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Title: SPINECOR: A non-rigid brace for the treatment of Idiopathic Scoliosis: Initial Post-Treatment Results.

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SPINECOR: A non-rigid brace for the treatment of Idiopathic Scoliosis:

Initial Post-Treatment Results.

Purpose: The objective of this study is to assess the success of treatment during the follow-up of a group of 195 Idiopathic Scoliosis (IS) patients consecutively treated with the SpineCor brace. A survival analysis was performed to estimate the cumulative probability of success during treatment, at follow-up and for the combined treatment and follow-up period. Success was defined as either a correction or stabilization of ±5° or more, and failure as a worsening of more than 5°. The patient cohort was categorized before treatment as either less than 30° (G1), and greater than 30° (G2). The survival analysis (G1 and G2) indicated a cumulative probability of success that increased during treatment with the patient wearing the brace (Year 1: .30, .39; Year 2: .62, .79; Year 3. .92, .8 9), stabilized during the post-treatment follow-up period (Year 1 post treatment: .94, .89; Year 2 post-treatment: .85, .81), and an overall probability of success of .92 and .88 after 4 years of combined treatment and post-treatment follow-up. For the 29 patients who had a minimum follow-up of 2 years (initial Cobb angle: 30°±9°) the trend during treatment was a decrease in spinal curvature at three months with a mean difference of 10° (SD: 5°), at termination of treatment a mean difference of 7° (SD 7°); and at a follow-up time of 1, and 2 years there was a difference of 4° (SD: 7°), 5° (SD: 7°) in reference to the initial out of brace condition. At 2 years follow-up there was an overall correction of greater than 5° for 55% of the patients, 38% had a stabilization and 7% worsened more than 5°. This initial cohort of patients demonstrated a general trend of initial decrease in spinal curvature in brace, followed by a correction and/or stabilization at the end of treatment, which was maintained through 1, and 2 years follow-up.

Key Words: Idiopathic Scoliosis, Orthopaedic Treatment, Orthosis, Prognosis, and Reducibility.

Introduction

The treatment of Idiopathic Scoliosis (IS) with a rigid brace used to be considered as either a therapeutic panacea, or excessive and disappointing until it found its proper place in the range of treatment options [16, 18, 20]. Although there is evidence that rigid brace treatment is effective in altering the natural history of IS [11, 16], a significant challenge still exists for clinicians to define an optimal treatment approach. It is recognised that factors such as the amplitude of the curvature [6, 10], the level of maturation [6,10], and the maximum reducibility of the curvature [6, 14] are associated with a positive post-treatment outcome. However, questions still remain regarding the optimal application of external forces [6,14], and the consequence of rigid brace treatment on the integrity of the muscular system when a rigid brace is applied. The nature of the challenge faced by clinicians arises from the multiple factors that contribute to curve progression [9], as well as the complex issue of optimally applying external forces to the spine to favour curve correction and stabilisation during periods of rapid growth and development [1,8]. With this in consideration as well as knowledge of the unique spinal region specific vertebral morphology [3,13,15] and mobility [19], a unique spinal curvature specific "corrective movement principle" [4,5] was developed to correct and stabilise a spinal curvature, which is maintained and favoured by a nonrigid brace SpineCor [4,5]. The primary objective of this study is to evaluate the preliminary results of the first cohort of patients treated with the SpineCor System.

Methodology

Clinical Study Cohort

The therapeutic indication for treatment was based on a diagnosis of Idiopathic Scoliosis where the patients demonstrated a progression of the Cobb angle of at least 5' confirmed by two X-rays at 6-month intervals. Other factors such as patient maturity, high growth potential, family history of surgery for severe Idiopathic Scoliosis, and a rib hump that is greater than 7 degrees were also considered. Specific inclusion and exclusion criteria included the following

Inclusion Criteria:

- Idiopathic scoliosis diagnosed and confirmed, there must be no significant pathological malformation of the spine under X-ray examination.
- Girl or boy.
- Initial Cobb angle equal or above 15°
- Initial Cobb angle equal or less than 50°
- Risser 0,1, 2 or 3.
- Scoliosis with suspected high risk of evolution (family history or other prognostic factor) or proven progressive (Cobb angle increase of 5° or more in the last six months).

Exclusion criteria:

- Postural scoliosis: When a supine P.A. X-ray shows an almost complete reduction and that there is a leg length discrepancy.
- Patient who cannot follow all the treatment instructions.
- Patient with a congenital malformation of the spine such as Spina Bifida aperta or Spondylolisthesis.
- Neuromuscular Scoliosis.

