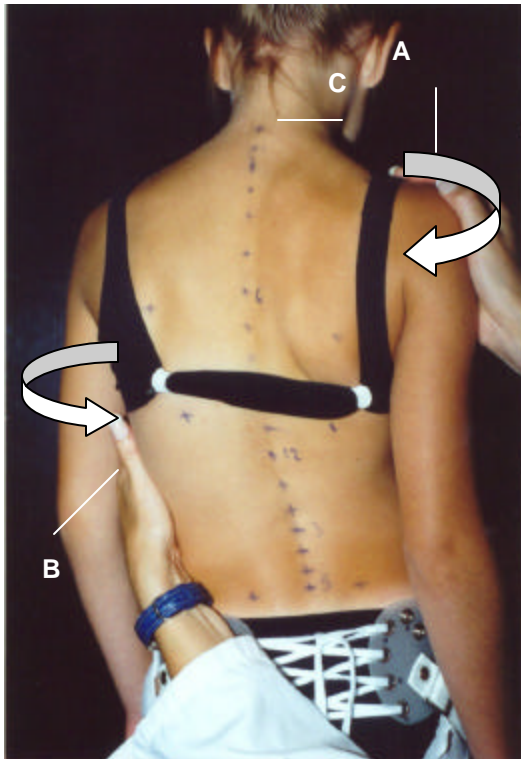


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# SpineCor System



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## 1. INTRODUCTION

The SpineCor system is a flexible brace that is principally prescribed for Idiopathic Scoliosis patients with a Cobb angle between 15° and 50° and Risser sign 0 to 2. The brace is fitted on the patient in accordance to a sub-classification of the traditional SRS definition of curve types. The SpineCor Assistant Software guides the therapist through the fitting process. The brace is prescribed to be worn by the patients 20 out of 24 hours per day until they have reached maturity, with radiological evaluations performed prior to and immediately following the fitting of the brace, and every 4 to 6 months afterwards. To accommodate for the growth of the patient, components to the brace are expected to be changed every 1.5 to 2 years. A patient manual is provided that guides the patient in properly wearing the brace, as well as maintenance. The orthotist is suggested to follow a 2day training program to learn the the proper fitting of the SpineCor brace.

## INDICATIONS

The SpineCor System was designed, developed, and tested for the treatment of idiopathic scoliosis only.

## CONCEPT

The new therapeutic approach is based on a new concept upon the etiology and pathogenesis of idiopathic scoliosis. It is a pathology of the neuro-musculoskeletal system in growth and maturation. The cause is genetic, and the pathogenesis involves a three-dimensional deformation of the spine, postural disorganization, unsynchronized growth and particular movement pattern of the body.

