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Clinical Study

Idiopathic scoliosis patients with curves more than 45 Cobb degrees refusing surgery can be effectively treated through bracing with curve improvements

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Abstract

BACKGROUND CONTEXT: It is a broad consensus today that scoliosis curves cannot be improved through bracing, and the Scoliosis Research Society (SRS) methodological criteria for bracing have the avoidance of progression as their only objective. Consequently, in curves more than 45°, fusion is considered as basically the only possible treatment.

PURPOSE: The purpose of the study was to verify in a series of patients who utterly refused surgery if it was possible to achieve improvements of scoliosis of more than 45° through a complete conservative treatment (bracing and exercises).

STUDY DESIGN/SETTING: Retrospective cohort from a prospective database.

PATIENT SAMPLE: Out of 1,148 idiopathic scoliosis (IS) patients at the end of treatment, the sample comprised 28 subjects older than 10 years, still growing, with at least one curve above 45°, who had continually refused fusion. The group comprised 24 females and four males, including 14 in which previous brace treatments had failed; at the start of treatment, the age was 14.2±1.8 years and Cobb degrees in the curve were 49.4° (range, 45°–58°). Subgroups considered were gender, bone age, type of scoliosis, treatment used, and previous failed treatment.

OUTCOME MEASURES: Self-report measurement: SRS-22; physiological measures: Cobb degrees, Bunnell angle of trunk rotation (ATR), aesthetic index (AI), and sagittal plumb line distances.

METHODS: The methods comprised full-time treatment (23 or 24 hours per day) for 1 year with Risser cast, Lyon, or Sforzesco brace; weaning of 1 to 2 hours every 6 months; with strategies to maximize compliance through the Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT) management criteria applied and specific scientific exercises approach to scoliosis exercises (SEAS) performed.

RESULTS: Reported compliance in the 4.10±1.2 treatment years was 94%, with satisfaction regarding treatment and excellent results at the SRS-22. Two patients (7%) remained above 50° Cobb but six patients (21%) finished between 30° and 35° Cobb and 12 patients (43%) finished between 36° and 40° Cobb. Improvements have been found in 71% of patients and a 5° Cobb progression in one patient. Statistically, we found highly significant reductions of the main (−9.25°), average (−6.6°), thoracic (−7.8°), and lumbar (−15.9°) curves. Statistically significant improvements have been found for the AI and ATR, with a general decrease in plumb line distances.

CONCLUSIONS: Bracing can be successfully used in patients who do not want to undergo operations for IS with curves ranging between 45° and 60° Cobb, given sufficient clinical expertise to apply good braces and achieve great compliance. Future studies could demonstrate the percentages at which this result can be achieved.

Keywords: Adolescent idiopathic scoliosis; Juvenile idiopathic scoliosis; Bracing; Surgery

FDA device/drug status: not applicable.

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EVIDENCE & METHODS

Context
Curves greater than 45° in growing children are often addressed surgically. In this article, radiographic and clinical outcomes in patients who refused surgery and who were treated with a bracing/exercise regimen were assessed.

Contribution
Given significant compliance with brace wear (nearly continuous) over long temporal periods (4 to 7 years), the authors found that 71% of children older than 10 years of age with greater than 45° curves (at the beginning of treatment) improved their curves by a minimum of 5° and reported good clinical outcomes on validated measures.

Implication
The results are intriguing, but the article has several shortcomings, including small numbers, a retrospective case series design, and use of a brace and treatment regimen developed by the authors themselves, which might bias the findings. The findings might serve as a nisus for prospectively designed, independently assessed studies. Additionally, brace application, compliance, and length of treatment issues need to be assessed for the ability to generalize.

—The Editors

Introduction

The clinical question is what can we do in patients with more than 45° Cobb, still growing, who do not want to be fused. Moreover, is there any possibility that we can truly avoid fusion at least in some patients who have more than 45° Cobb and still growing?

The broad consensus is that bracing in idiopathic scoliosis (IS) is at least able to stabilize curves but is not able to reduce them. Consequently, the avoidance of progression is considered the main objective of brace treatment [1,2]. In the most important study on brace efficacy produced by the Scoliosis Research Society (SRS), the end point of the failure of treatment was not the inability to improve the curve, but instead the curvature was allowed to progress at least 6° from the radiographic measurement at the start of treatment [3]. The SRS criteria for bracing studies propose, as an outcome, only the percentage of patients who have a curve progression of less than 6°; the criteria do not mention the percentage of patients improved [4].

This approach (avoiding progression) could be considered correct when curves are under the usual thresholds of risk in adulthood [1,5], but it is obviously not enough when facing important curves in which the treatment should be intended to reduce them. The generally accepted idea that improvement is not possible brings forth the consequence that curves more than 45° are most often considered immediately surgical, without even trying conservative treatment [1,6–8]. On rare occasions, attempts have been made in these curves to treat conservatively; they have been proposed in the literature, although not without debate [6,7,9,10].

Certain articles published over the past few years have proved that it is possible to improve minor curves and, in some cases, major ones as well. Studies by Negrini et al. [11] and Aulisa et al. [12], which followed the SRS and Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT) criteria for bracing [13], showed statistically significant improvements in 40.9% and 94% of patients, respectively, in curves between 25° and 40° at the start of treatment. In a retrospective study on a prospective database by Negrini et al. [14], the curvatures exceeding 40°, which numbered 11 at the start of observation, were reduced to three at the end of treatment. Recently, improvements with bracing have been reported also by Landauer et al. [15], Maruyama et al. [16], Rigo et al. [17], and Weiss et al. [18].

If it is possible to improve scoliosis, it could also be possible to hypothesize a conservative brace treatment so as to avoid surgery at least in a percentage of patients having curvatures exceeding 45°. Since some years, we proposed brace treatment in scoliosis of more than 45° to patients who absolutely refused surgery and whose growth was not yet finished, with the aim of trying to reduce the curve, and improve overall balance of the spine so to decrease the risk of a future fusion. Moreover, we aim at improving aesthetics [5,19]. The aim of this article is to retrospectively review the results obtained by all patients treated in these years in the institute with curves more than 45° and refusing surgery.

Materials and methods

Study design

The subject study was a retrospective cohort study (on a prospective database) that was started in March 2003 and included all visits conducted since September 2003. When the study was carried out in July 2009, 7,511 patients and 23,056 evaluations were included in the database in which 4,751 patients had IS and 1,148 had reached the end of treatment (Fig. 1).