The following curve types were treated with the SpineCor Brace: Thoracic (mid and high, n = 72), thoracolumbar (with or without pelvic obliquity, n = 58), lumbar (n = 22) and double curves (n = 43). The presence of a hypo-kyphosis was not considered as a contraindication for treatment with the SpineCor System.

The initial pre-therapeutic x-ray, which was used as a reference, wais systematically taken following the classic method, using a digital technique where the irradiation is half as much as that of a standard x-ray [17]. The initial evaluation included a PA 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 System following the same schedule: the first control on the day of the fitting and at 6 weeks and 3 months, then every 5 months on average until weaning. The lateral x-rays were obtained once a year. At the end of the treatment, the controls are continued at a rate of once every 6 months to 2 years depending on the age of the child. These evaluations were performed without the brace on the patient.

Description of the Bracing System and treatment protocol.

The dynamic corrective brace SpineCor resembles a non-rigid harness and was developed at Sainte-Justine Hospital between 1992 and 1993. It consists of a pelvic base, which is a belt that includes three pieces of soft thermodeformable plastic stabilised by 2 thigh bands and 2 crotch bands, a bolero made of cotton and 4 corrective elastic bands of variable size (.20 to 1 meter). It is important to note that there are a number of configurations possible for the placement of the elastic bands. The therapeutic principle is based on the definition of a specific corrective movement for each type of curve [4, 51, with an adjustment of the corrective bands to reproduce and favour this corrective movement (Fig 1, Fig 2). The patients were requested to wear the brace 20 out of 24 hours. The brace is stopped near skeletal maturity, or after 2 years of regular menstruation.

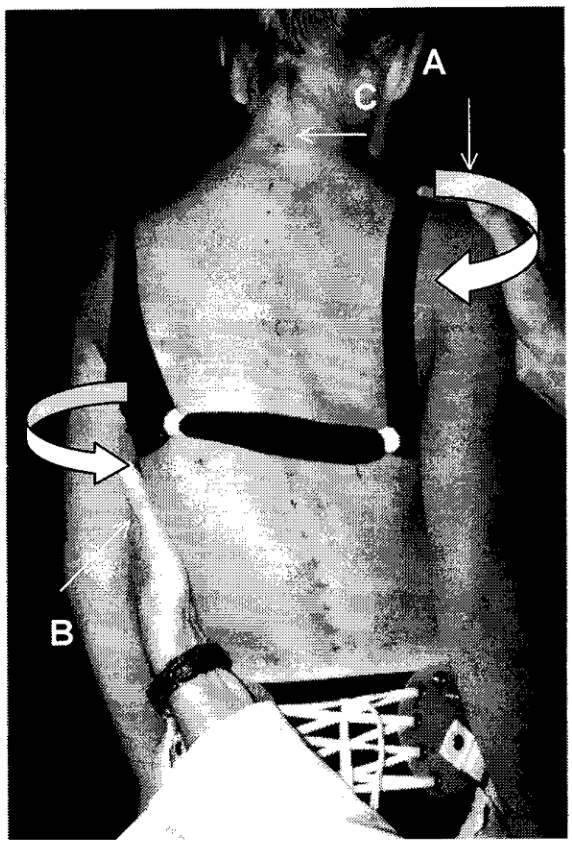

Figure 1: Corrective movement principle on a Right Thoracic Patient.

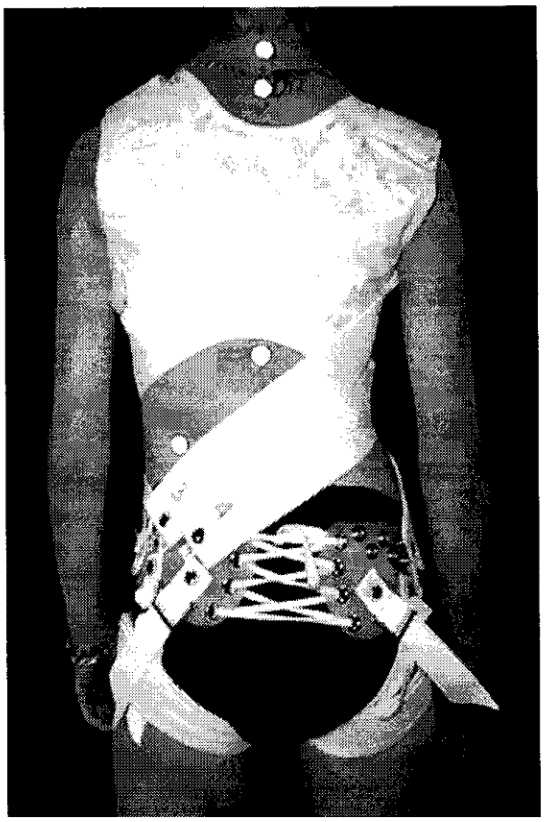

Figure 2: The SpineCor System fitted on a Right Thoracic patient.

