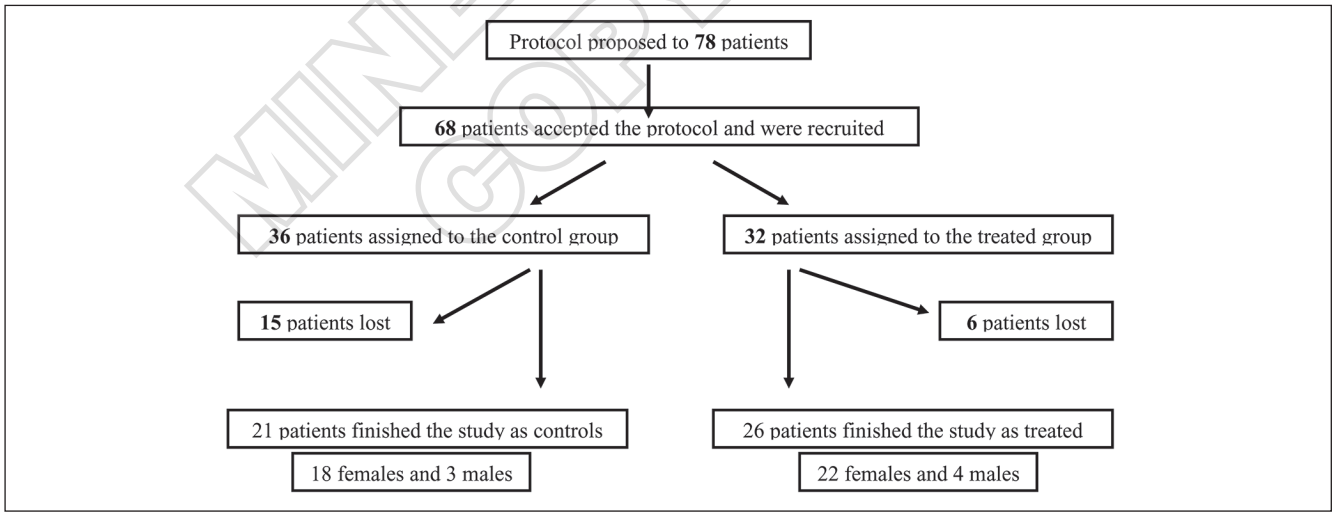

Figure 3.—Flow chart for the studied population.

the control group and for minimum of 7 years for the treated group. (A minimum of 2 years post maturation were maturation was considered at a Risser sign of 4 or more)

Assessment of orthosis efficacy

The assessment of brace efficacy was done following the outcome criteria proposed by the Scoliosis Research Society Committee on Bracing and Nonoperative Management.[26]

Improvement of more than 5° or stabilization of ± 5° of the scoliosis curvature was defined as a positive outcome.[26] The data collected were analyzed as followed: 1) percentage of patients who have 5° or less curve progression and the percentage of patients who have 6° or more progression at 3 and 5 years postrandomization (skeletal maturity) for each group; 2) percentage of patients with curves exceeding 45° at maturity; 3) minimum of 3 and 5 years follow-up postrandomization for each group. At 5 years postrandomization all patients regardless of the group were at minimum 2 years postmaturity.

In the control group, failure of the treatment was considered a progression of minimum 6° during a follow-up period. The patient was then offered a treatment but did not become part of the treated group.

Descriptive statistics, Chi-square and the Fisher exact test were employed to analyze and compare the two populations (95% confidence interval).

Results

Sixty-eight patients (36 in the control group and 32 in the treated group) diagnosed with idiopathic scoliosis and with a Cobb angle between 15 and 30° participated in this study. The two groups (controls and treated) had the same inclusion criteria and the two groups were comparable (Table I). All the patients were at least at 2 years post maturation at our cut point of 5 years post randomization. Even though the mean Cobb angle at the beginning of this study was comparable for the two groups (20° for controls compared to 22° for the treated), an important difference is observed at 3 and 5 years post randomization.

The orthosis was worn for a mean period of 25 months (minimum of 18 months with a maximum treatment time of 3 years).

Intent to treat analysis

An intent to treat (ITT) analysis was performed at 5-year follow-up on all the patients that accepted the study protocol. We applied a worst-case analysis, considering all the drop-outs as failure to the treatment. We see a lot more drop-outs in the control group compared with the treated group and we can estimate that the patients demonstrating a progression in the control group will be around 75% compared with only 34% in the treated group (Table II).

