

Efficacy of the Symmetric, Patient-oriented, Rigid, Three-dimensional, active (SPoRT) concept of bracing for scoliosis: a prospective study of the Sforzesco versus Lyon brace

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Aim. Bracing is considered to be effective in the treatment of adolescent idiopathic scoliosis. The concept prevailing today includes an asymmetrical construction, mainly using a mechanical three-point system. We developed the new Sforzesco brace, based on the SPoRT concept (Symmetric, Patient-oriented, Rigid, Three-dimensional, active). The aim of this study is to verify the results of this concept and brace, compared to three-point classical systems.

Methods. We performed a prospective, pair-controlled study. It was possible to match 15 patients, out of the first 18 consecutively treated with the Sforzesco brace (Group SPoRT), with previous patients treated with the Lyon brace (Group LY). SPoRT included 14.2±1.7 year old patients, with 47±7° Cobb worst curves, and 11±4° Bunnell; LY included 13.6±1.6 year old patients, with 43±7° Cobb and 12±5° Bunnell. The brace had to be worn 23 h per day and patients were evaluated after 6 months both clinically and radiographically (without the brace). Appropriate statistics were used.

Results. At the baseline there were slight differences between the groups, with SPoRT worse than LY. All radiographic and clinical parameters decreased significantly with treatment in both groups, apart from thoracic Cobb degrees in LY. SPoRT had better results than LY ($P < 0.05$) radiographically (worst curve $-10 \pm 5^\circ$ vs $-5 \pm 7^\circ$, all curves $-8 \pm 7^\circ$ vs $-6 \pm 7^\circ$), for sagittal profile (distance from plumbline: T12 -6 ± 9 mm vs $+2 \pm 8$ and L3 -7 ± 12 vs 0 ± 10) and aesthetics of the shoulders (9 improved and 6 unchanged vs 5 and 8) and waists (10 improved and 5 unchanged vs 5 and 8). Finally, clinical results in terms of patient recovery were better in SPoRT than LY (12 improved and 3 unchanged vs 8 and 5).

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Conclusion. When a new treatment is introduced, it is not possible to wait years (end of therapy) before verifying its utility, and in scoliosis bracing a short term study already gives very important clues. This study confirms the immediate efficacy of brace treatment (even in such high degree cases) whatever the brace concept used, with only 2 (out of 30) progressed curves. In SPoRT we had no progressions, and obtained a statistically significant 80% better radiographic results than LY in the worst scoliosis curve, and 40% in the average of all curves, as well as improved aesthetics and sagittal profile (that is crucial in scoliosis bracing). The Sforzesco brace should be used, and the SPoRT concept explored in the long term to verify if the classical three-point system should be totally (or partially) abandoned.

Key words: Idiopathic scoliosis - Brace - Correction.

Bracing is effective in the treatment of adolescent idiopathic scoliosis,¹⁻⁶ even if some doubts have been raised over recent years.^{7, 8} Today, 3 main concepts of bracing prevail: traction (two-point system), pushes on the trunk and side-bending (three-point systems). The first one is represented by the Milwaukee brace,⁹ a cervico-thoraco-lumbo-sacral orthosis (CTLSO), that applies a correction in the frontal and horizontal planes through an active elongation required for the patient to avoid the collar, and some specific mobile thrusts on the trunk: the main limitations of this concept include the psychological

