

## Brace treatment during pubertal growth spurt in girls with idiopathic scoliosis (IS): A prospective trial comparing two different concepts

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### Abstract

**Study design:** Prospective comparison of the survival rates of two different bracing concepts with respect to curve progression and duration of treatment during pubertal growth spurt in two cohorts of patients followed up prospectively.

**Objectives:** To determine whether the results obtained by the use of a soft brace (SpineCor) is comparable to the results of the Chêneau derived TLSO during pubertal growth spurt.

**Background data:** In recent peer reviewed literature, the SpineCor is described as an effective method of treatment for patients with scoliosis. However, until now, no controlled study has been presented comparing the results obtained with this soft brace to a sample treated with other bracing concepts proven effective.

**Methods:** Twelve patients with Cobb angles between 16–32° during pubertal growth spurt are presented as a case series treated with the SpineCor. The survival rate of this sample is described and compared to a matched group of patients treated with the Chêneau brace of the same age group. All girls treated in both studies were pre-menarchial with the first clinical signs of maturation (Tanner 1–3).

**Results:** During the pubertal growth spurt, most of the patients (11/12) with SpineCor progressed clinically and radiologically as well (at least 5°). Progression could be stopped changing SpineCor to the Chêneau brace in most of the samples described (7/10). The average Cobb angle at the start of treatment with the SpineCor was 21.3°, after an average observation time of 21.5 months, 31°. The control sample, primarily treated with the Chêneau brace ( $n = 15$ ), showed at average no progression. Cobb angle at the start of treatment was 33.7° and after the observation time of 37 months, 33.9°. Radiological improvements can be reported for some of the cases (3/15) as well as progressions (3/15). At 24 months of treatment time, 73% of the patients with a Chêneau brace and 33% of the patients with the SpineCor where still under treatment with their original bracing concept, at 42 month follow-up time 80% of the patients with Chêneau braces and 8% of the patients with the SpineCor survived with respect to curvature progression. The differences of the proportions statistically where highly significant.

**Conclusions:** The SpineCor does not change natural history of idiopathic scoliosis during the pubertal growth spurt. The use of the Chêneau brace seems to do so. Oncoming studies with the aim to test the efficiency of braces should be based on samples at immediate risk for progression (only girls with first signs of maturation but pre-menarchial).

**Keywords:** *Idiopathic scoliosis, brace treatment, SpineCor, Chêneau brace, RSC-brace, outcome.*

**Diseño del estudio:** Comparación prospectiva de la relación de sobre vivencia de dos conceptos ortésicos diferentes en relación a la progresión de la curva y a la duración del tratamiento durante el brote de crecimiento puberal en dos grupos de pacientes, a los cuales se les hizo seguimiento en forma prospectiva.

**Objetivos:** Determinar si los resultados obtenidos con el uso de la órtesis suave (SpineCor) son comparables con los resultados de la órtesis Chêneau derivada TLSO durante el brote de crecimiento puberal.

**Antecedentes:** En las revisiones realizadas por especialistas en el tema en forma reciente de la literatura médica, el SpineCor se describe como un método efectivo de tratamiento para pacientes con escoliosis. Sin embargo hasta ahora no ha sido presentado un estudio controlado que compare los resultados obtenidos con la órtesis suave en relación a una muestra tratada con otros conceptos ortésicos que han probado ser efectivos.

**Métodos:** Pacientes (12) con ángulos de Cobb entre 16 y 32 grados durante el brote de crecimiento puberal son presentados como una serie de casos tratados con SpineCor. El rango de sobre vivencia de esta muestra es descrita y comparada en relación a un grupo pareado de pacientes tratados con la órtesis Chêneau del mismo grupo de edad. Todas las niñas tratadas en ambos estudios se encontraban en edad premenstrual con los primeros signos clínicos de maduración (Tanner 1-3).

