


The SpineCor

Dynamic Corrective Brace



The First and Only
Dynamic Corrective Brace for Idiopathic Scoliosis



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SpineCor System

The SpineCor® System is based on a new etiopathogenic concept .
This concept developed by a team of 65 researchers clearly identifies the origins
of idiopathic scoliosis and the drivers for progression.

Neuro-musculo-skeletal dysfunction

Postural disorganisation

TREATMENT

Minimise

Reduce

Scoliosis

Reduce

Stabilise

Growth asymmetry

Spinal deformation

**The SpineCor treatment approach targets the four
key progression factors of idiopathic scoliosis:**

- 1 Neuromuscular dysfunction
- 2 Growth Asymmetry
- 3 Postural disorganisation
- 4 Spinal deformation

Whilst it is rarely possible to completely reverse a child's scoliosis, using the SpineCor® Global approach to treatment, addressing all 4 of the key progression factors, it is possible to minimise or reduce these factors or stabilise the Scoliosis in 89% of cases.

The therapeutic approach

The SpineCor® Therapeutic approach uses curve specific corrective movement strategies to dynamically open curves.

38°



Curve Type:
RT Thoracic Type I



Corrective Movement:
RT Thoracic Type I

22°



Curve Reduction:
Resulting from
corrective movement
alone.
NO BRACE!

The SpineCor® curve classifications and corrective movements are the result of many years of research.

Corrective movements must be well understood by clinicians applying the brace.

Substantial curve reduction can only be achieved by progressively overcorrecting the postural deformity.

In brace curve reductions with the SpineCor® Dynamic Corrective Brace are NOT comparable to those in rigid braces. SpineCor® will generally show LESS reduction in treatment but GREATER stable permanent reduction post treatment compared to rigid bracing.

Scoliosis correction achieved by SpineCor® treatment has been shown to be at least stable in 93% of cases 5 years post treatment. 27% of patients actually continued to reduce their Cobb angles post treatment.

Largely Cobb angles achieved in brace with SpineCor® during treatment are sustained post treatment. Less than 5% of patients have demonstrated progression post treatment following the SpineCor® treatment protocol.

Treatment Indications

Idiopathic curves Cobb angles 20°-50°.
Risser 0-3 or Pre-Menarché.

Obtaining Optimal Results

SpineCor® has shown to be beneficial in reducing and stabilising large curves in children with advanced skeletal maturity, however, optimal results will ALWAYS be achieved by early treatment.

The percentage of curve improvement, stabilisation and worsening by SRS definitions have been shown in studies to be the same for patients 15°-30° and 31°-50° only the amount of correction changes.

Given an overall therapeutic success of 89% (improvement/stabilisation of initial Cobb angle) the ultimate treatment outcome and potential to avoid surgery will always be better the earlier treatment is started.

Of curves 20°-29° with Risser 0 or 1 68% WILL progress. (Lonstein & Carlson) Early SpineCor® treatment with its high patient acceptability and no side effects should be considered for such curves.

Diagnosis

and practical application

The SpineCor® Assistant Software (SAS V3) guides clinicians through the process of curve classification, brace fitting and follow-up. The SAS Software may be used by both prescribers and treatment providers and is easily installed on most computers.

Brace fitting now requires no special tools, equipment or environment.

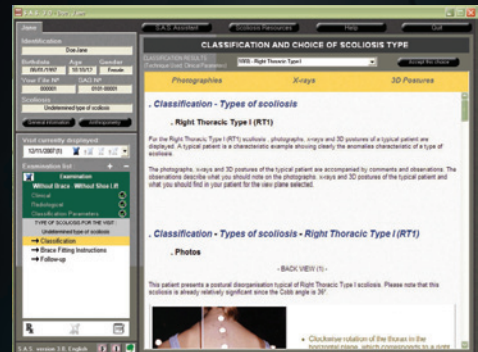
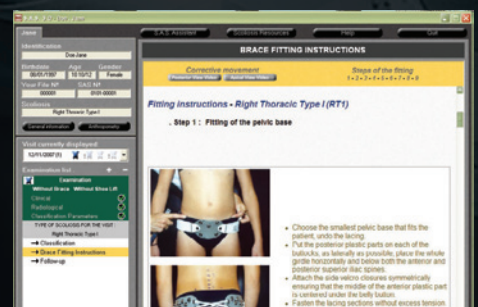
Once familiar with the system brace fitting and setup time takes less than 1 hour.

Brace follow-up adjustments are advised each 3 months. The process of reviewing the brace fitting and making any necessary adjustments takes less than 30 minutes.

Overall clinical time for the brace provider is potentially less with SpineCor® than with rigid bracing systems.

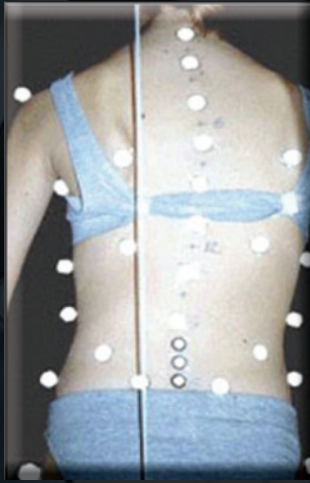
Overall time for prescribers overseeing the treatment should be no different to that required for patients under rigid bracing treatment.

X-ray reviews are advised each 6 months to safely monitor treatment in the brace (after initial diagnostic and fitting confirmation x-rays).