Statistical Analysis

The patient visits were defined in the following manner. Initial state defines the patient's status prior to treatment, treatment 3 months (3M) defines the patient's status in brace at 3 months into treatment, end of treatment (IET) is the evaluation date without brace when the weaning commenced, follow-up 1 year (F1), 2 years (F2), 3 years (F3), 4 years (F4) is defined as the out of brace follow-up. More specifically differences (Cobb angle, and percent change) between the initial condition and each following condition (Difference = Initial - 3M, Initial - ET, Initial - F1, Initial - F2) as well as the changes that occurred during treatment and follow-up (Difference=3 Months-ET, 3 Months - F1, 3 Months - F2, ET - F1, ET- F2, Fl-F2) were analyzed. The difference between visits was used to identify a success as either improvement of more than 5° or stabilization of ±5°, or as a failure by an aggravation of the spinal curvature of more than 5°.

The results were analyzed such that an appreciation could be obtained for the general trend in treatment for the patients that had a minimum 2-year follow-up, as well as an indication of the efficacy of the brace by performing a survival analysis including all of the patients in the cohort.

A repeated measures analysis of variance was performed on the patients who completed treatment to define the overall treatment trend of patients with a minimum follow-up of 2 years. Since this type of analysis will only include patients with an available visit at each time interval (initial state, 3M, ET, F1 year and F2 years), the results of 29 patients with a minimum 2 years follow-up were presented. Therefore the patients who completed treatment but had a follow-up of less than 2 years, withdrew prematurely, or progressed to surgery were not included in the repeated measures analysis of variance. These patients were included in the following survival analysis.

The survival analysis is similar to the approach used by Nachemson et al., 1995, [11]. The whole cohort of patients was divided according to the amplitude of the initial Cobb angle such that Group 1 (G1) consisted of patients with a Cobb angle less than 30° and Group 2 (G2) consisted of patients with a Cobb angle of greater than 30°. Criteria for success was defined as a correction or stabilization of the Cobb angle, and failure as an aggravation of the Cobb angle. With the initial visit as a reference point survival curves were constructed for a) the patients that are still under treatment as well as the withdrawals (Survival Analysis A), b) the patients that have completed treatment which includes surgical patients (Survival Analysis B). A third survival curve was constructed with the end of treatment status, and the last available visit available during post treatment follow-up as references points. This analysis included all patients who completed treatment including surgical patients (Survival Analysis C).

Results

For this group of consecutively treated Idiopathic Scoliosis patients the average age at the commencement of treatment was 13 years (SD: 1 year), with 176 female and 19 male subjects. The initial major Cobb angle for the patients with a major curve of less than 30° was 23° (SD: 5°, n = 115), and for patients with a major curve of greater than 3W the Cobb angle was 36° (SD: 4°, n = 80). The initial cohort characteristics by curve amplitude and curve type as well as the minimum Cobb angle during treatment are presented in Table 1, and the Risser sign in Table 2.

Table 1: Initial Characteristics of Idiopathic Scoliosis Patient Population.

	Initial Cobb angle (Deg)			Cobb Angle Minimum During Treatment (Deg)		Percent Reduction	
	n	1 Mean	Stdev	Mean	Stdev	Mean	Stdev
All Patients	195	29	8	18	10	38	26
Thoracic	72	30	8	20	10	35	24
Thoracolumbar	58	25	8	13	8	50	26
Lumbar	22	24	6	16	7	36	25
Double	43	32	7	23	11	31	26
Less than 30°	115	23	5	13	8	45	28
Thoracic	37	24	4	15	7	41	26
Thoracolumbar	44	22	4	10	7	54	27
Lumbar	18	22	4	15	7	36	27
Double	16	24	5	15	9	42	32
Greater than 30°	80	36	4	26	8	28	20
Thoracic	35	36	4	26	8	28	21
Thoracolumbar	14	36	4	23	6	35	19
Lumbar	4	33	2	21	6	37	18
Double	27	37	4	28	8	23	18

Table 2: Risser sign for the Idiopathic Scoliosis patient population.

	R0	R1	R2	R3	R4
Group 1 (Cobb < 30°)	86	7	12	10	0
Group 2 (Cobb > 30°)	46	12	7	13	2

At the last available visit there were 109 patients still under treatment with a mean treatment time of 1.5 years (SD: 1 year), and 71 have terminated treatment with a post treatment follow-up time ranging from 0 to 4.5 years with 8 patients who underwent surgery. The patients who progressed to surgery had an initial mean Cobb angle of 34° (SD: 5°), with a mean end of treatment Cobb angle of 45° (SD: 6°) after 2 years (SDA year) of -treatment. There were also 15 patients who withdrew from treatment after a mean of 1.2 years (SD: .72 years) for which non-compliance and re-location were the principal reasons.