## DIAGNOSIS

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

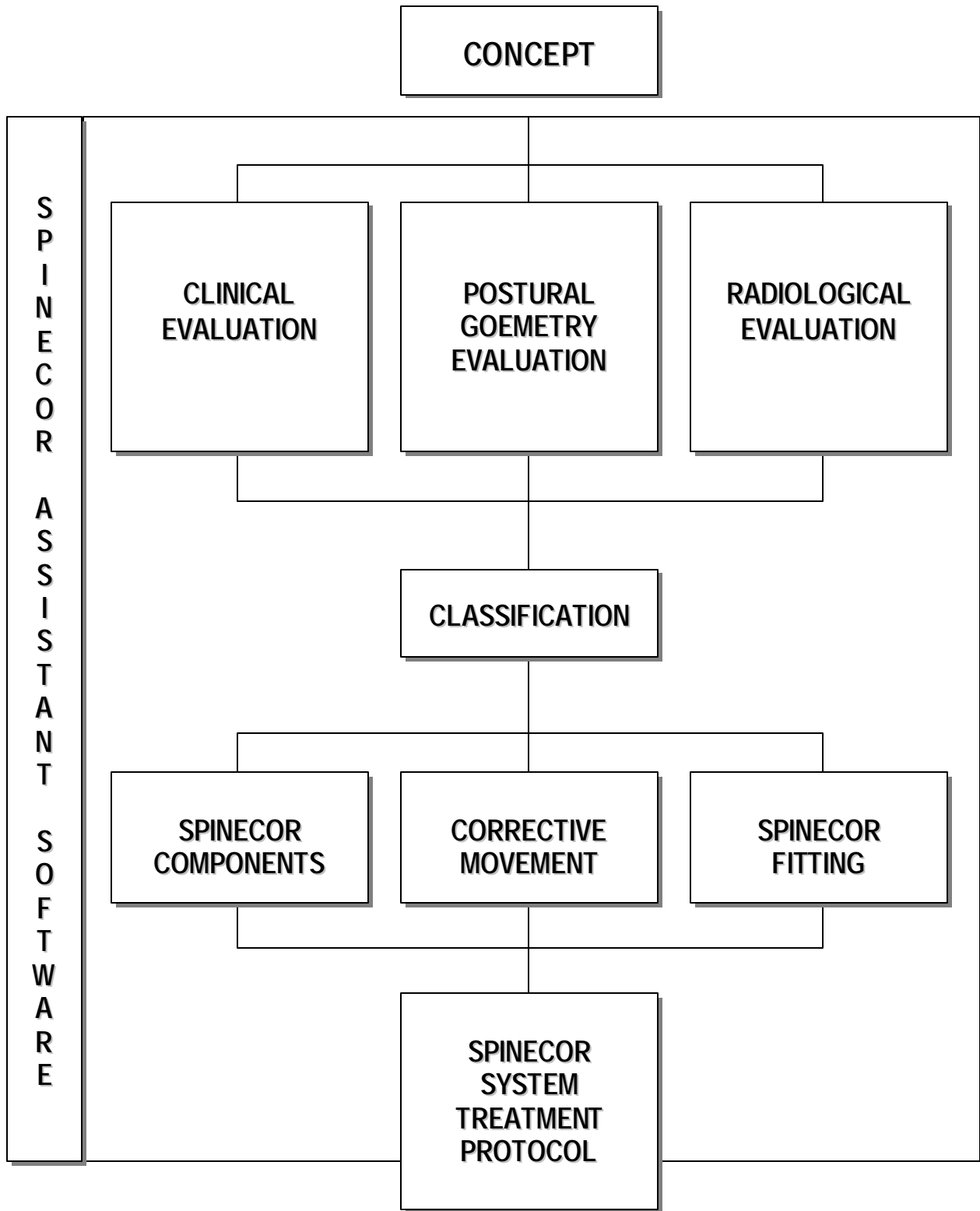
## TREATMENT

A specific corrective movement is performed, and the brace is applied according to the SpineCor Assistant Software instructions. The moderate tension in the elastic bands allows the repetition and amplification of the corrective movement as the child undertakes everyday activities. This results in a progressive curve reduction. The brace is worn 20 hours out of 24. The four hours out of the brace must not be taken at once, usually the patient divides them into two breaks: morning and evening. Sports are to be encouraged and done while wearing the brace. To obtain a neuro-muscular integration of the new strategy of movement, the average duration of the treatment is 18 months. Because of the progressive changes, absence of external support during the treatment, and intact muscles, there is no loss of correction after the brace discontinuation. Physical therapy is NOT a necessity in the SpineCor program (SpineCor itself may be considered a physiotherapy 20 hours out of 24). However, when the patient is willing to undergo a physio program, or a faster consolidation of the reduction of the curve is desired, the Global Postural Reeducation (GPR) program is considered. For the patients at the beginning of the treatment, the physio is carried out with the brace on; for the patients in the weaning period the exercises are done without the brace.

## PROGNOSIS

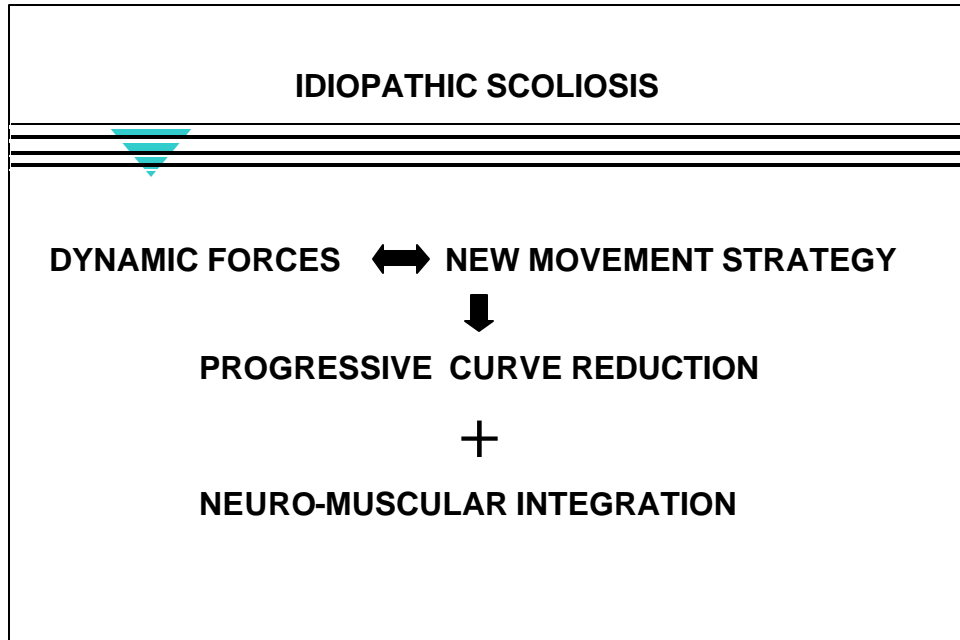
To really change the natural progression of idiopathic scoliosis, it is essential to reduce the curvature enough to eliminate the negative impact of abnormal biomechanics and growth. Therefore, it is possible to achieve a complete or almost complete correction of moderate curves, if the treatment is started before the main growth spurt (before Risser 1 and menarche). In curves over 30 degrees of Cobb angle, or when the treatment started during or after the main growth spurt, the goal of the treatment is a stabilization of the deformity. The therapeutic success is possible in more than 80% of cases. The reference reducibility calculated as early as at 3-4 months of treatment, is useful in defining the prognosis. However, for individual prognosis, the impact of the severity of the bone deformation, pattern of the growth and compliance must be considered.

## 2. THE SPINECOR SYSTEM APPROACH





4. NEW THERAPEUTIC APPROACH AND TREATMENT STRATEGY



**IDIOPATHIC SCOLIOSIS**

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**SPINECOR DYNAMIC BRACE TREATMENT**

<b>START TREATMENT</b>	<b>PRINCIPAL OBJECTIVE</b>	<b>QUALITY OF RESULT</b>
<b>BEFORE MAIN GROWTH SPURT</b>	<b>CORRECTION</b>	<b>HIGH</b>
<b>DURING OR AFTER MAIN GROWTH SPURT</b>	<b>STABILISATION</b>	<b>MODERATE</b>

## 5. CLINICAL EVALUATION

Patient's feet in the foot template, the therapist sitting behind the patient.

1. Evaluation of the orientation of the body levels in relation to the foot template.
  - a. In the **horizontal** plane: rotation of the shoulders, rotation of the thorax, rotation of the pelvis
  - b. In the **frontal** plane: tilt of the shoulders, tilt of the pelvis, lateral shift of T1 in relation to S1 (plumbline)
  - c. Prominence: levels and values (scoliometer)
  - d. Global appreciation of the posture: normal, minor disturbance, major disturbance
  - e. Standing and sitting height, weight
  - f. Pain: type, level, zone, frequency



Example: counterclockwise rotation of the shoulders;  
clockwise rotation of the pelvis

Example: counterclockwise tilt of the shoulders

## 6. RADIOLOGICAL CLASSIFICATION

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

Observation of specific parameters, by combining frontal and sagittal x-rays, in order to get the maximum 3D information is involved.

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

## 7. POSTURAL GEOMETRY

The purpose of the Postural Geometry evaluation is to quantify non-invasively in 3-dimensions the position and orientation of pelvic girdle, shoulder girdle, spine and thorax. This evaluation provides a qualitative view of the patient in three planes (sagittal, frontal and transverse) and a quantification of linear and angular postural parameters.