**Resultados:** Durante el brote de crecimiento puberal la mayoría de los pacientes (11/12) con SpineCor progresaron tanto clínicamente como radiológicamente (por lo menos 5 grados). La progresión pudo ser detenida cambiando el SpineCor por una órtesis Chêneau en la mayoría de la muestra descrita (7/10). El promedio del ángulo de Cobb al inicio del tratamiento con el SpineCor fue de 21.3 grados, después de una observación promedio de 21.5 meses fue de 31 grados. La muestra de control primariamente tratada con la órtesis de Chêneau ( $n = 15$ ) no mostró en promedio progresión alguna. El ángulo de

Cobb al inicio del tratamiento fue de 33.7 grados, y después del tiempo de observación de 37 meses fue de 33.9 grados. Alguna mejoría radiológica puede ser reportada para algunos de los casos (3/15) así como progresiones (3/15). A los 24 meses del tiempo de tratamiento, 73% de los pacientes con la órtesis de Chéneau y 33% de los pacientes con el SpineCor se encontraban aún bajo tratamiento con el concepto ortésico original, a los 42 meses del tiempo de seguimiento 80% de los pacientes con las órtesis de Chéneau y 8% de los pacientes con el SpineCor sobre vivieron en relación a la progresión de la curvatura. Las diferencias de las proporciones fueron altamente significativas en forma estadística.

*Conclusiones:* El SpineCor no cambia la historia natural de la escoliosis idiopática durante el brote de crecimiento puberal. El uso de la órtesis de Chéneau sí parece hacerlo. Estudios futuros con la meta de evaluar la eficiencia de las órtesis deberán estar basados en muestras que se encuentren en riesgo inmediato de progresión (niñas solamente con los primeros signos de maduración pero en edad premenstrual).

## Introduction

The outcome after treatment of patients with idiopathic scoliosis (IS) with the help of certain bracing concepts support the hypothesis that brace treatment has to be regarded as effective [1–5]. The Boston brace has proven effective in preventing progression [1,4], but in the international literature there is no evidence that Boston brace treatment can lead to improvements of Cobb angle and cosmesis at the same time. Cosmetic improvements have been documented for Chéneau braces of the latest standard [6] as well as for the Rigo-System Chéneau brace (RSC-brace) [7].

The effectiveness of brace treatment depends on the treatment time/day. Night-time bracing has not been proven effective in meta-analysis [8] nor in controlled trials [9]. However, aggressive marketing is performed for night-time braces with the help of uncontrolled studies [10–12].

Goldberg *et al.* [13] have reported that incidence of surgery is not significantly reduced by American strategies of bracing. Neither Milwaukee braces nor the American TLSO underarm braces have had a significant impact on the incidence of surgery when compared to an untreated control group from Ireland.

In central Europe, however, the excellence of brace construction seems different. In a review of the literature, it has been shown that the initial correction in braces applying European standards is much greater than the initial corrections in American braces [2].

As early as 1985, Hopf and Heine [5] have shown that an improvement of the Cobb angle can be achieved with the Chéneau brace correcting >40% initially. Landauer [3] has demonstrated that a correction effect of more than 40% in the Chéneau brace leads to an improvement of the Cobb angle, of on average 7°, in the compliant patient in the long term (2 years after weaning).

Three retrospective analyses of the incidence of surgery were undertaken for patients with scoliosis treated conservatively, by comparison with incidence in an untreated control group. Two studies from central Europe [14,15] and one study from

Japan [16] matched to the control study (incidence of surgery of 28.1%) and presented surgery rates of 5–7%. One of the studies included a worst case analysis including all drop-outs as failures [15]. Statistically, comparing the rate of surgery untreated vs. conservative treatment (physiotherapy and braces when indicated), the differences found were highly significant in all three studies [14–16].

Soft braces have been developed to improve wearing comfort and compliance. The Olympe Brace [17] and the St Etienne Brace [18] have to be named applying the classical three-point correction principles in a soft way. In the 1990s, another ‘soft brace’ came up: Coillard and Rivard [19] introduced the SpineCor which, however, had a German precursor in the 19th century, published in the book of Schanz [20] (Figure 1). Schanz cites Fischer as the source of the figure; however, no further reference is given.