Outcome for Idiopathic Scoliosis Patients with a minimum 2-year follow-up after treatment with the SpineCor System.

From the 71 patients who completed treatment, there were 29 who had a minimum follow-up time of 2 years (mean 29 months SD: 4 months) and 42 who did not have a minimum 2 years follow-up. The initial Cobb angle for this sub-cohort of patients was 29° (SD: 7°), and after 3 months of treatment the mean Cobb angle was 19° (SD: 11°) corresponding to an overall mean decrease of 10° (SD: 5°) representing a mean reducibility of 40% (SD: 28%). At the end of treatment (time=24 months; SD 9 months; Risser 3 or 4) the mean Cobb angle was 21° (SD: 21°), at 1 year follow-up it was 25° (SD: 11°) and at 2 years follow-up it was 24° (SD: 11°).

At 2 years follow-up there was an overall correction in reference to the patient's initial state of greater than 5° for 16 patients (mean: 10°; range: 6° (16%) to 15° (83%)). All of these patients had a reduction at 3 months of greater than 5° representing a mean reducibility of 51% (SD: 28%). At 2 years follow-up there was a stabilisation for 11 patients (mean: 2° (9%); range –3° (19%) to 5° (25%)). Of these patients, 6 had an initial reduction of less

than 5°, which was maintained through to follow-up, and 5 patients had an initial reduction of greater than 5°, which was lost by 2 years follow-up. There were 2 patients that worsened, (mean: -8° (31%); Range: -6° (-17%) to -10° (33%) at 2 years follow-up. Both patients had an initial reduction of greater than 5°, which was lost during treatment. The evolution during treatment for the improved stabilised and aggravated patients are presented in Figure 3.

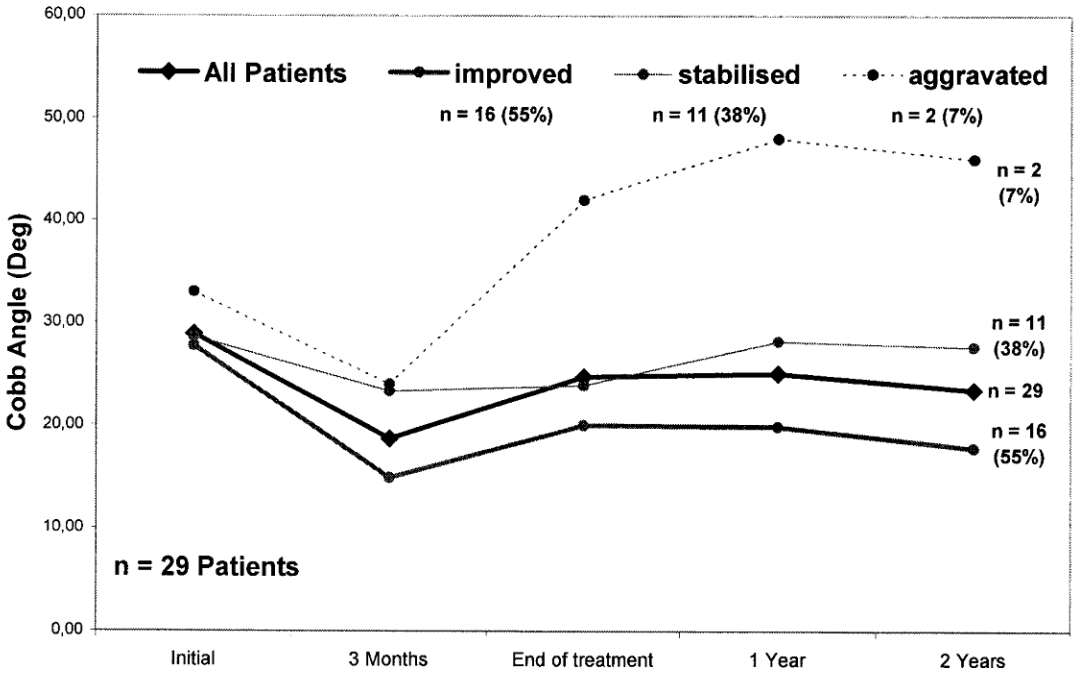

Figure 3: SpineCor weaned patient results with a minimum 2-year follow-up.

