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ORIGINAL ARTICLE

Long-term results after brace treatment with Progressive Action Short Brace in adolescent idiopathic scoliosis

Angelo G. AULISA [1] *, Renato M. TONIOLO [1], Francesco FALCIGLIA [1], Marco GIORDANO [1], Lorenzo AULISA [2]

[1]Unit of Orthopedics and Traumatology, Institute of Scientific Research, Bambino Gesù Children's Hospital, Rome, Italy; [2]Department of Orthopedics, IRCCS A. Gemelli University Polyclinic Foundation, Sacred Heart Catholic University, Rome, Italy

*Corresponding author: Angelo G. Aulisa, Unit of Orthopedics and Traumatology, Institute of Scientific Research, Bambino Gesù Children's Hospital, Piazza S. Onofrio 4, 00165 Rome, Italy. E-mail: angelogabriele.aulisa@fastwebnet.it

ABSTRACT

BACKGROUND: In the literature, there are few papers on long-term results after brace treatment and there is no consensus on whether scoliotic curves stop progressing at skeletal maturity. To date the factors that could influence curve behaviour following bracing have not been fully determined.
AIM: The aim of this study was to evaluate the results and the loss of the scoliotic curve correction in a cohort of patients treated with Progressive Action Short Brace (PASB) brace during adolescence and to compare patient outcomes of under and over 30 Cobb degrees 10 years after brace removal.
DESIGN: This is an observational controlled cohort study nested in a prospective clinical on-going database including 1536 patients with idiopathic scoliosis.
SETTING: Inpatients and outpatients in Rome.
POPULATION: The study enrolled 163 patients with idiopathic adolescent scoliosis who had been treated with the PASB brace at a 10 years minimum long-term follow-up examination.
METHODS: One hundred sixty-three (female) patients with adolescent idiopathic scoliosis (AIS) treated with the Progressive Action Short Brace (PASB) at a mean age of 13.4 years (range 10-34) had accepted to undergo long-term follow-up examination. All patients had clinical and radiological examinations, but only 62 replied to some simple questions (including work status, pregnancy and pain) the population was divided into two groups based on Cobb degrees (<30° and ≥30°). Statistical analysis was applied to test the efficacy of our hypothesis.
RESULTS: The patients underwent a long-term follow-up after brace removal at a mean age of 13.46 years (±3.4). The prebrace mean curve was 28.98° (±7.918); after treatment, the mean was 13.88° and increased to a minimum of 15.35° in the 10 years following brace removal. However, there was no significant difference between the mean Cobb angle at the end of weaning and the mean Cobb angle at long-term follow-up. The curve angle at baseline of patients who were treated with a brace was reduced by 15° during the treatment, but at follow-up the curve size was found to have lost 2°. The over 30° group showed a prebrace scoliotic mean curve of 37.26°; at the end of weaning, the mean curve angle was 22.98° which increased to a mean of 25.07° at follow-up. The <30° group showed a prebrace scoliotic mean curve of 24.40° which, at the end of weaning, had reduced to a mean of 8.69°, increasing to 9.98° at follow-up. There was no significant difference in the mean progression of curve magnitude between the <30° and ≥30° groups at the long-term follow-up. Work status was 62% full-time and 11% part-time. 24% had given birth. Three percent presented back pain related to instability of the spine. No patients underwent surgery after maturity but one patient had indication to surgical treatment.
CONCLUSIONS: The PASB brace is effective for the treatment of lumbar and thoracolumbar scoliosis and is characterized by positive long-term outcomes, including in patients demonstrating moderate curves. In both groups, at 10-years minimum follow-up after bracing, scoliotic curves did not deteriorate beyond their original curve size after bracing in both groups at the 10-years minimum follow-ups.
CLINICAL REHABILITATION IMPACT: At 10 years follow-up after bracing, scoliotic curves had not deteriorated beyond their original curve size.

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KEY WORDS: Braces; Scoliosis; Adolescent; Follow-up studies.