The SpineCor is described as follows: The SpineCor resembles a non-rigid harness and was developed at Sainte-Justine Hospital between 1992–1993. It consists of a pelvic base, which is a belt that includes three pieces of soft thermodeformable plastic stabilized by two thigh bands and two crotch bands, a bolero made of cotton and four corrective elastic bands of variable size (0.20–1 m). The authors note that there are a number of configurations possible for the placement of elastic bands (Figure 2). The therapeutic principle is based on the definition of a specific corrective movement for each type of curve [21–23] with an adjustment of the corrective bands to reproduce and favour the desired corrective movement. The patients are usually requested to wear the brace 20 out of 24 h. The brace is weaned near skeletal maturity or after 2 years of regular menstruation [23].

In a recent publication, Coillard *et al.* [23] present the post-treatment results of the SpineCor. Inclusion criteria for that outcome study were the diagnosis of idiopathic scoliosis, an initial Cobb angle between 15–50° and a Risser sign of 0–3. Survival functions were presented leading to the conclusion that ‘for patients followed up from the initiation of treatment to 2 years follow-up, there

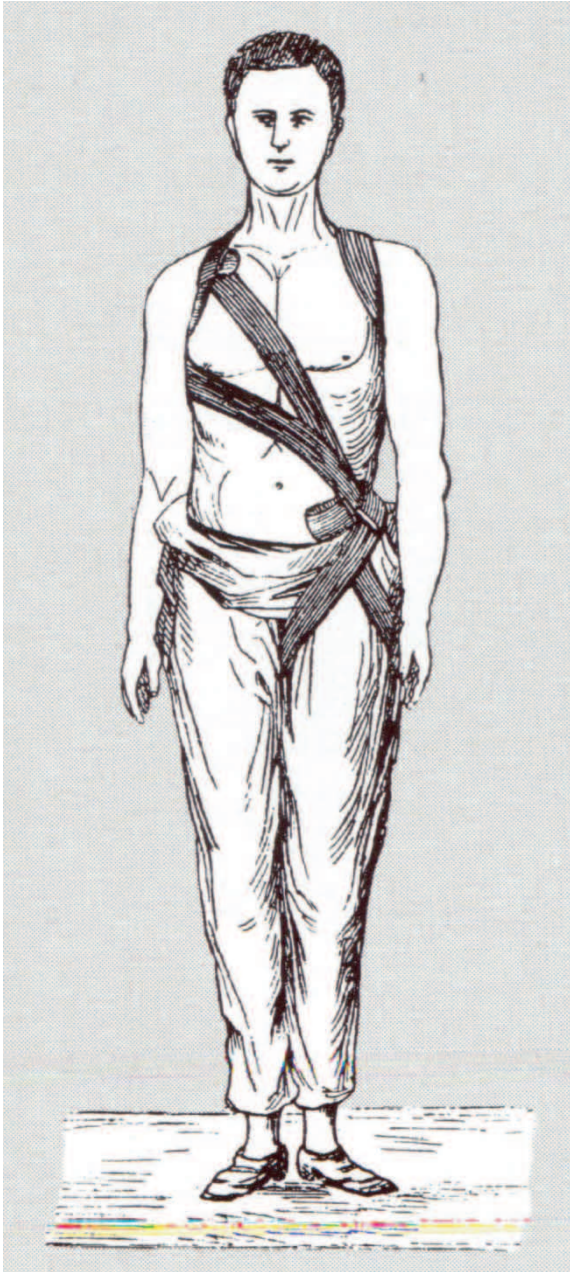


Figure 1. Precursor of the SpineCor system with corrective elastic bands of variable size (according to Fischer, taken from Schanz [20]).

was an overall correction/stabilization for 93% of the patients'.

One important problem of this study, however, has to be discussed: Scoliotic curves progress mainly during pubertal growth spurt [24]. As can be seen in Figure 3 [25], growth spurts in girls comprises only a short period of time while the age of 6–10 years, usually there is no change of curvature even in an untreated patient with a curvature of  $>20^\circ$ . On the other hand in post-menarchial girls with Risser stages 2 or 3 in minor curvatures, no change of Cobb angle has to be expected [26,27]. So, the inhomogenous

age group (6–14-years-old patients) offers no chance to distinguish between patients at immediate risk or at no risk for further progression of the curvature. A study of patients treated with the SpineCor brace during pubertal growth spurt seems desirable. Moreover, it seems important to compare the results of this new brace with braces of the up-to-now golden standard of treatment well described in the literature [1–5,14,15,28–30].