Patient Case Study

The following case study follows the treatment of an adolescent female patient with idiopathic scoliosis whose initial presentation at 9 ½ years and Risser 0 was with a 36° right thoracic curve.



Patient C – 9 ½ years old – 36°
Clinical aspect before treatment



Patient C – 9 ½ years old – 36°
Radiological aspect before treatment

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



Patient C – Wearing SpineCor Brace
Set-up for
Right Thoracic Type I



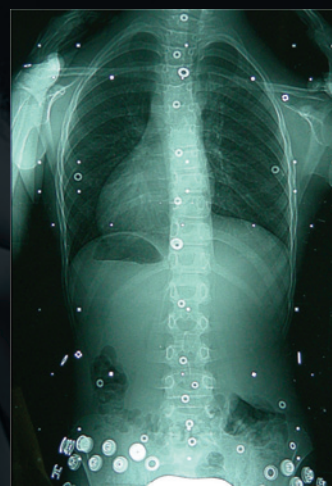
Patient C - Corrective Movement
Right Thoracic Type I

Each SpineCor® classification has a specific corrective movement strategy for progressive curve reduction.

In the case of Right Thoracic Type I, the corrective movement is counter clockwise rotation of the thorax and clockwise rotation of the shoulder girdle.

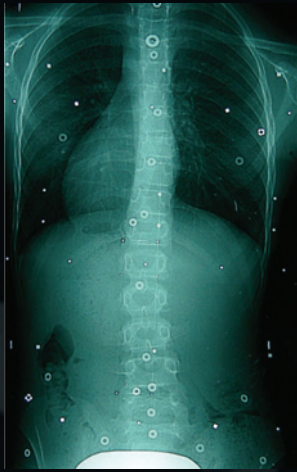


Patient C – Day of Brace Fitting – 24°



Patient C – 6 months in Brace 4°

Corrective mo



Patient C – After 15 months
of Brace
Treatment 2° – Without
Brace in Place



Patient C – Clinical Aspect
Before Treatment



Patient C – Clinical Aspect
After Treatment

Patient C's postural correction and Cobb angle reduction have been maintained 3 years post bracing.

vovement

Patient advantages

- Movement – treatment allows and encourages normal activities, sports, dance, riding etc.
- Cosmesis – easily worn underneath the patient's regular clothing for optimal cosmesis.
- Comfort – cool to wear with minimal irritation. 4 hours break from treatment daily.
- Success – 89% effective; clinically proven in a 400 patient 10 year study.
– A treatment with no side effects.
- Expenditure – a cost effective treatment option.

Easily worn under clothing



Cool to wear with minimal irritation

Treatment Duration & Weaning

Average treatment duration for adolescent idiopathic scoliosis is 26 months.

Bracing is not weaned before the following criteria are satisfied:

- Risser 4+
- 24 months post menarché
- Minimum brace wearing duration of 18 months
- With Brace and Without Brace x-rays show the same or very similar Cobb angles (5° or less difference)

Providing the above criteria are met the patient should have developed a neuromuscular integration of the corrective movement strategy to maintain a stabile curve. Long term 5 year post treatment studies show 93% of cases do not increase their Cobb angles from the point of weaning.

worldwide Treatment Results

SpineCor® is now used in 17 countries and over 100 treatment centers around the world.

Data collected from 52 of these treatment centers show therapeutic success* in over 90%+ of Idiopathic Scoliosis patients.

Due to the large variation of progression risk in patients with Idiopathic Scoliosis, comparison of different treatment methods has historically been very difficult.

In 2006 The Scoliosis Research Society (SRS) published guidelines for all future studies of Idiopathic Scoliosis treatments. The strict inclusion and exclusion criteria allowed study of only the highest progression risk group of patients. Together with Standardized outcome measures, the SRS guidelines make possible for the first time ever comparison of treatment methods. Since only the highest progression risk patients are studied, outcomes for all brace treatments are not as favourable as generally believed, however the first study in 2007 published in the Journal of Pediatric Orthopedics shows a very clear difference in outcome for three different treatment methods.

Comparison Studies

The treatments studied were:

SpineCor -a flexible dynamic brace developed 15 years ago

TLSO - (generic term for Boston type) rigid plastic spinal braces extensively used around the world for over 30 years

Providence - a relatively new night-time-only rigid plastic brace used by a small number of clinics in the United States

The results table below shows a dramatic difference in treatment outcomes, 15% success (by SRS definitions) with the most commonly used TLSO treatment versus 59% with the SpineCor dynamic corrective brace.

SCOLIOSIS CURVE	● TLSO	● PROVIDENCE	■ - SPINECOR
Correction/Stabilisation	15%	31%	59%
Progression over 6°	85%	69%	41%
Progression over 45°	56%	45%	1%
Progression to surgery	79%	60%	23%

● Janicki J A, Poe-Kochert C, Armstrong DG, Thompson GH. A comparison of the Thoracolumbosacral Orthosis and Providence Orthosis in the Treatment of Adolescent Idiopathic Scoliosis: Results using the New SRS Inclusion and Assessment Criteria for Bracing Studies. J Pediatr Orthop. 2007 Jun; 27(4):369-374.

■ Coillard C, Vachon V, Circo AB, 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 Jun; 27(4):375-379.

* Patients included in these studies range from 20° - 50° and Risser 0 - 3 or pre-menarché. Therapeutic success is defined according to the SRS definitions as either improvement (Cobb reduction of 6° or greater) and stabilization (Cobb increase of up to 5°).



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