Adolescent idiopathic scoliosis (AIS) is a structural three-dimensional spinal deformity characterized by lateral curvature of the spine and vertebral rotation, appearing in normal children during puberty. AIS is characterized by great variety and only 0.3-0.5% of the curves have a progression that requires treatment.[1, 2]

In AIS, brace treatment is the method most commonly used to stop the evolution of the deformity in immature adolescents and, as reported in recent literature, to obtain a partial recovery of the curve.[3-9] The efficacy of bracing is strongly correlated with wearing time and patient compliance.[10, 11]

Long-term follow-ups indicate that patients with scoliosis may have a higher prevalence of back pain and of worsening quality of life (QoL) if the curve becomes extremely large.

Therefore, brace treatment in AIS helps prevent problems during adulthood. Moreover, there is no consensus as to whether scoliotic curves stop progressing at skeletal maturity.[12]

Long-term cohort studies are the only possible means of collecting data on scoliosis due to the difficulty of undertaking randomised clinical trials.

In a recent study, we evaluated 93 patients with a long-term follow-up, 53 treated with the Lyon Brace and 40 with the Progressive Action Short Brace (PASB).[13] The PASB is a custom-made thoraco-lumbar-sacral orthosis (TLSO) indicated only for the treatment of thoraco-lumbar and lumbar curves. In this study we demonstrated that bracing could be effective long term in patients with AIS with a slight loss of correction 10 years post bracing. This new study differs from the previous one in the number of patients enrolled, but above all in the location of the curve. The biomechanical behavior of the lumbar and thoraco-lumbar curves in adulthood is different from that of the thoracic curves and can more frequently induce instability of the spine.

The aim of the present study was to evaluate the loss of the scoliotic curve correction at long-term follow-up in a greater number of patients treated with PASB during adolescence and to compare patient outcomes under and over 30 Cobb degrees, and to evaluate if the initial curve severity could influence long-term results.

Materials and methods

Design

This is a retrospective cohort observational study nested in a prospective clinical on-going database including 1536 patients with idiopathic scoliosis. Patients were recruited both in public hospitals and in private clinics. The patients were recruited from 1984 to 2008 and only those followed for a minimum of ten years after weaning were selected.

The inclusion criteria were: 1) idiopathic adolescent scoliosis; 2) PASB brace; 3) X-ray at baseline, at end of treatment and at a minimum of 10 years from the end of treatment; and 4) Risser stage 0-4.

Patient population

This is a retrospective study based on an ongoing database including 1536 patients treated for idiopathic scoliosis between 1980-2018. Informed consent was obtained from all participants. This study was conducted in accordance with the World Medical Association Declaration of Helsinki of 1975, as revised in 1983, and all the participants gave informed consent to allow the use of clinical data for research purposes.

One hundred sixty-three (female) patients with AIS treated with PASB agreed to attend a long-term follow-up examination at a minimum of 10 years from the end of treatment (range 10-34) (Figure 1). The treatment dropout rate in all the patients treated with PASB (553) was only 10.4%.

All patients had radiological examination but only 62 were asked to answer some simple questions.

Demographic characteristics were obtained. Patients were observed in the standing erect position and during the forward bending test.

At the start of treatment patients had curves with a mean magnitude of 28.98° Cobb (range 20-60°). Age at the start of treatment was 10-17 years, with a Risser score between 0 and 4. Seventy-two patients presented a lumbar curve and 91 a thoracolumbar curve.

Bracing protocol

All patients were prescribed a full-time brace (*i.e.* maximum 22 h daily, minimum 18 h daily). Curves above 25 degrees with Risser 0-1 are considered progressive, instead for curves of less than 25° Cobb degrees, progression was

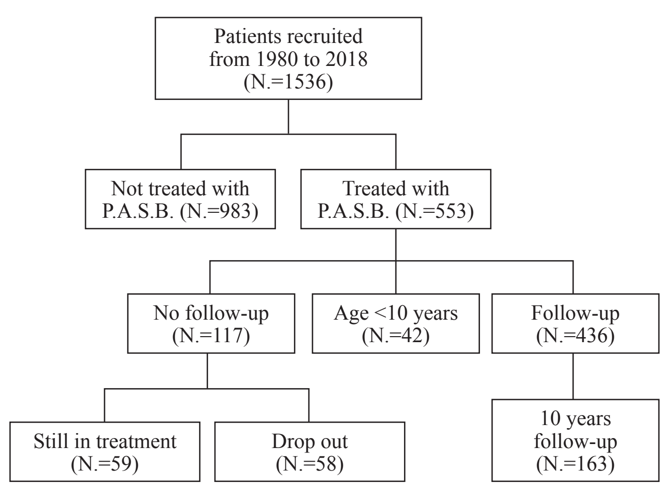

Figure 1.—Selection flowchart according to STROBE.