### Materials and methods

To determine whether the results obtained by the use of the SpineCor are comparable to the results of the most practiced bracing concept in central Europe, a prospective trial was performed comparing the outcome of two different bracing concepts in girls with idiopathic scoliosis (IS) during pubertal growth spurt.

The following study design was chosen: prospective comparison of the survival rates of two different cohorts of patients treated with two different bracing concepts with respect to treatment time and curve progression during pubertal growth spurt.

### Inclusion criteria

- Diagnosis of Idiopathic Scoliosis (IS);
- Pre-menarchial status;
- First clinical signs of maturation evident (Tanner 2–3); and
- Agreement to be followed up prospectively in the practice of the senior author.
- Because the Risser sign was not visible on all x-rays at the start of the treatment, one was not able to take the Risser sign as an inclusion criteria, despite wanting to. However, pre-menarchial girls with Tanner 2 or 3 usually have Risser 0 and so the samples followed up under the inclusion criteria given are both in the pubertal growth spurt.

Between April 1999 and June 2000, all pre-menarchial girls with first signs of maturation (Tanner 2–3) treated as inpatients at the centre or as outpatients at the practice of the senior author were chosen for a prospective follow-up of the treatment with the Chêneau brace. From December 1999, treatment with the SpineCor has been offered to the girls with curvatures between  $15\text{--}30^\circ$  and girls diagnosed before December 1999 or girls with curvatures exceeding  $30^\circ$  were treated with the Chêneau brace at first choice. One patient with a curvature of more than  $30^\circ$  ( $32^\circ$ ) has chosen the SpineCor instead of being braced with the Chêneau hard brace.

All patients have been asked to be followed-up in the practice of the senior author. The senior

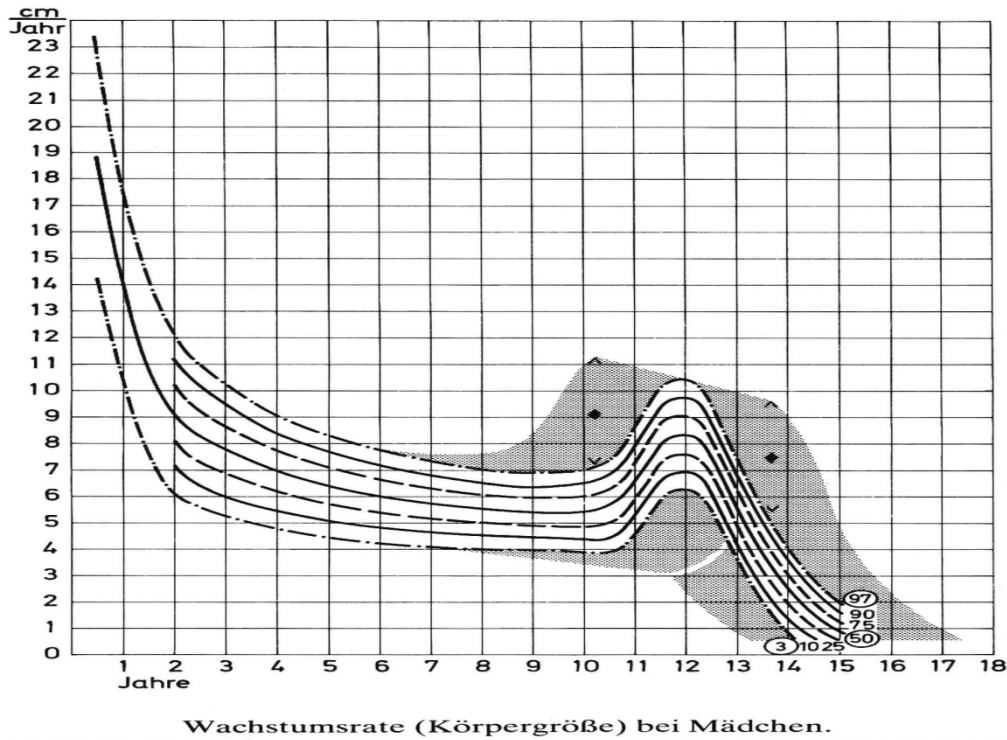


Figure 2. Risk for progression is highest during the pubertal growth spurt [25]. Before and after this peak of growth velocity (in girls between 11–13 years of age) even curves with more than 25° may stay stable [26, 27]. [Translated legend: Growth rate (body length) in girls.]



