

# Quality Control of Idiopathic Scoliosis Treatment in 147 Patients While Using the RSC® Brace

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## ABSTRACT

*The objective was to determine the primary correction of the Cobb angles of 147 idiopathic scoliosis subjects wearing the Rigo System Chêneau (RSC) brace. The RSC brace is a scoliosis brace that incorporates expansion and pressure areas to treat all aspects of the 3D scoliotic deformity not only in the frontal plane but also in the sagittal and transverse planes. RSC brace uses specific clinical and radiological classifications to define the most effective principles of correction. The experimental hypothesis predicted that those subjects who are treated with the RSC brace would report a significant primary correction of the major, minor, thoracic, and lumbar Cobb angles for both the main and Society of Scoliosis Orthopedic and Rehabilitation Treatment (SOSORT) restrictive criteria groups. The primary correction of main group was 43°, 42°, 48°, and 37° for thoracic, lumbar, major, and minor curve, respectively. The primary correction of SOSORT group was 54°, 59°, 61°, and 52° for thoracic, lumbar, major, and minor curve, respectively. The present experiment focused on the radiographic measurements of idiopathic scoliosis subjects before treatment and the primary correction with the RSC brace. The results are based on a sample size of 147 subjects in the main group and 25 subjects in the SOSORT (restrictive criteria) group. As a result, the RSC brace system had significant primary corrections in both the main and SOSORT groups. Because the initial in-brace radiographs presented with favorable results, it is predicted that the RSC brace prevents curve progression at the end of the treatment. (J Prosthet Orthot. 2011;23:69–77.)*

There are numerous different philosophies and design possibilities in the conservative treatment of idiopathic scoliosis (IS). Most important is that the goals of treatment are clearly defined. These are primarily to prevent the progression of the scoliotic deformity from the beginning to the end of the treatment.<sup>1</sup>

Many factors influence the course of treatment, which depends on the initial patient clinical presentation and orthosis compliance. Ultimately, the results by the completion of the growth phase should present a reduced Cobb angle and improved trunk, shoulder and pelvic alignments as well as the accompanying change in the clinical presentation. The name of a scoliosis orthosis and design does not always represent a particular standard. In practice, it is often seen that patients are fit with and delivered malfunctioning orthotic designs and shapes of well-known brands. Often these are paid by health insurance providers without adequate follow-up of fit and function. Although there is significant information available to patients and their families, they are often left completely on their own with the diagnosis and therapy. However, currently it has been recognized how important it is to provide adequate scoliosis information and a solid treatment plan for scoliosis physical therapy.

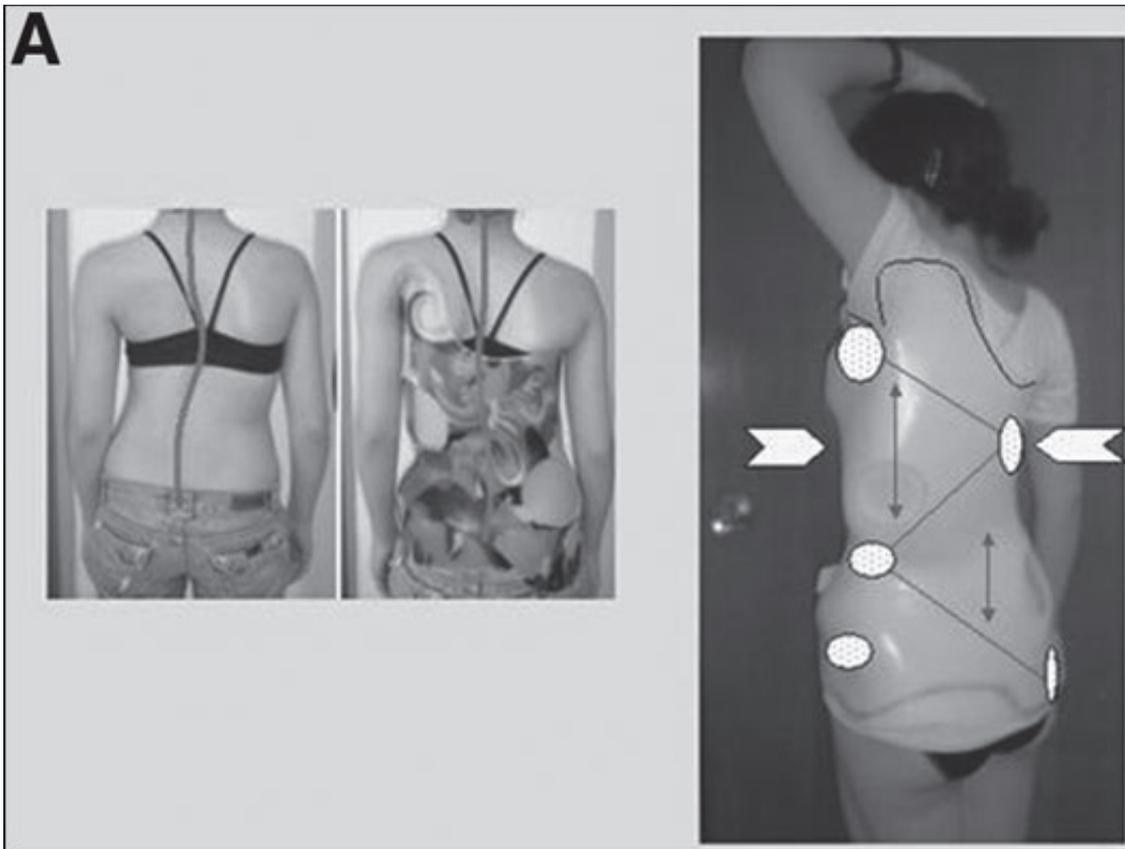
The number of patients presenting with immense aesthetic and psychological problems because of large curvatures and all the resulting pathological mechanisms at the end of their growth phase could be significantly reduced if a correct and, above all, timely diagnosis is made. Comprehensive support and communication should be provided to all interdisciplinary team members on the specific curve type, orthosis design, treatment protocol, and follow-up process. This would improve the specific physical therapy program designed for the patient and optimize the orthosis fitting and function as well as the follow-up process and orthosis adjustments.

## TREATMENT OF SCOLIOSIS

Scoliosis is a multifactorial deformity that affects all three body planes of the trunk and spine. It presents as lateral curvature with torsion of the spine and chest, often associated with abnormal sagittal profile, such as flatback.<sup>2</sup>

## RSC BRACE DESIGN, FUNCTION, AND CLASSIFICATION

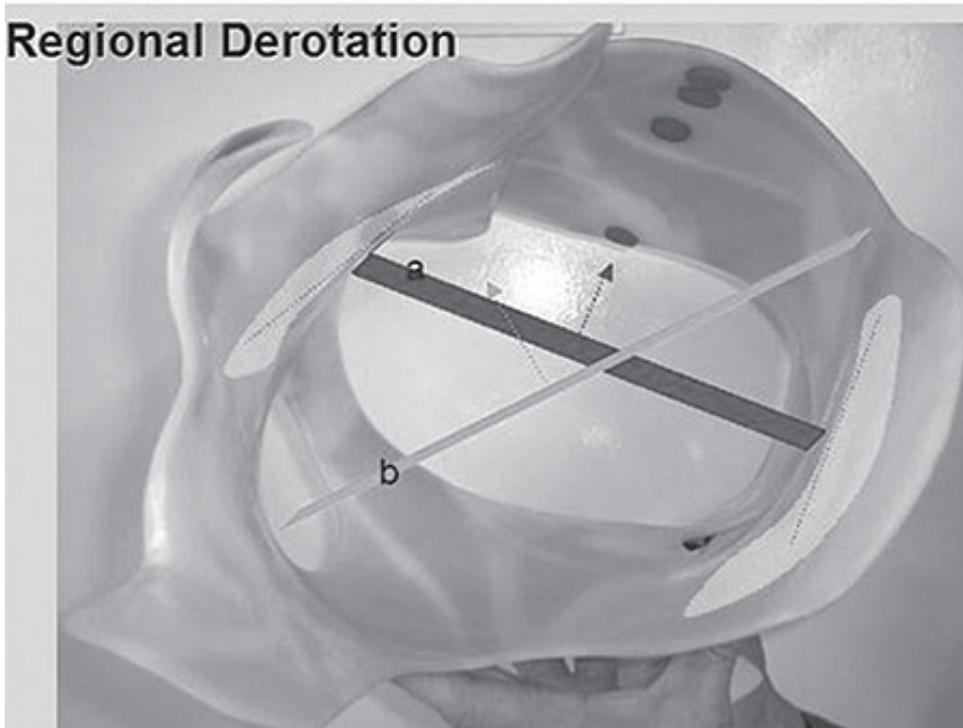
The general correction principle of scoliosis was that of detorsion and sagittal normalization, which would effectively correct the coronal plane, resulting in some elongation of the spine without any significant distraction force.<sup>3–6</sup> The Rigo System Chêneau (RSC) brace was designed to follow this principle by means of pressure zones and expansion zones, which derotated different parts of the trunk. Normalization of the sagittal profile was achieved from the derotation, because the spine was coupled to the ribs in the thoracic area, and in the lumbar area, it moved indirectly when the abdominal muscles were selectively pressed. The pressure zones were designed to provide corrective forces in the coronal and sagittal planes, acting as a three-point pressure system. Also, derotation was corrected in the transversal plane by pressure zones.<sup>7</sup> These three-dimensional pressure systems are illustrated further in Figure 1A, Figure 1B, and Figure 1C.