General Treatment Trend

For the 29 patients that had a minimum 2 year follow-up a repeated measures analysis of variance was performed, comparing the initial state, 3months in brace, end of treatment, 1 year and 2 years follow-up. Since this is a preliminary analysis of an initial cohort of 29 patients, a significance level of $p<0.01$ was chosen. There was a significant difference between the initial condition and 3months (10°±5°), end of treatment (7°±7°) as well as follow-up 1 and 2 years (4°±7° and 5°±7°) respectively. There was no difference between 3 months and end of treatment (-3°±8°), and followup 1 year (-6°±7°), but a difference between 3 months and the 2 year follow-up (5°±7°). At the end of treatment there was no difference with follow-up 1 year (-3°±61°), and 2 years (-2°±5°), as well as between 1 and 2 years follow-up (1°±4°). (See Table 3 and Table 4).

Table 3: Difference between each time interval during the course of treatment with the SpineCor System and during follow-up.

	Initial - 3M, ET, 1Y, 2Y				**3M - ET, 1Y, 2Y**			**ET-11Y,2Y**		**1Y-2Y**
	3M	**ET**	**1 Year**	**2 Year**	**End T**	**1 Year**	**2 Year**	**1 Year**	**2 Year**	
ALL	10(5)	7(7)	4(7)	5(7)	-3(8)	-6(7)	-5(7)	-3(6)	-2(5)	1(4)
Improved	12(4)	10(6)	8(5)	9(3)	-2(4)	-4(5)	-2(3)	-2(7)	-1(5)	2(5)
Stable	7(6)	5(5)	0(3)	1(3)	-2(9)	-6(5)	-5(7)	-4(6)	-4(6)	1(3)
Aggravated	10(3)	-7(1)	-13(1)	-13(1)	-17(1)	-23(1)	-23(1)	-6(0)	-6(0)	0

Table 4: Repeated measures analysis of variance for patients with a minimum follow-up of 2 years.

Conditions	P Value	P < 0.01
Initial vs Three Months In Brace	*P = 0.0000*	*
Initial vs End of Treatment	*P = 0.0003*	*
Initial vs Follow-up 1 year	*P = 0.0002*	*
Initial vs Follow-up 2 years	*P = 0.0006*	*
3 Months vs End of Treatment	*P = 0.0135*	
3 Months vs Follow-up 1 year	*P = 0.0181*	
3 Months vs Follow-up 2 years	*P = 0.0081*	*
End of Treatment Follow-up 1 year	*P = 0.999*	
End of Treatment Follow-up 2 years	*P = 0.999*	
Follow - Up 1 year vs 2 years	*p = 0.999*	

Survival Analysis of Patients treated with the SpineCor System

Survival Analysis A: Patients under Treatment and Withdrawals (n = 124). Initial Visit in reference to the last available visit.

The cumulative probability of success at 1 year, 2 years and 3 years in treatment is presented in Table 5 and Figure 4. In general the probability of obtaining a positive treatment effect was increased as the duration of treatment increased for both groups of patients. There was a significant difference between the patients of G1 and G2 as identified by the log rank test. (p=.03).

Table 5: Cumulative probability of success of patients under treatment including withdrawals with the SpineCor System.

Time	Group 1 <	Group 2 >
1 year	.30 (CI .18 -.41)	.39 (CI.25 -.52)
2 years	.62 (CI .49 -.75)	.79 (CI 67 -.90)
3 years	.92 (CI .84 - 1.0)	.89 (CI.80 -.99)

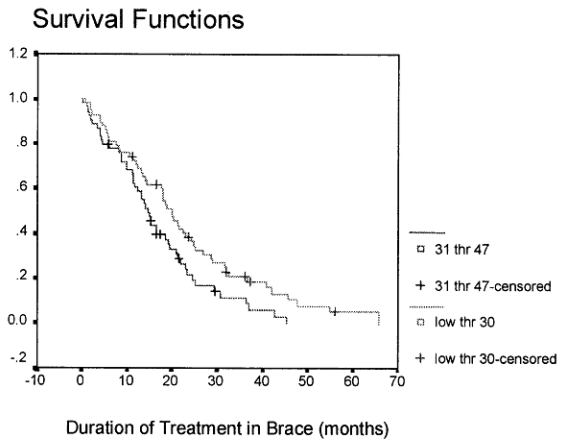

Figure 4: Survival function for 124 SpineCor patients under treatment (including withdrawal).

Note : *In figure 2, 1 equals the probability of 100% failure, indicating that the probability of failure decreases with time. To obtain the probability of success calculate :* *1 – prop failure*.

Survival Analysis B: **All Patients Who Terminated Treatment (n=71).**

Global success at follow-up: Initial visit in reference to last available visit.