assessed using 2 consecutive radiographs taken at 6-month intervals. Progression was defined as an increase greater than 5° in both curve magnitude (Cobb's method) and apical torsion (Perdriolle's method) in an immature skeleton. Weaning was started when ring-apophysis fusion[14] was seen on a lateral view radiograph and consisted of 2 to 4 hours bracing reduction at 4-month intervals. Radiology reports with measurements of the curve were available for all patients.

Follow-up 10 years after brace removal

One hundred sixty-three patients were evaluated at long-term follow-up. One hundred twenty-six patients accepted to attend for a check-up, bringing with them a recent radiographic report. Finally, only 37 sent the radiographic report. Only 62 patients attending the check-up completed the QoL questionnaire.

X-rays were taken at conventional times: baseline (t_1), intermediate time between t_1 and t_3 (t_2), end of weaning (t_3), at 10-years minimum follow-up after t_3 (t_4). The X-rays in t_2 are taken while in the brace, as they are useful to check the corrective action of the brace.

X-rays in t_1, t_2, t_3 and t_4 were performed in all the patients (163).

A full length anteroposterior (AP) radiograph and a lateral view standing radiograph were taken. In the last ten years the radiographs were taken in posteroanterior (PA) to reduce the radiation dosage. The AP or PA view was used to determine the patient's skeletal age (Risser's sign), the curve magnitude (Cobb's method [CM]) and the torsion of the apical vertebra (TA: Perdriolle's method).[15, 16] Measurements were obtained by two independent observers (senior surgeons). The end vertebrae were preselected to reduce interobserver bias.[16]

Sixty-two patients answered simple questions:
- work status (yes or no, full or part-time);
- pregnancy (yes or no);
- back pain (yes or no).

Subgroup analysis

Patients were divided into two groups based on Cobb degrees: those with a curve <30 Cobb degrees and those with a curve ≥30 Cobb degrees. In literature it has been reported that curves of less than 30° at skeletal maturity tend not to progress regardless of curve pattern, unlike curves with a magnitude above 30°, which have a higher tendency to progress even after skeletal maturity.[1] It was on this basis that we decided to study these subgroups.

Statistical analysis

Standard statistical methods have been used for descriptive statistics. Normally distributed continuous variables were analyzed using an independent sample *t*-test. Changes in CM and TA from baseline to follow-up were assessed *via* one-way analysis of variance for repeated measures. Mean differences between time points and 95% confidence intervals were calculated. Correlations between changes in CM across Cobb at baseline, at the end of weaning and at follow-up were determined *via* the Pearson test. All analyses were performed according to the intention-to-treat principle. All tests were 2-sided, with significance set at a P value less than 0.05. Results are presented as mean±standard deviation (SD). Analysis was performed using GraphPad Prism version 8.4.0 for Windows, GraphPad Software, San Diego, CA, USA.

Logistic regression and ROC curve

Logistic regression was used to determine predictively the individual probability of success in each case.

A reduction at the last control of more than 11 Cobb degrees compared to the initial value was considered a success (variable: 1); a smaller reduction, stabilization or worsening was considered a failure (variable: 0).

Logistic regression was applied by Stepwise Regression, assuming as dependent variable: success (0 or 1); and as independent starting variables: age, duration of treatment, initial Cobb and Perdriolle degrees, Risser Index.

Results

Demographics

One hundred sixty-three patients (females) with mean age 32.17 (±3.3) years were studied. The mean prebrace scoliotic curve was 28.98 (±7.9) degrees and the mean Perdriolle Score of the apical vertebra of the scoliotic deformity was 12.63 (±4.88).