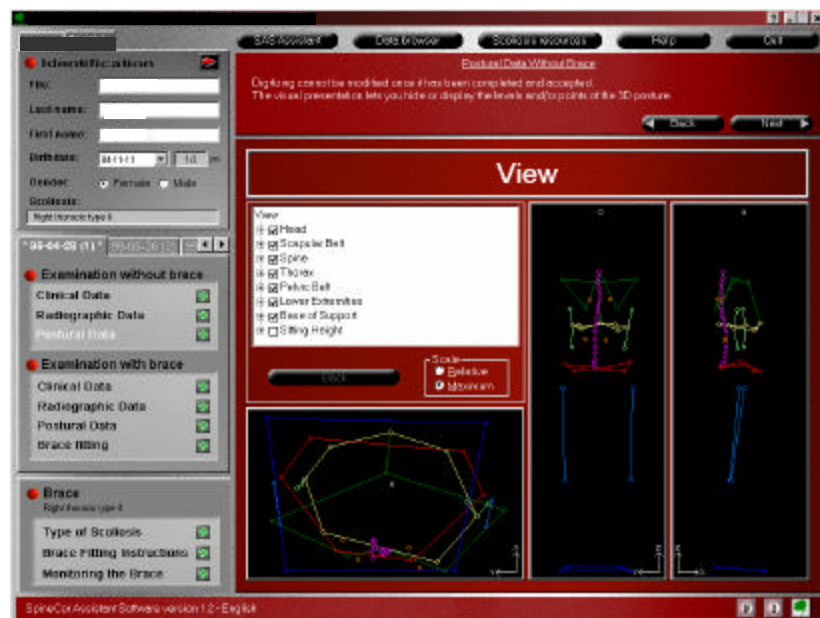
The specific purpose of the model within the context of SpineCor and SpineCor Assistant Software is the following:

- Quantify the initial posture of the patient and assist in the classification process of the scoliosis patient.
- Verify the action of the brace on the posture of the patient.

## THE FREEPOINT DEVICE

The FreePoint device includes a probe used to digitize the landmarks and a wall-mounted metal triangle. The probe has a tip (indicating the landmark location) and two ultrasound emitters. The two emitters are positioned away from the tip to prevent sound reflections from affecting the data. Three receivers, each located on an angle of the metal triangle, capture the ultrasound emissions. The position in space of the digitized landmark is calculated by triangulation based on the ultrasound propagation time to each of the three receivers.

3D Reconstruction of a patient's posture with the FreePoint system.

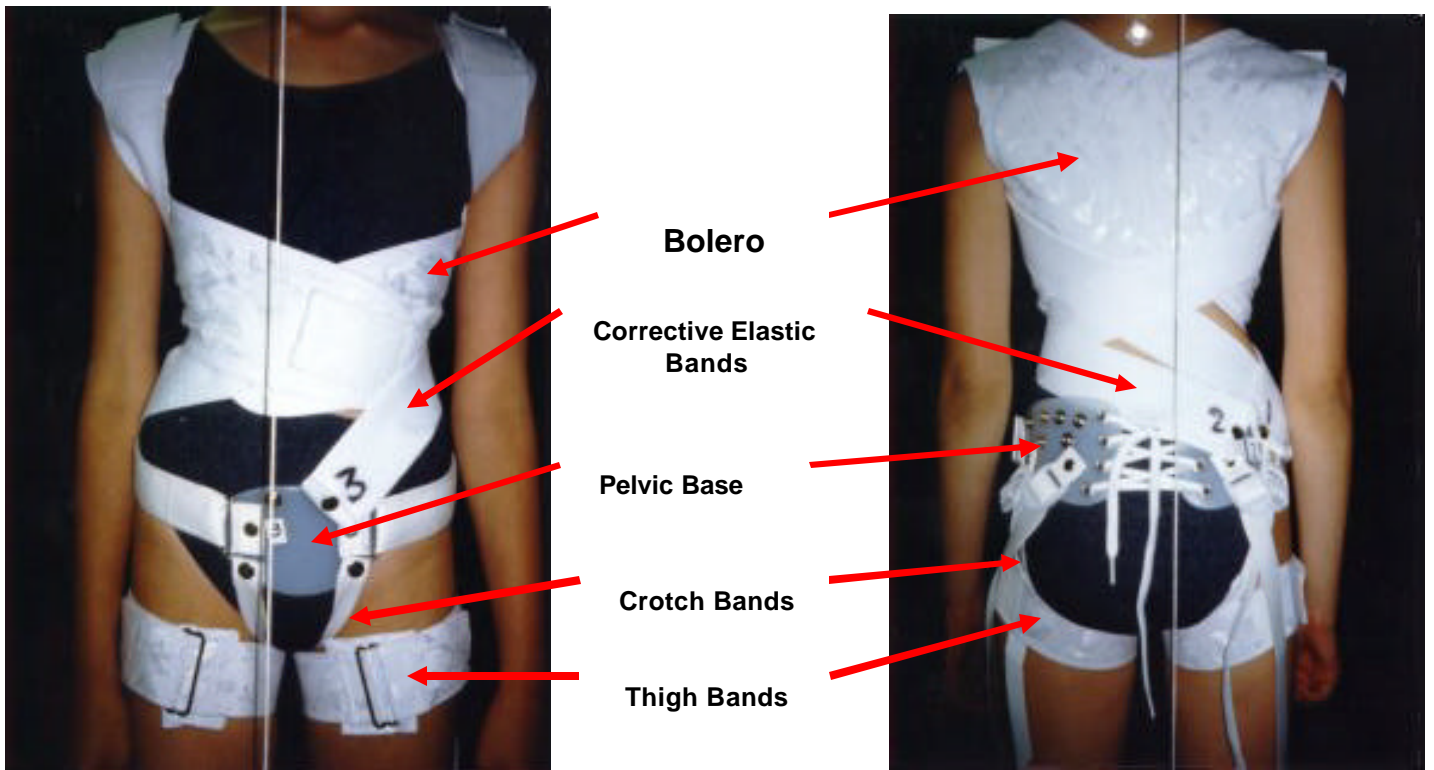


## 8. BRACE COMPONENTS

The **dynamic corrective brace** is made up of two components:

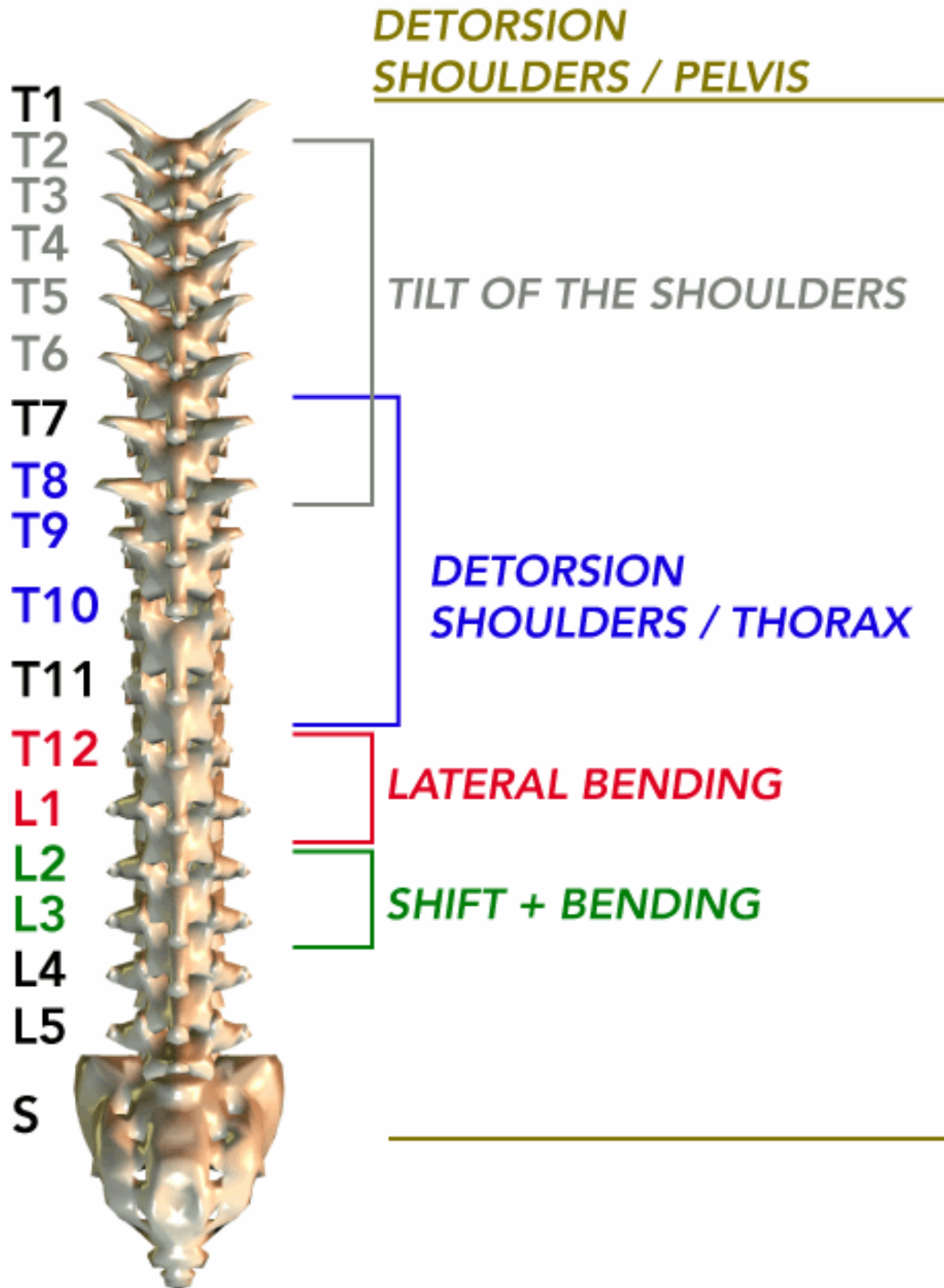
- The first component consists of the **pelvic base**, the **crotch bands** and the **thigh bands**. Its role is to act as an **anchoring point and support** for the actions applied to the patient's trunk by the elastic bands. When the pelvic base is stable, the traction by the elastic bands is provided along the stable lines. The flexible nature of the pelvic section of the brace permits free movements of the trunk and engagement of the pelvis in the corrective movement.
- The second component consists of the **bolero** and the **corrective elastic bands**. Its function is directly related to the **active principle of the dynamic corrective brace**. It allows a custom fitting of the brace aimed at modifying the postural geometry of the moving spinal column.

The corrective elastic bands of different length allow for many possibilities in brace adjustment for an optimal correction. Overall, there are 4 major ways to fit the corrective bands, corresponding to the thoracic, thoracolumbar, lumbar and double scoliosis. The SpineCor Assistant Software provides the guidelines for the choice of the bands and snaps.





9. PRINCIPAL CORRECTIVE MOVEMENTS AND SPINECOR FITTINGS



**TILT:**  
SHOULDERS



HIGH THORACIC CURVES

**DETORSION:**  
BETWEEN SHOULDERS & THORAX



THORACIC CURVES

**LATERAL BENDING**  
TRUNK



THORACOLUMBAR CURVES

**LATERAL SHIFT**  
TRUNK



LUMBAR CURVES  
(+ LATERAL BENDING)

**DETORSION:**  
BETWEEN SHOULDERS & PELVIS



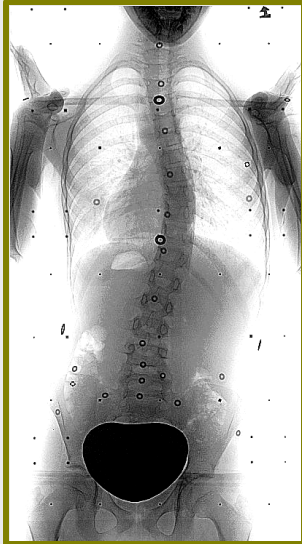
MAJOR DOUBLE CURVES

# **10. SPECIFIC CLINICAL AND RADIOLOGICAL CLASSIFICATION**

**AND**

**CORRECTIVE MOVEMENTS**

**RIGHT THORACIC 1**



- No lumbar curve
- Clockwise rotation of the thoracic vertebrae
- Clockwise rotation of the underlying lumbar vertebrae

