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Guido Pasquini, Francesca Cecchi, Christian Bini, Raffaello Molino-Lova, Federica Vannetti, Chiara Castagnoli, Anita Paperini, Roberta Boni, Claudio Macchi, Biase Crusco, Simone Ceppatelli, Alvaro Corigliano

All authors are affiliated to Don Gnocchi Foundation, Florence, Italy

Corresponding address: Guido Pasquini, Don Gnocchi Foundation, Via di Scandicci 269, 50143 Florence, Italy. Telephone number +39 055 739657 fax +39 055 7393026

e-mail: gpasquini@dongnocchi.it

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Abstract

BACKGROUND: Bracing therapy for patients with Adolescent Idiopathic Scoliosis (AIS) continues to be a controversial issue. As a consequence, to achieve an adequate level of evidence, there is a strong need for specific studies conducted according to standard outcome and management criteria.

AIM: To assess the outcomes of a modified version of the Cheneau brace, ("Cheneau-P") in patients with AIS, based on SRS and SOSORT criteria.

D**ESIGN:** Retrospective study.

METHODS: Sixty-seven patients, 56 females and 11 males, participated in the study. Inclusion criteria were: diagnosis of AIS, age ≧ 10 years, Risser score 0-2, Cobb degrees 20- 40, no previous treatment, beginning of brace treatment within 1 year after menarche and minimum 2-year follow-up. According to SRS criteria, bracing outcomes were classified, as follows: "improved" (reduction of the curve ≥6°), "unchanged" (5° curve progression or reduction), "worsened" (≥6° curve progression), and "over 45°" (curve exceeding 45° or undergone surgery during the follow-up). The outcomes "improved" and "unchanged" were considered as successful outcomes. Groups and related subgroups were created according to curve type (thoracic , thoraco-lumbar, lumbar and double major) and magnitude (20°-30°; 30°-40°) and to skeletal age (Risser score 0, 1, 2). A separate analysis was also performed on the 37 patients, 30 females and 7 males, who completely fulfilled the SRS eligibility criteria, showing spinal curves between 25 and 40 Cobb degrees.

RESULTS: In the whole group SRS outcome after bracing treatment was successful in 93% and in 81% of patients, at per protocol (PP) and intention to treat (ITT) analysis, respectively, the latter also including drop-outs as worst outcomes. Cobb angles significantly decreased in all subgroups except in patients showing double major curves, lower curve magnitude (20°-30°) and Risser score 2. Rib humps and balance rate also significantly improved in the whole sample (12.78 ± 4.54 at T0 vs 6.83 ± 4.33 at T1 $p< 0.001$; 60% at T0 vs. 94% at T1 $p<0.001$, respectively). In the subgroup that

completely fulfilled the SRS eligibility criteria, the outcome was successful in 92% and 83% of patients, at PP and ITT analysis, respectively, the latter also including, even in this case, drop-outs as worst outcomes.

CONCLUSIONS: This study shows that in patients with AIS the treatment with the "Cheneau-P" brace is associated with a remarkably high rate of successful outcomes, both in the whole sample and in the subgroup of patients completely fulfilling the SRS criteria.

CLINICAL REHABILITATION IMPACT: The "Cheneau-P" brace proved effective as a conservative treatment for AIS by stabilizing curve progression and limiting the need for surgical treatment.

Key words: scoliosis, adolescent idiopathic scoliosis, AIS, SRS criteria, SOSORT guidelines, Cheneau, brace.

Introduction

Adolescent Idiopathic Scoliosis (AIS) is characterized by the developmental lateral deformation of the spine, with a Cobb angle of at least 10 degrees, and vertebral rotation.[1] The cost for its surgical correction is relevant: in 2009 in the United States it was approximately $514 million and ranked second only to appendicitis among children 10 to 17 years old.[2]

Bracing of patients with AIS has been controversial for a long time.[3] Although it has been considered as a standard treatment in continental Europe, this was not the case in UK, USA and other Countries.[4,5] In 2010 a Cochrane Review concluded that the only alternative to bracing was the so-called "wait and see" strategy, i.e. careful observation until possible surgery, while, at the same time, it highlighted the low-quality evidence in favor of bracing.[6] The same Review also underlined the need for Randomized Control Trials (RCTs) or, at least, for studies conducted following uniform criteria, such as those proposed by the SRS (Scoliosis Research Society) and the SOSORT (Society On Scoliosis Orthopedic and Rehabilitation Treatment) guidelines,[5,7,8] which provide the methodological reference for the inclusion criteria and presentation of bracing results (SRS), and the clinical reference framework for an appropriate bracing treatment (SOSORT).[5,8]

More recently, the multicenter clinical trial Bracing in Adolescent Idiopathic Scoliosis Trial (BrAIST) conducted on 242 patients has concluded that, in patient at high risk for curve progression who would eventually warrant surgery, those who received bracing treatment showed a significantly greater likelihood of reaching skeletal maturity with a lower curve progression and of avoiding surgery, when compared to those who received observation only.[9]

However, planning and conducting RCTs on the treatment of AIS is "per se" a difficult task, and the several available bracing technique require specific observational studies to achieve an adequate level of evidence.[3,10,11]

The aim of this study was to retrospectively assess the outcome of a modified version of the Cheneau brace, which we have been using since '80, in the treatment of patients suffering from AIS, based on SRS and SOSORT criteria.