One hundred five (64%) of patients had prebrace Cobb angle less than 30° and 58 (36%) had greater than 30°.

Mean time of the brace application was 5.17 (±2.18) years. Patients underwent long-term follow-up at a mean of 13.41 (range 24.3) years after brace removal.

Cohort results

In all 163 patients the mean scoliotic curve was reduced by 15.10° at the end of weaning.

Changes in CM over time were statistically significant from t_3-t_1 (P for trend <0.0001), with a mean value of 28.98° (±7.92) Cobb at start of treatment (t_1) and was reduced to 13.88° (±10.8) following brace removal (t_3), and increased to 15.35° (±11.68) at long term follow-up (t_4) (Table I).

There was no significant difference in the mean Cobb angle between the end of weaning and long-term follow-up period.

The mean prebrace Perdriolle angle of 12.63° (±4.88) was reduced to 7.54° (±6.35) following brace removal, and increased to 8.24° (±6.18) at long term follow-up (Table I).

143 patients (87.7%) completed the long-term follow-up with less than 30°, 16 patients (9.8%) with between 30-40° and 4 patients (2.5%) with more than 41°.

Three patients at long-term follow-up showed a curve increase of more than 50 Cobb degrees, but only one of them had progression of the curve after the end of weaning. In this case, we suggested surgical treatment but the patient, having just given birth, preferred to postpone the surgery.

Analysis of the total sample shows a significant correlation between Risser, Rotation at baseline and mean curve correction in Cobb degrees, but not for Cobb at baseline and mean curve correction in Cobb degrees (Table II, Figure 2).

Logistic regression

A reduction at the last control of more than 11 Cobb degrees compared to the initial value was considered a success, based on this subdivision, the 163 cases studied showed: successes in 107 cases; failures in 56 cases, and a prevalence of successes of 65.6%.

The model discarded, for the non-significance of the coefficients, all the variables except for the initial value of Risser.

It provided a regression equation for logit L: L=log odds=1.343-0.3455** Risser.

The OR was 0.3455 (95% CI: -0.6939 to -0.01412).

To see how the result could vary according to the de-

TABLE I.—*Demographic and radiological characteristics of the study sample.*

Parameters	Baseline (t_1)	Intermediate between t_1 and t_3 (t_2)	End of treatment (t_3)	10 years minimum follow-up (t_4)
Age (years)	12.74±1.9	/	17.1±2.0	32.17±3.3
Risser	1.712±1.01	/	/	/
Menarche	12.59±1.15	/	/	/
Cobb degrees	28.98±7.92	12.34±8.6	13.88±10.8	15.35±11.68
Perdriolle degrees	12.63±4.8	7.52±5.35	7.54±6.35	8.24±6.18

TABLE II.—*Correlations between mean curve correction in Cobb degrees and Perdriolle at baseline, Cobb at baseline and Risser.*

	Mean curve corrections *vs.* Risser	Mean curve corrections *vs.* Cobb t_1	Mean curve corrections *vs.* rotaz t_1
Pearson *r*	-0.2180	-0.06780	-0.2142
95% confidence interval	-0.3597 to -0.06649	0.2192 to 0.08682	0.3566 to -0.06203
R^2	0.04752	0.004597	0.04587
P (two-tailed)	0.0052	0.3898	0.0062
Significant ? (α=0.05)	Yes	No	Yes