**RIGHT THORACIC 2**



- Lumbar hemicurve
- Clockwise rotation of the thoracic vertebrae
- No rotation or counterclockwise rotation of the lumbar vertebrae
- No tilt of the last lumbar vertebrae

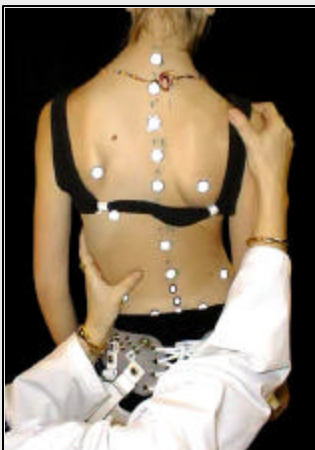
**RIGHT THORACIC**



- Lumbar countercurve
- Clockwise rotation of the thoracic vertebrae
- No rotation or counterclockwise rotation of the lumbar vertebrae
- Counterclockwise tilt of the last lumbar vertebrae
- Lumbar Cobb inferior to the thoracic

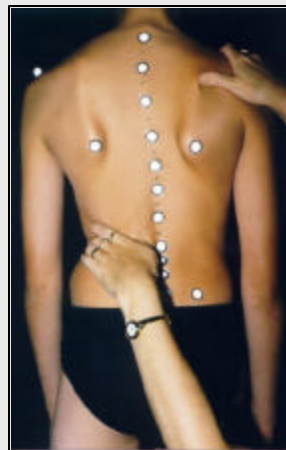
**ALL RIGHT THORACIC CURVES:**

- Apex: T7 - T10
- Clockwise rotation of the thoracic vertebrae
- Decreased distance between the ribs on the concave side at the level of the apex
- Hypokyphosis



**Corrective movement: detorsion between the thorax and the shoulder girdle:**


- Bring the thorax counterclockwise.
  - Bring the shoulders clockwise.
- For RT1 obtain a slight left lateral shift.  
For RT3 add a slight bending of the trunk to the left to open the lumbar curve.




**PRINCIPAL CORRECTIVE MOVEMENT:**

Detorsion between the thorax and the shoulder girdle

**NB: shoe lift is dangerous in thoracic curves**



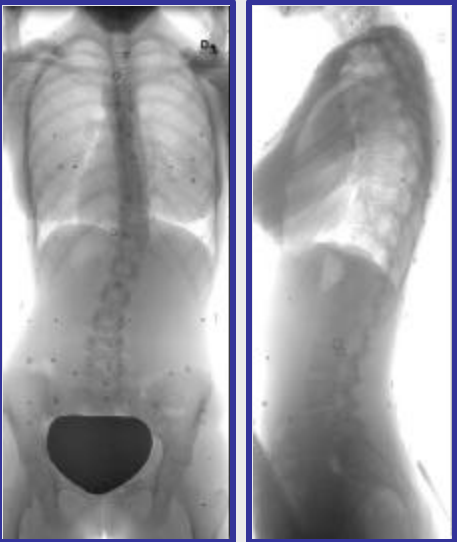
**RIGHT THORACIC  
"EUROPEAN" CURVE**




- Apex1 (major Th curve): T6 – T7, apex2: T12-L1
- Asymmetry of the distance between the ribs
- Kyphosis flattened between T3 and T8 and counterclockwise rotation of the TL
- Cobb Th > Cobb TL

**Corrective movement:**

- Bend the trunk to the left
- Obtain a clockwise tilt for the shoulders



**RIGHT T 11  
CURVE**



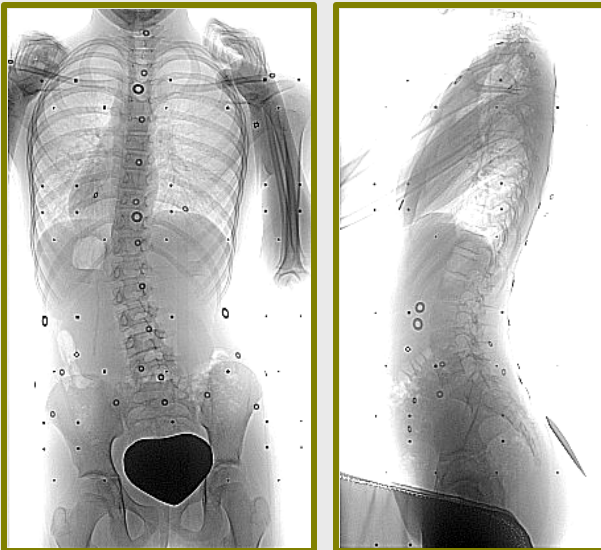
- Apex: T11
- Tendency for hyperkyphosis
- Risser 1 and higher

**Corrective movement:**

- Obtain a counterclockwise rotation of the thorax and shift it to the left
- Obtain a clockwise tilt for the shoulders

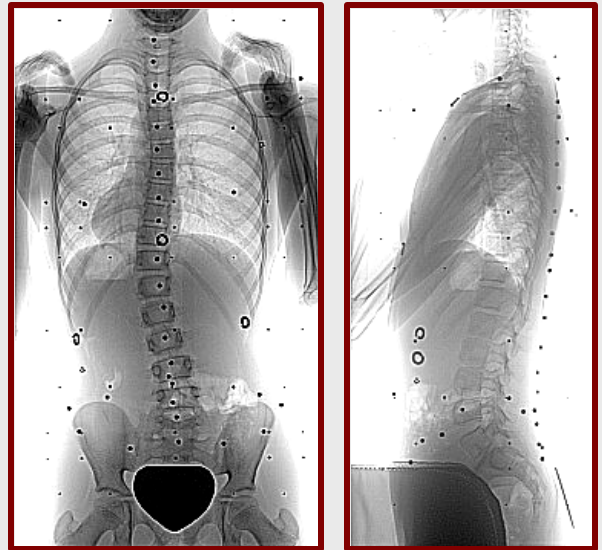


**LEFT THORACOLUMBAR 1**



- Unique curve, apex: T12 - L1
- Counterclockwise tilt of the pelvis
- L5 tilted in reference to S1
- Sagittal curves slightly or not modified
- Major postural disturbance

**LEFT THORACOLUMBAR 2**



- Major thoracolumbar curve, apex: T12 - L1
- Often - right thoracic countercurve
- Pelvis is horizontal at the beginning
- L3 tilted in reference to L4, or L4 tilted in reference to L5
- Sagittal curves flattened, thoracolumbar junctional kyphosis

**Principal corrective movement for the left thoracolumbar curves:**

Left lateral bending of the thorax in relation to the pelvis



In LTL1 add a shoe lift to level the PSIS  
NB: Avoid any shift of the trunk to the right.