Materials and Methods

Intervention

Our management of scoliosis through bracing fulfilled the SOSORT criteria in the following domains: Experience/Competence, Behaviors, Prescription, Construction, Brace check and Follow-up.[7] However, the final score should be considered "good", as proposed in the SOSORT checklist, because the brace management doesn't include the physiotherapist in the professional team and consequently 5 items were not applicable.

The modified version of the Cheneau brace used at our Centre was the so-called "P" Cheneau brace (Figure 1), where "P" stands for Pozzolatico, a little Tuscan village on the hills south-west of Florence that has been the site of our Centre for over 50 years, where this brace was first developed. The brace, which is modeled on each individual patient, is open in the front side, rests on iliac crest and ends up with a sub-axillary support that extends up to the acromion. The differences between the classic Cheneau and our modified version is the sub-axillary support, which replaces the fore sternum closure. The main advantages of this closure are: a) the possibility to have an harmonic growth of the thorax due to minor constraining, thus avoiding any possible brace induced deformity b) a better compliance to treatment, as the brace can easily be disguised under the clothes. The mechanism incorporates the concept of spine translation and the use of the three points hold.[3] Pressure thoracic pads were applied in a postero-lateral position at the most prominent rib level and pushing was directed antero-cranially, while the lumbar pressures were applied on the transverse process of lumbar vertebras.

The protocol foresaw wearing the brace at least 22 hours per day, with orthopedic technician checks every 2 months and medical checks every 4 months, to assess the clinical progression and the correct positioning of pressures, and to increase, or decrease, the thickness of pressure blocks according to curve changes, along with routine repairs. The brace was prescribed to be worn until skeletal maturity was achieved (Risser score 4 or 5) and removed with a program of gradual

dismissal. During brace treatment patients did not receive any physiotherapy but were free and encouraged to perform sport activities.

The protocol included an initial X-ray, taken in both AP and LL projections, an X-ray in AP projection while wearing the brace, three months after the beginning of treatment, and, subsequently, once a year, until the end of treatment. A final X-ray was taken at least 48 hours after the complete withdrawal of the brace to assess both skeletal age and the stability of the correction achieved. Data reported in this study are drawn from the initial and final X-ray. Although scheduled follow-up visits were not foreseen in the standard original protocol, as ours is a referral Center for scoliosis, regular two-year clinical follow-ups were always conducted on most critical patients. With regard to less critical patients, those whose follow-up data were missing were contacted by phone and invited to a clinical follow-up visit in our Center.

Subjects

Examining the records of 843 patients visited in our Scoliosis Unit from 1996 to 2006 and diagnosed any spinal disorder, we selected all those who received a diagnosis of AIS. The steps to reach the final sample are shown in the flowchart.(Figure 2) Eligibility was based upon the following criteria: diagnosis of AIS, age$\geq$10 years, Risser score 0-2, Cobb degrees 20-40, no previous treatment, beginning of the treatment within 1 year from menarche, minimum 2-year follow-up. Patients with curves between 20° and 25° Cobb degrees were included in the study only if curve progression was documented by changes in rib hump and confirmed by X-rays. Patients with missing or incomplete data were excluded from the study. The final sample was represented by 67 patients, 56 females and 11 males. Further, we also performed a separate analysis in the subgroup of 37 patient, 30 females amd 7 males, who completely fulfilled SRS criteria[5] (spinal curves between 25 and 40 Cobb degrees at the beginning of treatment).

The Institutional Ethical Committee approved the study protocol and participants' parents, or proxies, signed their informed consent to give access to filed clinical data for scientific purposes.

Outcome measures

As recommended by the SRS Committee on Bracing and Non-operative Management, bracing outcomes were assessed when skeletal maturity was achieved and were classified as follows: (1) "improved" (reduction of the curve ≥ 6°), (2) "unchanged" (5° curve reduction or progression), (3) "worsened" (≥ 6° curve progression), and (4) "over 45°" (curve exceeding 45° or patients who were recommended for - or had undergone - surgery during the follow-up).[5,12] Altogether, based upon the natural history of curve progression, outcomes 1 and 2 are considered as successful outcomes for bracing treatment.[5,13,14]

We also reported clinical outcomes such as the rib hump (expressed in millimeters and measured using a bubble level and a hard meter) and the spine balance (expressed as categorical variable and measured using a plumb-line: a spine showing a distance from C7 plumb-line to S1 >10 mm was considered as unbalanced). Finally, we also reported the number of patient whose curve did not exceed 30° Cobb at the end of treatment, because this is considered in the literature as positive prognostic factor.[15]

Statistics

Statistical analysis was performed using the software STATA 7.0, from Stata Corporation (College Station, Texas, USA). Data are reported as means ± standard deviations, or as absolute values with percentages in brackets. Groups and related subgroups were created according to the type and magnitude of the curve and skeletal age. One-way ANOVA and two-way χ^2 test were used to ascertain possible differences between the subgroups within the three groups, as appropriate. One-way ANOVA for repeated measures (REP-ANOVA) and McNemar test were used to ascertain possible differences within each subgroup before and after the treatment, as appropriate. With regard to SRS outcomes, we addressed both Intention to Treat (ITT) and Per Protocol (PP) analyses, including drop-outs as worst outcomes at the ITT analysis .

