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RESEARCH

Wearing a brace for idiopathic scoliosis above 18 hrs/day shows a dose–response effect on the outcomes improvement and end-of-treatment Cobb angle below 30 degrees

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Abstract

Purpose The Brace Adolescent Idiopathic Scoliosis Trial (BrAIST) reported a bracing dose–response curve in AIS for brace-wearing time (BWT) up to 18 h/day (h/d) on the outcome end-of-treatment < 50°. We aimed to examine the dose–response curve for this and other relevant outcomes in cases of BWT > 18 h/d.

Methods Design: Retrospective secondary analysis of consecutively collected data. Participants: braced AIS patients with curves < 45° and a subgroup with BrAIST inclusion criteria. Treatment: different braces, prescribed 18 to 24 h/d, according to curve topography, Cobb angle and a shared decision-making approach. We divided patients into BWT quartiles and developed dose–response curves using the BrAIST methodology for the end-of-growth outcomes END < 50°, END < 30°, avoidance of progression, and improvement.

Results We included 884 patients (85% female), with a mean age of 13.0 ± 1.3 years and a mean Cobb angle of 28 ± 7°. In the higher BWT quartiles, we found larger scoliosis curves but also better final Cobb angle results. The dose–response curves showed statistically significant improvements for the outcomes END < 30° and improvement (outcomes improvements ranging 45–60% and 25–35%, respectively). The outcomes END < 50° and avoiding progression showed a ceiling effect due to a very high success rate (range 97–98% and 85–87%, respectively).

Conclusion BWT > 18 h/d is associated with avoiding surgery (END < 50°), reduced progression, and increased improvement rates, and achieving END < 30°, which is particularly relevant because it reduces the risk of problems in adulthood. Decisions on daily BWT should be based on the desired outcomes and an honest conversation with the patients and parents.

Keywords Adolescent idiopathic scoliosis · Brace · Patients compliance · Dose–response

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Background

Scoliosis is an abnormal spine curvature involving the trunk [1]. It is called idiopathic when no recognised cause exists [2]. It affects approximately 3% of the population and is more frequent in adolescents and girls [3]. Current treatments include observation, scoliosis-specific exercises, bracing, and, in severe cases, surgery [1].

Until a few years ago, the efficacy of braces for adolescents with idiopathic scoliosis (AIS) was debated [4]. The conservative experts of the Society On Scoliosis Orthopedic and Rehabilitation Treatment (SOSORT) were not able to perform an RCT because they were not in equipoise, defined as "a state of genuine uncertainty on the part of the clinical investigator regarding the comparative therapeutic merits of each arm in a trial" [5] – also referred as the "parachute evidence" paradox [6]. The surgical experts of the Scoliosis Research Society (SRS) proved to feel in equipoise [7]. They participated in an RCT, the Bracing Adolescent Idiopathic Scoliosis Trial (BrAIST) [8], providing clear evidence of the superiority of bracing over observation.

The debate over the bracing AIS now centres on the daily brace-wearing time (BWT). BrAIST reported a bracing dose–response curve, plotting BWT versus the outcome of "avoiding surgery" (remaining < 50°), showing no further improvement above 18 h per day (h/d). Many consider this result a solid scientific basis for the maximum brace prescription. SOSORT experts prescribe more hours [9], and papers comparing the BrAIST database to another prospective one showed that a higher dosage provides better results [10, 11].

We need further evidence to solve this debate, which may come from different treatment aims. The SOSORT and SRS non-operative committee recommendations for bracing studies proposed four outcome criteria: avoiding surgery, avoiding progression, improving, and remaining < 30° [12]. The literature showed that this last threshold significantly reduces the risks of progression [13, 14] and pain [15, 16] in adulthood.

Developing the dose–response curve for all the outcomes proposed by the SOSORT and SRS non-operative committee [12] could provide evidence relevant to resolving the current debate on bracing hours prescription. With this objective, we planned a secondary analysis of information from a previous paper, including a large dataset of prospectively collected patients [11]. We aimed to examine the dose–response curve for all relevant outcomes in AIS patients with a brace prescription > 18 h/d, followed up until the end of growth.