TABLE I.—*Study population.*

	Age (years)	N.	Initial Cobb angle (°)	
			Mean	StDev
Control group	12±2	36	20	4.10
Treated group	12±2	32	22	4.94

TABLE II.—*Intent to treat.*

	Non events (success)	Events (failure)	Total
Treated	21	11	32
% total	30.88	16.18	47.06
% in group	65.63	34.38	
Control	9	27	36
% total	13.24	39.71	52.94
% in group	25.00	75.00	
Total	30	38	68
	44.12	55.88	100.00
Statistics	Value	Probability	
Chi-square	11.3408	0.0008	

Considering completers only, after 3 years from randomization, only 9.5% of patients (2/21) in the control group had an improvement of the Cobb angle larger than 5° angle compared 38.5% in the treated group (P<0.05) and after 5 years the results were 9.5% *vs.* 50% (P<0.05).

Five years post randomization, 57.2 % of patients (12 out of 21) from the control group corrected or stabilized their initial Cobb angle compared to 73.1% of patients (19 out of 26) in the treated group. Looking at the progression, 42.8% (9/21) of patients in the control group compared to 26.9% in the treated group had 6° or more of worsening. 3 out of the 12 control patients that progressed in the first 3 years after randomization stabilized their Cobb angle

Three patients out of 21 controls and 3 patients out of 26 treated had Cobb angles that exceeded 45° at the end of our study. Three immature patients out of 21 controls (14.3%) required surgical fusion while in trial. The average curve magnitude at the beginning of the treatment in this particular group was 27° (range: 20-30°) and they all had a Risser 0. In the treated group, only 2 immature patients (7.7%) had surgical recommendation during our study and only one-treated patients had surgical recommendation after the 3-year follow-up point (after the end of the treatment). The average Cobb angle for this group at the beginning of the study was 22°(range: 20-24°) and Risser 0.

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 with trunk shift (Table III).

Discussion

As discussed in our previous publication,[15, 16, 25] the decision to begin orthotic treatment for idiopathic scoliosis is a complex process and often not necessarily detached in term of the psychosocial and body image concerns for many patients and their families. It is therefore crucial that any treatment decision should be based on the best evidence available with respect to the efficacy of the brace treatment, and finally the patients own characteristics (Cobb angle, curve type, age of onset) as well as their specific risk factors.[17, 28] The efficacy of bracing, however, has not been 100% proved and accepted by the scientific community and perhaps one of the main reasons is the lack of randomized controlled trials. While certain risk factors for curve progression have been identified, there is no reliable way of estimating the likelihood of progression.

Bracing is currently the standard of care for treating AIS. It is unknown which adolescents in particular may benefit from bracing and out of those who undergo bracing how many will manage to avoid progression and/or surgery. Some authors even questioned the use of bracing systems in altering the progression of the disease and in reducing the surgical rates.[20, 29]

Unfortunately, very few randomized trials comparing some type of treatment with the natural history of adolescent idiopathic scoliosis were done. This is the first RCT comparing bracing *vs.* observation after many studies attempting in the randomization and failed due to patients willingness to participate to treatment.[23, 24, 30]

Dolan *et al.* conducted one trial in the USA.[30] In this trial the orthotic treatment is compared with watchful waiting and the trial was supposed to be completed in august 2012. Unfortunately, the BrAIST trial had to be stopped because of poor recruiting. Although BrAIST began as a randomized trial, the majority of families declined participation in order to pursue their own treatment preferences.[24] In this

TABLE III.—*Results stratified by Cobb angle at the beginning of treatment.*

	3-year postrandomization		5-year postrandomization	
	Success*	Progression**	Success*	Progression**
15-19°				
Control group N.=10	8	2	10	-
Treated group N.=14	14	0	13	1
20-30°				
Control group N.=11	2	9	2	9
Treated group N.=12	8	4	7	5

* Patients who have 5° or less progression; ** Patients who have 6° or more progression.