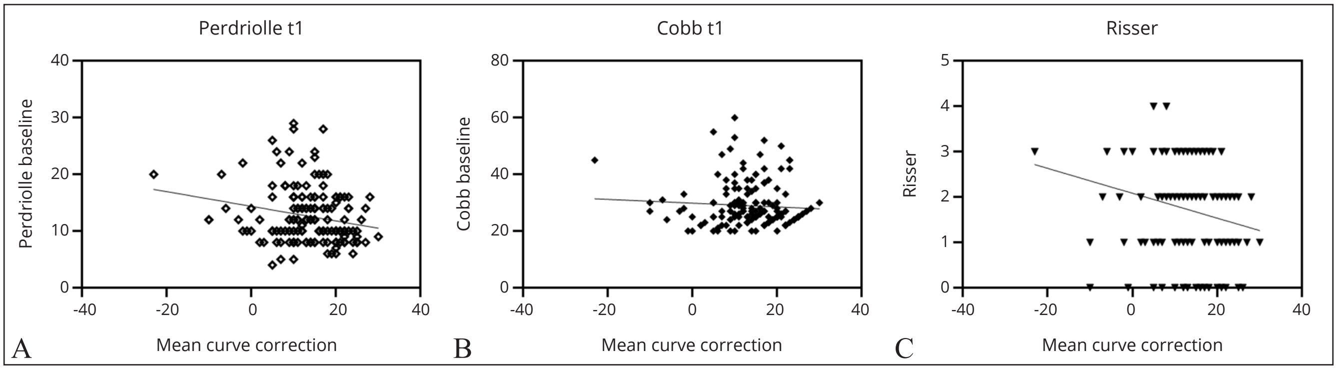

Figure 2.—Correlations between mean curve correction in Cobb degrees and: A) Perdriolle at baseline; B) Cobb at baseline; and C) Risser.

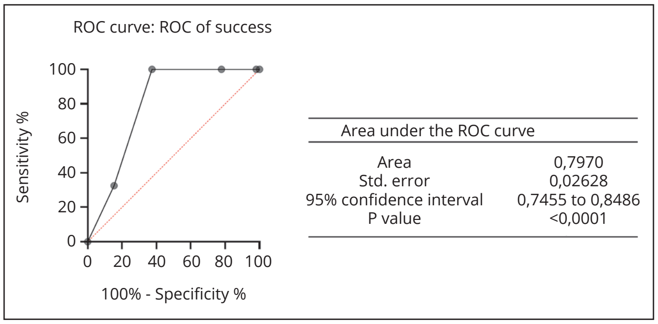

Figure 3.—ROC curves of Risser.

cision-making threshold adopted, a ROC curve was constructed. The graph in Figure 3 shows how the curve determined with Risser shows a significant area under the curve (AUC=0.79) (P<0.05). Furthermore, Table III shows the sensitivity values for some threshold values.

Comparison <30 *vs.* ≥30

One hundred five patients (64%) had curves with Cobb degrees <30 whereas 58 patients (36%) had curves over 30°.

The group over 30° showed a prebrace scoliotic mean curve of 37.26°, of 22.98° at the end of weaning, increasing to 25.07° at long-term follow-up; the group <30° showed a prebrace scoliotic mean curve of 24.40°, of 8.69° at the end of weaning, increasing to 9.98° at long-term follow-up. (Table IV, Figure 4).

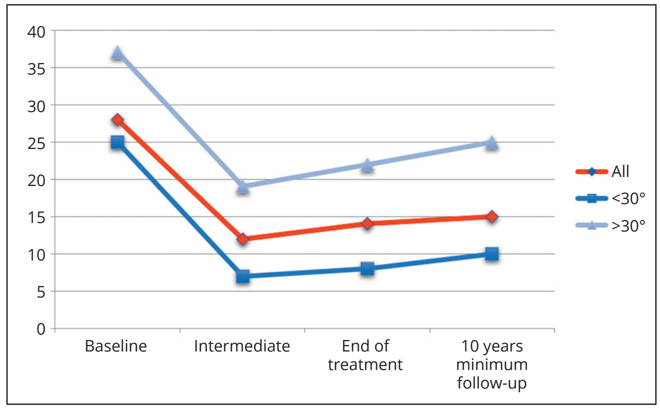

Figure 4.—Radiological trend in Cobb degrees of the whole sample and of 2 groups <30° and >30°.

Significant differences were determined for CM across Cobb at baseline and at the end of weaning. Instead not significant differences were determined for CM between end of weaning and long-term follow-up period (Table V, VI).

The mean curve correction was 15.82° in the group with Cobb <30° and 14.28° in the group with Cobb ≥30°.

Long-term follow-up revealed minimal increase in the Cobb angle in both groups. The mean Cobb angle increase was 1.29° in the group with Cobb <30° and 2.09° in the group with Cobb ≥30°. Difference between groups was not statistically significant.