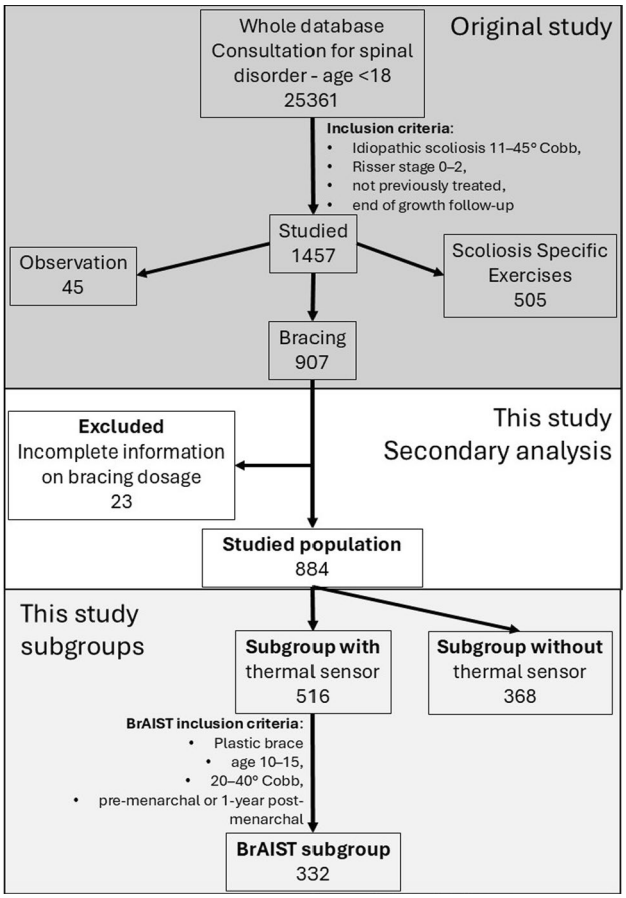

Fig. 1 Flowchart of patient selection and subgrouping

Methods

Study design

Secondary analysis of a retrospective study of prospectively collected data from a tertiary referral institute specialised in conservative treatment of spinal disorders [11]. Ethical and funding information are reported in the original study. We reported our results using the STROBE checklist [17].

Material and methods

Participants

The original study [11] examined a database of 25,361 consecutive children (aged under 18 years) who came to our Institute for a consultation (Fig. 1). It reported the final results of 1457 AIS patients with 11–45° Cobb angle, Risser stage 0–2. The topographical curve classification included 24% single (36% thoracic, 49% thoraco-lumbar, 14% lumbar), 67% double (54% thoracic/lumbar, 33% thoracic/thoraco-lumbar and 5% Moe), and 9% triple curves. Patients were not previously treated and were followed up until the end

of growth, defined as the achievement of European Risser 3, corresponding to US Risser 4. We included all patients from the start of electronic data recording (March 2003) to December 31, 2017. From this dataset, the inclusion criterion for the current secondary analysis was wearing a brace, and the exclusion criterion was incomplete information on brace-wearing time (BWT). We divided the participants into two groups: those with and those without brace wear monitoring, using a thermal sensor. For the best possible comparison with the BrAIST dose–response curve, we considered the most similar subgroup (BrAISTsg): use of plastic braces with a thermal sensor, age 10–15, Cobb angle 20–39°, and for females, being pre-menarchal or 1-year post-menarchal.

Intervention

All patients were treated with one of the following braces, described according to the international classification of braces [18]: 1) anterior closure, three-dimensional push-up TLSOs (Thoraco-Lumbo-Sacral Orthosis), either monocot rigid (Sibilla) or bivalve highly-rigid (Sforzesco) [19]; 2) for thoracolumbar and lumbar curves, either the short version (LSO—Lumbo-Sacral Orthosis) of the Sibilla brace or a ventral closure frontal & transverse plane detorsion monocot rigid LSO (PASB – Progressive Action Short Brace) [20]; the choice between the two was due to physician's preferences in agreement with the patient; 3) for patients with curves between 20 and 30° refusing the plastic brace, an elastic multisegmented three-dimensional frontal closure movement-based TLSO (Spinecor) [21]. The Institute's physicians selected the type of brace (elastic, rigid, or very rigid) and proposed the dosage based on the individual prognosis, with a minimum prescription of 18, up to 24 h/d. The worse the prognosis, the higher the brace rigidity and the proposed BWT. Further details are available in the original study [11]: we implemented an Evidence-Based Practice Approach based on shared decision-making to involve adolescents (and their parents) in the choices about their care and increase treatment adherence as much as possible. Consequently, the approach was based on the Institute's protocols, driving physicians' prescriptions, but was ultimately completely individualised. We also applied the gradual weaning protocol described in the original study [11]. All patients performed Scoliosis-Specific Exercises (SSE) according to the Scientific Exercises Approach to Scoliosis (SEAS) [22]. Patients recruited after 2012 received a prescription for a brace thermal sensor.