Finally, one-way χ^2 test (also known as "goodness of fit" test) was used to ascertain the distribution of categorical outcomes within each subgroup. Significance was set at the two-sided 0.05 level.

Results

Mean age at the beginning of the treatment was 13.15 years ± SD 1.7 in the whole group and 13,16 years ± SD 1.7 in the 25-40° subgroup. No relevant adverse event occurred during the bracing treatment.

Table 1 shows the baseline characteristics of the whole sample according to curve type and magnitude and to skeletal age. There was no significant age and gender difference within the three groups. Thoracic curves showed significantly wider Cobb angles when compared to lumbar curves and significantly more prominent rib humps, when compared to lumbar and double main curves. Curves with larger magnitude also showed significantly more prominent rib humps. Finally, patients with lumbar curves showed a significantly lower balance rate when compared to those with other types of curves, and patients showing a Risser score 2 also showed a significantly lower balance rate when compared to those with Risser score 1.

Table 2 shows the clinical outcomes after bracing treatment according to baseline type and magnitude of the curve and to skeletal age. There was no significant difference in bracing duration within the three groups. Cobb angles significantly decreased in all subgroups except in patients showing double major curve, smaller curve magnitude and Risser score 2. Rib humps also significantly decreased in all subgroups except in patients with Risser score 2. Balance rates significantly increased in all subgroups except in patients with thoracic curve, in those with larger curve magnitude and in those with Risser 1.Worth of note, at the end of treatment, in 81% of patients the spinal curve did not exceed 30 Cobb degrees.

Table 3 shows ITT and PP analyses according to SRS outcomes, with ancillary analyses according to baseline curve type and magnitude and skeletal age. SRS outcomes showed a significantly uneven distribution both at ITT and PP analyses in the whole group and within all subgroups, strongly shifted towards the positive outcomes without any significant difference within each group. By summing up the outcomes “improved” and “unchanged”, in the whole group SRS

outcome after bracing treatment was successful in 93% and in 81% of patients, at per protocol (PP) and intention to treat (ITT) analysis, respectively.

Further, at PP analysis, successful rate was100% in patients with thoraco-lumbar and lumbar curve, in those with larger magnitude curve and in those showing Risser score 1, while in the remaining subgroups successful SRS outcome ranged from 87%, in patients with thoracic curve, to 92%, in patients showing Risser score 2.

Table 4 shows the baseline characteristics in 25-40° subgroup. There were no significant differences in age, gender, initial Cobb degrees and balance within the three groups. Rib hump was significantly more prominent in thoraco-lumbar compared to double-major curves and in the 30-40° group compared to 25-30°.

Table 5 shows clinical outcomes after bracing in the 25-40° subgroup. Cobb degrees and Rib Hump decreased and Balance rate increased significantly. Statistical analysis according to curve type and magnitude and to skeletal age was not performed, as the number of patients in each sub-group was very low. However, there was a positive trend in reducing the Cobb degrees and rib hump and in increasing balance rate, comparable to that found in the whole sample (Tab 2). Worth of note,70% of 25-40° subgroup did not exceed 30° Cobb at the end of the treatment.

In the subgroup 25-40 Cobb degrees, the outcome was successful in 92% and 83% of patients, at PP and ITT analysis, respectively. (Table 6)

Discussion

The aim of this study was to retrospectively assess the outcomes of a modified version of the Cheneau brace in the treatment of patients suffering from AIS and we found that both in the whole sample (20-40 Cobb degrees) and in the 25-40° subgroup patients showed a successful SRS outcome in more than 80% of cases. Further, this modified version of the Cheneau brace also proved particularly effective in reducing hump amplitude and in increasing spine balance rate.

Worthy of note, within the successful outcomes, which included both "improved" and "unchanged" SRS outcomes, 30% of patients in whole sample and 41% in the 25-40° subgroup actually showed "improvement" of the spinal curve. As a whole, these results are in line with those reported by Negrini et al who showed that, by combining the use of brace and physiotherapy, "improvement" of the spinal curve was achieved in about 51% of cases.[16]

With regard to the subgroups created according the curve type, the modified "P" Cheneau brace significantly reduced the Cobb angles in all types of curve except in double major curves: however, by categorizing the outcomes according to the SRS criteria, our treatment was also significantly effective in double major curves. This apparently contradictory result might be explained by the fact that patients with double major curve who showed the outcome "worsened", had quite relevant changes in Cobb angles (6.8° ± 1.3°).[14]

Thoracic and double major curves showed the outcome "worsened" in 13 % and 12% in the whole group and in 22% and 8% in the 25-40° subgroup, respectively, which is in accordance with the widespread notion that thoracic and double major curves are the most critical to treat conservatively. [16-18] Negrini et al also reported a comparable "worsened" rate (14%) for thoracic curves, without any "worsened" outcome among double major curves, while, in the same study, Negrini et al reported a much lower rate of "improved" (15% vs. 56% of our 25-40° series).[17] Despite these discrepancies, explainable "per se" by the small amount of patients in each subgroup, the overall results confirm the difficulties in the treatment of thoracic and double major curves using conservative methods.

With regard to the subgroups created according the magnitude of the curvature before treatment, the patients with wider Cobb angles (30-40°) showed a significant angle reduction (tab 2 and 5) and, accordingly, a high rate of "improved" outcome (tab 3 and 6), suggesting that the Cobb angle is probably the most important parameter for clinical assessment and decision making, and that it is also a major prognostic factor for the conservative treatment of AIS.