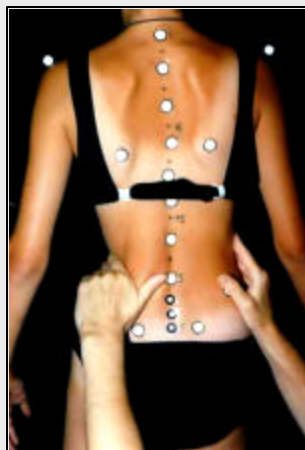
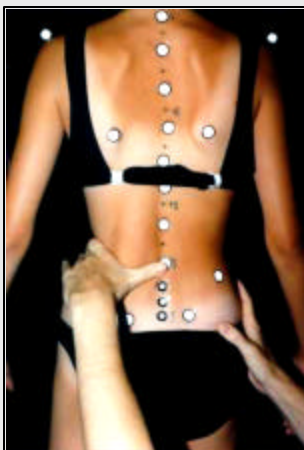
In LTL2 add a slight shift of the thoracic base to the right and a clockwise detorsion for the shoulders.



LEFT LUMBAR



- Unique curve, apex: disk L1/L2 - L3
- Moderate pelvic obliquity
- Lordosis at the lower limit of the norm at the beginning



Corrective movement:

- The main corrective movement is a **shift** of the trunk to the right in relation to the pelvis.
- Add a slight lateral flexion of the trunk to the left.
- When necessary, add a shoe lift to level the PSIS.

RIGHT THORACIC LEFT LUMBAR 1



- Thoracic Cobb ~ Lumbar Cobb
- Thoracic Rotation ~ Lumbar Rotation
- Kyphosis and lordosis near normal

RIGHT THORACIC LEFT LUMBAR 3



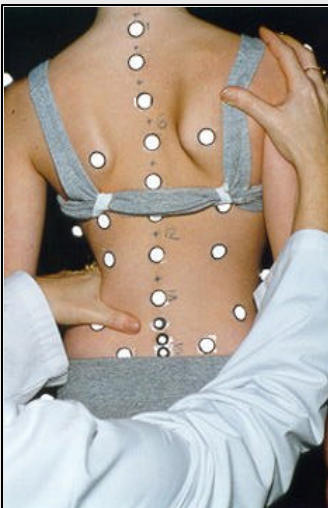
- Thoracic Cobb ~ Lumbar Cobb
- Lumbar Rotation >> Thoracic Rotation
- Pelvic obliquity (minimal at the beginning)
- Kyphosis and lordosis diminished; K ~ 1/3 L

Corrective movement:

The principal **corrective movement** is a **detorsion between the shoulders and the pelvis** in the horizontal plane.

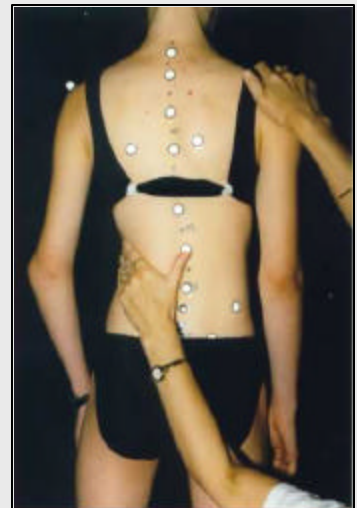
- Bring the pelvis counterclockwise, bring the shoulders clockwise;
- Add a lateral flexion of the trunk to the left.

In RTLL3 a shoe lift is often necessary to level the PSIS.



NB: Avoid any shift of the trunk to the right, which is negative for the thoracic curve.

NB: In double curves the corrective movement seems to disorganise the posture, but it is positive in terms of the desired reduction of the Cobb angles.





**11. SPINECOR TREATMENT PROTOCOL**

	1 <sup>st</sup> VISIT	2 <sup>nd</sup> VISIT 4 to 6 weeks later	3 <sup>rd</sup> VISIT 3 months later	FOLLOWING VISITS every 3 to 6 months
Verification of the brace as worn by the patient		X	X	X
Clinical evaluation	X	X	X	X
P/A x-ray without brace	X or x-rays < 1 month			Decision by MD according to evolution
Lateral x-ray without brace	X or x-rays < 1 month			Decision by MD according to evolution
Supine x-ray (A/P)	X or x-rays < 1 month			
Anatomical marking	X	X	X	X
FreePoint without brace	X	X	X	X
Corrective movement	X	X	X	X
Brace fitting	X	X	X	X
FreePoint with brace (and shoe lift if prescribed)	X	X	X	X
P/A x-ray with brace (and shoe lift if prescribed)	X	X	X	Decision by MD according to evolution
Lateral x-ray with brace (and shoe lift if prescribed)			X	At least once a year

## 12. RESULTS

### 12.1 SPINECOR PATIENTS INITIAL COHORT

At Sainte-Justine hospital patients have been treated with the SpineCor system since 1993. 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 30° the Cobb angle was 36° (SD: 4°, n = 80). For the two groups of patients the initial Risser sign was 0 for 86 and 45 patients, Risser 1 for 7 and 11 patients, Risser 2 for 12 and 7 patients, Risser 3 for 10 and 13 patients, and 2 patients with a Risser 4. The initial cohort characteristics by curve amplitude and curve type as well as the minimum Cobb angle during treatment are presented in Table 1.

Table 1 : Initial Characteristics of Idiopathic Scoliosis Patient Population.