Variables

We compared the subgroups and, within each of them, the brace wearing-time (BWT) quartiles (see below) for the following baseline variables: 1) general: females, females with menarche (percentage and 95% Confidence Intervals [95CI]), and age (years); 2) anthropometric: weight (kg), height (cm) and Body Mass Index (BMI) (kg/m^2); 3) clinical: Trunk Aesthetic Clinical Evaluation (TRACE) index in percentage [23], Angle of Trunk Rotation (ATR) (degrees); 4) radiographic: Cobb degrees and Risser stage; 5) medical: prescription in hours/day (h/d). All measures were recorded by the treating physician.

We calculated two BWTs for the total treatment time: 1) in patients with the thermal sensors, we used the measured BWT obtained by adding all the sensor measures at each consultation for the entire period of treatment; 2) in patients who did not wear the thermal sensor, we used the reported BWT obtained as the sum of all the reported BWTs at each consultation: they were calculated by multiplying the daily BWT reported by the patient and parents by the number of days passed since the prescription or, in case of the first brace wearing, from the brace delivery.

We finally calculated the compliance by dividing the BWT by the prescribed BWT. The latter was obtained by multiplying the prescribed BWT at each consultation by the days passed between the prescription (or brace delivery after the first consultation) and the subsequent consultation.

We considered the four SOSORT and SRS non-operative committee outcomes [12]: 1) remaining < 50° (END < 50), 2) avoiding progression > 5°, 3) finishing < 30° (END < 30), and 4) improving > 5°. Since the population included patients who started treatment < 30°, the outcome END < 30 considered the increase in the population < 30° between the start and end of observation using the formula (patients < 30° at the end of growth) – (patients < 30° at the start of treatment).

Data and statistical analysis

We followed the methodology proposed in BrAIST [8] to develop the dose–response curves. The BrAIST considered the BWT in the first 6 months, providing a clear and easy-to-read plot of the brace dosage over a 24-h period. Since we had the whole treatment BWT, we multiplied the first prescription by compliance and obtained a representation of the treatment performed over the first prescription.

The curves describe the response to the brace for the four considered outcomes of the entire population, BrAISTsg, and the two subgroups of patients who did or did not wear the sensors. We then divided each of the considered patient subgroups (Total, BrAISTsg, with or without a thermal sensor) into four quartiles based on the brace-wearing hours.

Regarding the statistical analysis, a two-tailed one-proportion z-test was used to compare the total group with its BrAISTsg, assessing the proportion in BrAISTsg relative to the reference in the Total group. A one-sample z-test (or a

one-sample Wilcoxon signed-rank test for non-normal distributions) was applied to analyse differences in numerical values. For comparisons between the two independent groups (with and without a thermal sensor), a two-tailed z-test for two population proportions was conducted. Numerical values were analysed using an unpaired t-test (or the Wilcoxon rank-sum test when appropriate).

To evaluate differences in mean values within a specific group across the four quartiles of the BWT value, a one-way ANOVA (or Kruskal–Wallis test) was performed. Post-hoc comparisons were conducted using the Tukey–Kramer method in cases where significant differences were found. Differences in the proportions of outcomes (Improved, Not-progressed, END < 30, and END < 50) across the four quartiles were assessed using a chi-square test, followed by post-hoc comparisons with Holm's correction in the case of significant differences.

For the comparison of Cobb angle values before and after treatment within a specific group or quartile, a paired-sample t-test (or Wilcoxon signed-rank test) was applied. A significance level (α) of 0.05 was used for all tests. Statistical analyses were conducted using MATLAB software (v.R2024b, MathWorks Inc., Natick, MA).