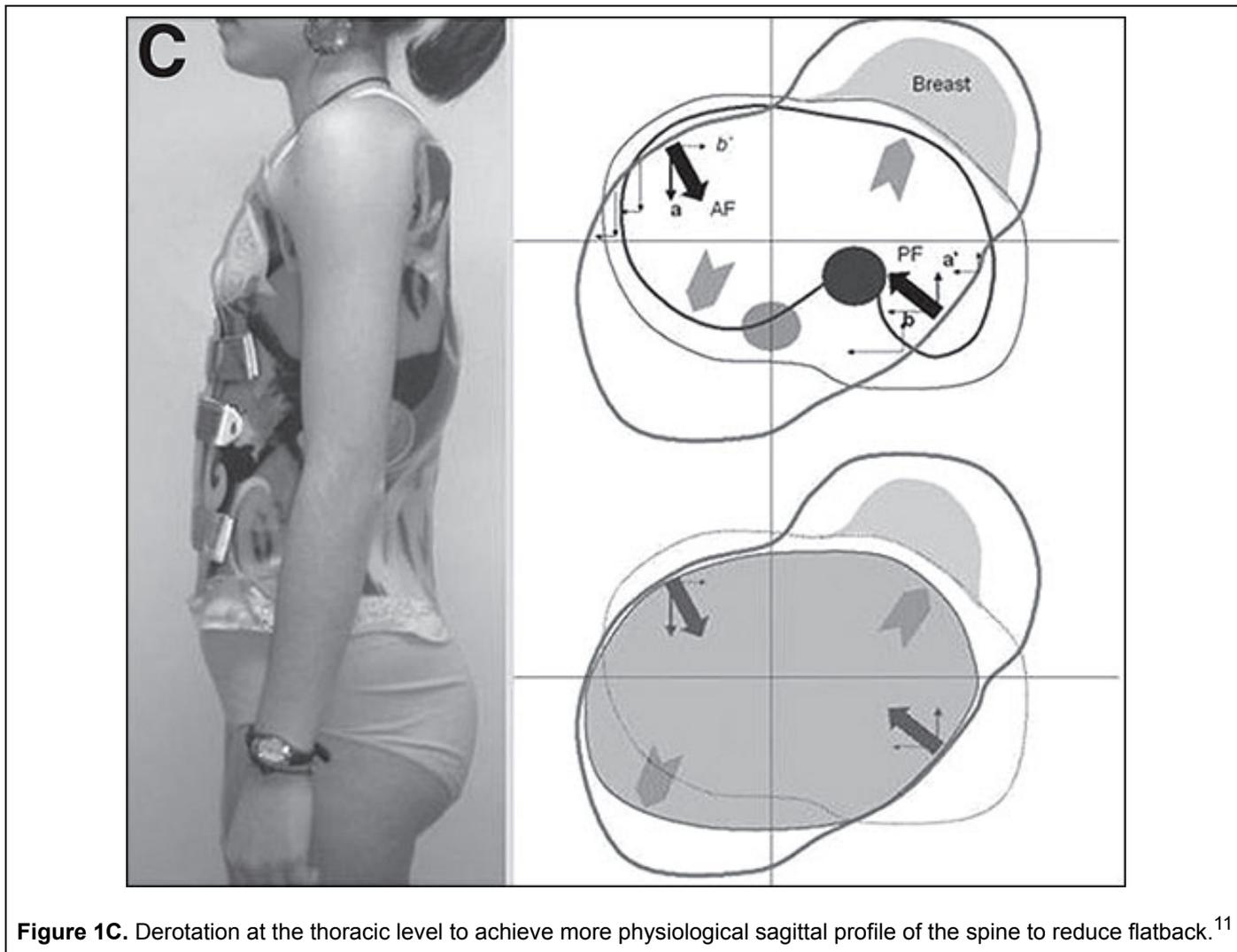
**Figure 1A.** Frontal plane alignment and correction with the Rigo System Chêneau (RSC) brace. Sagittal plane normalization and derotation are also achieved through elongation of the spine and ventral/dorsal pressure systems.<sup>1</sup>

## B

### Regional Derotation



**Figure 1B.** Derotation forces in the transverse plane acting at the thoracic (b) and lumbar (a) section. Note that there are large expansion areas that must be present for correction. In this particular case, there is a right ventral expansion space at the thoracic level and a left dorsal expansion space at the lumbar level.<sup>11</sup>



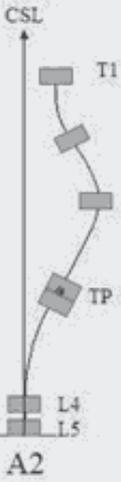
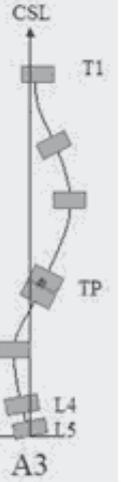
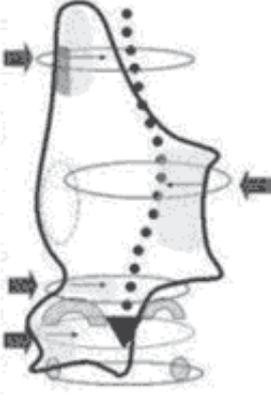
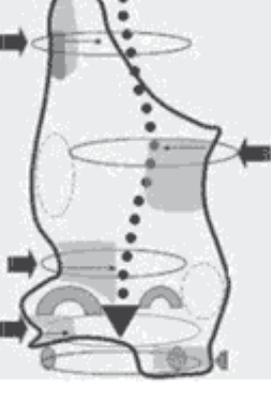
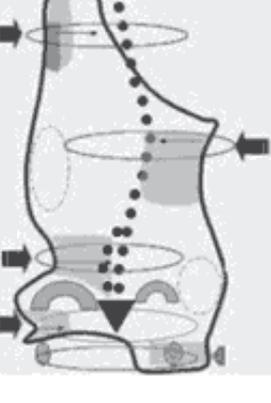
**Figure 1C.** Derotation at the thoracic level to achieve more physiological sagittal profile of the spine to reduce flatback.<sup>11</sup>

Currently, The Rigo classification is the only classification developed specifically for orthosis design, as opposed to other forms that adapted a classification that was developed initially for surgical decision making. This classification is used in conjunction with the design of the RSC brace, a derivative of the Chêneau brace.<sup>8-10</sup>