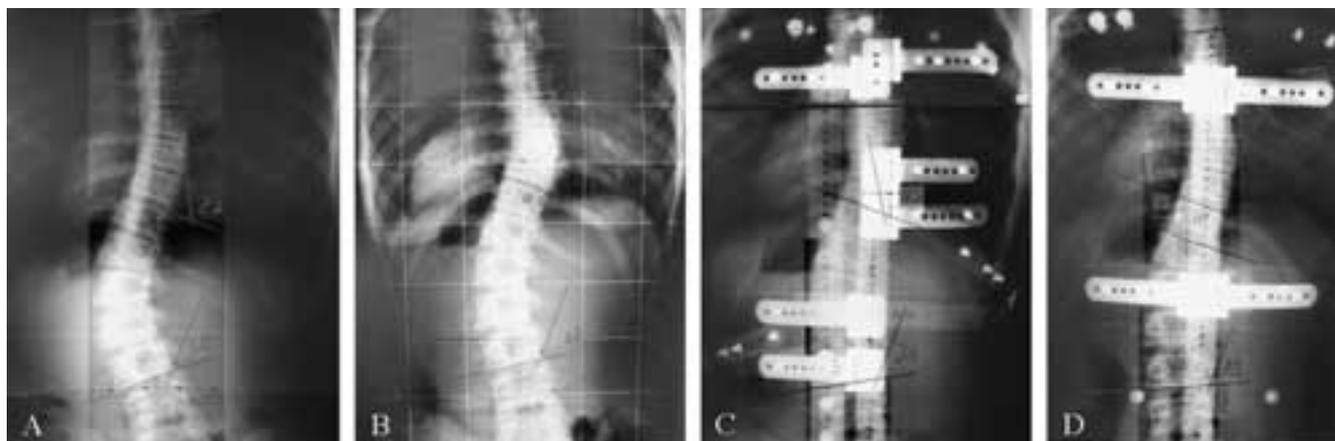


Figure 1. — First use ever of the Sforzesco Brace. Silvia R., girl, born July 1991, menarche June 2003. After performing radiographs in Lyon (C) and Sforzesco (D) braces, it was decided to carry on the Sforzesco brace treatment 23 hours per day, with SEAS-02 exercises. Pretreatment (A) and short-term results after 10 months (radiograph without the brace) are shown (B). Clinical and radiographic data of this patient are reported in Table I.

TABLE I.—Results of this patient in Figure 1.

	A. Pre-treatment (0 months)	C. Lyon brace (0 months)	D. Sforzesco Brace (0 months)	B. Short-term results (10 months)
Date	January 2004	March 2004	March 2004	January 2005
Age (years/months)	12/6	12/8	12/8	13/6
Cobb degrees T5-T12	27	32	26	32
Cobb degrees T12-L3	42	30	25	32
Raimondi degrees L1	20	18	9	12
Take-off L3	21	8	6	13
Risser	2	3	3	3
Thoracic Bunnell degrees	7			5
Lumbar Bunnell degrees	13			0
Thoracic rib hump	7			5
Lumbar hump	18			0
Aesthetic Index	3			1.5
Sagittal plumbline distance (C7-T12-L3)	35-20-25			35-5-10
Frontal plumbline distance (C7)	0			25 left

burden on the spine¹⁰⁻¹⁴ and the negative action in the sagittal plane,¹⁵ while results too did not seem comparable to other braces.¹⁶ Today, the three-point concept seems to prevail, mainly in the pushes version, with a wide variety of different thoraco-lumbo-sacral orthoses (TLSO): most of them include an asymmetrical construction to reverse scoliosis, in best cases three-dimensionally, with braces such as Lyon,¹⁷ Boston,¹⁸⁻²⁰ Chêneau,^{5, 21-25} Wilmington,²⁶⁻²⁸ progressive action short brace (PASB).^{29, 30} The side-bending concept includes the night-time over-correction braces, like Charleston¹⁰ and Providence.³¹ Recently, a proprioceptive concept has also been proposed, based on

soft bands (SpineCor),^{25, 32-34} but results already do not seem to be comparable to rigid bracing.²⁵ Nevertheless, the idea that the brace is also a real rehabilitation tool through its esteroceptive and proprioceptive inputs increased by exercises, proposed by Sibilla^{35, 36} for rigid braces too, should be better explored in the future. Recently, we developed a new concept of bracing, obtained through the use of a particular TLSO (called Sforzesco), that we called Symmetric, Patient-oriented, Rigid, Three-Dimensional, active (SPoRT). After some promising preliminary results in single patients, obtained comparing radiographs of the Sforzesco and Lyon brace (Figure 1, Table I), we

developed a study to verify the clinical efficacy of this brace and concept. Definitive results can be scheduled only at the end of full treatment, that requires some years to be completed, but in the meantime it is not acceptable, either ethically or therapeutically, to pursue a not effective therapy without any specific data. The aim of this paper is to verify for the first time in the short-term the results of the SPoRT concept (Sforzesco brace), compared to a classical three-point system (Lyon brace).

Materials and methods

Population

We considered the first 18 consecutive patients treated for 6 months and 23 h per day with the Sforzesco brace after their first evaluation at our Institute. In our database we found 71 previous patients, treated for 6 months and 23 h per day with the Lyon brace after their first evaluation at our Institute, to be coupled with the previous sample. Our prospective database consecutively includes all examinations of all patients treated at our Institute since February 2003: at the moment of the study (August 2005) there were 2 358 patients and 6 886 examinations in the whole database. We defined 4 coupling criteria for patients and 5 for curves (Table II): each criterion had strict and large limits. Patients were coupled if they had at least 50% strict criteria, and no more that one criterion not fulfilled (Table II). We were not able to couple 3 patients of the original sample treated with the Sforzesco brace, and so they were excluded from further analysis (Table III). At the end, the SPoRT (Sforzesco Brace) Group included 15 patients with the most important curve of $47\pm 7^\circ$ Cobb and the LY (Lyon Brace) Group included 15 patients with $43\pm 7^\circ$ Cobb (Table IV).

Treatment

All patients had been required to wear the brace 23 h per day and to perform exercises according to the Scientific Exercises Approach to Scoliosis, version 2002 (SEAS-02). All braces were made by the same orthotists. All patients were evaluated at start of treatment and after 6 months of bracing by the same treating physician, both clinically and radiographically. We searched for the actual results, so radiographs were made immediately after wearing the brace.