Results

Out of the 907 braced patients in the original study, we excluded 23 (2.5%) because the observational database did not report complete information on BWT for any reason (Fig. 1). The final population consisted of 884 patients (85% female), with an average age of 13.0 ± 1.3 years, a mean Cobb angle of 28 ± 7°, and a Risser grade of 1 ± 1 (Table 1). The only statistically significant differences were 1) the number of female participants with menarche in BrAISTsg compared to the total population and 2) the clinical and radiographic parameters slightly statistically (but not clinically) worse in the subgroup without a thermal sensor.

We found some statistically significant differences among BWT quartiles for the anthropometric parameters. However, none was clinically significant: no more than 2.5 kg, 3 cm, and 1.5 kg/m^2 for weight, height, and BMI, respectively. The highest BWT quartiles exhibited the worst clinical and radiographic outcomes in all groups (Table 2). While the clinical differences among BWT quartiles were barely clinically significant, the same was not true for the radiographic differences: the 4th BWT quartile showed curves 5° or more above those in the other quartiles, except for a 3° difference for BrAISTsg only.

At the end of growth (Table 3), we found no differences in compliance among the groups and subgroups. Cobb degrees improved significantly in all groups and subgroups. BrAISTsg proved to be different from the others in terms of the number of patients improved.

We also found a statistically significant improvement in Cobb degrees in all BWT quartiles of all groups except for the first one (Table 4). With the exclusion of the first quartile, compliance was always above 93% and increased, with BWT quartiles peaking at 99–100% at the highest. On the contrary, improvement in Cobb degrees did not always increase with BWT quartiles.

Figure 2 presents the dose–response curves for all considered outcomes across all groups. They showed statistically significant improvements for the outcomes END < 30

Table 1 Baseline data of the whole population and the subgroups

		Total	BrAIST	P	With thermal sensor	Without thermal sensor	P
Numerosity		884	332		516	368	
Females	%	85(83–88)	80(76–84)	< 0.05	84(81–88)	86(83–90)	ns
Menarche	% females	53(49–56)	41(35–46)	< 0.05	52(48–57)	53(48–58)	ns
Age	years	13 ± 1.3	12.8 ± 1.3	ns	13 ± 1.4	12.9 ± 1.3	ns
Height	cm	158.5 ± 8.8	158.8 ± 8.6	ns	158.8 ± 8.4	157.9 ± 9.5	ns
Weight	kg	48 ± 9.3	47.7 ± 9.3	ns	48.1 ± 9.2	47.8 ± 9.4	ns
Curve type	Double T/Tl-L						
	Single T						
	Single Tl						
	Single L						
	Others						
BMI	kg/m^2	19 ± 2.9	18.8 ± 2.8	ns	19 ± 2.8	19.1 ± 3	ns
TRACE	%	48.3 ± 14.7	48.7 ± 15	ns	49.2 ± 14.9	47 ± 14.2	< 0.05
ATR	deg	10 ± 3.3	10 ± 3.3	ns	10.1 ± 3.4	9.9 ± 3.3	ns
Cobb angle	deg	30 ± 7	30 ± 6	ns	31 ± 7	30 ± 7	< 0.05
Risser	stage	1 ± 1	1 ± 1	ns	1 ± 1	1 ± 1	ns
First prescription	h/d	21.2 ± 1.9	21.6 ± 1.7	ns	21.5 ± 1.8	20.8 ± 2.1	ns

We report average ± Standard Deviation or percentages (95% Confidence Interval). T: Thoracic; L: Lumbar; Tl: Thoracolumbar. H/d: hours per day; deg: degrees; NS: Not Significant

Table 2 Baseline data of the population and subgroups divided by brace-wearing time (BWT) quartiles