trial brace treatment for the control group patients, in case of progression, is not offered. In comparison, we offered all of our control patients, a brace treatment if they experienced a progression of 6°or more. All these patients, were considered as a failure of treatment (in this case: observation), and were free to chose a treatment of their choice. Recently, another study conducted in the Netherlands by Bunge *et al.*, failed to include patients. One of the reasons for their failure could be the fact that for the patients in the control group, a treatment was offered only with a progression of minimum 10°. This and the fact that lately there is an important amount of information on treatment types accessible on the Internet, can explain the poor participation.[23] We were confronted with similar problem during our study and not while we recruited the patients. Out of the 68 patients that were recruited and accepted to participate in this randomized controlled trial only 47 finished the trial. 15 patients from the control group (15/36; 41%) were lost compared to only 6 (6/32; 18%) from the treated group. The difference in the dropout rate can be explained by the willingness of most of the patients to do something about their spinal problem. Moreover, after the recruitment of 68 patients, the Ethics Committee, at their annual review, asked us to stop the recruitment, because the results at that time showed a 52% progression in the control group compared with 5% in the treated group. This again shows that SpineCor Brace could be an effective mode for the treatment of idiopathic scoliosis and reveals a positive treatment outcome in the long run and that orthotic treatment is a viable treatment for Idiopathic scoliosis.

Previous studies reported the efficacy of the SpineCor brace in 2003 in the European Spine Journal [15] and 2007 in The Journal of Pediatric Orthopedics [16] on patients suffering from adolescent idiopathic scoliosis. More recently, the efficacy of SpineCor System was demonstrated on juvenile patients.[25] Regardless of the study, up to 33% of patients still correct their Cobb angle 5 years after the brace treatment is stopped. The continual correction could be explained by the capacity of the SpineCor brace to create a neuromuscular integration of the Corrective Movement© through active biofeedback. Recently, Gammon *et al.*,[31] in a retrospective cohort study compare the SpineCor System with the traditional TLSO bracing using the SRS standardized criteria. Although there were no significant difference (P=0.62) in the success rate of treatment, the 2-year follow-up was done after the beginning of the treatment and not after the weaning of the brace. Thus, an important percentage of patients were still in treatment at the follow-up point. Most studies that use rigid brace systems show a slow loss of correction from the fitting point until the end of the treatment (when the curve is similar to the beginning of the treatment) and this is followed by an aggravation after the weaning point [32] while for the SpineCor System, the correction is sometimes less important in brace but it is continued several years after the weaning of the brace.[16, 25] The only thing that was missing to definitely prove the efficacy of the SpineCor brace was a randomized controlled trial.

In one prospective controlled study comparing a brace treatment with observation published in 1995 by Nachemson *et al.*,[19] the researchers found a significant reduced failure rate in favor of the brace group of approximately 50% to 20% even though the patients were not all followed-up to maturity. In our cohort of patients we observed a reduction in the risk of progression from 57.1% in the control group to fewer than 19.2% in the treated group for the 3-year postrandomization follow-up point and 42.8% to 26.9% for the 5-year postrandomization, respectively.

At three-year postrandomization we found a significant difference (P=0.012) looking at the correction rates from 9.5% in the control group to 38.5% for the treated group. This difference is even more important at 5 years post randomization (P=0.003) when in the control group only 9.5% compared with 50% in the treated group corrected their Cobb angle with at least 5°.

Regardless of treatment, 23-42% of patient stabilized their curves at 3 and 5 years post randomization and there was no statistical difference between groups, however, the correction and the progression of the curve both favored the treatment.

Several authors [3, 6, 8, 9] reported that curve of 10-30° are more likely not to progress. Rogala *et al.*[6] reported only a 10.3% progression in patients with Cobb between 10-19° and 21% in patients with initial curve between 20-30°. Although they surveyed their patients for only 2 years, the publication posed a new question: are patients with small curves over treated? Subsequently Clarisse,[8] in reviewing patients with angles between 10-30% found a progression in only 35% of the patients and Bunnell [9] reported

a 28% progression in a group of 326 patients with Cobb angle of 20-29°. Lonstein and Carlson,[2] reported 17% of progression with 10° in patients with initial Cobb of 15-19° and 34% of 5° progression in patients with initial curve of 25-29°. Our study demonstrated for the control group, a progression of 57.1% at 3-year postrandomization and 42.8% at 5 years. According to these results one can conclude that in the natural history of adolescent idiopathic scoliosis, a minimum of 50% of patients will progress if left untreated. In the treated group, in the long term only 26.9% progressed with 5° or more.

In 1982 Willner and Uden,[33] proposed and demonstrated an interesting concept concerning the progression of idiopathic scoliosis. They reported that the initial progression in curves under 30° does not mean always a continued progression. In our study we observed the same phenomenon. At 3-year postrandomization, 57.1% of controls progressed with at least 5° but at 5 years post randomization, 14.3% of these patients, corrected their Cobb angle finishing the trial with a progression of less than 5°. These results confirm those of Willner and Uden. They reported a 12-25%, depending on the final Cobb angle, of patients that stopped or reversed their initial progression.