With regard to the subgroups created according to the skeletal age before treatment assessed by the Risser score, in the whole sample patients with younger skeletal age (Risser score 0 and 1) showed a significant or borderline Cobb angle reduction (-2.8 ± 6.7° and -4.4 ± 6.1°, respectively).

Finally, in the 25-40°the curves with Cobb angle between 25-30° showed a greater percentage of "unchanged" outcome with respect to the "improved", while the curves with Cobb angle of between 30-40° showed a reverse trend (tab 6).

These results are consistent with the clinical experience, as the operation of the pressures is in relation with the magnitude of the hump: in fact, the higher the hump, the greater the mechanical action exerted by the pressures; on the contrary, the lower the rib hump, the lower the deep action on the spine, with prevailing only of the aesthetic correction. To the best of our knowledge, brace therapy is not aimed to eliminate the vertebral rotation, but to stabilize curves of low amplitude, and to reduce curves of high amplitude maintaining this outcome in the long term .

Among the findings concerning secondary outcomes, rib humps significantly decreased in all subgroups except in patients with Risser score 2, while spinal balance rates significantly increased in all subgroups except in patients with thoracic curves, in those with larger curve magnitude and in those with Risser 1, probably due to a ceiling effect. Interestingly, the improvement of spinal balance, which is probably due to the translation mechanism of the trunk operated by the brace [6,8], and to end the treatment below to 30° Cobb might play a protective role against the progression of the curve in adulthood (i.e. during pregnancy) or in senescence, but this hypothesis still needs to be proved by long-term studies.

This study was conducted by using the SRS/SOSORT criteria, as recommended by the Cochrane Review [6], and this represents the strength of the study. However, a limitation on clinical outcomes may be represented by the lack of enclosure of physiotherapy along with brace treatment. Further, other intrinsic methodological limitations need to be acknowledged. First, a control group, represented by patients treated by the classic Cheneau brace, was not available. Second, sample

size, though aligned with that of most studies available in the literature, is still relatively small to generalize indications.

In conclusion, this study shows a remarkable success of the modified "P" Cheneau brace as a conservative treatment for AIS according to the SRS/SOSORT criteria, with over 80% of our patients presenting "improved" or "unchanged" and none of them needing referral to surgery.

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Tab. 1 - Baseline characteristics of the study sample according to the type and magnitude of the curve and skeletal age.

Tab. 2 - Clinical outcomes after bracing treatment according to baseline type and magnitude of the curve and skeletal age.

Tab.3 - Tab.3 - SRS outcomes after bracing treatment in the whole sample: Intention To Treat (ITT) and Per Protocol (PP) analyses, along with ancillary analyses according to baseline type and magnitude of the curve and skeletal age.

Tab. 4 - Baseline characteristics of the 25-40° subgroup according to the type and magnitude of the curve and skeletal age.

Tab. 5 - Clinical outcomes after bracing in the 25-40° subgroup according to baseline type and magnitude of the curve and skeletal age.

Tab.6 - SRS outcomes after bracing treatment in the 25-40° subgroup: Intention To Treat (ITT) and Per Protocol (PP) analyses, along with ancillary analyses according to baseline type and magnitude of the curve and skeletal age.

Figure 1 – Modified version of Cheneau brace (Cheneau-P)

Figure 2 – Flow-chart of the selection of study sample

Tab. 2 - Clinical outcomes after bracing treatment according to baseline type and magnitude of the curve and skeletal age.

	n. (%)	Bracing (years) (mean ± SD) (1)	< 30° Cobb at the end of treatment n. (%) (2)	Cobb T0 (degrees) (mean ± SD)	Cobb T1 (degrees) (mean ± SD)	One-way REP-ANOVA	Rib Hump T0 (mm) (mean ± SD)	Rib Hump T1 (mm) (mean ± SD)	One-way REP-ANOVA	Balance T0 n. (%)	Balance T1 n. (%)	McNemar test
Whole sample	67 (100)	3.37±1.25	54 (81)	26.10±5.33	23.15±6.70	p<0.001	12.78±4.54	6.83±4.33	p<0.001	40 (60)	63 (94)	p<0.001
Type												
-Thoracic	15 (22)	3.14±1.17	13 (86)	29.00±6.98	23.60±8.42	p=0.016	15.87±5.85	8.07±6.22	p=0.002	11 (73)	14 (93)	p=0.083
-Thoraco-Lumbar	15 (22)	3.93±1.75	12 (80)	26.40±5.15	21.93±5.71	p=0.028	13.73±4.46	7.93±3.35	p<0.001	10 (67)	15 (100)	p=0.025
-Lumbar	12 (18)	3.33±0.98	12 (100)	23.25±2.86	18.92±5.12	p=0.024	10.75±2.45	4.49±1.29	p<0.001	1 (11)	10 (83)	p=0.003
-Double Major Curve	25 (38)	3.16±1.00	17 (68)	25.56±4.57	25.60±5.82	p=0.966	11.32±3.39	6.55±4.13	p<0.001	18 (72)	24 (96)	p=0.014
Magnitude												
-20-30°	51 (76)	3.53±0.83	43 (84)	23.75±3.02	22.65±5.88	p=0.111	11.73±3.58	6.62±3.93	p<0.001	29 (57)	49 (96)	p<0.001
-30-40°	16 (24)	3.32±1.36	11 (69)	33.63±3.95	24.75±8.77	p<0.001	16.13±5.68	7.49±5.49	p<0.001	11 (69)	14 (88)	p=0.083
Risser Score												
-0	46 (69)	3.47±1.26	37 (80)	26.02±5.06	23.20±6.64	p=0.007	12.52±4.31	6.38±2.89	p<0.001	28 (61)	45 (98)	p<0.001
-1	9 (13)	3.00±1.00	8 (89)	25.33±4.06	20.89±6.51	p=0.052	13.00±3.94	5.22±2.82	p=0.001	8 (89)	8 (89)	p=1.000
-2	12 (18)	3.25±1.40	9 (75)	27.00±7.26	24.67±7.01	p=0.194	12.52±4.31	9.74±7.76	p=0.167	4 (33)	10 (83)	p=0.014