TABLE II.—Coupling criteria considered in the study: patients were matched if they respected at least 50% of strict criteria and no more than one criterion was not fulfilled.

	Matching criteria	
	Strict	Large
<i>Patient criteria</i>		
Gender	Same	Different
Radiological curves	Same number	Different number
Risser stage difference	<2	<3
Previous treatment	No	Yes
<i>Curve criteria</i>		
Side	Same	Different
Radiographic location	Same	Different
Cobb degrees difference	<6	<11
Bunnel degrees difference	<4	<6
Difference in number of vertebrae involved	<2	<3

THREE POINT CONCEPT: THE LYON BRACE

The Lyon brace we propose is totally classical¹⁷ (Figure 2C) and follows a three-points system for lateral and horizontal correction. With time we introduced variations to reduce the flattening effect on the kyphosis.

SPoRT CONCEPT: THE SFORZESCO BRACE

The Sforzesco brace (Figures 2A, 2B) is a custom-made TLSO developed with the same material as the Lyon brace, but with only 2 big lateral elements that completely cover the back from the pelvis to the armpits, and the abdomen; the elements are linked to a posterior aluminium central bar, and the brace closes anteriorly with straps on the abdomen and another transverse aluminium bar at the manubrium sternalis. This brace arose progressively out of some ideas. First, the limits of the actual three-point systems are mainly in the sagittal plane.³⁷ Second, the observations and evolutions we made, starting from the Chêneau brace, made us think of the advantages of symmetry to increase the estero-proprioceptive stimuli of the orthosis to obtain a better three-dimensional correction.^{35, 36} Third, the importance of rigidity, testified by casts,^{35, 36, 38, 39} but also by the efficacy we verified in our experience with the Lyon brace, which is higher than the Chêneau one, and that we ascribe to the material. Fourth, the need to substitute casts: in the past, they were widely applied before bracing¹⁷,

TABLE III.—Population considered in the study: patient matching with comparison of all coupling criteria.

		Patient Coupling Criteria				Curve 1 Coupling Criteria					Curve 2 Coupling Criteria				
	Curves	Gender	Previous treatment	Risser	Side	End vertebrae	N. vertebrae	Cobb	ATR	Side	End vertebrae	N. vertebrae	Cobb	ATR	
<i>Patients included</i>															
SPoRT	1	2	F	No	2	Right	T6 T12	7	47	9	Left	T12 L4	5	39	11 [^]
LY	1	2	F	No	3	Right	T5 T11	7	37	8	Left	T11 L4	6	29	3 [^]
SPoRT	2	1	F	No*	3	Right	T6 L1	8	45	12					
LY	2	1	F	Brace	3	Right	T6 T12	7	40	13					
				20 h/d*											
SPoRT	3	2*	F	No	3	Left	T11 L4	6	52	17					
LY	3	1*	F	No	4	Left	T10 L3	6	46	18					
SPoRT	4	2	F	Brace	2	Right	T5 T12	8	46	13*	Left	T12 L4	5	25	0
				13 h/d*											
LY	4	2	F	No*	3	Right	T5 T11	7	42	17*	Left	T11 L4	6	21	0
SPoRT	5	2*	M	No	4 [^]	Right	T6 T11	6	47	8					
LY	5	1*	M	No	0 [^]	Right	T10 L3	6	56	11					
SPoRT	6	2*	M*	No	2	Left*	T11 L4	6	47	13					
LY	6	1*	F*	No	3	Right*	T11 L3	5	42	11					
SPoRT	7	1*	F	No	0	Right	T7 L1*	7	55*	12					
LY	7	2*	F	No	0	Right	T5 T11*	7	49*	15					
SPoRT	8	2	M*	No	1	Left	T8 L1*	6*	41	14	Right	T3 T8*	6	24*	0
LY	8	2	F*	No	2	Left	T12 L3*	4*	38	12	Right	T6 T12*	7	32*	3
SPoRT	9	2	F	Brace	0	Left*	T4 T10	7	43	10	Right*	T10 L3	5	46*	10*
				23 h/d*											
LY	9	2	F	No*	0	Right*	T6 T11	6	39	10	Left*	T11 L4	5	37*	15*
SPoRT	10	2	F	No	4	Right*	T8 L2	7	45*	13 [^]	Left*	T1 T8	8	22	5*
LY	10	2	F	No	4	Left*	T9 L2	6	51*	22 [^]	Right*	T3 T9	7	24	0*
SPoRT	11	1*	M	No	0	Left*	T8 L2*	7	44*	6					
LY	11	2*	M	No	1	Right*	T4 T11*	8	35*	7					
SPoRT	12	2*	F*	Brace	0	Right	T5 L1*	9	30	18					
				23 h/d*											
LY	12	1*	M*	No*	0	Right	T5 T12*	8	33	15					
SPoRT	13	1	F	No*	2	Left*	T10 L3*	6 [^]	61	17					
LY	13	1	F	Brace	2	Right*	T4 T12*	9 [^]	57	15					
				21 h/d*											
SPoRT	14	2*	M*	No	0*	Right	T6 L2	9 [^]	44	11					
LY	14	1*	F*	No	2*	Right	T10 L3	6 [^]	39	10					
SPoRT	15	2	F*	Brace	4	Left*	T6 T12	7*	26*	10	Right*	T12 L4	5	42	0*
				18 h/d*											
LY	15	2	M*	No*	3	Right*	T6 T10	5*	32*	8	Left*	T10 L3	5	40	5*
<i>Patients excluded</i>															
SPoRT	16	2	M	No	5	Left	T2 T9	8	33	17	Right	T9 L2	6	68	0
SPoRT	17	2	F	No	3	Right	T6 T11	6	65	14	Left	T11 L4	6	46	12
SPoRT	18	1	M	No	0	Right	T10 L3	6	56	11					