The reported success of bracing programs in the management of the adolescent idiopathic scoliosis is variable between the different authors and it seems to be centered on slowing/stopping the progression of the curve. We believe that slowing/stopping the progression should be the prime objective of any conservative treatment, although a correction of even 5 degrees could make a huge difference for the patient (or his/hers career), and should therefore explored.

The results obtained in our study clearly show that the SpineCor System could alter the natural history of the idiopathic scoliosis. Moreover, it seems that an early treatment approach yields better results. However, a limitation of the present study is that the results are based on relatively small sample size, although the differences between the two groups are statistically significant and an ITT tends to confirm these results. Another limitation was that the proportion of thoracic/thoraco-lumbar/double curves in this study does not necessarily reflect the real proportion seen in the worldwide population.

In the treatment decision of idiopathic scoliosis, one should always consider that we are treating a patient and not only a disease. Together with the Cobb angle and Risser sign several other factors should be taken in consideration: family history, gender, curve pattern, curve severity, age at the diagnosis, menarche etc.

Conclusions

This randomized controlled trial shows that SpineCor Brace could be an effective mode for the treatment of idiopathic scoliosis and reveals a positive treatment outcome in the long run. A screening test, to identify asymptomatic children at risk of developing idiopathic scoliosis, is definitely needed and may be used to improve stratification of patients, which in turn allow clinicians to predict their clinical outcome.

The brace appears to be efficient compared to the natural history of the disease. Among those who completed the course of treatment with the brace, the correction appears to be maintained at the long term because 73.1% of patients stabilized or corrected their Cobb angle. It seems that although there is no significant difference in the stabilization of the spine between the treated and the control patients, there is a huge difference in the correction and the progression of the curve.

This fact favours the use of the SpineCor brace in the treatment of idiopathic scoliosis.

References

1. Burwell RG. Aetiology of idiopathic scoliosis: current concepts. Pediatr Rehabil 2003;6:137-70.
2. Lonstein J, Carlson M. The prediction of curve progression in untreated idiopathic scoliosis during growth. J Bone Joint Surg A 1984;66:1061.
3. Lonstein JE, Winter RB. Milwaukee brace treatment of juvenile idiopathic scoliosis. Presented at the 23rd Annual Meeting of the Scoliosis Research Society, Baltimore, MD, October 1, 1988.
4. Torell G, Nordwall A, Nachemson A. The changing pattern of scoliosis treatment due to effective screening. J Bone Joint Surg A 1981;63:337.
5. Miller J, Nachemson A, Schulz A. Efficacy of braces in mild idiopathic scoliosis. Spine 1984;9:632.
6. Rogala E, Drummond D, Gurr J. Scoliosis: Incidence and natural history. J Bone Joint Surg A 1978;60:173.
7. Duval-Beaupère G. Pathogenic relationship between scoliosis and growth. Scoliosis and Growth 1971;58-64. Edimburgh: Churchill Livingstone; 1971.
8. Clarisse P. Pronostic evolutif des scoliosis idiopathiques mineures de 10 degrees a 29 degrees, en periode de croissance [Thesis]. Lyon: Universite Lyon; 1974.