Figure 3. Patient with a SpineCor from dorsal and ventral. Therapeutic principles based on the definition of a specific corrective movement for each type of curve [23].

author as well as the technicians involved have been trained and supervised by the authors of one of the first cohort studies for the SpineCor brace [19].

Twelve patients with Cobb angles between 16–32° represent a case series of patients treated with the SpineCor soft brace (21.3° at average, Risser 0 (in one case not visible on the x-ray), average age

11 years) followed up prospectively. Seven of 12 patients had a thoracic, three a double major and two had a lumbar curve pattern. All of the patients in this group had Adolescent Idiopathic Scoliosis (AIS).

Fifteen patients with Cobb angles between 20–52° represented the group of patients treated with the Chêneau brace (at average 33.7°, Risser 0 (in two

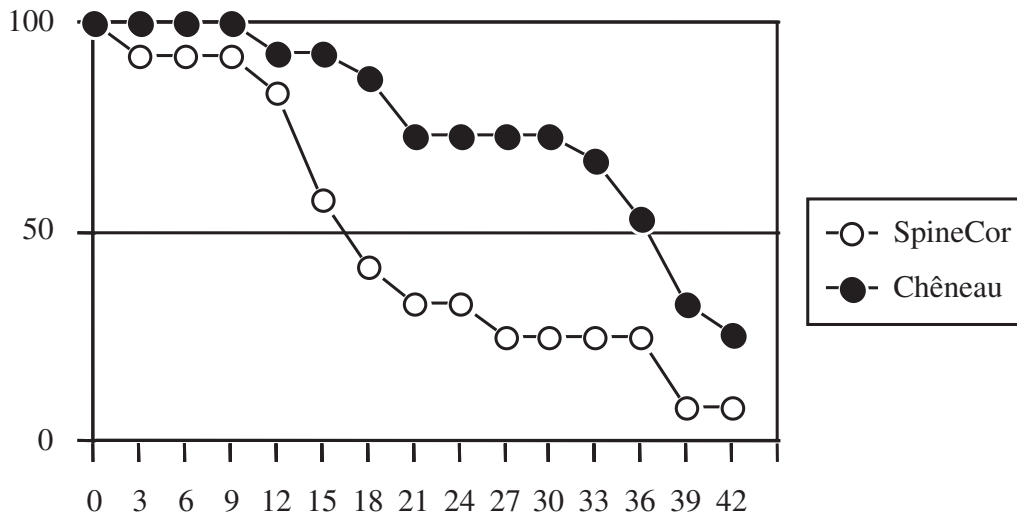


Figure 4. Proportion of survival regarding the duration of treatment SpineCor vs. Chêneau brace. Definition of survival was: patients not weaned and still treated with the bracing concept originally started with. The duration of treatment with the SpineCor was significantly less than with the Chêneau brace.

cases not visible on the x-ray) with one exception having Risser 1, although being pre-manarchial with Tanner 3 stage of maturation, 11.5 years). Seven of 15 patients had a thoracic curve pattern, five were double major, one thoracolumbar and two lumbar. So, there was not a big difference regarding curve pattern in both samples. All of the patients in this group had Adolescent Idiopathic Scoliosis (AIS) with the exception of the two patients with the biggest Cobb angles having Early Onset Idiopathic Scoliosis (EOIS, juvenile form, worse prognosis than AIS).

The patients of both samples were followed-up closely every 3 months clinically (scoliometer values, surface topography) and radiologically in case progression was evident. The test parameter used to measure progression was Cobb angle [31]; an increase of  $\geq 5^\circ$  in angle of the most severe curvature was used to define 'progression'. A one-sided statistical test to compare two independent proportions was used to test the hypothesis that the proportion of patients with progression differed between the two study groups [32]. The same test was used to test the hypothesis that the duration of treatment was different between the two study groups.