Population

We considered all the consecutive patients included in our database who had finished treatment, and according to our data, complied with the following inclusion criteria at the start of treatment: diagnosis of IS; past age of 10 years at first evaluation at the institute and start of

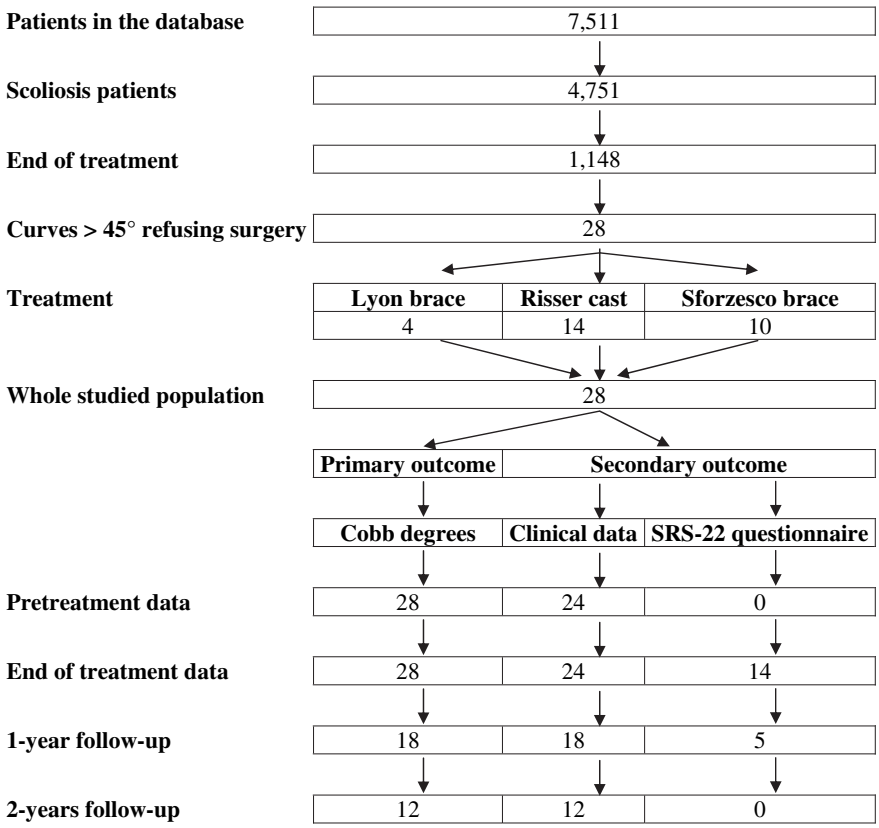

Fig. 1. Flowchart of the selection process for the population included in the study, treatment proposed, and outcome data collected. SRS, Scoliosis Research Society.

treatment; Risser from 0 to 4 and ringapophysis not closed; Cobb angle of 45° or more in at least one curve; and surgery proposed and steadfastly refused before starting treatment. Consequently, we considered 28 patients (24 females and 4 males); at the start of treatment, the age was 14.2±1.8 years, whereas Cobb angle in the worst curve was 49.4° (range, 45°–58°) (Table 1; Fig. 2). We had 19 single curves (14 right thoracic, 1 left thoracolumbar, and 4 left lumbar) and 9 double curves (seven right thoracic left lumbar, one right thoracic left thoracolumbar, and one Moe type). We had subgroups according to gender, Risser test (Risser 0–2 vs. Risser 3–4), type of IS (juvenile idiopathic scoliosis [JIS] vs. adolescent idiopathic scoliosis [AIS]), treatment proposed (Risser cast [RC] vs. brace [C23]), and previous treatment (Table 1).

Treatments

Patients were treated with two different protocols, according to the date on which the treatment started: patients who came to the institute before 2005 had been treated with the RC followed by the Lyon brace or with the Lyon brace only if they refused the inpatient approach required for casting; and those who came to the institute in 2005 or later were treated with the Sforzesco brace. The change of protocol followed the development of the new Sforzesco brace to replace casting, as reported in the previous studies [20–23]. In the study, we will look at the entire group, as well as the two subgroups, to determine whether the Sforzesco brace is truly comparable to Risser casting as previously reported [20].

The RC [20,24,25] (RC subgroup) had to be worn a year (three casts at 4 months each) and was followed by the Lyon brace according to the following protocol: 23 hours per day for the first 6 months, followed by a reduction of 2 hours for every 6 months. Bracing (with the Lyon brace [26,27] until 2004 or Sforzesco brace [20–23] from 2005) had to be worn for 23 hours each day for a year, followed by 6 months at 22 hours per day after which a 2-hour reduction was implemented every 6 months. This protocol has been developed in our institute for many years to help the postural neuromuscular system to maintain the correction thus achieved [23] and maximize compliance. In fact, although scoliosis is a bone deformity, there is also a postural component of the curve [28] that always increases it [29] and can be at the base of its progression [23,30]. Moreover, movement has been shown to be a crucial progression factor [31,32], whereas it can also be reorganized to become a stability factor [33]. Braces directly interfere with such neuromuscular functions [30,34]. Because posture and movement require long-term adaptations [30,35–37], the longer the weaning phase is, the better the neuromuscular system should adapt, hopefully maintaining the inputs received by the brace even after complete weaning. In this respect, proper stabilization exercises

Table 1
Baseline characteristics of the entire sample and the identified subgroups

Subgroups		Abbreviation	Number	M/F	Age	BMI	Cobb degrees	AI	ATR
	Total		28	24/4	14.2±1.8	21.3±4.4	49.4±3.8	4 (2–6)	12.5±6.6
Gender	Females	F	24		14.1±1.7	21.3±4.7	48.9±3.7	4 (2–6)	13.1±6.8
	Males	M	4		15.6±3.4	21.1±3.7	52.2±4.1	6 (4–6)	9.5±5.0
	p				NS	NS	NS	<.01	NS
Type of idiopathic scoliosis	Adolescent	AIS	24	21/3	14.3±1.9	21.3±4.5	49.3±3.7	4 (2–6)	13.1±6.6
	Juvenile	JIS	4	3/1	13.3±0.8	21.0±5.6	50.2±5.0	4 (3–6)	9.5±6.6
	p			NS	NS	NS	NS	NS	NS
Skeletal maturity	Risser 0–2	R02	12	11/1	13.1±1.2	21.1±5.7	48.7±2.9	4 (2–6)	12.9±6.4
	Risser 3–4	R34	16	13/3	15.1±1.7	21.4±3.6	50.0±4.4	4 (2–6)	12.3±6.9
	p			NS	<.05	NS	NS	NS	NS
Treatment	Brace	C23	14	12/2	14.8±2.0	20.8±4.7	48.6±3.4	4 (2–6)	12.8±3.6
	Risser cast	RC	14	12/2	13.4±1.4	22.0±4.1	50.3±4.2	4 (2–6)	12.3±9.1
	p			NS	<.05	NS	NS	NS	NS
Previous treatment	No		15	12/3	14.0±1.7	21.4±4.4	48.8±4.3	4 (2–6)	13.4±7.3
	Yes		13	12/1	14.3±2.1	20.2±3.2	48.8±4.2	4 (2–6)	15.1±6.7
	p			NS	NS	NS	NS	NS	NS

M/F, male/female; BMI, body mass index; AI, aesthetic index; ATR, angle of trunk rotation; NS, not significant.
Values are average±standard deviation, apart from AI were median and range have been reported.

should play a major role, as recently shown [23,38]. All this should positively interfere with bone tissue formation [31,32], even if the postural system per se is a part of the problem to be corrected [28–30].