*: large criterion; ^: criterium not fulfilled; T: thoracic; L: lumbar.

²⁹ or as a treatment per se,^{40, 41} but today, even if still applied in some institutes,^{35, 38} this treatment seems to have lost popularity ⁴⁰ (this word is used because there isn't any evidence-based choice: no studies exist on this topic): casts treatment is complex, time-consuming, costly, and has a high impact on the patient's

quality of life,⁴⁰ but not using casts could eliminate an important tool against high degree scoliosis and possibly increase the rate of surgery. Because of this background, we developed a new brace and its application, on the basis of the above mentioned ideas, led us to develop a new concept that we called SPoRT.

TABLE IV.—Population considered in the study: comparison between the groups at the baseline.

	SPoRT Mean±SD (Range)	LY Mean±SD (Range)
Females/Males ratio	10/5	12/3
Weight (kg)	48±7	50±8
Height (cm)	159±6	161±6
Age (years.months)	14:2±1.7	13:10±1.6
Risser stage	2 (0-4)	2 (0-4)
Menarche	80%	92%
Years and months from menarche	1.12±1.2	1.04±0.7*
Months between visits	8±4	9±4
Hours/day of bracing	5±9	3±8
Sport (days/week)	1.5±1.4	0.9±1.2

*: P<0.05.

Symmetric: to construct the elements of the brace, the material eliminated on one side of the cast to create a thrust is added symmetrically and three-dimensionally on the other side, to give room for correction; correction is then completed through pushes inserted into the brace. Patient-oriented: in its whole con-

struction we maintain a body shape, avoid any corner, and symmetrical means not visible; moreover, a brace can be taken away during the day while a cast cannot, and the latter is at least 1-2 cm wide instead of 4 mm. Rigid: the material has a high rigidity, increased because it is shaped in only 2 big pieces. Three-dimensional: the shape of the brace is symmetrically but also anatomically constructed in all planes, starting from a good lordosis and allowing space to create kyphosis; on the same line are the pushes. Finally, the SPoRT acronym per se recalls the “active principle”⁴² of passive brace treatment, obtained through specific exercises, sport, and as much movement as possible. The constructional characteristics of the Sforzesco brace will be presented in another paper.

Outcome criteria

The primary outcome criteria considered were Cobb degrees (a difference of 5° was considered as a significant variation)⁴³⁻⁵⁰ and Bunnell degrees (a difference of 3° was considered as a significant variation).^{2, 51-54} We were not able to compare the rotation on



Figure 2.—Braces compared in the study. Posterior (A) and anterior (B) view of the Sforzesco brace worn by a girl with a thoracic right lumbar left curve (SPoRT concept and group); Lyon brace (C) for the same clinical situation (3-point concept and LY group).

TABLE V.—*In both groups most of the final outcome were significantly better than baseline values.*