(1) One-wayANOVA for bracing (year) Type subgroup p=0.240 Magnitude subgroup p=0.456 Risser score subgroup p=0.557

(2) Two-way $\chi 2$ test for "<30° Cobb at the end of treatment": Type p= 0.123 Magnitude p= 0.274 Risser score p= 0.727

Tab. 1 - Baseline characteristics of the study sample according to the type and magnitude of the curve and skeletal age.

	n. (%)	Age (years) (mean ± SD)	One-way ANOVA	Female sex n. (%)	Two-way $\chi 2$ test	Cobb (degrees) (mean ± SD)	One-way ANOVA	Rib Hump (mm) (mean ± SD)	One-way ANOVA	Balance n. (%)	Two-way $\chi 2$ test
Whole sample	67 (100)	13.15 ± 1.70	----------	56 (84)	----------	26.10 ± 5.33	----------	12.78 ± 4.54	----------	40 (60)	----------
Type											
-Thoracic	15 (22)	12.60 ± 2.06	p = 0.358	12 (80)	p = 0.969	29.00 ± 6.98	p = 0.039 (1)	15.87 ± 5.85	p = 0.004 (2)	11 (73)	p = 0.001 (3)
-Thoraco-Lumbar	15 (22)	13.64 ± 1.40		13 (87)		26.40 ± 5.15		13.73 ± 4.46		10 (67)	
-Lumbar	12 (18)	13.50 ± 1.09		10 (83)		23.25 ± 2.86		10.75 ± 2.45		1 (11)	
-Double Major Curve	25 (38)	13.04 ± 1.81		21 (84)		25.56 ± 4.57		11.32 ± 3.39		18 (72)	
Magnitude											
- 20-30°	51 (76)	13.18 ± 1.62	p = 0.816	42 (82)	p = 0.628	23.75 ± 3.02	----------	11.73 ± 3.58	p < 0.001	29 (57)	p = 0.398
- 30-40°	16 (24)	13.06 ± 1.95		14 (88)		33.63 ± 3.95		16.13 ± 5.68		11 (69)	
Risser Score											
-0	46 (69)	12.74 ± 1.50	----------	37 (80)	p = 0.580	26.02 ± 5.06	p = 0.770	12.52 ± 4.31	p = 0.767	28 (61)	p = 0.035 (4)
-1	9 (13)	13.78 ± 1.09		8 (89)		25.33 ± 4.06		13.00 ± 3.94		8 (89)	
-2	12 (18)	14.25 ± 2.22		11 (92)		27.00 ± 7.26		12.52 ± 4.31		4 (33)	

Multiple internal comparisons (Bonferroni):

(1) "Cobb x Curvature Type": T vs. TL p = 1, **T vs. L p = 0.030**, T vs. DM p = 0.261, TL vs. L p = 0.699, TL vs. DM p = 1, L vs. DM p = 1.

(2) "Rib Hump x Curvature Type": T vs. TL p = 1, **T vs. L p = 0.014**, **T vs. DM p = 0.009**, TL vs. L p = 0.420, TL vs. DM p = 0.491, L vs. DM p = 1.

(3) "Balance x Curvature Type": T vs. TL p = 0.690, **T vs. L p = 0.001**, T vs. DM p = 0.927, **TL vs. L p = 0.002**, TL vs. DM p = 0.722, L vs. DM p < 0.001.

(4) "Balance x Risser Score": 0 vs. 1 p = 0.106, 0 vs. 2 p = 0.088, **1 vs. 2 p = 0.011**.

Tab.3 - SRS outcomes after bracing treatment in the whole sample: Intention To Treat (ITT) and Per Protocol (PP) analyses, along with ancillary analyses according to baseline type and magnitude of the curve and skeletal age.