The first full-time bracing of the 1-year phase (with either the RC or the brace) is intended to achieve the maximum possible correction [20]; the remaining is a gradual weaning of the brace with the goal of maintaining the achieved correction (and occasionally even increase it) through a very slow decrease in brace wearing. This should allow a progressive adaptation of the postural system, with the determinant help of stabilizing exercises [38]. Moreover, this protocol shows a significantly positive psychological impact, appearing to the patient and family as a reward system based on the results achieved.

The foregoing protocols were adapted individually in all cases according to the demonstrated stability. This was verified clinically for every 6 months, allowing a maximum of 2° angle of trunk rotation (ATR) worsening from the last evaluation, and radiographically (X-ray without the brace for the same number of hours corresponding to the weaning time) [23], each year allowing a maximum of 4° Cobb worsening

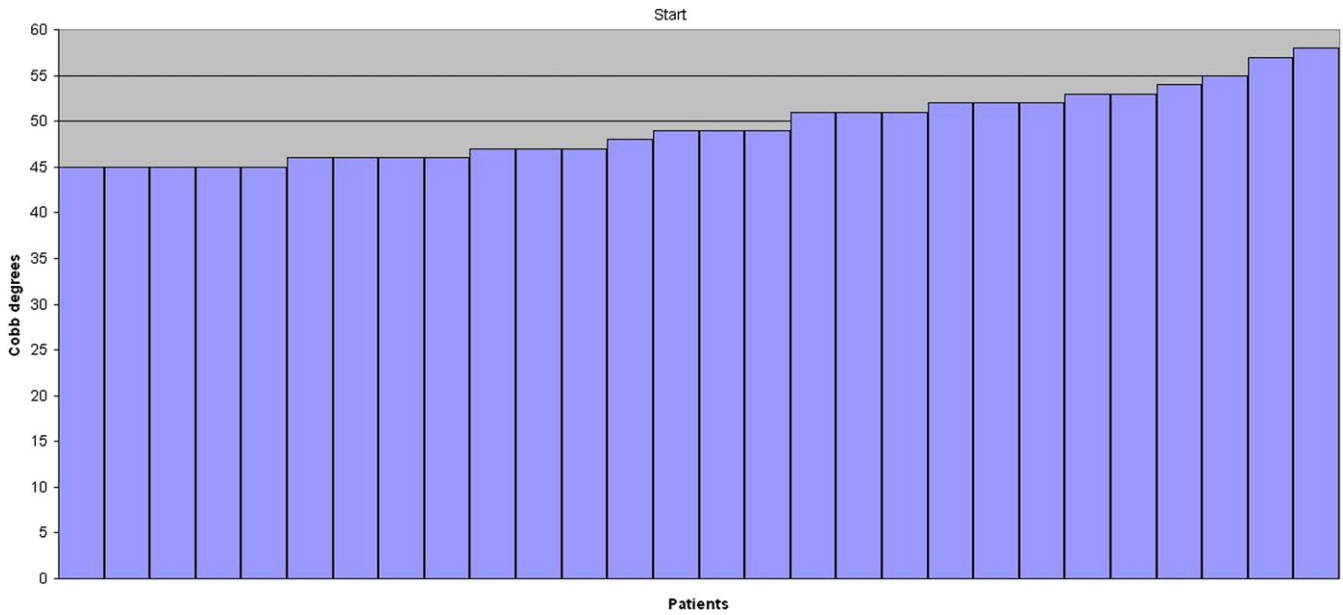

Fig. 2. Radiographic characteristics of the worst curve in the considered sample of patients at the start of the study.

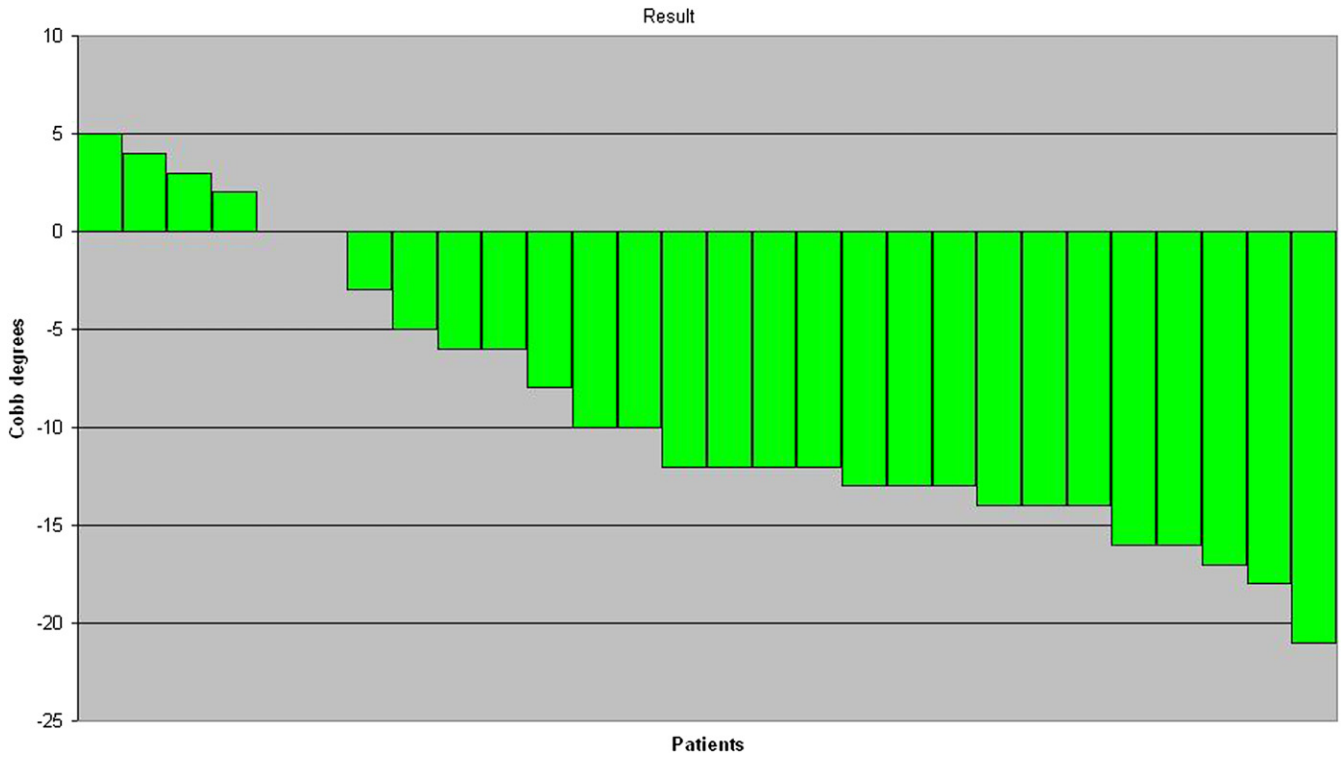

Fig. 3. Radiographic results of the worst curves in Cobb degrees. Only one patient (4%) worsened 5° or more, whereas 21 of 28 (71%) improved 5° or more.