	SPoRT			LY		
	N	Pre Mean±SD (Range)	Post Mean±SD (Range)	N	Pre Mean±SD (Range)	Post Mean±SD (Range)
<i>Cobb degrees</i>						
Maximal curve	15	47±7	37±7*	15	43±7#	38±10*
All curves	26	40±11	32±11*	22	40±9#	34±10*
Thoracic curves	10	36±10	31±7*	10	40±8	38±12
Thoraco-lumbar curves	8	46±9	37±10*	5	47±7	35±9*
Lumbar curves	8	41±12	35±9*	7	34±7#	27±5*
<i>Bunnell degrees</i>						
Maximal curve	15	13±3	8±4*	15	14±4	10±5*
All curves	22	11±4	6±4*	20	12±5	8±5*
Thoracic curves	11	10±4	7±4*	10	12±4#	11±4*
Thoraco-lumbar curves	4	11±3	6±3*	3	17±6	10±4*
Lumbar curves	7	13±3	6±4*	7	9±4	4±4*
<i>Rib Hump (mm)</i>						
Maximal curve	15	19±5	12±6*	15	22±7§	16±9*
All curves	21	17±6	9±7*	19	20±8	12±10*
Thoracic curves	9	17±8	14±6*	10	22±8§	18±10*
Thoraco-lumbar curves	5	17±6	9±5^	3	24±10	13±5*
Lumbar curves	7	17±4	10±4*	6	15±2	10±4^
<i>Distance from plumbline (mm)</i>						
C7 frontal	15	2±13	1±4	15	8±21	6±9
C7 sagittal	15	26±16	22±14^	15	31±16#	23±16*
T12 sagittal	15	20±12	15±12*	15	19±11	21±13
L3 sagittal	15	25±18	18±19*	15	28±17	28±16
<i>Aesthetics</i>						
Shoulders symmetry	15	1 (0-1)	0.5 (0-1)*	15	0.5 (0-1)#	0 (0-1)^
Scapulae symmetry	15	1 (0-2)	0.5 (0-1)*	15	1 (0-2)§	0.5 (0-2)
Flanks symmetry	15	1 (0-1)	0.5 (0-1)*	15	0.5 (0-1)§	0.5 (0-1)
Aesthetic index	15	3 (1-4)	1 (0.5-3)*	15	1.5 (1-4)#	1 (0.5-3.5)*

Pre vs Post *: P<0.05; ^: P<0.1. Pre SPoRT vs Pre LY; #: P<0.05; §: P<0.1.

radiographs, has been measured according to Perdriolle or Rainaldi,^{55,56} because the data have been collected in the control group (LY). According to our clinical standard evaluation criteria, in our database, we also had some secondary criteria. The height of the hump, whose repeatability has been proven,⁵⁴ is measured in millimeters and a difference of 5 mm has been considered as a significant variation. The distance from the plumbline in the sagittal plane has been measured in centimeters at the C7, T12 and L3 vertebrae, while in the frontal plane (decompensation) at C7: the inter-examiner repeatability of the latter only has been proven,^{54,57} while the intra-examiner repeatability is under evaluation; variations were considered significant when they reached 1 cm.⁵⁸ The aesthetic index is the sum of 3 items subjectively evaluated on a three-

point scale (0: symmetric, 0.5 slight difference, 1 relevant difference) by the treating physician: height of shoulders, symmetry (2 subitems: height and protrusion) of the scapulae and symmetry of the flanks; the repeatability evaluation of the aesthetic index as well as of its single items is under way; provisionally, variations were considered if there was a change of 0.5 for single items, and 1 for the aesthetic index.

Statistical analysis

Statistical analysis was performed, after evaluation of the distribution of variables, through t-test (paired for in-group comparisons, and unpaired between groups), Mann-Whitney, Fisher's Exact and χ^2 tests. Statistical significance was set with $\alpha=0.05$.