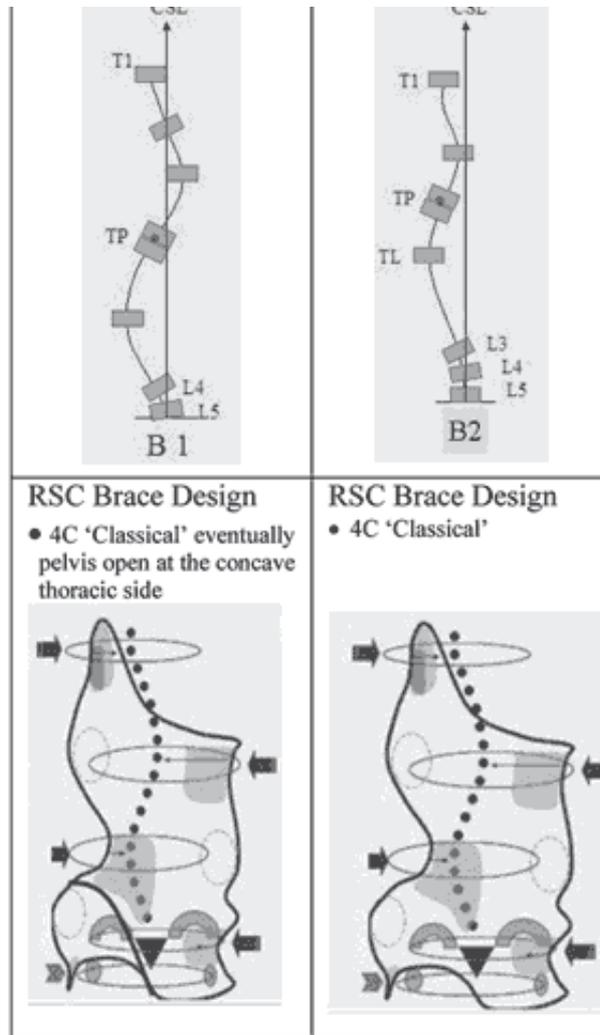
The specific design of the orthosis depends on the curve pattern observed in the frontal plane; however, the transverse and sagittal plane deformities are taken into consideration as well; therefore, the brace design is modified accordingly. Clinical and radiological criteria are evaluated to determine the curve pattern.<sup>8-10</sup> These curve patterns along with their criteria are illustrated in Figure 1D and Figure 1E .

**D**

A1	A2	A3
<b>Clinical Criteria</b> <ul style="list-style-type: none"> <li>• Pelvis translated to the concave thoracic side</li> <li>• Trunk imbalance to the convex thoracic side</li> <li>• Long thoracic rib hump going down into the lumbar region</li> </ul>	<b>Clinical Criteria</b> <ul style="list-style-type: none"> <li>• Pelvis translated to the concave thoracic side</li> <li>• Trunk imbalance to the convex thoracic side</li> <li>• Noticeable rib hump/no lumbar or minimal lumbar prominence</li> </ul>	<b>Clinical Criteria</b> <ul style="list-style-type: none"> <li>• Pelvis translated to the concave thoracic side</li> <li>• Trunk imbalance to the convex thoracic side</li> <li>• Noticeable rib hump/minor lumbar prominence</li> </ul>
<b>Radiological Criteria</b> <ul style="list-style-type: none"> <li>• Single long thoracic/fractioned lumbar</li> <li>• TP imbalance to the convex thoracic side</li> </ul>	<b>Radiological Criteria</b> <ul style="list-style-type: none"> <li>• Single thoracic/no or minimal functional lumbar</li> <li>• TP imbalance to the convex thoracic side</li> </ul>	<b>Radiological Criteria</b> <ul style="list-style-type: none"> <li>• Single major thoracic/lumbar minor</li> <li>• TP imbalance to the convex thoracic side</li> </ul>

<p><b>CONVEX THORACIC SIDE</b></p> <ul style="list-style-type: none"> <li>• T1 imbalance to the convex thoracic side</li> <li>• L4 horizontal or tilted to the convex side</li> </ul>	<p><b>CONVEX THORACIC SIDE</b></p> <ul style="list-style-type: none"> <li>• T1 imbalance to the convex thoracic side</li> <li>• L4 horizontal</li> </ul>	<p><b>CONVEX THORACIC SIDE</b></p> <ul style="list-style-type: none"> <li>• T1 imbalance to the convex thoracic side</li> <li>• L4 tilted to the concave thoracic side/negative L5-4 counter-tilting</li> </ul>
 <p>CSL T1 TP L4 L5 A1</p>	 <p>CSL T1 TP L4 L5 A2</p>	 <p>CSL T1 TP L4 L5 A3</p>
<p><b>RSC Brace Design</b></p> <ul style="list-style-type: none"> <li>• 3C 'Open pelvis on the convex thoracic side'</li> </ul> 	<p><b>RSC Brace Design</b></p> <ul style="list-style-type: none"> <li>• 3C 'Classical'</li> </ul> 	<p><b>RSC Brace Design</b></p> <ul style="list-style-type: none"> <li>• 3C 'Classical'</li> </ul> 

B1	B2
<p><b>Clinical Criteria</b></p> <ul style="list-style-type: none"> <li>• Pelvis translated to the convex thoracic side</li> <li>• Trunk imbalance to the concave thoracic side</li> <li>• Noticeable rib hump and lumbar or thoracolumbar prominence</li> </ul>	<p><b>Clinical Criteria</b></p> <ul style="list-style-type: none"> <li>• Pelvis translated to the convex thoracic side</li> <li>• Trunk imbalance to the concave thoracic side</li> <li>• Noticeable thoracolumbar prominence associated to a minor thoracic hump.</li> </ul>
<p><b>Radiological Criteria</b></p> <ul style="list-style-type: none"> <li>• Double thoracic and lumbar or thoracic and thoracolumbar</li> <li>• TP imbalance to the concave thoracic side</li> <li>• T1 imbalance to the concave thoracic side</li> <li>• Positive L5-4 counter-tilting</li> </ul>	<p><b>Radiological Criteria</b></p> <ul style="list-style-type: none"> <li>• Major thoracolumbar combined with a minor thoracic curve</li> <li>• TP imbalance to the concave thoracic side</li> <li>• T1 imbalance to the concave thoracic side</li> <li>• Positive L5-4 counter-tilting (often, positive L4-3 counter-tilting)</li> </ul>



**Figure 1D.** Rigo curve types and corresponding RSC brace design based on specific clinical and radiological criteria (A1, A2, A3, B1, and B2).<sup>8,9</sup>

**E**

C1	C2	E1	E2
<b>Clinical Criteria</b> <ul style="list-style-type: none"> <li>• Pelvis centered</li> <li>• Trunk balanced</li> <li>• Noticeable rip hump with lumbar spine rectilinear</li> </ul>	<b>Clinical Criteria</b> <ul style="list-style-type: none"> <li>• Pelvis centered</li> <li>• Trunk balanced</li> <li>• Noticeable rip hump combined with a noticeable lumbar prominence</li> </ul>	<b>Clinical Criteria</b> <ul style="list-style-type: none"> <li>• Pelvis translated to the concave lumbar side</li> <li>• Trunk imbalance to the convex lumbar side</li> <li>• Noticeable lumbar prominence with no thoracic hump</li> </ul>	<b>Clinical Criteria</b> <ul style="list-style-type: none"> <li>• Pelvis translated to the concave thoracolumbar side</li> <li>• Trunk imbalance to the convex thoracolumbar side</li> <li>• Noticeable thoracolumbar prominence with no thoracic hump</li> </ul>
<b>Radiological Criteria</b> <ul style="list-style-type: none"> <li>• Single thoracic with no lumbar curve</li> <li>• TP on CSL</li> <li>• T1 on CSL</li> </ul>	<b>Radiological Criteria</b> <ul style="list-style-type: none"> <li>• Thoracic major and lumbar minor or double thoracic and lumbar (false double)</li> <li>• TP on CSL</li> <li>• T1 on CSL</li> <li>• Negative L5-4 counter-tilting</li> </ul>	<b>Radiological Criteria</b> <ul style="list-style-type: none"> <li>• Single lumbar with no thoracic curve</li> <li>• TP imbalanced to the convex lumbar side according to CSL</li> <li>• T1 imbalanced to the convex lumbar side</li> </ul>	<b>Radiological Criteria</b> <ul style="list-style-type: none"> <li>• Single thoracolumbar with no thoracic curve</li> <li>• TP imbalanced to the convex thoracolumbar side according to CSL</li> <li>• T1 imbalanced to the convex thoracolumbar side</li> </ul>
<p>C1</p>	<p>C2</p>	<p>E1</p>	<p>E2</p>
<b>RSC Brace Design</b> <ul style="list-style-type: none"> <li>• Neutral pelvis</li> </ul>	<b>RSC Brace Design</b> <ul style="list-style-type: none"> <li>• Neutral pelvis</li> </ul>	<b>RSC Brace Design</b> <ul style="list-style-type: none"> <li>• Short lumbar brace</li> </ul>	<b>RSC Brace Design</b> <ul style="list-style-type: none"> <li>• Short thoracolumbar brace</li> </ul>

**Figure 1E.** Rigo curve types and corresponding RSC brace design based on specific clinical and radiological criteria (C1, C2, E1, and E2).<sup>8,9</sup>

Further description of the Rigo classification was outlined by Rigo et al.,<sup>8</sup> and RSC biomechanical brace principles were outlined by Rigo and Weiss.<sup>11</sup>

In 2010, Rigo et al. documented their findings on the intraobserver and interobserver reliability of the Rigo classification. Later, Wood<sup>9</sup> presented a detailed description of the Rigo classification and its reliability at the International Society for Prosthetics and Orthotics World Congress in 2010 in Leipzig, Germany.