from the previous results [38]. A discussion was held each time with the patient and family. The primary objective was to optimize compliance, eventually reducing a bit more of the hours if needed by the patient so as to avoid failure (brace withdrawal); in the case of a loss of correction during treatment, the reduction was slowed (to 1 hour or none) if the patient was deemed able to stand this slowing. In every case, we avoided prescribing the use of a brace for less than 18 hours per day before the patient reached Risser 3. The weaning process continued from that day at the rate of 2 hours for every 6 months and required a period ranging from 2.5 to 3.5 years to reach completion [38].

We prescribed specific scientific exercises approach to scoliosis (SEAS) exercises for each patient, to be performed twice a week [38,39]. During treatment, we followed the SOSORT criteria, and based on that classification we had an excellent approach, with 43 of 44 questions receiving ''yes'' responses [13].

Outcome criteria

The primary outcome criteria were the radiographic results (Cobb degrees), and we had all data from all the patients obtained after 48 to 72 hours without the brace (our standard weaning time in which to determine final brace total weaning); 12 (43%) patients reached a 2-year follow-up, and 18 (68%) patients reached 1-year follow-up. To validate the radiographic readings, two of the authors blindly remeasured all the radiographs we had been able to collect from the patients of this cohort (23 radiographs). We found no statistically significant difference among the three sets of measurements (paired analysis of variance).

The secondary outcome criteria comprised the clinical results (ATR, aesthetic index [AI], and sagittal plumb line distances) obtained in the last 24 (of 28) consecutive patients. Since 2005, we introduced also the use of the SRS-22 questionnaire [40,41] in the Italian version [42], and we report its results at the end of treatment in 14 patients who have the first evaluation during treatment of 2.9 ± 1.1 years before; in five, we had the follow-up data at 1 year. The subgroup with neither all the clinical data nor the SRS-22 answers differed statistically from the remainder of the sample for any other considered parameter.

We considered the results in the main curves (if there was more than one curve, both were considered main curves if their difference was below 10° Cobb) and in all curves deemed important and measured by the treating physician (average curve): 53 in the 28 patients, 16 lumbar, 4 thoracolumbar, 28 thoracic, and 5 proximal thoracic.

Reported compliance has also been considered [11]. At each visit, the patient and his/her parents were carefully queried regarding how many hours per day she/he had used the brace and the average usage during the period reported. This was compared with the prescription, and a percentage of compliance was computed.

Computations and statistical analyses

We used the paired analysis of variance, the Tukey-Kramer test, paired *t* test, and chi-square analysis according

to what was appropriate. Evaluating the percentage of patients changed, we considered significant clinical changes if the repeatability error was exceeded, namely: Cobb degrees, 5° [43]; ATR, 2° [44]; AI, two points [45]; and plumb line distances, 10 mm for C7 and 15 mm for L3 [43]. We did not perform more advanced statistics for subgroups (such as regression analysis, whether multiple or not) because the retrospective cohort design we had adopted did not permit solid inferences to be gathered.

Results

The treatment period lasted 4 years and 10 months (range, 1.45–7.42): 5 patients used the brace for 6 years or more, 16 patients used it for 4 to 5 years, and 7 patients used it for less than 3 years. These seven patients (25%) followed a personalized prescription with rapid weaning when compared with the classical protocol. This was because of either very good results or a high risk of withdrawal; this group included also the patient with the lowest compliance; four more patients (14.2%) required only once, for the same reasons, an increase in the progressive weaning of more than 2 hours (3 or 4 hours). During the overall treatment, on average in this cohort the brace was declared to be worn for 17.8±1.7 hours per day. The average reported compliance was 94%, and only three patients remained below 90% (45%, 83%, and 87%, respectively).

According to the SRS-22 questionnaire, the patients were satisfied with treatment (between four and five points, apart from one 3 and one 2.5) and had good results in all subscales (pain and activity four to five with one 3 each, health and aesthetics three to five). There were no statistically significant differences with results during treatment of 2.9 years before, whereas at the 1-year follow-up there was an improvement (only two patients had one 3, both in the Aesthetics scale) ($p<.05$).

We observed improvements both radiographically and clinically in most of the parameters considered, but the best results were obtained in the main curves: 71% of patients improved at least 5° Cobb, whereas only one patient worsened (4%) (Fig. 3); and regarding the curve average, these percentages were 64% and 7%, respectively. Moreover, 71% of patients in this cohort concluded treatment below 45°, with 2 patients (7%) remaining above 50°, 6 patients (21%) finishing between 30° and 35°, and 12 patients (43%) between 36° and 40° (Fig. 4). None of the patients who reached the 1- and 2-year follow-ups showed an increase in curvature.

The average improvement was 9.25°±8.04° Cobb ($p<.0001$) in the main curve and 6.63°±7.45° Cobb ($p<.0001$) for the curve average; thoracic and lumbar main curves decreased 7.78°±6.83° ($p<.0001$) and 15.91°±10.42° ($p<.0005$), respectively, whereas the decrease of 7.00°±4.24° in the only two thoracolumbar main curves was not statistically significant (Table 2). The improvement of lumbar main curvature was statistically