9. Bunnell W. The natural history of idiopathic scoliosis. Clin Orthop Relat Res 1988;229:20.
10. Negrini S, Aulisa AG, Aulisa L, Circo AB *et al*.; 2011 SOSORT guidelines: Orthopaedic and rehabilitation treatment of idiopathic scoliosis during growth. Scoliosis 2012 20;7:3.
11. Carr W, Moe J, Winter R, Lonstein J. Treatment of idiopathic scoliosis in the Milwaikee brace. J Bone Joint Surg A 1980;62:599.
12. Mellencamp D, Blount W, Anderson A. Milwaukee brace treatment of idiopathic scoliosis. Clin Orthop 1977;126:47.
13. Keiser R, Shufflebarger H. The Milwaukee brace in idiopathic scoliosis. Evaluation of 123 completed cases. Clin Orthop 1976;118:19.
14. Edmonsson AS, Morris JT. Follow-up study of Milwaukee brace treatment in patients with idiopathic scoliosis. Clin Orthop Relat Res 1977:58Y61.
15. Coillard C, Leroux MA, Zabjek KF, Rivard CH. SpineCor nonrigid brace for the treatment of idiopathic scoliosis: post-treatment results. Eur Spine J 2003;12:141Y148.
16. Coillard C, Vachon V, Circo A, Beausejour M, Rivard CH. Effectiveness of the SpineCor brace based on the new standardized criteria proposed by the Scoliosis Research Society for Adolescent Idiopathic Scoliosis. J Pediatr Orthop 2007;27:375-9.
17. Negrini S, Atanasio S, Fusco C, Zaina F. Effectiveness of complete conservative treatment for adolescent idiopathic scoliosis (bracing and exercises) based on SOSORT management criteria: results according to the SRS criteria for bracing studies – SOSORT Award 2009 Winner. Scoliosis 2009;4:19.
18. Katz DE, Herring A, Browne RH, Kelly DM, Birch JG. Brace wear control of curve progression in adolescent idiopathic scoliosis. J Bone Joint Surg A 2010;92:1343-52.
19. Nachemson AL, Peterson LE. Effectiveness of treatment with a brace in girls who have adolescent idiopathic scoliosis. A prospective, controlled study based on data from the Brace Study of the Scoliosis Research Society. J Bone Joint Surg A 1995;77:815-22.
20. Donnelly MJ, Dolan LA, Weinstein SL. How effective is bracing for treatment of scoliosis? Am Fam Physician 2003;67:32.
21. Goldberg CJ, Dowling FE, Hall JE, Emans JB. A statistical comparison between natural history of idiopathic scoliosis and brace treatment in skeletally immature adolescent girls. Spine 1993;18:902-8.
22. Korfage IJ, Juttmann RE, Das BV, Diepstraten AF, Hazebroek-Kampschreur AA, Maas van der PJ. [Idiopathic scoliosis in adolescents; an inventory into the possibilities of studying the efficacy of screening and treatment] Idiopathische scoliose bij adolescenten; inventarisatie van mogelijkheden van onderzoek naar de effectiviteit van screening en behandeling. Ned Tijdschr Geneeskd 2002;146:1228-33.
23. Bunge EM, Habbema JD, de Koning HJ. A randomised controlled trial on the effectiveness of bracing patients with idiopathic scoliosis: failure to include patients and lessons to be learnt. Eur Spine J 2010;19:747-53.
24. Weinstein SL, Dolan LA, Wright JG, Dobbs MB. Effects of bracing in adolescents with idiopathic scoliosis. N Engl J Med 2013;369:1512-21.
25. Coillard C, Circo AB, Rivard CH. SpineCor treatment for juvenile idiopathic scoliosis: SOSORT award 2010 winner. Scoliosis 2010;5:25.
26. Richards BS, Bernstein RM, D_Amato CR, Thompson CH. Standardization of criteria for adolescent idiopathic scoliosis brace studies: SRS Committee on Bracing and Nonoperative Management. Spine 2005;30:2068Y2075.
27. Nguyen VH, Badeaux J, Leroux M, Coillard C, Rivard CH. Classification des scolioses idiopathiques et résultats thérapeutiques. Annales des chirurgies 1998;52:856.
28. Dolan LA, Weinstein SL. Surgical rates after observation and bracing for adolescent idiopathic scoliosis. Spine 2007;32(19 Suppl):S91-S100.
29. Noonan KJ, Weinstein SL, Jacobson WC, Dolan LA. Use of the Milwaukee brace for progressive idiopathic scoliosis. J Bone Joint Surg Am 1996;78:557Y567.
30. BrAIST. [cited 2014 September 10]. Available from: http://clinicaltrials.gov NCT00448448
31. Gammon SR, Mehlam CT, Chan W, Heifetz J, Durrett G, Wall EJ. A comparison of thoracolumbosacral orthosis and SpineCor treatment of adolescent idiopathic scoliosis patients using the scoliosis research society standardized criteria. J Pediatr Orthop 2010;30:531-8.
32. Gabos PG, Bojescul JA, Bowen JR, Keeler K, Rich L. Long-term follow-up of female patients with idiopathic scoliosis treated with the Wilmington orthosis. J Bone Joint Surg Am 2004;86-A:1891-9.
33. Willner S, Udén A. A prospective prevalence study of scoliosis in Southern Sweden. Acta Orthop Scand 1982;53:233-7.

Conflicts of interest.—Charles H Rivard and Christine Coillard are consultants to Spinecorporation Ltd. Alin Circo has no competing interests.