## METHODS

## DESIGN

The experimental hypothesis predicted that those subjects who are treated with the RSC brace would report a significant primary correction of the major, minor, thoracic, and lumbar Cobb angles for both the main and Society of Scoliosis Orthopedic and Rehabilitation Treatment (SOSORT) restrictive criteria (RC) groups.<sup>12,13</sup>

## SUBJECTS

The main group consisted of 147 subjects with double curves ranging from 7° to 65° for the major Cobb angles and 1° to 60° for the minor Cobb angles. There were 17 male and 130 female subjects, age ranging from 5 to 15 years. The 147 subjects were diagnosed with progressive IS and were treated by using a RSC brace that involved a medical team collaboration between Manuel Rigo (MR) in Spain, Ortholutions in Germany, and the exclusive RSC brace treatment center.

The SOSORT (RC) group included only 25 subjects who were selected from the main 147 subjects after the selective criteria outlined by SOSORT was applied. The criteria limited subjects to only those who were female, were at least 10 years old, presented clinical signs of puberty, and had Cobb angles from a minimum 25° to maximum 35° with Risser sign of 0.<sup>12</sup>

## PROCEDURE

Each subject had radiographs taken before brace treatment and with the RSC scoliosis brace at the 6- to 8-week follow-up appointment. The radiographs taken 6 to 8 weeks after treatment were taken with the subject wearing the RSC brace (i.e., "in-brace" radiographs). The Cobb angles were measured from these radiographs for comparison to obtain the primary correction results.

The Cobb angles for the thoracic and lumbar curves were noted before brace treatment and at the first in-brace radiograph. Also, the data were analyzed to compare major and minor curves, depending on which curve was larger and more structural. Mean Cobb angle values and standard deviations were determined among the subjects for both the main group and the SOSORT (RC) group. From these results, the primary corrections were determined. A sample t-test was performed to determine the statistical significance of the results. The data were analyzed for both the main group of 147 subjects and the reduced SOSORT criteria group of 25 subjects.

## RSC SCOLIOSIS BRACE TREATMENT

The RSC® Management System is a patented method for producing computer-standardized custom-molded scoliosis orthoses for patients with scoliosis since 2001. This brace system is based off handmade molds from MR dating back from the early 1990s to the present. Treatment using a RSC brace involves a medical team collaboration among MR in Spain, Ortholutions in Germany, and the exclusive RSC brace treatment center. Dynamic measurements were taken with the patient in a corrected, extended posture. Also, static measurements were taken to establish an exact computeraided design and computer-aided manufacturing system (CAD/CAM) reproduction of an original Rigo brace.<sup>14</sup>

The individual curve pattern and brace design for each patient is personally selected by MR, based on the radiographs and clinical photographs (photographs of the morphology and clinical presentation) of the patient. The biomechanical design of every specific curvature model is retained to 100%. The curve pattern is classified according to the classification of Rigo. Next, the fabrication for each brace is custom made and drawn from an extensive library of CAD/CAM shapes of MR's own handmade molds. These custom-made RSC braces are sent to the RSC certified treatment centers and fitted directly by trained teams.

All stages of treatment, including clinical photographs with patient in and out of brace, radiographs, and team notes are posted on a secure database. The subsequent brace fittings, follow-up photographs, and in-brace radiographs are evaluated by MR and Ortholutions in collaboration with the RSC brace treatment center. This medical team approach optimizes the treatment and results. Complications and complex questions can also be discussed and clarified here at any time with the team of experts. Information and solutions to problems are communicated in a timely and straightforward manner. Through the communication platform, the system facilitates trained teams and optimizes treatment quality control through constant development in knowledge. The complete scoliosis bracing treatment protocol improves standards and reduces the number of bracing failures.

At this moment, patients treated with CAD/CAM RSC braces in Germany have shown similar in-brace correction in comparison with those treated with handmade orthoses from the original author of the brace, MR, as reported at SOSORT in Montreal.<sup>15</sup> These RSC scoliosis braces are delivered only by certified treatment centers or fitted by the manufacturer himself. The brace treatment system is integrated into an internationally established physiotherapy program, the Barcelona Scoliosis Rehabilitation School concept, which was developed by MR and is based on the teaching of Katharina Schroth and Christa Lehnert-Schroth. This method also includes modifications from a French school.<sup>16</sup>

### *Measurements and Clinical Photographs*

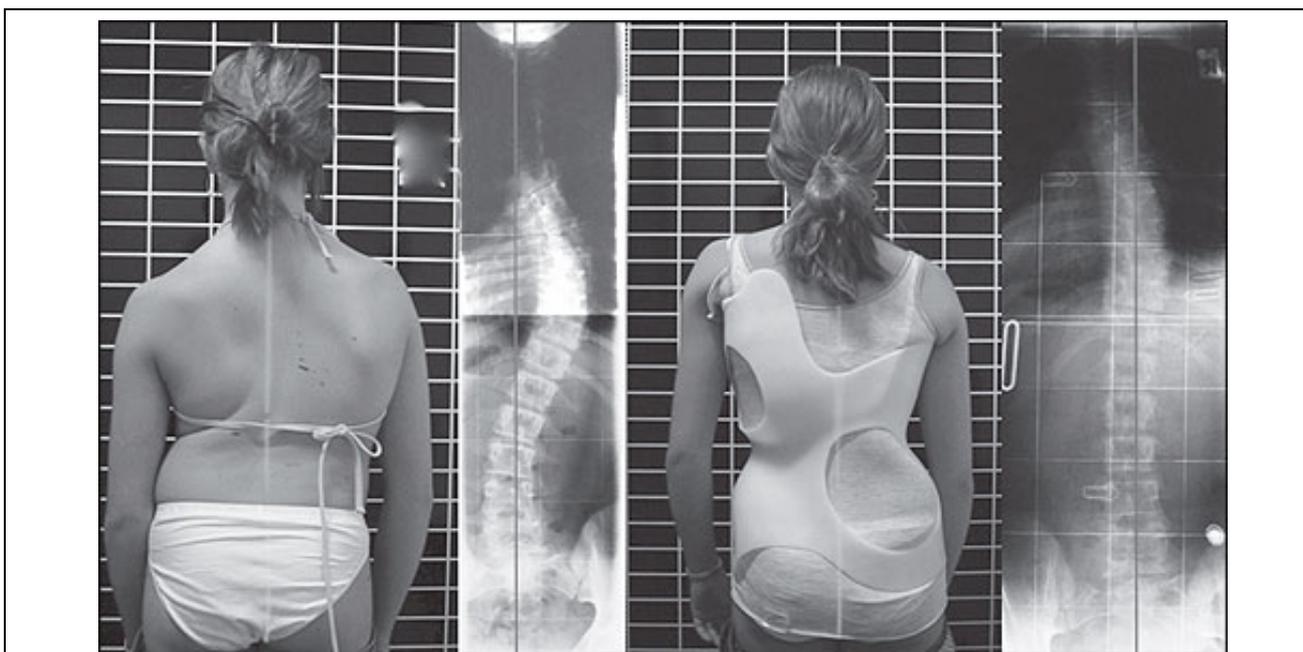
At least four clinical photographs (four clinical views) are required for the clinical documentation of each patient during the

measurement process, fitting, and follow-up visits. This is facilitated by using the Otto Bock LASAR posture apparatus to identify the pelvic, trunk, and shoulder alignments.