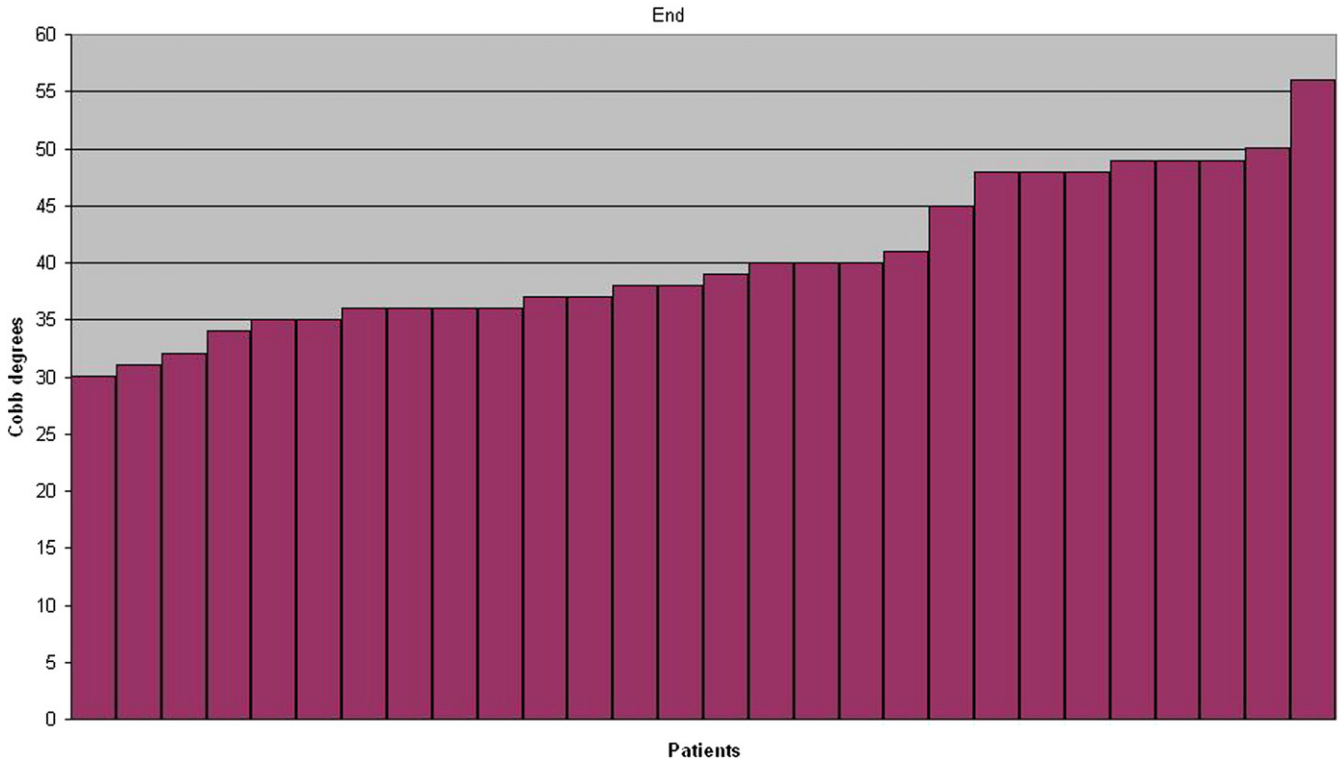

Fig. 4. Radiographic characteristics of the worst curve in the considered sample of patients at the end of the study. Two patients (7%) remained above 50°, six patients (21%) finished between 30° and 35°, and 12 patients (43%) finished between 36° and 40°.

Table 2
Radiographic results in the different regions of the spine in the total sample and in the considered subgroups

Curves studied	Region of the spine	Total	Subgroups							
			Females	Males	AIS	JIS	Risser 0–2	Risser 3–4	Brace	Risser cast
Main curve	Lumbar	−15.9±10.4	−14.3±12.9	−15.5±5	−14.1±10.7	—	−17.8±12.7	−12.2±8.3	−12±3.4	−17±13.9
	Thoracolumbar	−7±4.2	−7±4.2	—	−7±4.2	—	—	−7±4.2	—	−7±4.2
	Thoracic	−7.8±6.8	−7.4±6.9	−11.5±6.4	−8.4±6.9	−3.3±4.6	−5.1±6.4	−9.8±6.7	−10.9±5.7	−3.7±6.1
	p*	<.01	<.1	NS	<.1	NA	<.05	NS	NS	<.01
All curves	Lumbar	−10.5±8.2	−7.5±7.3	−17.5±2.5	−10.1±5.6	−8±14.7	−8.5±7.7	−11.7±7.7	−9.6±7.6	−10.4±8.2
	Thoracolumbar	−5.2±4.3	−5.2±4.3	—	−4.7±5.0	—	—	−7±3	—	−5.2±4.3
	Thoracic	−7±7.2	−6.6±7.3	−13.5±4.4	−7.1±7.4	−6.2±6.9	−5.8±6.2	−8.7±7.8	−11.1±5.5	−3.9±7.0
	p*	NS	NS	NS	NS	NS	NS	NS	NS	<.1

AIS, adolescent idiopathic scoliosis; JIS, juvenile idiopathic scoliosis; NA, not applicable; NS, not significant.
* Statistically significant differences could be reached only between thoracic and lumbar curves because of the reduced thoracolumbar groups.

significantly higher than thoracic one (p<.01). This remained true in the RC and Risser 0 to 2 subgroups (−17.00°±13.90° vs. −3.70°±6.11° and −17.80°±12.74° vs. −5.10°±6.38°, respectively), whereas it was not in the C23 and Risser 3 to 4 subgroups.

Improvements have been observed also in the ATR (−3.2±3.9°; p<.001) and AI (−4; p<.0001) in general and in all subindexes (shoulders, scapulae, and waist), whereas we observed a decrease (worsening) of the C7 plumb line (−11.6±14.9 mm; p<.01) (Table 3).

Looking at the subgroups, the four males considered presented lumbar curves and aesthetics that were worse than the females at the start of treatment; the results of the males were better than those of the females in the main (p<.05), average (p<.01), and lumber curves (p<.05) (Table 3). The four JIS had a worse sagittal plane than AIS at the start of treatment, but at the end of treatment, there were no differences in all parameters (Table 3). As expected, Risser 0 to 2 group was younger than Risser 3 to 4 at the start of treatment (Table 1); treatment lasted longer (5.68±1.18 vs. 4.18±1.27 years; p<.005), but no other differences were found in the pretreatment data or in the results (Table 3). The difference was found neither at the start of treatment nor in the results, regardless of whether the patients had previously failed treatment.

Looking at the two treatment protocols used in this study, the patients in the RC group tended to be younger (p<.1) (Table 3) and had been treated longer (5.46±1.37 years vs. 4.19±1.22 years; p<.05), with more hours of treatment prescribed (27,750±5,466 vs. 37,854±7,563 hours; p<.001) and done (25,472±6,839 hours vs. 36,446±7,891; p<.005) than C23. Moreover, the last group was engaged in sports 1.44±0.98 times per week versus 0.49±0.62 times per week in the RC (p<.05). In both groups, there were improvements in the main (Fig. 5) and lumbar curves as well as the AI, whereas the C23 also improved in terms of the thoracic and average curves. There were statistically different results among the groups in the thoracic curve in favor of C23 (Table 3), whereas from a statistical perspective, the plumb line distances worsened in the RC group, which differentiated it from C23 (Table 4).

Discussion

The above results mean that it is possible to answer the clinical questions offered at the beginning of this article.