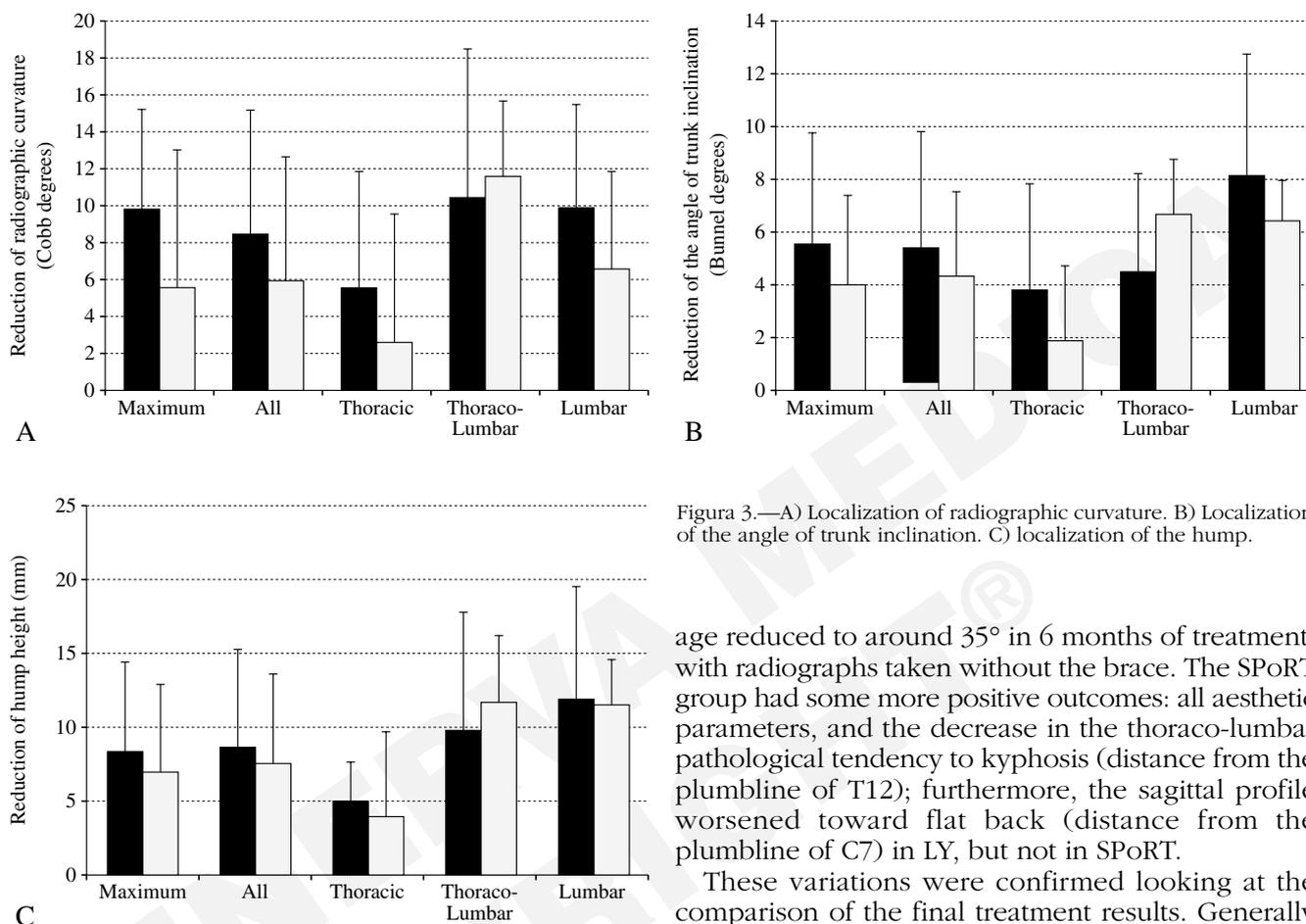


Figura 3.—A) Localization of radiographic curvature. B) Localization of the angle of trunk inclination. C) localization of the hump.

age reduced to around 35° in 6 months of treatment, with radiographs taken without the brace. The SPoRT group had some more positive outcomes: all aesthetic parameters, and the decrease in the thoraco-lumbar pathological tendency to kyphosis (distance from the plumbline of T12); furthermore, the sagittal profile worsened toward flat back (distance from the plumbline of C7) in LY, but not in SPoRT.

These variations were confirmed looking at the comparison of the final treatment results. Generally speaking, all SPoRT results were better than LY (Figure 3): this was statistically true from a radiographic point of view (+43% of maximal Cobb degrees correction and +30% for all curves) and aesthetically (apart from shoulder symmetry, that did not reach statistical significance), but also in the sagittal profile for the distance from the plumbline of T12 (Table VI). Notably the only, but light and not statistically significant exception to the rule of SPoRT better than LY was for all thoraco-lumbar parameters: Cobb degrees (-2°), Bunnell degrees (-2°) and height of the hump (-2 mm) (Figure 3).

Finally, we looked at the clinical results in terms of number of patients who improved, changed or worsened. Even if there was no aggravation of any patient in the SPoRT group for Cobb degrees, Bunnell degrees and height of the hump, while this was not true in LY, there were no statistical differences; on the contrary, aesthetic results were better after Sforzesco brace

Results

When compared to the LY group, the SPoRT included patients with a higher degree of curvature (particularly lumbar +7° Cobb, but also maximal curve +3° and total of curves +1°), greater aesthetic impact (the aesthetic index +3 and symmetry of the shoulders +1) and a reduced amount of thoracic rotation only (-2° Bunnell) (Table V); even if age was not different between the groups, the 8 females with menarche in the SPoRT group had it 8 months before the 11 in the LY group (Table IV).

In both groups, results obtained by treatment were radiographically and clinically significant and positive (Table V): in terms of Cobb degrees, it must be noticed that curves abundantly over 40° were on aver-

TABLE VI.—SPoRT results are generally better than LY ones, mainly in terms of Cobb degrees, aesthetics and sagittal profile.