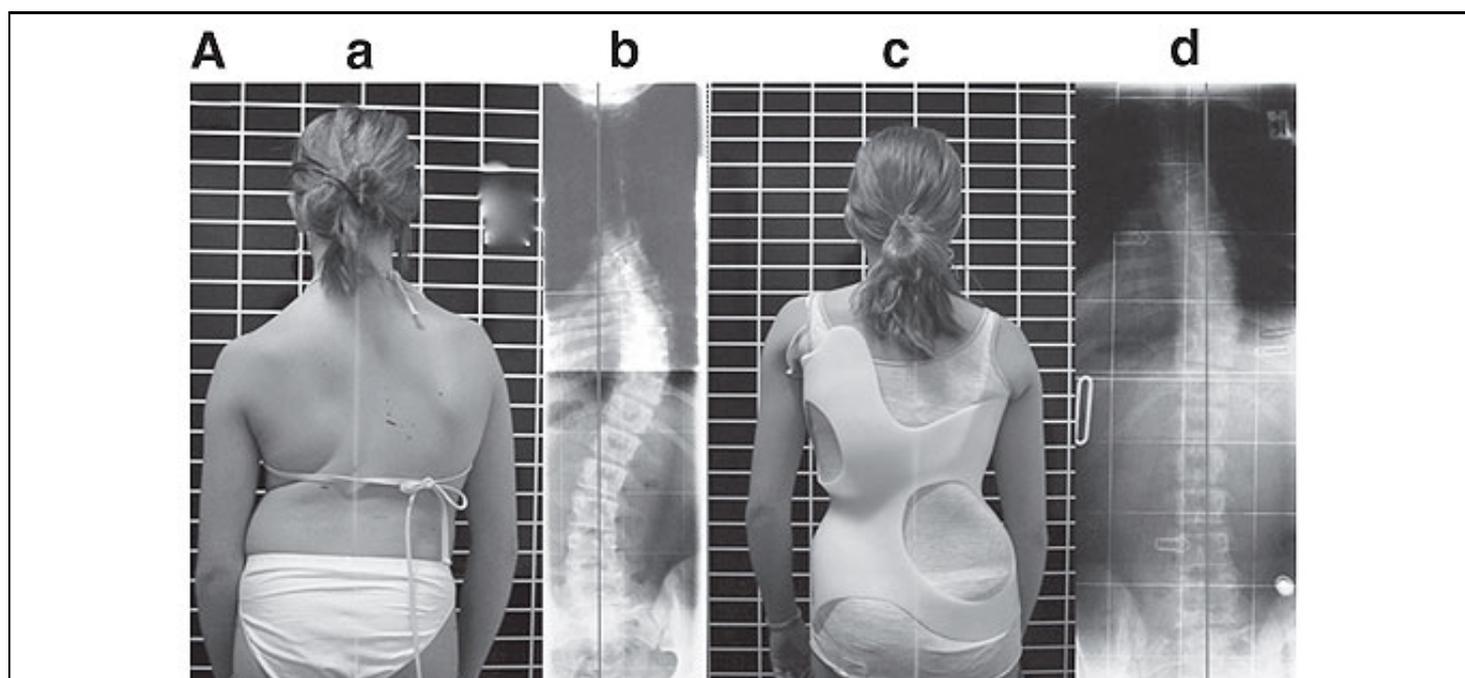
### BRACE DESIGN

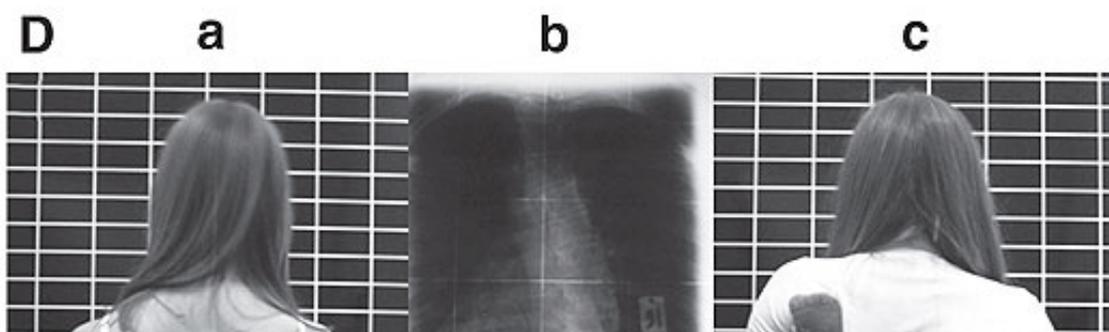
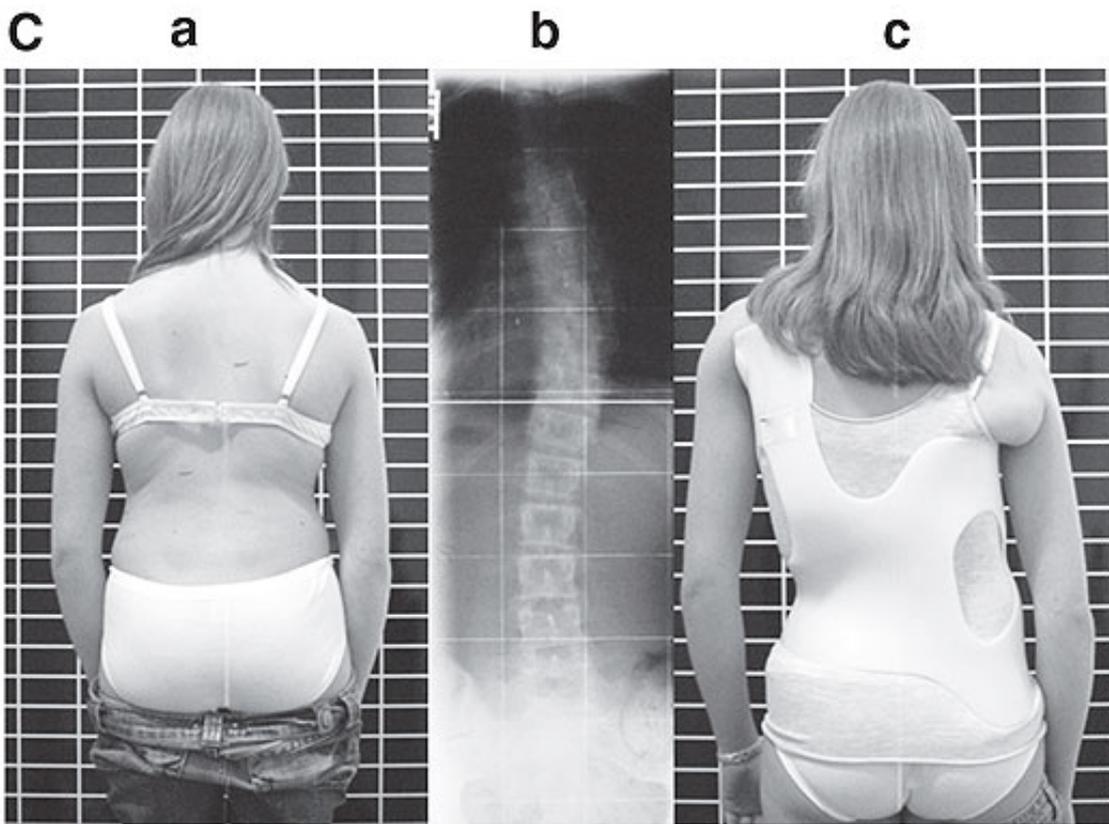
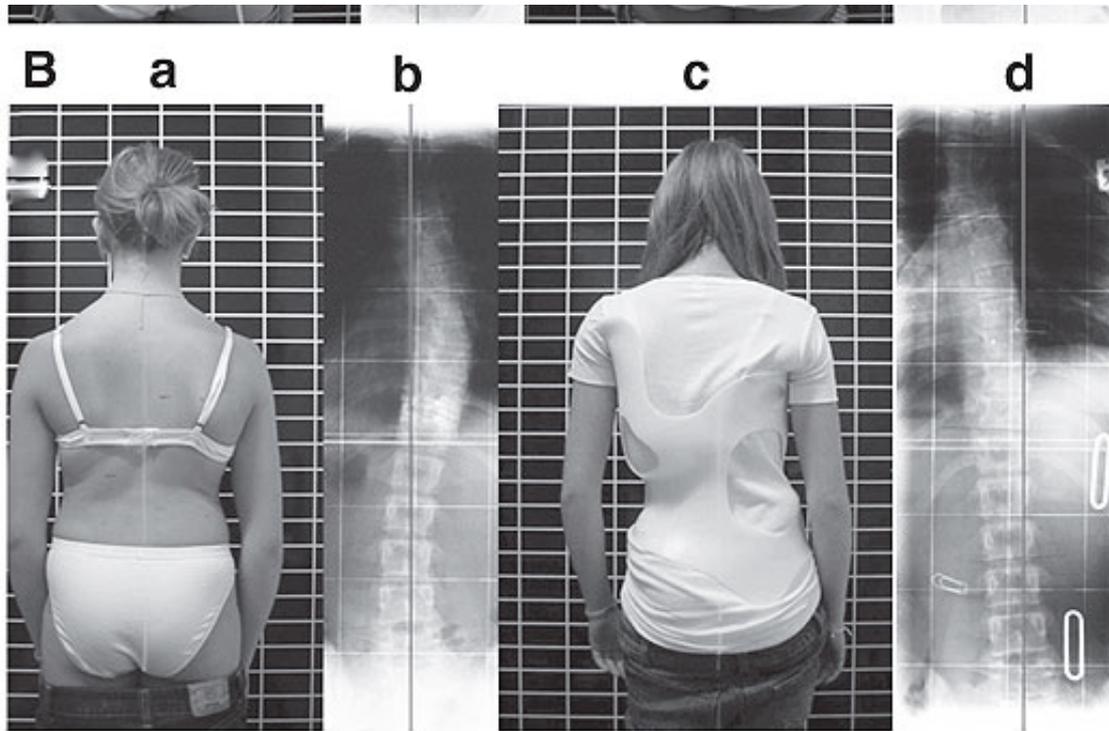
The RSC braces for the subjects in this study were based on the original brace principles outlined in the RSC Brace Design, Function, and Classification section. However, each subject in this study was assessed and evaluated individually; hence, the brace design was based on the individual characteristics of the subjects' scoliosis. As an example of the thought process in how the brace is designed, subject 1 in the brace design section is provided to show how the scoliotic curves can change and how the appropriate RSC design needs to change accordingly.