Table 3
Clinical and radiographic results in the whole sample and subgroups

Subgroups		Cobb degrees				ATR				AI			
		Av	I (%)	U (%)	W (%)	Av	I (%)	U (%)	W (%)	Av	I (%)	U (%)	W (%)
Entire sample	Main curves	−9.25±8.04*	71	25	4	−3±3.81*	63	29	8	−4 (−2; 2)*	67	29	4
Gender	Females	−8.15±7.89*$	67	29	4	−3.2±3.99*	65	25	10	−1 (−3; 2)*$	60	35	5
	Males	−15.5±6.28*$	100	0	0	−2.75±3.3	75	25	0	−3 (−4; −2)*$	100	0	0
Type of scoliosis	Adolescent	−6.33±7.58*	86	14	0	−3.4±3.95#	65	25	10	−2 (−3; 2)*	70	25	5
	Juvenile	−8.5±11#	57	36	7	−1±2.45	50	50	0	−2 (−4; 1)	50	50	0
Skeletal maturity	Risser 0–2	−9.31±7.72*	58	42	0	−2.45±3.91	64	18	18	−1 (−3; 1)*$	55	45	0
	Risser 3–4	−11.34±7.89*	81	13	6	−3.54±3.8	69	31	0	−2 (−4; 2)*$	77	15	8
Treatment	Brace	−11.29±5.96*	86	14	0	−2.92±2.75#	77	15	8	−1 (−3; 2)*	62	31	8
	Risser cast	−7.11±9.42*	57	36	7	−3.18±4.92	55	36	9	−2 (−4; 1)*	73	27	0

AI, aesthetic index; ATR, angle of trunk rotation according to Bunnell; Av, average±standard deviation; I, improved; U, unchanged; W, worsened.
Prepost differences: *, statistically significant (p<.05); #, statistical tendency to difference (p<.1). Among subgroups differences: $, statistical tendency to difference (p<.1). Average improvements were statistically significant in all parameters for the main curves.

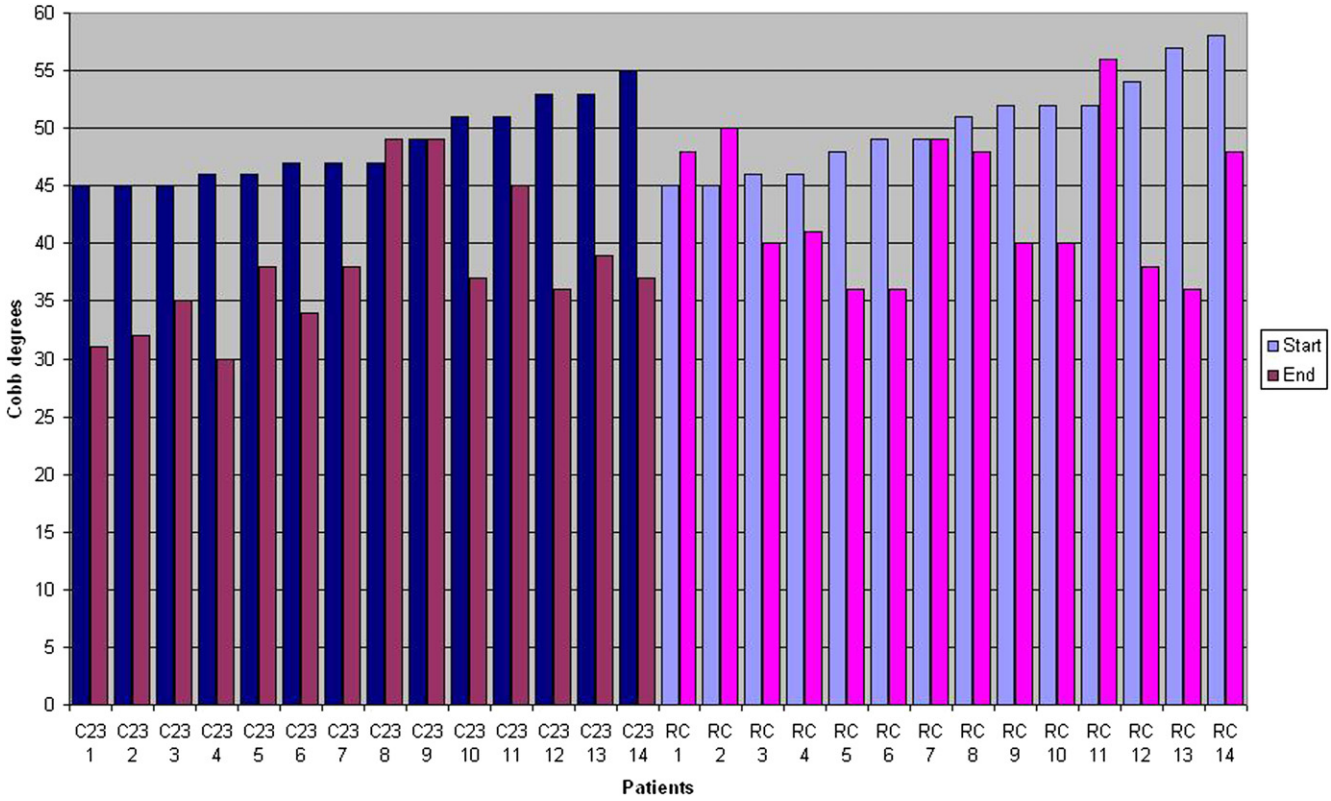

Fig. 5. Individual results in the worst curves in the two subgroups of patients treated only with bracing (Lyon or Sforzesco: brace [C23] subgroup) vs. those who had previously been treated with casting (Risser cast [RC] subgroup): in deep (C23) or light (RC) blue for start of treatment; in deep (C23) or light (RC) purple for end of treatment. The results were superior in the C23 subgroup.

First, there is a possibility of truly avoiding fusion for at least some patients with curves more than 45° Cobb and still growing (Fig. 6). It is possible to improve in some cases up to 20° Cobb (Fig. 7). Second, if the patient refuses to be fused, one can propose a brace treatment that, for the sake of possible success, must be done properly (good compliance) for some years (4–7 years, depending on the starting bone age). The improvements found were more than simply statistical but were also clinically significant (around 10° Cobb on average, with 71% of patients improved 5° Cobb or more). Obviously, a long-term follow-up of this cohort is advisable, but the short-term follow-up performed in a subgroup of patients showed no progression.

Table 4
Results in the sagittal plane according to the plumb line distances

Subgroups	Plumb line distances	C7	L3
	Total (main curves)	−11.58±14.91*	0.79±17.18
Gender	Females	−11.56±16.1*	1.88±15.9
	Males	−16.67±5.77	11.67±23.09
Type of scoliosis	Adolescent	−13.13±15.69*	−2.81±14.6§
	Juvenile	−3.33±5.77	20±20§
Skeletal maturity	Risser 0–2	−13.75±21.34	6.88±20.34
	Risser 3–4	−10±8.66*	0±12.85
Treatment	Brace	−9.62±14.36	8.85±16.09§
	Risser cast	−15.83±16.56*	−10±6.32*§

A decrease of the distances in C7 means a reduction of kyphosis, an increase of the L3 distance means an increase of lordosis, whereas that in T12 a decrease of junctional kyphosis. Prepost differences: *, statistically significant ($p<.05$). Among subgroups differences: §, statistically significant ($p<.05$).