On average, 42 months follow-up time all girls were at least 18 months post-menarchial, all at Risser 4 (in three cases not visible on the x-ray) and presented with a tanner stage 5. More than 80% of the patients involved in this study ( $n=27$ ) were 2 years post-menarchial and, therefore, had no risk for a larger short time progression anymore.

## Results

During the pubertal growth spurt, most of the patients (11/12) with the SpineCor progressed

clinically and radiologically as well. The patients with a progression during SpineCor treatment were offered to change to the Chêneau brace. Progression could be stopped changing SpineCor to Chêneau in most of the patients of the described sub-sample (7/10). One patient from the SpineCor sample, though progressive (from  $19-25^\circ$ ), did not need another brace, being at no more risk for progression after the treatment with the SpineCor (2 years post-menarchial). After an average observation time of 21.5 months, the curves treated with the SpineCor increased from  $21.3^\circ$  before start of the treatment to  $31^\circ$ .

The control sample primarily treated with the Chêneau brace showed on average no progression. Cobb angle at the start of treatment was  $33.7^\circ$  and after the observation time of on average 37 months,  $33.9^\circ$ . Radiological improvements have been found for three of the cases and progression in another three of this patient sample.

At 24 months of treatment time, 73% of the patients with a Chêneau brace and 33% of the patients with the SpineCor where still under treatment with their original bracing concept ( $\alpha=0.05$ ;  $t=2.25$ ;  $p=0.0122$ , see also Figure 4), at 24 months follow-up time 93% of the patients with Chêneau braces and 33% of the patients with the SpineCor survived with respect to having no curvature progression ( $\alpha=0.05$ ;  $t=3.98$ ;  $p<0.0001$ ), at 42 month follow-up time 80% of the patients with Chêneau braces and 8% of the patients with the SpineCor survived with respect to having no curvature progression ( $\alpha=0.05$ ;  $t=5.55$ ;  $p<0.0001$ , see also Figure 5). The differences between the proportions of progressive curves in patients treated with SpineCor compared to the proportions of progressive curves in patients treated

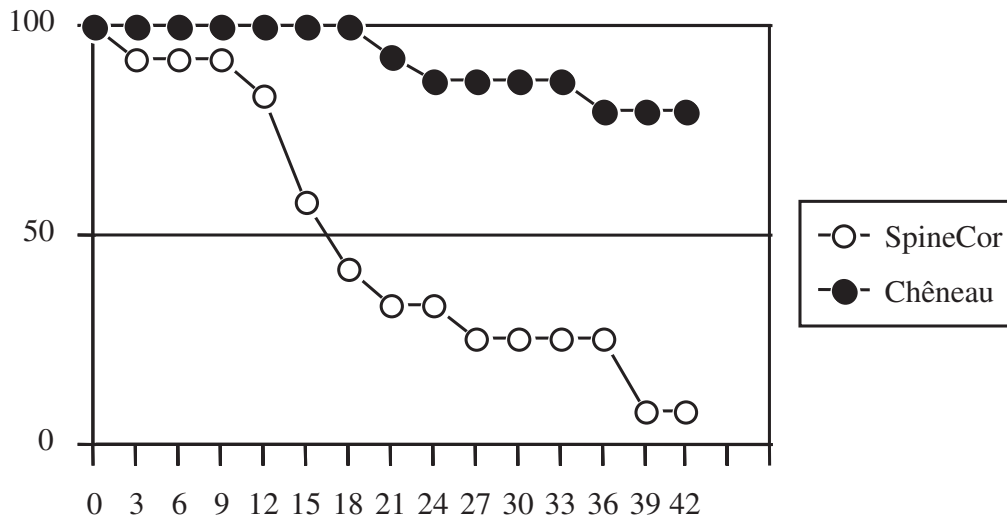


Figure 5. Proportion of survival regarding progression of curvature SpineCor vs Chêneau brace. Definition of survival was: patients without documented progression. The rate of progression under SpineCor treatment (92%) was significantly higher than the progression rate with the Chêneau brace (20%).

with Chêneau braces, though statistically was highly significant.