TABLE III.—*Sensitivity values for some threshold values.*

Values	Sensitivity %	95% CI	Specificity %	95% CI	Likelihood ratio
<0.5000	32.52	25.80% to 40.04%	84.66	78.34% to 89.39%	2.120
<1.500	100.0	97.70% to 100.0%	62.58	59.94% to 69.64%	2.672
<2.500	100.0	97.70% to 100.0%	22.09	16.40% to 29.06%	1.283
<3.500	100.0	97.70% to 100.0%	1.840	0.5017% to 5.271%	10.19

TABLE IV.—*Changes in curve magnitude in Cobb degrees from the beginning of treatment (t_1) to 10-year minimum follow-up from end of weaning in all sample and in the subgroup.*

Parameters	Baseline (t_1)	Intermediate between t_1 and t_3 (t_2)	End of treatment (t_3)	10 years minimum follow-up (t_4)
Cobb ≥30°	37.26±7.5	19.45±8.1	22.98±9.7	25.07±11.2
Cobb <30°	24.40±2.6	8.41±5.9	8.69±7.3	9.98±7.8
Cobb total sample	28.98±7.92	12.34±8.6	13.88±10.8	15.35±11.68

TABLE V.—*Differences in CM across t_1-t_4 in the 105 patients with Cobb <30° as determined by one-way ANOVA with Bonferroni's* post-hoc *test.*

105 patients with Cobb <30°	Mean difference	*t*	P<0.05?	Summary	95% CI of diff.
Baseline (t_1) *vs.* end of treatment (t_3)	15.70	8.703	<0.0001	–	9.38 to 22.02
Baseline (t_1) *vs.* 10 years minimum follow-up (t_4)	14.42	8.049	<0.0001	–	8.14 to 20.69
End of treatment (t_3) *vs.* 10 years minimum follow-up (t_4)	-1.285	0.7121	0.3539	ns	-7.60 to 5.033

TABLE VI.—*Differences in CM across t_1-t_4 in the 58 patients with Cobb ≥30° as determined by one-way ANOVA with Bonferroni's* post-hoc *test.*

58 patients with Cobb ≥30°	Mean difference	t	P<0.05?	Summary	95% CI of diff.
Baseline (t_1) *vs.* end of treatment (t_3)	14.28	8.079	<0.0001	–	8.07 to 20.47
Baseline (t_1) *vs.* 10 years minimum follow-up (t_4)	12.19	6.898	<0.0001	–	5.99 to 18.39
End of treatment (t_3) *vs.* 10 years minimum follow-up (t_4)	-2.086	1.181	0.9997	ns	-8.28 to 4.112

Questionnaire

The work status of the 62 patients was full time in 62% patients, part time in 11%. Twenty-four percent of patients had a pregnancy. Pain was present in 14% of patients.

Discussion

The main purpose of the study was to evaluate the efficacy of brace treatment with PASB in adolescent idiopathic scoliosis and the loss of the scoliotic curve correction at long-term follow-up, and to analyze the results of curve stabilization at long-term follow-up in our case series.

Although the study is focused on the variation of Cobb degrees, we are also aware that conservative treatment must pursue a double result: aesthetic and functional.[2, 8, 12] The literature confirms that, in the first phase, it is the aesthetic result that motivates the patient to continue the treatment (spine hump).[2, 9] It is only later that evaluation of the Cobb degrees becomes more important. The requirement to reduce, as far as possible, the magnitude of the curve arises from the need to improve the biomechanical behavior of the deformed spine: a smaller entity of the curve corresponds to a lower concentration of loads, which is responsible for the onset of instability phenomena.

Studies supporting the effect of bracing correction at long-term follow-up are limited in number and not homogeneous in the selection of cases.[17-21]

In a study on a series of 109 patients treated for AIS, Danielsson and Nachemson[20] observed a mean loss of correction of 7.9°at 22 years after discontinuation of brace treatment. Similar results are published from Pellios *et al.*,[17] in their case-series of patients treated for AIS, reported long term results after Boston brace removal. In this study the Cobb angle before starting treatment was 28.2° (±8.7). This value decreased during brace application to 17.3° (±9.2), and was increased at the 25 years follow-up to 25.4° (±13.8). The mean loss of correction measured after brace discontinuation was 8.1° (at 25 years follow-up).