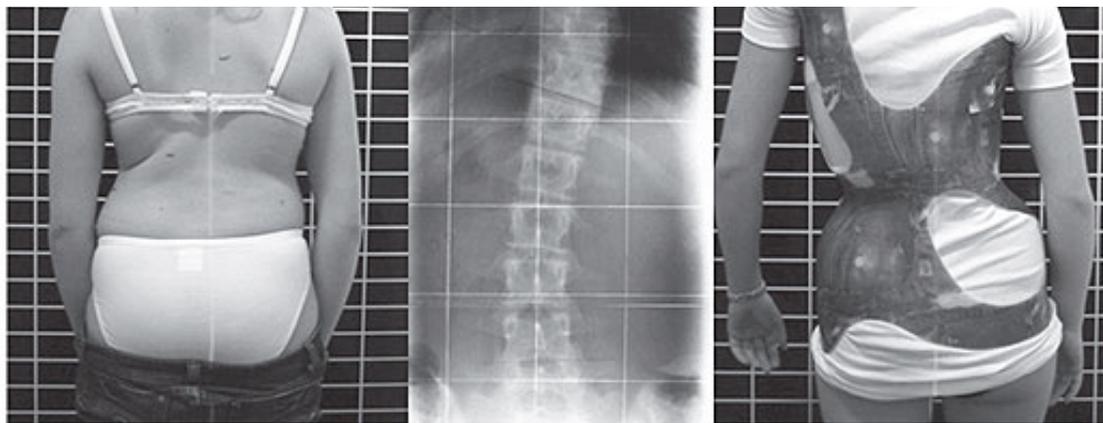
Subject 1 presents with a three-curve scoliosis, type A2 according to the Rigo classification of scoliosis ( Figure 2 ). The Cobb angle of the main thoracolumbar curvature was 49° before the start of treatment. The trunk imbalance was to the convex thoracic side with the collapse of the vertebral column on the concave side of the thoracic curve, and as a result, the shoulder was lower. The dorsal right and ventral left rib humps can be seen clearly in the clinical presentation. In reference to the central sacral line, which is a vertical line from the center of the sacrum, the overhang is to the right, and the prominence of the pelvis is presented on the left ( Figure 3Aa and Figure3Ab ).



**Figure 2.** Subject 1 presents with a three-curve scoliosis, type A2 according to the Rigo classification of scoliosis.







**Figure 3.** (A) Posterior view of subject 1. (a) Prebrace clinical photograph. (b) Prebrace radiograph of 49° Cobb angle. (c) In-brace photo of patient wearing an A2 module Rigo System Chêneau (RSC) brace at 6-week follow-up. (d) In-brace radiograph presents with 24° Cobb angle at the 6-week follow-up. (B) Posterior view of subject 1 at the 8-month follow-up. (a) The clinical photograph shows an aligned and balanced clinical presentation. (b) Out-of-brace radiograph of 35° Cobb angle. (c) In-brace photograph of the patient wearing a C1 module RSC brace. (d) In-brace radiograph presents with 18° Cobb. (C) Posterior view of the subject 1 at the 15-month follow-up. (a) The clinical photograph shows an aligned and balanced clinical presentation. (b) Out-of-brace radiograph of 37° Cobb angle, C1 type curve. (c) In-brace photograph of the patient wearing RSC brace. (D) Posterior view of subject 1 at the 27-month follow-up. (a) The clinical photograph shows an aligned and balanced clinical presentation. (b) Out-of-brace radiograph of 37° Cobb angle, A2 type curve. (c) In-brace photograph of the patient wearing RSC brace.

The orthosis corrects the collapsed thoracic concave side by the three-point pressure system in the coronal plane, producing the so-called mirror effect ( Figure 3Ac ). The patient is overcorrected to the left by the orthosis, the vertebral column is straightened also, and the ventral left rib hump is reduced. To open the collapsed thoracic concave side and to establish the three-dimensional correctional mechanism, the shoulder of the thoracic concave side in type A2 curvatures (triple curvature) needs to be raised by the brace construction. The main thoracic curvature is corrected in the brace to a Cobb angle of 24°. The radiograph of the position in the orthosis shows that the ribs on the concave thoracic side are distinctly more "opened" than beforehand, and the central sacral line shows that the overhang to the right has been eliminated through the brace ( Figure 3Ad ).

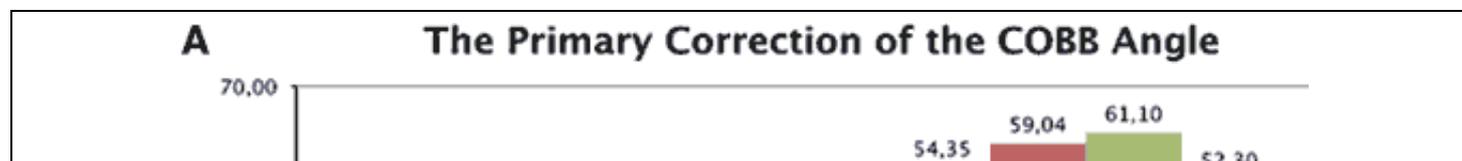
Subject 1 presents at the 8-month follow-up with improved symmetry of the trunk, and as a result, the collapse of the thoracic concave side is significantly reduced, and the shoulder position is balanced ( Figure 3Ba ). The out-of-brace radiograph shows a Cobb angle of 35° ( Figure 3Bb ), which has improved and corrected the position of the ribs in the concave area of the thoracic curvature.