### Discussion

In this study, no patients have been lost for follow-up. Therefore, the results of the study can be compared to other studies with similar study design [4]. The material in the study performed by Nachemson and Peterson [4], however, is slightly different including also post-menarchial girls (65 pre-menarchial, 46 post-menarchial) with clear signs of maturation (82 with Risser 0–1, 28 with Risser 2–5) and Cobb angles on average less than in the Chêneau sample. Prognosis in the study of Nachemson and Peterson [4] though has to be regarded as more benign when compared to the Chêneau sample from this study.

Follow-up time is not much shorter in this study compared to Nachemson and Peterson's (42 vs. 48 month) and the patients in this study were not at great risk of progression at the end of the observation period.

The proportion of patients without progression (rate of success) under Boston brace treatment was 74% (worst case 50%), whereas the Chêneau sample from this study did slightly better, with a success rate of 80% (no patients lost, one patient Risser 1, others 0). Success rate for the SpineCor sample was 8% compared to the success rate of the natural history sample in the Nachemson and Peterson study [4] of 34%. So, one cannot expect the SpineCor treatment to change natural history.

It is obvious that the choice of materials used in this study (girls only with first signs of maturation but pre-menarchial) enables one to receive more precise information than studies including inhomogeneous age groups [23] or also post-menarchial girls [4].

Conservative treatment of scoliosis patients with the help of the Chêneau brace has proven effective to prevent surgery [14,15]. However, up to now no samples of brace treated patients have been followed-up being at immediate risk of progression (beginning of the pubertal growth spurt). Only if patients not at risk for progression are excluded from such studies can a clear picture arise of how natural history may be influenced by brace treatment. Although there is already scientific information about lack of effectivity in certain bracing concepts [8,9], braces are still on the market, not affecting natural history nor incidence of surgery [13].

Undoubtedly, braces influence the quality of life of the patients treated [33]. Therefore, even though not all braces of high standard work efficiently in every patient, one has to make sure that patients are no more tortured with outdated and obviously ineffective bracing concepts.

The indication for bracing at the centre starts at a Cobb angle of 25° and a risk for progression of 60% and over calculated according to Lonstein and Carlson [26]. There is an upper limit of the indication around 60° because the indication for surgery is cosmetic in the cases with AIS [13] and because there are no severe functional limitations in patients not exceeding a Cobb angle of 90° [34]. However, for the sample treated with the SpineCor, the indications given by the authors



Figure 6. A patient in a Chêneau brace of actual standard. Without the brace decompensation is clearly visible. In the brace there is a decompensation to the opposite side and after 3 months of treatment already a clear reduction of curvature is visible. However, this can only be maintained as the brace is worn longer [35].

published in the *European Spine Journal* [23] were followed, although the risk for progression has been less than 60% for quite a few patients from this sample.

In this study, the average Cobb angle of the patients treated with the Chêneau brace was more than  $10^\circ$  higher than in the cohort treated with the SpineCor. The risk for progression, though, was much higher in the Chêneau sample than in the SpineCor cohort [26,27,34]. Therefore, the Chêneau brace has to be regarded as effective, having the greater task in this study.

Another fact of importance is that, during a brace treatment with high excellence the total time of brace wearing might be reduced. The results from this study seem to contradict this for the treatment time in the Chêneau brace was significantly longer than in the SpineCor. However, when taking into account that SpineCor patients mostly had to change to another bracing concept in case of progression, the total treatment time was longer in the SpineCor group.

The latest standard applied in Spain, Croatia, Austria, Israel and Germany at the moment is the Rigo-System Chêneau brace (RSC-brace) constructed on a CAD (computer aided design) basis including a library of, at the moment, 49 different models of choice. Those braces are comfortable to wear and provide a visible 3D

effect [7,15,35,36] which is appreciated by the patients (Figure 6).

### Conclusions

1. No evidence was found that SpineCor changed natural history of Idiopathic Scoliosis during pubertal growth spurt.
2. There is evidence that Chêneau braces built on a high standard of excellence change natural history.
3. Oncoming studies with the aim to test the efficiency of braces should be based on samples at immediate risk for progression (only girls with first signs of maturation but pre-menarchial).

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