Since the average treatment time is 2 years, the cumulative probability of success was calculated at 3, 4 and 5 year after the fitting of the SpineCor System with the last available visit out of brace for the weaned patients, which included the surgical patients. As presented in Table 6 and Figure 5, the cumulative probability of success at 4 years follow-up time was .92 and .88. At 5 years there was a considerable decrease, however at this time the confidence interval is 2 times that of 3 and 4 years. This is most likely due to the limited number of patients available for the analysis during this time period. There was no significant difference between the patients of G1 and G2 as identified by the log rank test.

Table 6: Cumulative probability of success of patients who have completed treatment in reference to the initial fitting of the SpineCor System.

Time	Group 1	Group 2
3 years	.97 (CI:.91- 1.0)	.95 (CI:.87-1.0)
4 years	.92 (CI:.82-1.0)	.88 (CI:.71-1.0)
5 years	.69 (CI:.44-.93)	.89 (CI:.62-1.0)

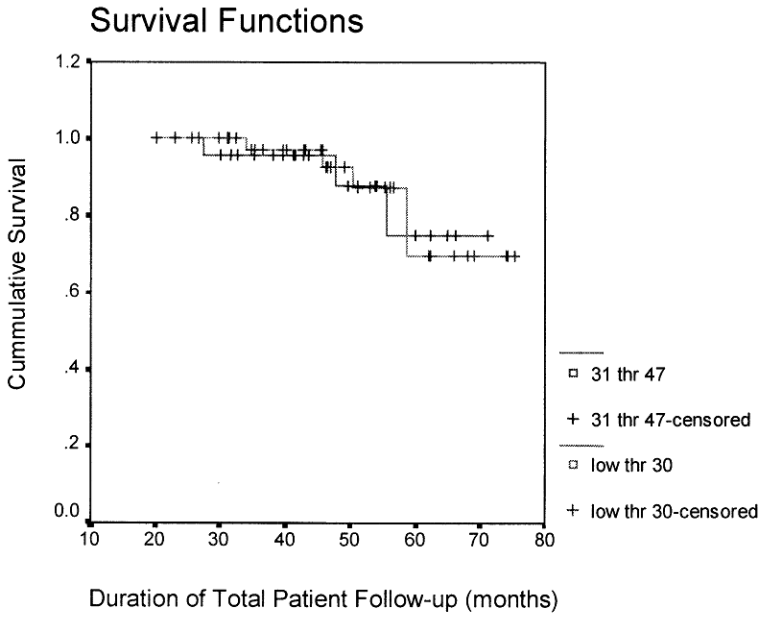

Figure 5: Survival function for 71 SpineCor patients completed treatment in reference to their initial status. The probability of success ranges from .97 at 3 years to .69 at 5 years for G1, and .95 to .89 for G2 respectively.

Note : The results at 5 years represents a small number of patients as reflected by the size of the Confidence Interval.

Survival Analysis C: All Patients who Terminated Treatment (n=71).

Global success at follow-up: End of Treatment in reference to last available visit.

The cumulative probability of success was calculated at 1, 2, and 3 years follow-up in reference to the end of treatment status with the SpineCor System. In general the cumulative probability of success increased as the duration of treatment decreased slightly during the follow-up period.(See Table 7, Figure 6) At 3 years there was a considerable decrease however, this is most likely due to the limited number of patients available for the analysis during this time period. There was no significant difference between the patients of G1 and G2 as identified by the log rank test.

Table 7: Cumulative probability of success of patients for the duration of time between end of treatment and the last available visit during follow-up.

Time	Group 1	Group 2
1 years	.94 (CI :.86- 1.0)	.89 (CI:.84-1.0)
2 years	.85 (CI :.71-.98)	.81 (CI:.62-1.0)
3 years	.68 (CI:.36-.99j	