We believe it is preferable, as a means to better understand such results, to discuss the strengths and limitations of the study described in this article. This is a retrospective cohort study, and therefore, it can offer only an efficacy analysis because the number of dropouts is not known. Currently, a prospective study is underway through our database, which was started in 2003, but we need at least 2 or 3 more years to reach the end of treatment in a sufficient number of patients. On completion of this prospective study, we will also be able to have an intent-to-treat analysis and the number of patients refusing such treatment (but whom we hope will serve as controls) and dropouts. The present study has been done on patients who had refused surgery at the start of treatment and continued to refuse it until the end of treatment. This particular population can have much greater motivation than others do, which could explain the high compliance rates thus reported (even if they are comparable to other published studies [11]). In any case, it must be taken into account that reported compliance is different from real compliance, but this was unavoidable in such a retrospective study. In other settings, it will be necessary to check for proper compliance, and in future studies, it will be essential to use compliance meters

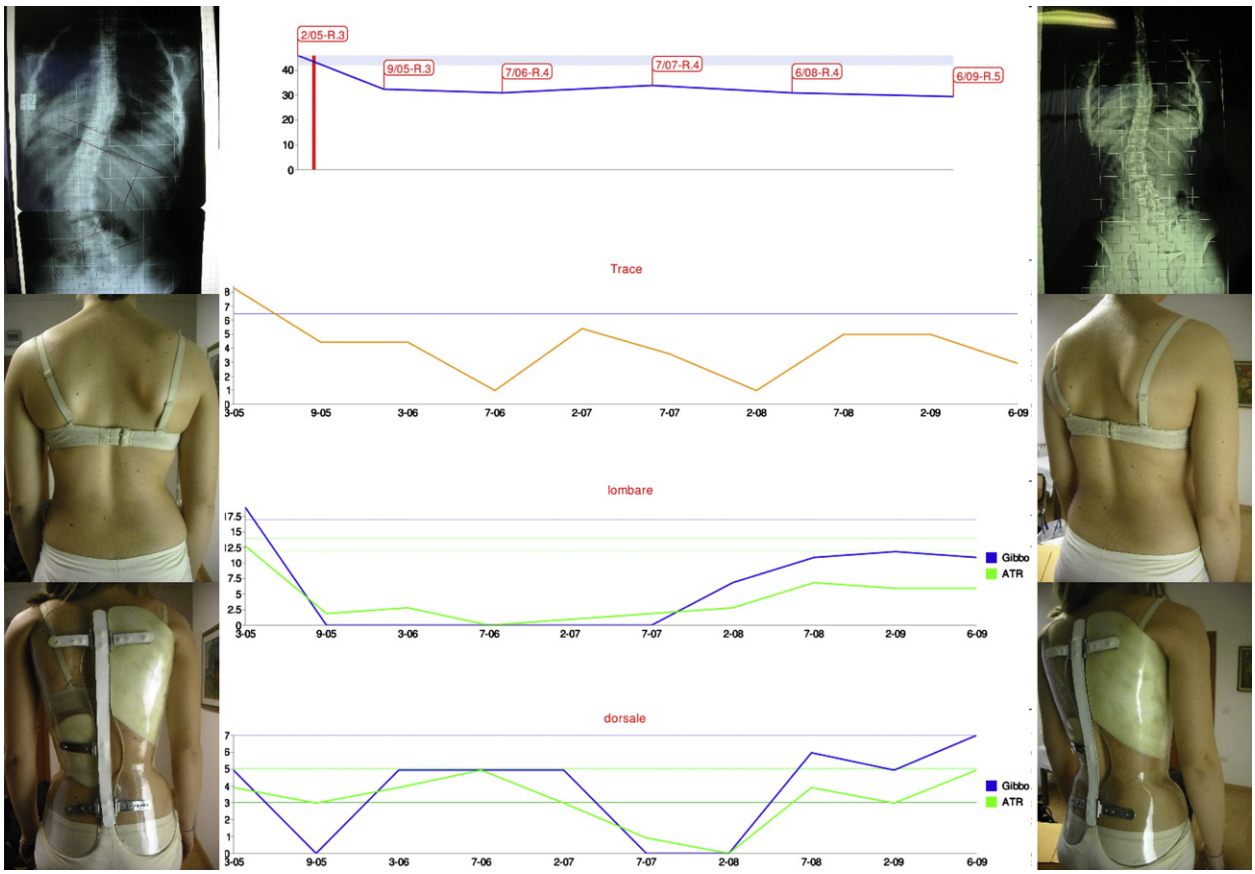

Fig. 6. Clinical and radiographic results in one female patient who started treatment at Risser 3, 46° Cobb lumbar curve (Trunk Aesthetic Clinical Evaluation [TRACE] 9/12) [34] and finished at 30° Cobb (TRACE 3/12). Left column, in top-down direction, starting frontal X-ray, actual posterior aesthetics, and actual brace, posterior view. Middle column, in top-down direction, evolution of radiographic and clinical parameters where significant changes from start have been reported under the blue lines: thoracic and lumbar Cobb degrees in blue lines with dates and Risser stages in the flags; TRACE [34] (aesthetics evaluation in 12 point) in yellow line; thoracic and lumbar (“Livello lombare”) Bunnell angle of trunk rotation in green and rib hump in blue lines. Right column, in top-down direction, final situation: frontal X-ray, aesthetics, and actual brace, posterolateral view.

[4,46–48] as soon as they are ready for everyday clinical use. In this study, we cannot draw the real percentages of improvement/worsening in such a population, because of the fact that some patients, or even many, could have dropped out. Thus, we can properly answer the initial clinical questions, but we cannot state the percentages at which surgery can actually be avoided. Finally, the lack of follow-up preclude the possibility to understand future variations; the 12 (43%) patients who reached the “classical” 2-year follow-up and the 18 (68%) patients who reached 1-year follow-up remained all stable, both clinically and radiographically, but future studies only will reveal which changes could occur with time. Nevertheless, because of the lack of knowledge in this field and in the actual consensus [1,2,4,49], these results are truly worth publication because they could change the actual paradigm of treatment.

Given a patient with a curve exceeding 45° and is past the age of 10 years and still growing, according to these results, a conservative treatment could be proposed, provided that the patient and family are highly motivated and the members of the treating team (physician, orthotist, and physiotherapist) [13] are highly skilled. According to these results, a brace treatment can be at least as effective as (but presumably more effective than) treatment with an RC, thereby confirming the previously published results in the short term [20]. Meanwhile, the patient’s gender, type of IS (AIS or JIS), and bone age according to Risser staging do not appear to play a major role.