	Initial Cobb angle (Deg)			Cobb Angle Minimum During Treatment		Percent Reduction	
	n	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
Grater 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

At the last available visit there were 109 patients still under treatment with a mean treatment time of 1.5 years (SD: 1year), and 71 have terminated treatment with a post-treatment follow-up time ranging from 0 to 4.5 years. From this cohort of 195 patients there were 8 patients who progressed to 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 (SD:1 year) of treatment. There were also 15 patients who withdrew from treatment after a mean of 1.2 years (SD: .72 years).

## 12.2 Outcome for Idiopathic Scoliosis Patients with a minimum 2 year follow-up after Treatment with the SpineCor system.

For the patients who have completed treatment there are 29 who had a minimum follow-up time of 2 years (mean 29 months SD : 4 months). 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 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:12°). At this time there were 61% of the patients who maintained the initial correction obtained at three months, with 35% aggravating and 4% improving. The mean Cobb angle at 2 years follow-up was 24° (SD:11°), where 66% maintained their end of treatment Cobb angle, 6% improved and 28% worsened.

At 2 years follow-up there was an overall correction in reference to the patients initial state of greater than 5° for 55% of the patients (mean: 10°; range: 6° (16%) to 15° (83%)), there was a stabilisation for 38% (mean: 2° (9%); range -3° (19%) to 5° (25%)) and 7% of the patients worsened, (mean: -8° (31%); Range: -6° (-17%) to -10° (-33%)). The evolution during treatment for the improved, stabilised and aggravated patients are presented in Figure 1.

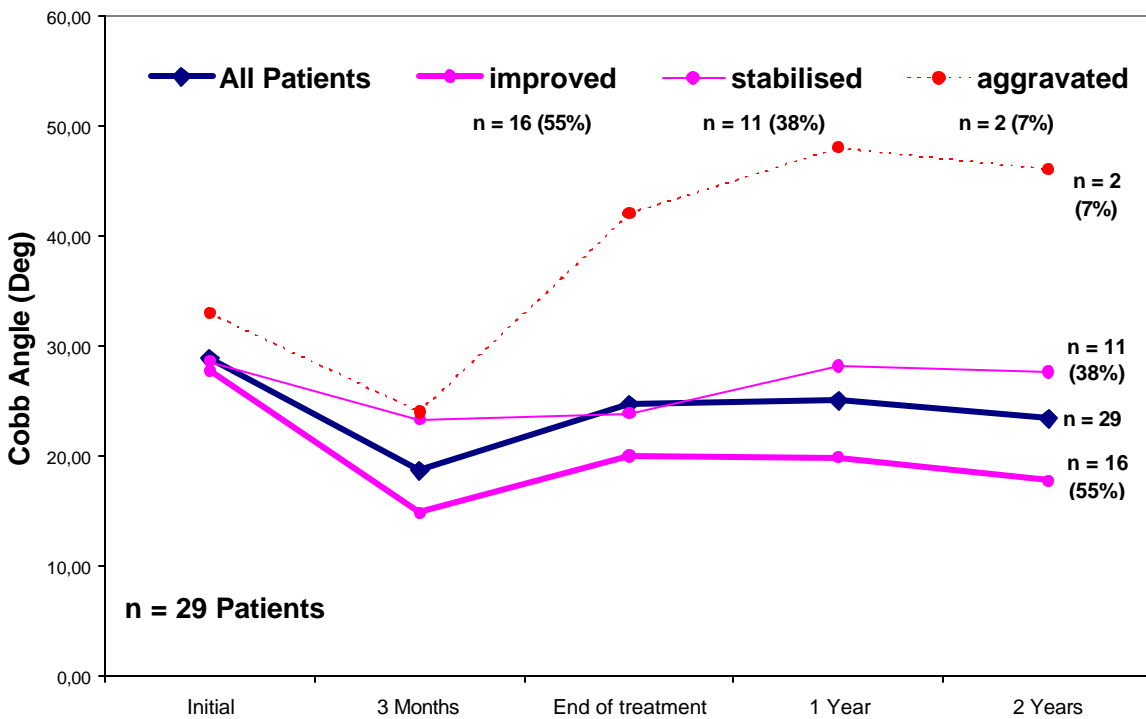


Figure 1: Spinecor weaned patient results with a minimum 2 year follow-up.

## 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 ( $10^{\circ} \pm 5^{\circ}$ ), end of treatment ( $7^{\circ} \pm 7^{\circ}$ ) as well as follow-up 1 and 2 years ( $4^{\circ} \pm 7^{\circ}$  and  $5^{\circ} \pm 7^{\circ}$ , respectively). There was no difference between 3 months and end of treatment ( $-3^{\circ} \pm 8^{\circ}$ ), and follow-up 1 year ( $-6^{\circ} \pm 7^{\circ}$ ), but a difference between 3 months and the 2 year follow-up ( $-5^{\circ} \pm 7^{\circ}$ ). At the end of treatment there was no difference with follow-up 1 year ( $-3^{\circ} \pm 6^{\circ}$ ), and 2 years ( $-2^{\circ} \pm 5^{\circ}$ ), as well as between 1 and 2 years follow-up ( $1^{\circ} \pm 4^{\circ}$ ). (See Table 2 and Table 3)

**Table 2 :** 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 – 1Y, 2Y		1Y – 2Y
	3 M	ET	1 Year	2 Year	End T	1 Year	2 Year	1 Year	2 Year	
<b>ALL</b>	10 (5)	7 (7)	4 (7)	5 (7)	-3 (8)	-6 (7)	-5 (7)	-3(6)	-2 (5)	1 (4)
<b>Improved</b>	12 (4)	10 (6)	8 (5)	9 (3)	-2 (4)	-4 (5)	-2 (3)	-2 (7)	-1 (5)	2 (5)
<b>Stable</b>	7 (6)	5 (5)	0 (3)	1 (3)	-2 (9)	-6 (5)	-5 (7)	-4 (6)	-4 (6)	1 (3)
<b>Aggravated</b>	10 (3)	-7 (1)	-13 (1)	-13 (1)	-17 (1)	-23 (1)	-23 (1)	-6 (0)	-6 (0)	0

**Table 3 :** 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	$p = 0.999\dagger$	
End of Treatment Follow-up 2 years	$p = 0.999\dagger$	
Follow – Up 1 year vs 2 years	$p = 0.999\dagger$	

† Note : The comparison between end of treatment and follow-up 1year and 2 years indicates that there is no worsening of the curve during the post-treatment follow-up period. This is in contrary with most rigid braces.