	n. (%)	"improved" n. (%) [95%CI]	"unchanged" n. (%) [95%CI]	"worsened" n. (%) [95%CI]	"over45°" n. (%) [95%CI]	χ2 test
ITT analysis (1)	76 (100)	20 (26) [16 - 36]	42 (55) [44 - 66]	5 (7) [1 - 12]	9 (12) [5 - 19]	p <0.001 (2)
PP analysis	67 (100)	20 (30) [19 - 41]	42 (63) [51 - 74]	5 (7) [1 - 14]	0 (0) [0 - 0]	p <0.001 (2)
Type						
-Thoracic	15 (22)	6 (40)	7 (47)	2 (13)	0 (0)	p = 0.312 (3)
-Thoraco-Lumbar	15 (22)	6 (40)	9 (60)	0 (0)	0 (0)	
-Lumbar	12 (18)	4 (33)	8 (67)	0 (0)	0 (0)	
-Double Major Curve	25 (37)	4 (56)	18 (72)	3 (12)	0 (0)	
Magnitude						
-20-30°	51 (76)	11 (22)	35 (69)	5 (10)	0 (0)	p = 0.022 (3)
-30-40°	16 (24)	9 (56)	7 (44)	0 (0)	0 (0)	
Risser Score						
-0	46 (69)	14 (30)	28 (61)	4 (9)	0 (0)	p = 0.643 (3)
-1	9 (13)	4 (44)	5 (56)	0 (0)	0 (0)	
-2	12 (18)	2 (17)	9 (75)	1 (8)	0 (0)	

(1) Drop-outs were classed as worst outcome ("over45°"). (2) From "one-way" χ2 test. (3) From "two-way" χ2 test.

Tab. 4 - Baseline characteristics of the 25-40° subgroup according to the type and magnitude of the curve and skeletal age.

	n. (%)	Age (years) (mean ± SD)	One-way ANOVA	Female sex n. (%)	Two-way $\chi 2$ test	Cobb (degrees) (mean ± SD)	One-way ANOVA	Rib Hump (mm) (mean ± SD)	One-way ANOVA	Balance n. (%)	Two-way $\chi 2$ test
25-40° subgroup	37 (100)	13.16 ± 1.70	----------	30 (81)	----------	29.78 ± 4.42	----------	13.94 ± 4.62	----------	23 (62)	----------
Type											
-Thoracic	9 (24)	13.67 ± 1.22		8 (88)		29.55 ± 4.12		14.55 ± 4.15		6 (66)	
-Thoraco-Lumbar	11 (30)	12.36 ± 2.30	p = 0.308	8 (73)	p = 0.585	32 ± 5.56	p = 0.129	16.91 ± 5.63	p = 0.025 (1)	7 (63)	p = 0.488
-Lumbar	4 (11)	13.25 ± 0.50		4 (100)		26.25 ± 2.5		11.00 ± 1.82		1 (25)	
-Double Major Curve	13 (35)	13.46 ± 1.50		10 (77)		29.15 ± 3.29		11.92 ± 3.12		9 (69)	
Magnitude											
-25-30°	21 (57)	13.24 ± 1.51	p=0.759	16 (76)	p=0.384	26.85±1.65	----------	12.28 ±2.76	p=0.011	11(52)	p=0.501
-30-40°	16 (43)	13.06 ± 1.95		14 (87)		33.62±3.94		16.12 ± 3.12		11 (70)	
Risser Score											
-0	25 (68)	12.8 ± 1.32		20 (80)		29.6 ± 4.18		13.92 ± 4.08		17 (46)	
-1	5 (13)	13.8 ± 1.30	----------	4 (80)	p = 0.941	28.4 ± 2.07	p = 0.484	11.8 ± 3.42	p = 0.389	3 (60)	p = 0.241
-2	7 (19)	14.0 ± 2.70		6 (85)		31.42 ± 6.29		15.57 ± 6.85		3 (43)	

Multiple internal comparisons (Bonferroni):

(1) "Rib Hump x Curvature Type": T vs. TL p = 1, T vs. L p = 1, T vs. DM p = 0.94, TL vs. L p = 0.13, **TL vs. DM p = 0.04**, L vs. DM p = 1.

Tab. 5 - Clinical outcomes after bracing in the 25-40° subgroup according to baseline type and magnitude of the curve and skeletal age.

	n. (%)	Bracing (years) (mean ± SD) (1)	< 30° Cobb at the end of treatment n. (%) (2)	Cobb T0 (degrees) (mean ± SD)	Cobb T1 (degrees) (mean ± SD)	Rib Hump T0 (mm) (mean ± SD)	Rib Hump T1 (mm) (mean ± SD)	Balance T0 n. (%)	Balance T
25-40° subgroup (3)	37 (100)	3.64±1.40	26 (70)	29.78±4.42	25.72±6.98	13.94 ± 4.62	7.46 ± 4.97	23 (62)	34 (92)
Type									
-Thoracic	9 (24)	3.22±1.30	7 (78)	29.55±4.12	24.22±5.70	14.55±4.15	8.11±3.33	6 (66)	7 (78)
-Thoraco-Lumbar	11 (30)	4.45±1.75	8 (73)	32.00±5.56	24.64±9.65	16.91±5.63	7.91±6.41	7 (63)	11 (100)
-Lumbar	4 (11)	3.75±0.96	4 (100)	26.25±2.50	20.25±5.91	11.00 ±1.82	4.49±1.29	1 (25)	4 (100)
-Double Major Curve	13 (35)	3.16±0.93	7 (54)	29.15±3.29	29.38±3.30	11.92 ± 3.12	7.54±5.41	9 (69)	12 (92)
Magnitude									
-25-30°	21 (57)	3.70±1.70	14 (67)	26.85±1.65	26.47±5.34	12.28 ±2.76	7.40 ±4.51	11(52)	21 (100)
-30-40°	16 (43)	3.50±0.83	12 (75)	33.62±3.94	24.75±8.77	16.12 ± 3.12	7.53 ± 5.68	11 (70)	14 (87)
Risser Score									
-0	25 (68)	3.71±1.39	17 (68)	29.6±4.18	25.68±6.74	13.92 ± 4.08	6.61±3.11	17 (46)	24 (96)
-1	5 (13)	3.00±1.20	4 (80)	28.4±2.07	23.00±7.97	11.80 ± 3.42	7.00±2.55	3 (60)	4 (80)
-2	7 (19)	3.85±1.57	5 (71)	31.42±6.29	27.85±7.49	15.57 ± 6.85	10.57±9.25	3 (43)	6 (86)