Such patients were, on average, older than those who are normally treated for AIS [2,11,12,39,40], but this is typical of the worst clinical situations [14] in which many patients have already been treated and treatment failed. All our JIS patients had already failed in terms of treatment, and this was also true for nine of the AIS subjects. Nevertheless, according to our data, the results were not affected by the fact that any of the patients had previously failed treatment.

The results confirm the previously published reporting improvements in patients treated with braces for AIS [11,12,14–18]. Additionally, they confirm other results in worst-case patients that demonstrated improvements [14]. The SOSORT criteria for management of braced

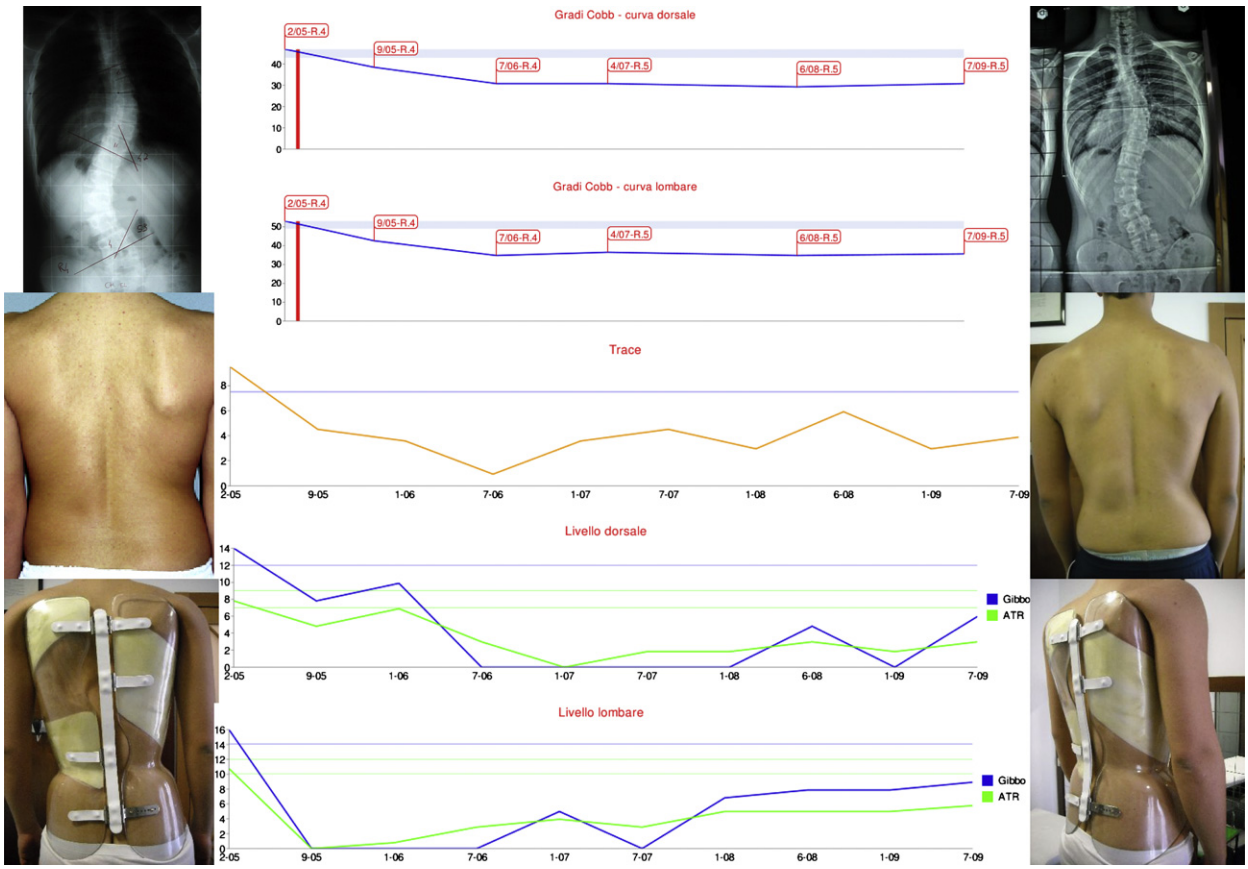

Fig. 7. Clinical and radiographic results in one male patient who started treatment at Risser 4, 47° Cobb thoracic and 53° lumbar curves (Trunk Aesthetic Clinical Evaluation [TRACE] 10/12) [34] and finished at 31° and 36° Cobb, respectively (TRACE 4/12). Left column, in top-down direction, starting situation: frontal X-ray, aesthetics, and actual brace, posterior view. Middle column, in top-down direction, evolution of radiographic and clinical parameters where significant changes from start have been reported under the blue lines: thoracic and lumbar Cobb degrees in blue lines with dates and Risser stages in the flags; TRACE [34] (aesthetics evaluation in 12 point) in yellow line; Thoracic and Lumbar Bunnell angle of trunk rotation in green and rib hump in blue lines. Right column, in top-down direction, final situation: frontal X-ray, aesthetics, and actual brace, posterolateral view.

patients [13] have been carefully followed throughout this treatment, and our results confirm the importance of such an approach, which presumably increases compliance [11,12]. Additionally, exercises could have a major role in the overall results, mainly in terms of increased maximum correction [39] and reduced loss of results during weaning [38] but possibly through increased compliance [13] as well.

The results vary among the various regions of the spine, depending on the treatment applied, so that they appear better in the lumbar region if an RC is used. Apparently, the exclusive use of a brace improves the results in the thoracic region, whereas the lumbar region does not seem to react as much as it does after casting; so, there is a closing of the gap between the two regions of the spine in the C23 subgroup. Larger samples, and more homogeneous (the group of braced patients comprised two different braces—Lyon and Sforzesco—according to different concepts and with different results) [21], could confirm or deny those results.

Other subgroup analysis failed for various reasons such as the following:

- The type of brace used (Lyon or Sforzesco) in the C23 subgroup: The patients who ended treatment using the Sforzesco brace were much older than those treated with the Lyon brace because the former has only been implemented for 5 years, and only oldest patients could have finished treatment in this period of time;
- Declared compliance: We had only three patients who declared less than 90% compliance;
- Duration of treatment and total hours of treatment: Patients with the highest values in these parameters were treated with the RC, with a polarization precluding such an analysis;
- Increased time of weaning when compared with described protocol: In fact, this reduction was allowed for very good results or for very poor compliance, and in such a reduced group of patients [7], it was not possible to reach any statistical significance.

Conclusions

Bracing can be successfully used in patients who do not want to be operated for IS with curvatures ranging between

45° and 60° Cobb, provided there is clinical expertise to apply good braces and achieve high compliance. In that respect, fulfilling the SOSORT criteria could be a key to success [11–13]. This study provides some evidence that bracing may be an effective treatment alternative to surgery, but a prospective study is required before definitive conclusions can be drawn.

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