	SPoRT Mean±SD (Range)	LY Mean±SD (Range)
<i>Cobb degrees</i>		
Maximal curve	-10±5	-6±7*
All curves	-8±7	-6±7*
Thoracic curves	-6±6	-3±7
Thoraco-lumbar curves	-10±8	-12±4
Lumbar curves	-10±6	-7±5
<i>Bunnell degrees</i>		
Maximal curve	-6±4	-4±3
All curves	-5±4	-4±3
Thoracic curves	-4±4	-2±3
Thoraco-lumbar curves	-5±4	-7±2
Lumbar curves	-8±5	-6±2
<i>Rib Hump (mm)</i>		
Maximal curve	-8±6	-7±6
All curves	-9±7	-8±6
Thoracic curves	-5±3	-4±6
Thoraco-lumbar curves	-10±8	-12±5
Lumbar curves	-12±8	-12±3
<i>Distance from plumbline (mm)</i>		
C7 frontal	1±14	1±18
C7 sagittal	-4±11	-7±15
T12 sagittal	-6±9	2±8*
L3 sagittal	-7±12	0±10
<i>Aesthetics</i>		
Shoulders symmetry	-1 (-1/0)	0 (-1/1)
Scapulae symmetry	-1 (-2/1)	-1 (-2/2)*
Flanks symmetry	-1 (-1/0)	0 (-1/1)*
Aesthetic Index	-1 (-3/-1)	-1 (-3/3)*

*: P<0.05; ^: P<0.1.

TABLE VII.—Clinical results did not reach statistical significance, even if in general SPoRT.

	SPoRT			LY		
	I	W	U	I	W	U
<i>Cobb degrees</i>						
Maximal curve	12	0	3	8	2	5
All curves	16	0	8	12	2	8
Thoracic curves	4	0	5	3	2	5
Thoraco-lumbar curves	6	0	1	5	0	0
Lumbar curves	6	0	2	4	0	3
<i>Bunnell degrees</i>						
Maximal curve	12	0	3	12	1	2
All curves	17	0	4	15	1	3
Thoracic curves	8	0	2	5	1	3
Thoraco-lumbar curves	3	0	1	3	0	0
Lumbar curves	6	0	1	7	0	0
<i>Rib Hump (mm)</i>						
Maximal curve	11	0	4	10	1	4
All curves	15	0	5	13	1	5
Thoracic curves	6	0	2	4	1	5
Thoraco-lumbar curves	3	0	2	3	0	0
Lumbar curves	6	0	1	6	0	0
<i>Distance from plumbline (mm)</i>						
C7 frontal	3	0	12	4	0	11
C7 sagittal	3	1	11	1	3	11^
L3 sagittal	0	4	11	0	1	14
<i>Aesthetics</i>						
Shoulders symmetry	9	0	6	5	2	8^
Scapulae symmetry	10	2	3	8	2	5
Flanks symmetry	10	0	5	5	2	8*
Aesthetic Index	7	0	8	3	1	11*

I: improved; W: worsened; U: unchanged; *: P<0.05; ^: P<0.1.

treatment than after Lyon bracing (aesthetic index and symmetry of the shoulders, with a tendency for that of the shoulders) (Coble *et al.*).

Discussion and conclusions

It sometimes happens that a new therapy changes your professional life, and the very good results, even exceptional in some cases (Figure 4, Table VIII), we had with the new Sforzesco brace required a formal study to be confirmed. In this study, we statistically verified the short-term efficacy of this new instrument for treating very important scoliosis at high risk of surgery, and the concept (SPoRT – Symmetrical, Patient-oriented, Rigid, Three-dimensional, active) we

developed because of it, compared to the classic three-point system obtained through the Lyon brace.

In SPoRT, almost all clinical and radiographic parameters (apart from the thoraco-lumbar ones, where high variability was verified) had better results than LY, with 80% more reduction of Cobb degrees in the worst curves (P<0.001), and 40% in the average of all (P<0.01). Aesthetics were improved (P<0.05), as well as the sagittal configuration of the spine (particularly thoracic and thoraco-lumbar distances – P<0.05) while the same could not be said for the lumbar one, and this should be carefully considered for future developments. In the indexed literature we are aware of very few studies comparing the results of different concepts of bracing: these have shown the superiority of Chêneau over SpineCor,²⁵ Boston over

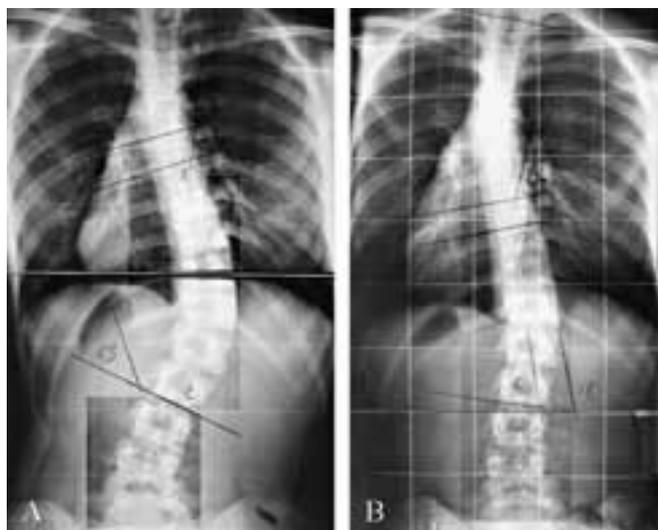


Figure 4.—One of the best results obtained to date with the Sforzesco Brace. Silvia S., girl, born August 1988, menarche December 2000, Sforzesco brace treatment 23 h per day, with SEAS-02 exercises. Pretreatment (A) and short-term results after 6 months (radiograph without the brace) are shown (B). Clinical and radiographic data of this patient are reported in Table VIII.