	BWT	TRACE		ATR		Cobb angle		First prescription	
		%	*P*	*Deg*	*P*	*Deg*	*P*	*Hours/day*	*P*
Total									
Q1	0.8–17.6	46.5 ± 14.2	$§	9.3 ± 3.2	§	28 ± 7	$§	20.1 ± 2.3	$§
Q2	17.7–19.9	46 ± 13.1	$§	9.6 ± 3.1	§	26.9 ± 5.6	$§	20.2 ± 1.8	$§
Q3	20–21.9	49.8 ± 14.5	*#	10 ± 3.2	§	30 ± 6.9	*#§	21.6 ± 1.2	*#§
Q4	22–23.7	50.9 ± 16.1	*#	11.2 ± 3.5	*#$	35.2 ± 5.8	*#$	22.9 ± 0.5	*#$
BrAIST									
Q1	3.1–17.9	46.9 ± 15.4	§	9.3 ± 2.9	§	29 ± 6	§	20.5 ± 2.2	$§
Q2	18–20.5	45.9 ± 13.4	§	9.6 ± 3.5		29.1 ± 5.4	§	21 ± 1.6	$§
Q3	20.6–22	48.5 ± 16.9		10.3 ± 3.3		29.7 ± 5.2	§	22 ± 1	*#§
Q4	22.1–24	53.6 ± 13	*#	10.8 ± 3.3	*	32.8 ± 4.7	*#$	22.9 ± 0.5	*#$
With thermal sensor									
Q1	3.1–17.7	47.2 ± 14.6	§	9.4 ± 3	§	28.4 ± 6.9	§	20.3 ± 2.1	$§
Q2	17.8–20.2	47.3 ± 12.7	§	10 ± 3.4	§	28.3 ± 6.7	§	20.8 ± 1.7	$§
Q3	20.3–21.9	50.4 ± 16		9.9 ± 3.3	§	30.1 ± 6.8	§	21.9 ± 1.2	*#§
Q4	22–24	52 ± 15.6	*#	11.2 ± 3.6	*#$	35.1 ± 5.8	*#$	22.9 ± 0.4	*#$
Without thermal sensor									
Q1	3.7–17	45.8 ± 14.6		9.3 ± 3.4	§	27.5 ± 7.3	§	20 ± 2.5	§
Q2	17.1–19.4	44.4 ± 12.8	§	9.2 ± 2.8	§	25.9 ± 5	$§	19.5 ± 1.8	$§
Q3	19.5–20.9	48.7 ± 12.4		9.9 ± 2.9		28.7 ± 5.9	#§	20.9 ± 1	#§
Q4	21–23.6	49.2 ± 16.4	#	11.2 ± 3.6	*#	35.8 ± 5.7	*#$	22.9 ± 0.5	*#$

We report average ± Standard Deviation or percentages (95% Confidence Interval). Q: quartile of BWT; h/d: hours per day; deg: degrees. Statistically significant differences between BWT quartiles ($P < 0.05$): *different from 1 st quartile; # different from 2nd quartile; $different from 3rd quartile; § different from 4th quartile

Table 3 Compliance and results in all groups

Groups	Compliance	Change in Cobb angle	SOSORT Outcomes			
			Improved	*Not progressed*	*END < 30*	*END < 50*
Total	91% ± 15%	−2.8 ± 8.2*	44% (41–48)	86% (84–89)	12% (10–14)	97% (96–98)
BrAIST	91% ± 14%	−2.3 ± 7.6*	38% (33–43)	85% (81–89)	14% (10–18)	98% (96–99)
With thermal sensor	91% ± 13%	−2.3 ± 7.8*	41% (37–45)	86% (83–89)	12% (10–15)	97% (96–99)
Without thermal sensor	90% ± 16%	−3.4 ± 8.7*	49% (44–55)	87% (84–91)	12% (8–15)	98% (96–99)

We report average ± Standard Deviation. For the SOSORT outcomes, we report percentages (95% Confidence Interval). END < 50: rate of population remaining < 50° at the end of growth; END < 30 increase of the population < 30° at the end of observation. *Statistically significant difference from the baseline ($P < 0.0001$)

and improvement > 5°), even if not always between some contiguous BWT quartiles. The outcomes of END < 50 and avoiding progression > 5° showed a very high success rate in all BWT quartiles, with mostly no statistically significant differences (Table 4).

Discussion

This study confirms the results of BrAIST [8], with the brace dose–response curve remaining stable above 18 h/d for the outcome END < 50. Using the brace at high dosage allows for achieving END < 50 in 97 to 98% and avoids scoliosis progression in 85 to 87% of cases in the different groups. We also found that with high BWT, it is possible to obtain results in the three other outcomes recommended by SOSORT and the SRS non-operative committee [12]: the outcome END < 30, relevant to avoid problems in adulthood [15, 16], increases between 45 and 60% and it is possible to achieve improvements in 25–35% of cases in the different groups.