(1) One-way ANOVA for "bracing" (years): Type p=0.109 Magnitude p= 0.707 Risser score p=0.542.

(2) Two-way $\chi 2$ test for "<30° Cobb at the end of treatment": Type p= 0.302 Magnitude p= 0.723 Risser score p= 0.864

(3) In the whole 25-40° subgroup REP-ANOVA for Cobb degrees p<0.001, for Rib Hump p<0.001 and McNemar test for Balance p<0.001.

Tab.6 - SRS outcomes after bracing treatment in the 25-40° subgroup: Intention To Treat (ITT) and Per Protocol (PP) analyses, along with ancillary analyses according to baseline type and magnitude of the curve and skeletal age.

	n. (%)	"improved" n. (%) [95%CI]	"unchanged" n. (%) [95%CI]	"worsened" n. (%) [95%CI]	"over 45°" n. (%) [95%CI]	χ2 test
ITT analysis (1)	41 (100)	15 (37) [22 - 51]	19 (46) [31 - 62]	3 (7) [0 - 16]	4 (10) [0 - 19]	p <0.001 (2)
PP analysis	37 (100)	15 (41) [25 - 56]	19 (51) [35 - 67]	3 (8) [0 - 17]	0 (0) [0 - 0]	p <0.001 (2)
Type						
-Thoracic	9 (24)	5 (56)	2 (22)	2 (22)	0 (0)	p = 0.205 (3)
-Thoraco-Lumbar	11 (30)	6 (55)	5 (45)	0 (0)	0 (0)	
-Lumbar	4 (11)	1 (25)	3 (75)	0 (0)	0 (0)	
-Double Major Curve	13 (35)	3 (23)	9 (69)	1 (8)	0 (0)	
Magnitude						
-25-30°	21 (57)	6 (29)	12 (57)	3 (14)	0 (0)	p = 0.115 (3)
-30-40°	16 (43)	9 (56)	7 (44)	0 (0)	0 (0)	
Risser Score						
-0	25 (68)	11 (44)	12 (48)	2 (8)	0 (0)	p = 0.873 (3)
-1	5 (14)	2 (40)	3 (60)	0 (0)	0 (0)	
-2	7 (18)	2 (29)	4 (57)	1 (14)	0 (0)	

(1) Drop-outs were classed as worst outcome (“over45°”). (2) From "one-way" χ2 test. (3) From "two-way" χ2 test.

Tab.3 - SRS outcomes after bracing treatment in the whole sample: Intention To Treat (ITT) and Per Protocol (PP) analyses, along with ancillary analyses according to baseline type and magnitude of the curve and skeletal age.

	n. (%)	"improved" n. (%) [95%CI]	"unchanged" n. (%) [95%CI]	"worsened" n. (%) [95%CI]	"over45°" n. (%) [95%CI]	χ2 test
ITT analysis (1)	76 (100)	20 (26) [16 - 36]	42 (55) [44 - 66]	5 (7) [1 - 12]	9 (12) [5 - 19]	p <0.001 (2)
PP analysis	67 (100)	20 (30) [19 - 41]	42 (63) [51 - 74]	5 (7) [1 - 14]	0 (0) [0 - 0]	p <0.001 (2)
Type						
-Thoracic	15 (22)	6 (40)	7 (47)	2 (13)	0 (0)	p = 0.312 (3)
-Thoraco-Lumbar	15 (22)	6 (40)	9 (60)	0 (0)	0 (0)	
-Lumbar	12 (18)	4 (33)	8 (67)	0 (0)	0 (0)	
-Double Major Curve	25 (37)	4 (16)	18 (72)	3 (12)	0 (0)	
Magnitude						
-20-30°	51 (76)	11 (22)	35 (69)	5 (10)	0 (0)	p = 0.022 (3)
-30-40°	16 (24)	9 (56)	7 (44)	0 (0)	0 (0)	
Risser Score						
-0	46 (69)	14 (30)	28 (61)	4 (9)	0 (0)	p = 0.643 (3)
-1	9 (13)	4 (44)	5 (56)	0 (0)	0 (0)	
-2	12 (18)	2 (17)	9 (75)	1 (8)	0 (0)	

(1) Drop-outs were classed as worst outcome ("over45°"). (2) From "one-way" χ2 test. (3) From "two-way" χ2 test.