Charleston,⁵⁹ TLSO over Milwaukee and Charleston,¹⁶ and the similarity of Milwaukee and Boston with a metal overstructure;⁶⁰ in a study, psychological outcomes showed superiority of TLSO over Milwaukee and Charleston.¹⁰ In all cases these studies related to patients with average Cobb angles under 35° Cobb.

Even if we found that one treatment (SPoRT) is superior to the other (LY), this study confirms the short-term efficacy of brace treatment whatever the brace concept used, with only 2 (out of 30) cases that progressed to very high degree scoliosis, usually considered surgical ($45 \pm 7^\circ$ for the worst individual curves, $40 \pm 10^\circ$ for all curves). Good results have been found with different concepts, even if on average always with a lesser degree of curvature.^{4, 6, 24, 25, 27, 28, 31, 33, 60-68} Only one study has shown the long-term efficacy of the Boston brace in curves with a 35-45 Cobb degree range (mean, 38.6°).⁶⁹

At the baseline, groups were not totally comparable, but, in general, the SPoRT group presented the worst cases as well as the best results. The compared group (LY) was retrospective, and we developed a very complex, but accurate method to match the cases between the groups. Due to the long period of treatment in this pathology, and to the low frequency of these high degree scolioses, a comparison of

TABLE VIII.—Results of the patient in Figure 4.

	A. Pre-treatment (0 months)	B. Short-term results (10 months)
Date	January 2004	January 2005
Age (years/months)	16/1	16/7
Cobb degrees T2-T8	22	22
Cobb degrees T8-L2	45	18
Raimondi degrees T12	22	20
Take-off L2	26	8
Risser	4	4
Thoracic Bunnell degrees	5	6
Lumbar Bunnell degrees	13	3
Thoracic rib hump	6	7
Lumbar hump	15	0
Aesthetic Index	4	2
Sagittal plumbline distance (C7-T12-L3)	50-20-30	40-5-10
Frontal plumbline distance (C7)	0	0

simultaneous groups, even if desirable, is very difficult. Moreover, a prospective randomized study should always be advisable, but until now it has never been applied in this field.² A short-term study does not allow us to draw final conclusions, but it is already able to give some clues on the future efficacy of a treatment. Furthermore, when a new treatment is introduced, it is not possible to wait some years before verifying its utility, both for patients in therapy and for children whose possible future need of the new options cannot be ignored.⁷⁰

In this study, all our early patients were included. Since those first cases, we have changed some particulars of the new brace, and developed new insights that should be verified in future studies, but already today the SPoRT concept offers very promising results, and could be able to substitute the classical three-point systems. Comparison with classical cast results should be performed in the future.

These results show the short-term higher efficacy of the SPoRT concept over the three-point ones as represented by the Lyon brace. Looking at the Sforzesco brace, a question that can be raised (and the authors were concerned about that at the beginning) is where the spine is forced to go in a brace with no lateral opening: the results comparing to the Lyon brace, that has plenty of room to escape, definitively overcome this problem. The concept of giving room is very well defined by some schools, such as that of Chêneau,^{24, 25, 71, 72} and also in this case the need could be questioned, but should be addressed with other

researches. It is our idea that space is created from the symmetrical construction of the Sforzesco brace, that pushes and gives room according to the asymmetries of the individual body, and that the spine is pushed and elevated towards the upper space: in a way this action is similar to that of the Milwaukee brace even if, avoiding traction from the top, it is possible to preserve a three-dimensional composite action.

Finally, this study proves the superior short-term efficacy of the Sforzesco brace on the Lyon brace, and allows us to consider it as a valuable therapeutic option to treat high-degree scoliosis. The SPoRT concept includes symmetric and rigid characteristics that are typical of this brace and not of the Lyon, but also the three-dimensional action of correction that presumably should be proven also with other evaluations, such as Perdriolle or Raimondi degrees^{55, 56} on the radiograph, and not only the Bunnell. In any case, the latter is relevant to aesthetics and matters to the patient more than the others, that nevertheless are related to final results. Also the sagittal plane configuration should be proven with lateral X-rays, that we do not routinely perform to avoid unduly increasing radiations to the patients. These aspects, and the other features of the SPoRT concept, such as the idea of being patient-oriented and active because it allows total freedom of movement and exercises, that still need to be tested, will be addressed in future studies.

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