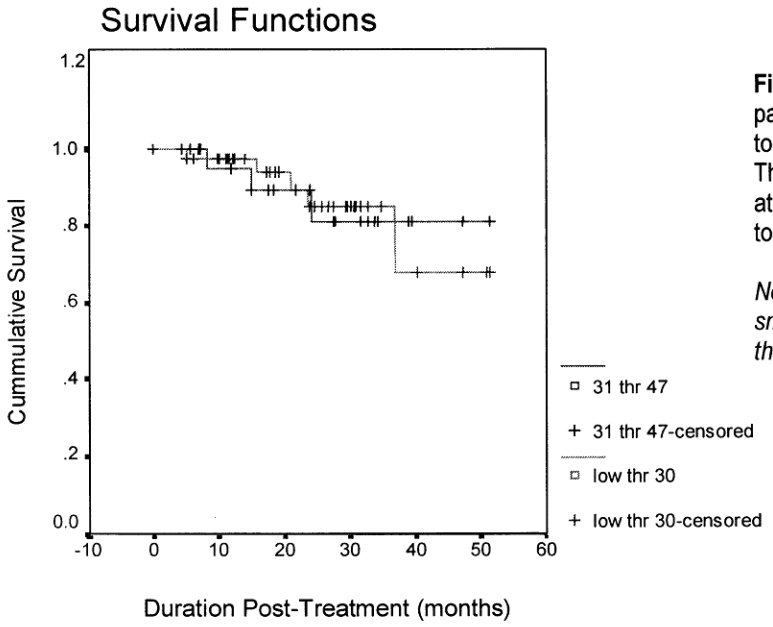

Figure 6: Survival function for SpineCor patients completed treatment in reference to their end of treatment status.
The probability of success ranges from .94 at 1 year to .68 at 3 years for G1, and .89 to .81 for G2 at 1 and 2 years.

Note : The results at 3 years represents a small number of patients demonstrated by the size of the Confidence Interval.

Discussion

The primary objective of this study was to perform a preliminary evaluation of the long term outcome results of the first patients who completed treatment with the SpineCor System. For the 29 patients who had a minimum follow-up of 2 years there was an overall correction greater than 5° for 55% of the patients, 38% had a stabilization and 7% worsened greater than 5°. The trend during treatment was to have a decrease in spinal curvature at three months with a mean difference of 10° (SD: 5°), at termination of treatment a mean difference of 7° (SD: 7°); and at a follow-up time of 1, and 2 years there was a difference of 4° (SD: 7°), and 5° (SD: 7°) in reference to the initial out of brace condition. The survival analysis indicated an increasing cumulative probability of success over time for the patients in treatment in brace increasing from .30 (G1) and .39 (G2) at 1 year, to .92 (G1) and .89 (G2) at 3 years in treatment. For the weaned patients the cumulative probability of success was .85 (G1) and .89 (G2) at 2 years after the brace was stopped being worn, with a global probability of .92 (G1) and .88 (G2) at 4 years after the initial fitting of the brace.

These results are similar to those reported previously by other bracing systems [2,6,10]. However, the principal difference is noted to involve the amplitude of initial correction and the amplitude of the final correction obtained at follow-up. Rigid bracing systems have been reported to have a maximum in brace reducibility that ranges between 50 to 62% [6, 14]. The reducibility of greater than 50% is associated with a maintained correction that can reach 7.2° at follow-up [6, 7, 10, 14], and a reducibility of 8% to 10% is associated with a failure of the brace [12]. In the present study, the mean reducibility for all patients was 38%, which is lower than that reported by other bracing systems [6,7,10,14]. However, if the patients are categorised according to those who had an overall correction, stabilisation or worsening at 2 years follow-up the results are very similar to other bracing systems

[6,7,10,14]. With the SpineCor System there was a significant correlation (r=-0.73) of the reducibility at three months and the amplitude of spinal curvature at two years follow-up. For the patients who had a decrease in spinal curvature of greater than 5° at 2 years follow-up the mean correction was 10° and the initial reducibility at three months was 51%. For the patients whose status did not change greater than or less than 5° at follow-up representing a mean change of 2°, the initial reducibility at three months was 27%. For the patients who deteriorated greater than 5° at follow-up with a mean aggravation of 10° there was an initial reducibility of 30% at three months. These results support the notion that the more the curve is reduced during the brace treatment, the better are the chances of correction and stabilisation [6,7,10,14]. However when considering with the initial reducibility as a global indicator it is also important to consider that in some cases this notion does not apply. For example in this study a patient with an initial low reducibility of 25% had a final correction of 12° which is opposite to the result of a patient who had a strong initial reducibility (50%) but had an eventual aggravation of the Cobb angle of 8°. These exceptions may be attributed to the presence of significant vertebral deformation as well as the difficulty encountered by all bracing systems in controlling the curve during periods of rapid growth. The difference in the amplitude of reducibility between SpineCor and other bracing systems may be related to the treatment principles used. Rigid braces rely on a more direct 3 point pressure principle in contrast to the SpineCor System, which involves the "corrective movement principle". The corrective movement acts indirectly on the spinal column and allows some degree of controlled mobility and movement. This approach provides the opportunity to re-educate and maintain the neuromuscular control of spinal corrective movement through active bio-feedback.