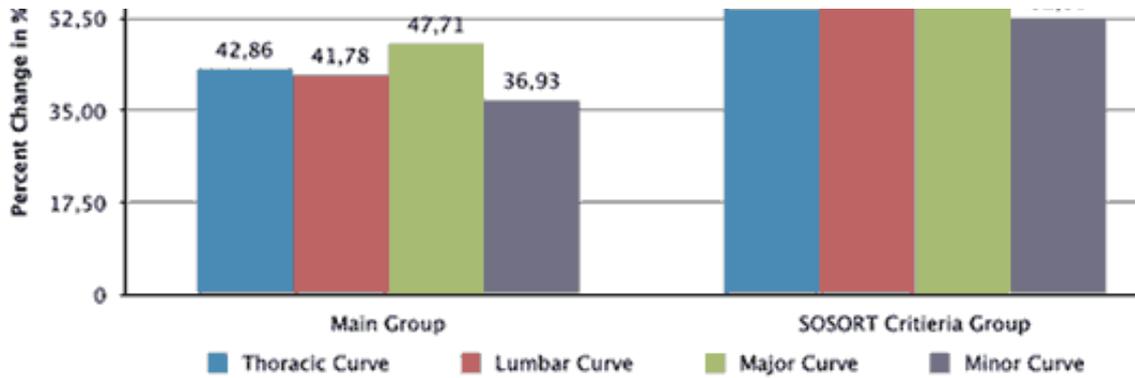
Also, it was noted that the curve pattern has changed from A2 type to C1 type curve pattern. Thus, the orthosis design was also changed from an A2 module RSC brace to a C1 module RSC brace. As a result of this curve pattern change, the correctional principles do not require displacement of the pelvis; instead a central stabilization can be seen. In comparison with the preceding A2 brace module, the left shoulder is not raised as much. This is because the collapsed thoracic concave side has improved and opened the right thoracic curve.

The laser line on the patient and the radiograph shows a slight decompensation to the left, caused by the varying stiffness of the curvatures and the correctional pressure of the scoliosis orthosis. The main curvature is corrected to an 18° Cobb angle in the RSC brace ( Figure 3Bc and Figure 3Bd ). Both the clinical presentation and the radiograph findings show a stable condition after 15 months (Figures 3Ca and b). The body alignment is almost in equilibrium. The Cobb angle of curvature is 37° without the orthosis ( Figure 3Cb ). The patient continues treatment with a C1 type brace module.

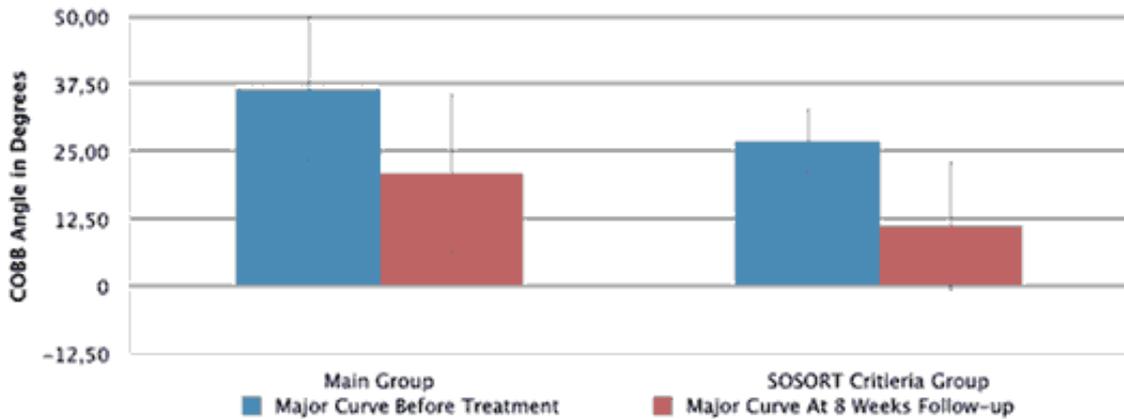
As seen in Figure 3Cc , the left axillary pad has again been raised somewhat to deflect the thoracic curvature even more. It can be seen clearly that the brace, through the three-point pressure system in the coronal plane (axillary pad, thoracic pad, and lumbar pad), reduces the rib hump and produces the accompanying overcorrecting postural deflection ( Figure 3Cc ).

A slightly worsened clinical situation presents 27 months later ( Figure 4 ). The pelvis projects noticeably more on the left, likewise involving a more noticeable collapse of the thoracic concave side. An observation of the shoulder girdle shows that the left shoulder has sunk down somewhat in comparison with Figure 3Ca .

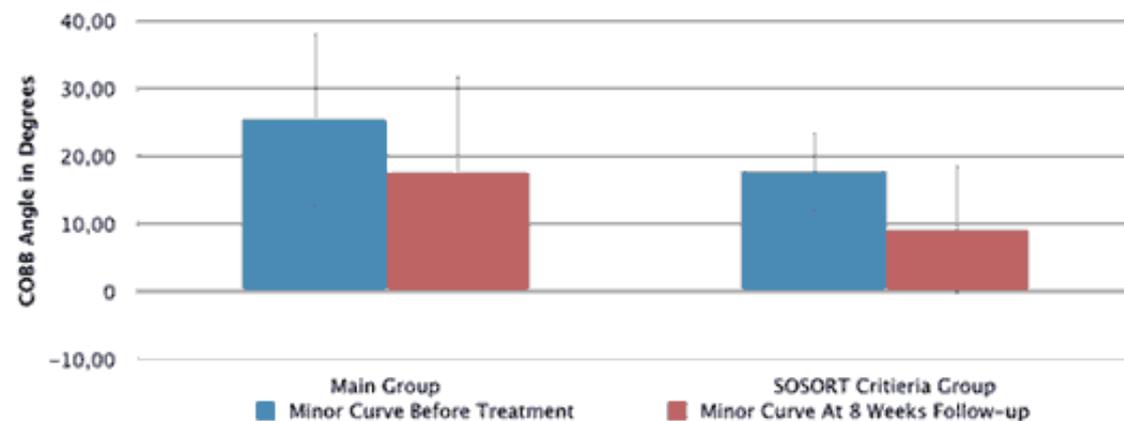




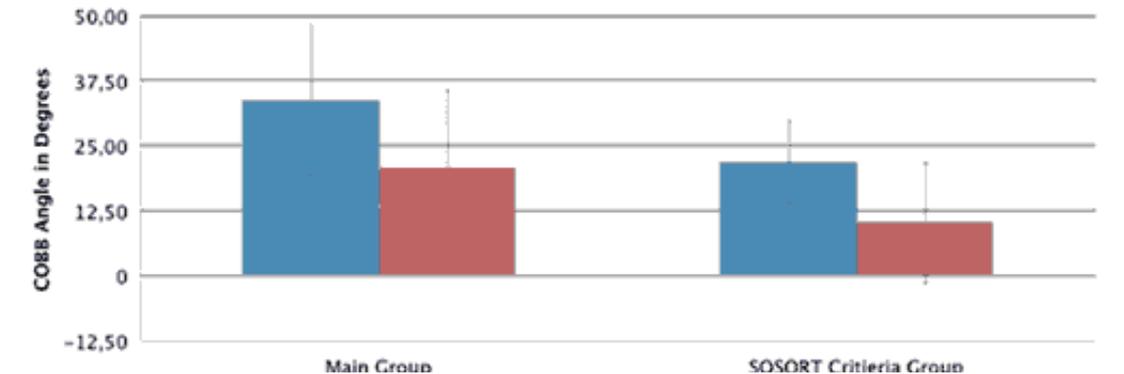
**B Major Curve COBB Values Before Treatment and at 8 Weeks Follow-Up**