SOSORT

INTERNATIONAL SOCIETY ON SCOLIOSIS ORTHOPAEDIC AND REHABILITATION TREATMENT

Questionnaire to verify the achievement of the SOSORT Criteria for bracing: "Standards of management of idiopathic scoliosis with corrective braces in everyday clinics and in clinical research" – Filled by Fabio Zaina for the Sforzesco group (ISICO)

This questionnaire has been developed to
allow each professional to self-test if he satisfies recommended management criteria for bracing
test in case of research studies if the management of patients has been adequate according to the actual standards
help patients understand if their caregivers satisfy the actual management needs

Ideally all the answers to the questions should be "Yes".
During the SOSORT Consensus, cumulative answers in terms of clinical behaviors were:
38% no negative answers
53% up to 1 negative answer
68% up to 5 negative answers
91% up to 8 negative answers

Consequently, provided all 44 answers are given (if it lacks one member of the team, all relative answers should be "no"), until new researches will refine the system, we propose
Excellent: 0-1 no out of 44
Good: 2-5 no out of 44
Sufficient: 6-8 no out of 44
Insufficient: 9 no or more out of 44

We are aware that these standards are not applicable everywhere in the world, currently, for many different reasons. Nevertheless, we strongly support their progressive application, and SOSORT is ready to support individuals and groups who need help in reaching these minimum standards through education and masterships.

For more information look at the journal Scoliosis (www.scoliosisjournal.com) where the original paper (Negrini S, Grivas TB, Kotwicki T, Rigo M, Zaina F. "Standards of management of idiopathic scoliosis with corrective braces in everyday clinics and in clinical research. SOSORT Consensus 2008") has been published in 2008, and to the SOSORT web site (www.sosort.org).

All professionals as a team

Do you work in a multiprofessional team (physician, orthotist and eventually physiotherapist), through continuous exchange of information, team meetings, and verification of braces in front of single patients? Yes

Do you give thorough advice and counselling to each single patient and family each time it is needed? Yes

Do the different professionals in your team give the same, previously agreed messages to patients and families? Yes

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Do you check each single brace in team (physician, orthotist, and possibly physiotherapist)? Yes
Do you follow-up regularly each single brace? Yes
Do you access the patient's mood and counsel him and the family at brace delivery and at other follow-ups? Yes
Do you check each single brace clinically and/or radiographically? Yes
Do you check the brace and patient compliance regularly and reinforce the usefulness of brace treatment to the patient and his/her family? Yes

Medical Doctors

Have you been trained by a previous master (i.e. a physician with at least 5 years of experience in bracing) for at least 2 years? Yes
Did you have at least 2 years of continuous practice in scoliosis bracing? Yes
Have you prescribed at least 1 brace per working week (~45 per year) in the last 2 years? Yes
Have you evaluated at least 4 scoliosis patients per working week (~150 per year) in the last 2 years? Yes
Do you prescribe each single brace to the constructing orthothist? Yes
Do you write the details of brace construction (where to push and where to leave space, how to act on the trunk to obtain results on the spine) when t already defined "a priori" with the orthotist? Yes
Do you prescribe the exact number of hours of brace wearing? Yes
Are you totally convinced of the brace proposed and committed to the treatment? Yes
Do you use any ethical mean to increase patient compliance, including thorough explanation of the treatment, aids such as photos, brochures, video, etc? Yes
Do you verify accurately if the brace fits properly and fulfils the need of the individual patient? Yes
Do you check the scoliosis correction in all the three planes (frontal, sagittal and horizontal)? Yes
Do you check clinically the aesthetic correction? Yes
Do you maximize brace tolerability (reduce visibility and allow movements and activity of daily life as much as possible for the used technique)? Yes
Do you check the corrections applied? Yes
Do you follow-up the braced patients regularly, at least every 3 to 6 months? Yes
Do you reduce standard intervals according to individual needs (first brace, growth spurt, progressive or atypical curve, poor compliance, request of other team members)? Yes
Do you take the responsibility to change the brace for a new one as soon as the child grows up or the brace loses efficacy? Yes

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Orthotists

Have you been working continuously with a master physician (i.e. a physician fulfilling to recommendation 1 criteria) for at least 2 years?	Yes
Did you have at least 2 years of continuous practice in scoliosis bracing?	Yes
Have you constructed at least 2 braces per working week (~100 per year) in the last 2 years?	Yes
Do you construct each single brace according to physician prescription?	Yes
Do you correct each single brace according to physician indications?	Yes
Do you check the prescription and its details and eventually discuss them with the prescribing physician, if needed, before construction?	Yes
Do you fully execute the agreed prescription?	Yes
Are you totally convinced of the brace proposed and committed to the treatment?	Yes
Do you use any ethical mean to increase patient compliance, including thorough explanation of the treatment, aids such as photos, brochures, video, etc?	Yes
Do you maximize brace tolerability (reduce visibility and allow movements and activity of daily life as much as possible for the used technique)?	Yes
Do you apply all changes needed and, if necessary, even rebuild the brace without extra-charge for patients?	Yes
Do you suggest to change the brace for a new one as soon as the child grows up or the brace loses efficacy?	Yes
Do you check regularly the brace ?	Yes
In front of any problem with the brace, do you refer to the treating physician?	Yes

Physiotherapists

Do you check the brace when you evaluate/treat a patient wearing a brace?	No
In front of any problem with the brace, do you refer to the treating physician?	No
In front of any problem with the brace, do you avoid to refer to the patient?	No
If you are a member of the treating team, have you been trained to face the problems of compliance, and the needs of explanation by the patient or his/her family?	No
If you are not a member of the treating team, do you avoid acting autonomously?	No