Better results are reported in a long-term study by Lange *et al*.[21] and in our preceding study.[13] In particular, Lange showed, in a series of 215 patients, a mean loss of correction of 4.1° Cobb 25 years after Boston brace removal.

The study by Aulisa *et al*.[13] showed that mean prebrace Cobb angle in 93 patients was not significantly different at 15 years follow-up, with a loss of correction of 2.7°, and that 78.5% of the patients completed the long term follow-up with a Cobb angle less than 30°.

In our study, the mean prebrace Cobb angle of 28.98° (±7.92) was reduced during brace application to 13.88° (±10.8) and increased slightly at 10 years follow-up to 15.35° (±11.68). The mean Cobb loss of correction was 1.47°.

Analysis of the results of patients treated with the PASB in our study confirmed the results obtained in the precedent study[13] on brace treatment, where the Lyon brace was used and in a smaller series of patients. In particular, the results of the present study are slightly better than those published in the literature regarding the course of curve progression following brace removal. We can affirm that although the biomechanical behavior of the lumbar and thoracolumbar curves in adulthood is different from that of the thoracic curves, this type of curve appears not to induce instability of the spine after 10 years.

The use of the PASB brace is effective for treatment of thoracolumbar and lumbar curves, showing good long-term results even in moderate curves. In particular we had only 4 patients with curves over 40° all of whom were patients that refused surgical treatment and started bracing with curves over 45°.[7] Moreover, only one had a progression of the curve. In this patient, with 45° Cobb at baseline, older age (16 years) and high grade of vertebral rotation (20° Perdriolle), the brace treatment only prevented evolution. In fact, at weaning the patient presented a curve of 45° Cobb. However, 6 years after weaning, spinal instability began with the development of a progressive rotary subluxation of L4 on L5 which induced a progressive worsening of the curve that reached 60° Cobb at follow-up. In this case, Surgery would be recommended as being the treatment of first chose.

It must also be stressed that the loss of 5 Cobb degrees is in the long term not sufficient to indicate surgery. The surgeon must always consider the degrees at baseline, the presence and extent of any clinical symptoms and the onset of significant instability phenomena.

These results confirm the importance of vertebral rotation in scoliosis; in fact to obtain a stable correction it is very important to obtain a reduction of Perdriolle as validated by analysis of the results with a mean correction of 5.09°.The correlations between mean curve correction in Cobb degrees and Risser underline the importance of the Risser and also the logistic regression confirms it, in fact an earlier intervention in younger patients increases the odds of success. In fact the fundamental condition for obtaining curve correction is the vertebral growth: a limited residual growth precludes any remodeling of the vertebral geometry. In particular, if treatment is started at the end of growth, the curve correction can only be obtained by deforming the disco-elastic structures and, unfortunately, the correction will vanish when the patient removes the brace.[7]

Subgroup results at long-term follow-up revealed a slight increase in the Cobb angle in both groups. However, the increase and the difference between groups were not statistically significant. These results are contrary to the natural history that showed a progressive and low increment of the curve at skeletal maturity in moderate curves.[1, 22] Moreover, these results confirm the correct indication published in the SOSORT Guideline.[2, 23]

Moreover, the low treatment dropout rate (just 10.4%) confirmed the importance of the guidelines and the high compliance of patients to use PASB.

Limitations of the study

The young age (mean of 32 years) of the patients partially limited the results of the study, but this limitation does not affect the validity of the study which aimed to assess the stability, over time, of the result obtained with brace treatment. It would have been useful to study older patients (>50 years) where the degenerative changes of the spine would have been more evident. Another limit of this paper is the lack of data concerning QoL. This is due to the long range of the study (38 years), and the nonuse of specific questionnaires in previous years.

Conclusions

The results demonstrate a slight loss of correction at a mean of 13 years post PASB bracing. We found no difference in long-term results and progression between <30 and ≥30 Cobb degrees. Furthermore, residual growth is a fundamental factor in treatment to obtain curve correction. In conclusion, the effectiveness of PASB bracing could be long term for patients with adolescent idiopathic scoliosis.

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