## 12.3 Survival Analysis of Patients treated with the SpineCor System

A survival analysis as utilised by Nachemson et al., 1995 was performed on the cohort of patients treated with the SpineCor system. The 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°.

A change in the Cobb angle at the end of treatment and/or the last available visit in reference to the initial visit was utilised to identify a correction (decrease of more than 5°), a stabilisation (change of  $\pm 5^\circ$ ), or aggravation (increase of more than 5°). 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 a survival curve was constructed for the patients that are still under treatment in addition to the withdrawal patients. The probability of obtaining a positive treatment effect increased as the duration of treatment increased for both groups of patients, with 95% confidence intervals of .84-1.0 and .80-.99 at 3 years of treatment in brace.

For the patients that have completed treatment the cumulative probability of success at 4 years follow-up (combined treatment time and post treatment follow-up time) had 95% confidence intervals that were 0.82 to 1.0 and .71 to 1.0).

A survival curve was also constructed for the patients who have completed treatment using the end of treatment status as the reference point vs the last available follow-up visit post-treatment as reference points. The confidence intervals for the cumulative probability of success at 2 years post-treatment follow-up was 0.71- 0.98 to 0.62-1.0 for groups 1 and 2 respectively.

## 12.4 INTERIM RESULTS OF A PROSPECTIVE RANDOMISED STUDY OF THE NATURAL HISTORY OF IDIOPATHIC SCOLIOSIS VERSUS TREATMENT WITH THE SPINECOR BRACE.

The objective of this prospective randomised study was to compare the natural history of Idiopathic Scoliosis patients to those treated with a SpineCor brace with a Cobb angle between 15 and 30 degrees. A cohort of 65 patients were randomly assigned to a control non-treated (n=36; age=12 years; Cobb angle:20±5 degrees) or treated group with the SpineCor brace (n=29; age=12 years; Cobb angle : 22±5 degrees). Inclusion criteria included an initial Cobb angle between 15 and 30 degrees, Risser 0, 1 or 2, high risk of progression (increase of Cobb angle of 5 degrees or more within the last 6 months), girl or boy and no significant malformation of the spine. Each patient underwent a comprehensive evaluation (radiological and clinical) prior to commencing the study, at 4 month intervals during treatment and follow-up. From both groups there were 3 patients who withdrew. For the remaining 33 control subjects there was a mean Cobb angle of 26±8 degrees and for the treated group, 20 are still in treatment with a mean Cobb angle in brace of 15±7 degrees. The remaining 6 patients, in the treated group, have been weaned from the brace but for less than 1 year.

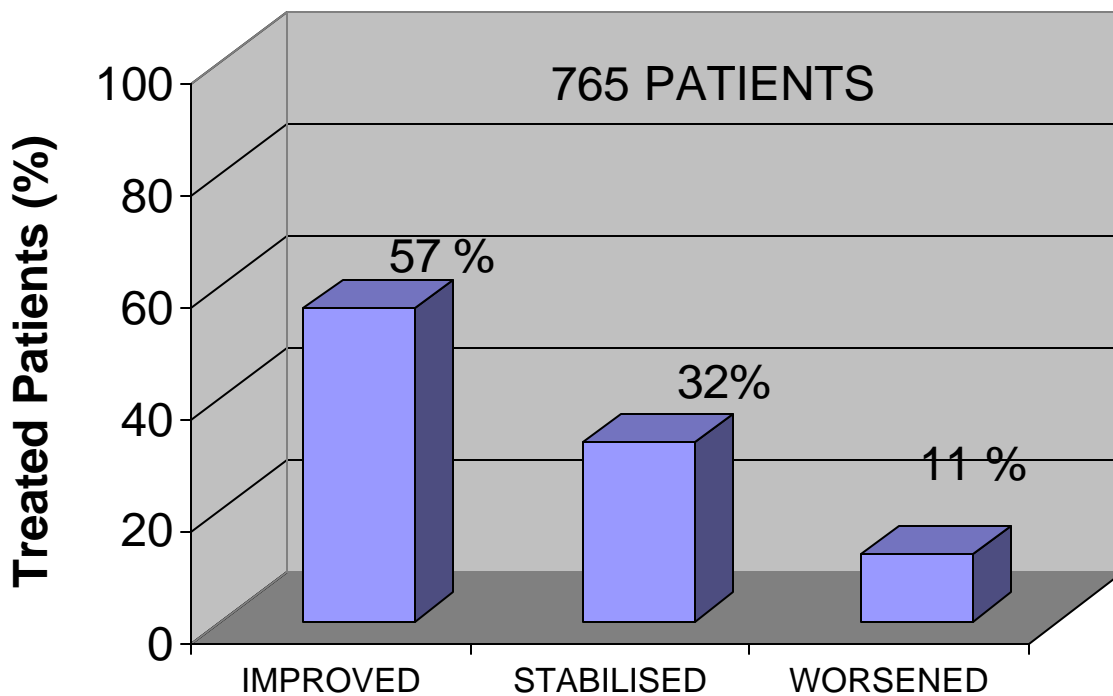
**Table 7 :** Percentage of patients improved, stable and worsened at the last available visit.

	Improved	Stable	Worsened
Control (n=33)	12	45	<u>42</u>
Treated (n=20)	76	14	<u>5</u>

This is the first prospective randomised study on Scoliosis patients investigating the Cobb angle between 15 and 30 degrees. This interim evaluation reveals a strong tendency where **42 percent of the control group worsen**, compared to the **treated group who showed a worsening of only 5 percent**. This interim result which shows this large difference in worsening between treated and non-treated patients questions the logic of continuing this prospective randomised study.

## 12.5 SPINECOR PATIENTS TREATED WORLD WIDE

The SpineCor system is currently being used at Sainte-Justine Hospital as well as 52 centres world wide with nearly 725 patients in-treatment as of April 2002. At the time of the last update of the latest available visit for these patients are presented in Figure 5, which demonstrates an improvement or stabilisation for 89% of the patients in treatment.



**Figure 6 :** The last available visit in brace for the patients treated world wide with the SpineCor system.

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