At the end of treatment the patients with a minimum 2 years follow-up in this study demonstrated a mean out of brace Cobb angle that was 5° lower than the initial pre-treatment status. The mean out of brace Cobb angle at termination of treatment was

similar to that found for other bracing systems where a correction of 1°-4° has been noted [6, 10]. In the present study 70% of the patients maintained their correction/stabilisation between the end of treatment up until 2 years follow-up. It is hypothesized by the authors that the controlled mobility and movement that is allowed by the SpineCor System contributes to maintaining neuromuscular system integrity as well as educating neuromuscular control patterns to function in a favourable manner. Once the brace is discontinued, the integrity of the neuromuscular system is still intact and the change in spinal curvature is maintained through follow-up. This may also account for the patients who showed a small improvement during follow-up. However, in some instances there was deterioration in the spinal curvature between the end of treatment and follow-up. For example, for 3 patients there was a deterioration of 6°, 7°, and 9° respectively. Two patients had a Risser 3 and one patient a Risser 4 at the termination of treatment with a Cobb angle of 28°, 18° and 18° respectively. During the 1st year of post-treatment follow-up, the respective Risser signs were 5, 4 and 5 with a loss in correction of 3°, 4° and 7° respectively. During the 2nd year of follow-up, with a Risser sign at 5 for all three patients, the first patient lost an additional 6°, the second 2° and the third remained the same. The angular loss during the first year post treatment may be related to the possibility that these three patients were not fully matured. However, for a patient who experienced an angular loss of 6° during the second year, despite going from Risser 4 to 5, the loss in curvature may no longer be related to growth but mostly to factors that include deformation of the vertebrae, condition of the disks, muscular imbalance and overall tonus. These factors may have been present early on in treatment for this patient who at the initiation of treatment had a Cobb angle of 38°. The difficulty in maintaining the correction and stabilisation of curves close to 40° has also been encountered by other bracing systems [6, 7].

The definition of bracing as an intermediate treatment option has largely relied on the comparison of the natural history of the disease with progression of the curvature during bracing treatment. A non-treated curve with a Risser sign between 0 and 1 and a Cobb angle between 20° to 29° had a 68% chance of progressing [9]. In a meta-analysis based on twenty studies there was a weighted mean proportion of success determined to be .93 for full time bracing [16]. A comparative study between electrical stimulation, bracing and natural history identified that bracing was associated with a success rate of 74% at four years, which was statistically superior to observation only (34%), and electrical stimulation (33%) [11]. The results of the present evaluation of the SpineCor System infers an equally important if not greater success rate as reported by other bracing systems. At four years the global probability of success was .92 and .88 for Cobb angles less than 30° and greater than 30° respectively. At a follow-up of 2 years, there was an improvement for 55%, stabilisation for 38%, and aggravation for 7%. However, a limitation to the present study is that the results are based on patients treated consecutively with the SpineCor System for all type of curves. A more direct comparison to a non-treated control group as well as a group treated with a rigid bracing system would provide a stronger basis for evaluating the efficacy of the SpineCor System, and is the focus of ongoing investigations.

Conclusion

This initial cohort of Idiopathic Scoliosis patients who were treated with the SpineCor System reveals a positive treatment outcome at 2 years follow-up. This is reflected through a cumulative probability of success, which increases during treatment, and maintained through 1 and 2 years follow-up. For the patients followed from the initiation of treatment through to 2 years follow-up there was an overall correction/stabilisation for 93% of the patients.

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Legend to Figures

Figure 1: The corrective movement principle for a Right Thoracic patient. This movement involves a rotation of the thorax in a counter-clockwise direction relative to the shoulders (A, B), and a slight down tilt of the right shoulder (A). The right lateral shift of T1 in relation to S1 should also be reduced (C).

Figure 2: The SpineCor System fitted on a Right Thoracic patient to favorise the corrective movement principle.

Figure 3: SpineCor weaned patient results with a minimum 2 year follow-up.

Figure 4: Survival function for 124 SpineCor patients under treatment (including withdrawal).

Figure 5: Survival function for 71 SpineCor patients completed treatment in reference to their initial status.

Figure 6: Survival function for SpineCor patients completed treatment in reference to their end of treatment status.

Legend to Tables

Table 1: Initial Characteristics of Idiopathic Scoliosis Patient Population.

Table 2: Risser sign for the Idiopathic Scoliosis patient population.

Table 3: Difference between each time interval during the course of treatment with the SpineCor System and during follow-up.

Table 4: Repeated measures analysis of variance for patients with a minimum follow-up of 2 years.

Table 5: Cumulative probability of success of patients under treatment with the SpineCor System.

Table 6: Cumulative probability of success of patients who have completed treatment in reference to the initial fitting of the SpineCor System.

Table 7: Cumulative probability of success of patients during follow-up that have finished treatment