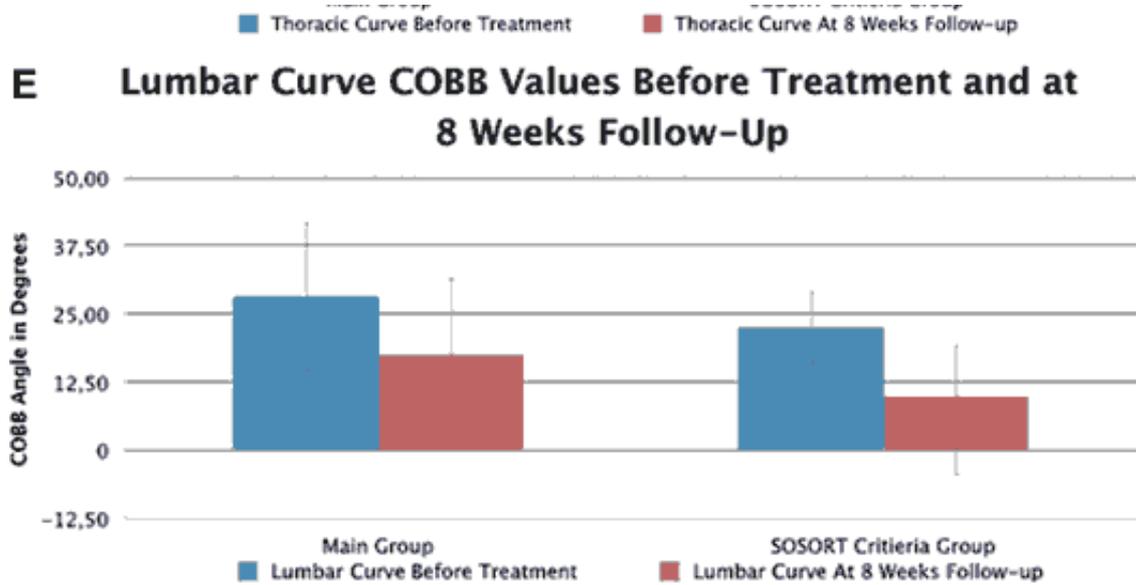


**C Minor Curve COBB Values Before Treatment and at 8 Weeks Follow-Up**



**D Thoracic Curve COBB Values Before Treatment and at 8 Weeks Follow-Up**





**Figure 4.** (A) The major, minor, thoracic, and lumbar curves' primary correction of the Cobb angles with the Rigo System Chêneau (RSC) brace. The primary correction of main group was 43°, 42°, 48°, and 37° for thoracic, lumbar, major, and minor curve, respectively. The primary correction of Society of Scoliosis Orthopedic and Rehabilitation Treatment group was 54°, 59°, 61°, and 52° for thoracic, lumbar, major, and minor curve, respectively. (B) The major Cobb angle measured from the radiograph before treatment and at the 6- to 8-week follow-up (primary correction) with the RSC brace. (C) The minor Cobb angle measured from the radiograph before treatment and at the 6- to 8-week follow-up (primary correction) with the RSC brace. (D) The thoracic Cobb angle measured from the radiograph before treatment and at the 6- to 8-week follow-up (primary correction) with the RSC brace. (E) The lumbar Cobb angle measured from the radiograph before treatment and at the 6- to 8-week follow-up (primary correction) with the RSC brace.

The radiograph confirms the new situation. Although the Cobb angle remains unchanged at 37°, the curve pattern has changed ( Figure 3Db ) and correlates again with the situation at the beginning of treatment (changed from a C1 type to an A2 type curve pattern according to the Rigo classification). Therefore an A2 module RSC brace was designed and fabricated for the patient. The shift of the pelvis to the right and the deflection of the thoracic segment produce the required postural overcorrection (mirror effect). At the beginning of treatment, the marked deformities of the vertebrae and ribs can be seen clearly on the radiograph in Figure 3Ab . The progression of the structural deformity of the ribs and vertebra of the thoracic curvature has been corrected. These orthoses modules have neutralized the unbalanced axial forces acting on the vertebrae and, thus, made it possible for the bony structures to grow more evenly.

## RESULTS

The main group (n = 147) and the SOSORT (RC) group (n = 25) had a mean age of 12.97 and 12.32 years, respectively ( Figure 5 ). The main group had 28 subjects with Cobb angles greater than 50° with 17 male and 130 female subjects. The SOSORT (RC) group had no curves over 50° and were all females, as outlined by SOSORT (RC).<sup>12</sup> The significance level for all the angles measured was  $p < 0.01$ .

**A Main Group**

		mean	standard deviation	percent change
Thoracic Cobb Angle	before treatment	33.70	14.59	42.86%
	8 week follow-up	20.77	14.91	
Lumbar Cobb Angle	before treatment	28.18	13.71	41.78%
	8 week follow-up	17.47	14.02	
average % change:				42.32%

		mean	standard deviation	percent change
Major Cobb Angle	before treatment	36.52	13.31	47.71%
	8 week follow-up	20.82	14.59	
Minor Cobb Angle	before treatment	25.28	13.00	36.93%
	8 week follow-up	17.41	14.35	
average % change:				42.32%

**B SOSORT Criteria Group**

		mean	standard deviation	percent change
Thoracic Cobb Angle	before treatment	21.88	8.20	54.35%
	8 week follow-up	10.32	11.83	
Lumbar Cobb Angle	before treatment	22.52	6.72	59.04%
	8 week follow-up	9.76	9.70	
average % change:				56.70%

		mean	standard deviation	percent change
Major Cobb Angle	before treatment	26.76	5.95	61.10%
	8 week follow-up	11.12	11.92	
Minor Cobb Angle	before treatment	17.64	5.83	52.30%
	8 week follow-up	8.96	9.47	
average % change:				56.70%

**Figure 5.** (A) The main group before treatment (initial) and at 8-week follow-up (primary correction) mean values, standard deviations, and percent change for the thoracic, lumbar, major, and minor Cobb angles. (B) The Society of Scoliosis Orthopedic and Rehabilitation Treatment (restrictive criteria) before treatment (initial) and at 8-week follow-up (primary correction) mean values, standard deviations, and percent change for the thoracic, lumbar, major, and minor Cobb angles.

## DISCUSSION

The results are consistent with the experimental hypothesis: those subjects who were treated with the RSC brace reported a significant primary correction of the major, minor, thoracic, and lumbar Cobb angles for both the main and SOSORT (RC) groups.

When the subject's radiograph values were measured for the main group (n = 147), the means were 36.52° and 20.82° before treatment and primary correction, respectively, for the major Cobb angles and 25.28° and 17.41° before treatment and primary correction, respectively, for the minor Cobb angles. The in-brace primary corrections for the major and minor Cobb angles were 47.71% and 36.93%, respectively, for the main group. The in-brace primary corrections for the thoracic and lumbar Cobb angles were 42.86% and 41.78%, respectively, for the main group.

When the subject's radiograph values were measured for the SOSORT group (n = 25), the means were 26.76° and 11.12° before treatment and primary correction, respectively, for the major Cobb angles and 17.64° and 8.96° before treatment and primary correction, respectively, for the minor Cobb angles. The in-brace primary corrections for the major and minor Cobb angles were 61.10% and 52.30%, respectively, for the SOSORT group. The in-brace primary corrections for the thoracic and lumbar Cobb angles were 54.35% and 59.04%, respectively, for the SOSORT group. The standard error in the experiment was small; hence, it did not affect the results.

The primary in-brace correction results were obtained at the 8-week follow-up, and these results can be related to the end of treatment results. Therefore, because the initial in-brace radiographs presented with favorable results, it could be predicted that the RSC brace prevents curve progression at the end of treatment. The main group of subjects were older, had higher Risser

signs, and had larger initial curves, which were more structural and difficult to correct compared with the SOSORT group.

The rationale of presenting the two groups of subjects was to show that even though the main group of subjects were clinically and radiological more difficult to treat, they still had significant primary corrections. The SOSORT group of patients had the most significant primary corrections of 61.10% and 52.30% for the major and minor curves, which was related to the strict RC that limited and controlled the subject types.

Conventionally, excellent scoliosis correction was considered when the vertebral column in the coronal plane had a 50% correction and was as close as possible to vertical. However, often significant in-brace primary correction of the Cobb has been achieved at the cost of having negative effects to the sagittal plane by increasing the thoracic hypokyphosis, also known as flatback and without regard for the rotational correction. The three-dimensional deformity of scoliosis needs to be evaluated and treated in all three anatomical planes. When more influence is put on the sagittal plane and rotational correction, the coronal plane deformity, however, does not become less important, as the coronal radiograph is still considered as a standard good correction.<sup>7</sup> However, it would be disadvantageous to flatten out and straighten the spine in all planes (sandwich effect) simply to achieve maximum Cobb angle correction in the coronal plane. As radiologically good correction of the Cobb angle has often been the medical team's primary focus, oftentimes this places a negative influence on the other planes, resulting in deformities such as flatback and poor clinical presentation of pelvis, trunk, and shoulders.

## CONCLUSION

The present experiment focused on radiograph measurements of IS subjects before treatment and the primary correction with the RSC brace. The results are based on a sample size of 147 subjects in the main group and 25 subjects in the SOSORT (RC) group. As a result, the RSC brace system had significant primary corrections in both the main and SOSORT groups. Because the initial in-brace radiographs presented with favorable results, it is predicted that the RSC brace prevents curve progression at the end of treatment.

Further investigation is then warranted to analyze the RSC brace with matched samples to determine whether the orthosis corrections are the same in different teams using this system, as this study has been conducted from a matched series from teams in Barcelona and Germany. Furthermore, a long-term follow-up of results would be ideal to determine the results at the end of treatment, rather than just at the first follow-up appointment 6 to 8 weeks into treatment.

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