While it is possible to draw a bracing dose–response curve combining the results of this study and BrAIST (Fig. 3) [8], it is essential to highlight similarities and differences between the two studies. The considered populations were the same, even if one was based in the USA and the other in Europe, and some social differences in the approach to bracing could exist. Patients were consecutively recruited,

Table 4 Compliance and results in all groups for all brace-wearing time (BWT) quartiles

	BWT	Compliance	Change in Cobb angle	SOSORT Outcomes							
				Improved		Not progressed		*END < 30*		*END < 50*	
				% (95IC)	*P*	*% (95IC)*	*P*	*% (95IC)*	*P*	*% (95IC)*	*P*
Total											
Q1	0.8–17.6	73% ± 18%	−0.5 ± 7.4	31% (25–37)	$§	81% (76–86)		−4% -	#$§	98% (96–100)	
Q2	17.7–19.9	93% ± 7%	−2.7 ± 7.1*	41% (34–47)	§	89% (85–93)		6% (3–10)	*$§	99% (98–100)	
Q3	20–21.9	97% ± 5%	−3.8 ± 7.6*	50% (44–57)	*	88% (83–92)		16% (11–21)	*#§	98% (96–100)	
Q4	22–23.7	100% ± 3%	−4.2 ± 9.8*	55%(49–62)	*#	88% (83–92)		30% (24–36)	*#$	95%(92–98)	
BrAIST											
Q1	3.1–17.9	75% ± 19%	0.1 ± 7.6	24% (15–33)	$§	80% (71–88)		1% (0–4)	#$§	99% (96–101)	
Q2	18–20.5	93% ± 7%	−2.5 ± 7*	35% (25–45)		89% (82–96)		14% (7–22)	*	99% (96–101)	
Q3	20.6–22	97% ± 4%	−3.2 ± 7.5*	48% (37–59)	*	83% (75–91)		17% (9–25)	*	98% (94–101)	
Q4	22.1–24	100% ± 3%	−3.6 ± 7.9*	46% (35–57)	*	88% (81–95)		24% (15–33)	*	96% (92–100)	
With thermal sensor											
Q1	3.1–17.7	76% ± 17%	−0.3 ± 7.1	29% (21–36)	$§	81% (74–87)		−2% -	#$§	98% (96–101)	
Q2	17.8–20.2	93% ± 7%	−1.6 ± 8.4*	35% (27–43)	§	86% (80–92)		9%(4–13)	*§	98% (95–100)	
Q3	20.3–21.9	97% ± 5%	−3.4 ± 6.8*	48% (39–57)	*	88% (82–93)		16%(9–22)	*§	98% (95–100)	
Q4	22–24	100% ± 3%	−4.1 ± 8.1*	52% (43–61)	*#	88% (83–94)		28%(20–36)	*#$	95% (92–99)	
Without thermal sensor											
Q1	3.7–17	69% ± 20%	−0.3 ± 7.5	28% (19–37)	#$§	80% (72–89)		−5% -	$§	97% (93–100)	
Q2	17.1–19.4	94% ± 7%	−4.8 ± 6.1*	57% (46–67)	*	92% (87–98)		4% (0–9)	§	100% (100–100)	
Q3	19.5–20.9	97% ± 4%	−4 ± 6.9*	50% (40–60)	*	90% (84–96)		13% (6–20)	*§	100% (100–100)	
Q4	21–23.6	99% ± 3%	−4.5 ± 12.3*	63% (53–73)	*	86% (79–93)		35% (25–45)	*#$	93% (88–99)	

Q: quartile; END < 50: rate of the population remaining < 50° at the end of growth; END < 30 increase of the population < 30° at the end of observation. *Statistically significant difference from the baseline (P < 0.0001). Statistically significant differences between BWT quartiles (P < 0.05): *different from 1 st quartile; # different from 2nd quartile; $ different from 3rd quartile; § different from 4th quartile

and BWT was monitored in both studies; the retrospective design of the current study should not influence the results. The most significant difference lies in the "per protocol" approach of an RCT versus the shared decision-making, evidence-based practice approach used in our sample [11]. This contrast leads to another, more significant difference: the highest BWT quartiles in our study included patients with the most severe deformities and higher dosages prescribed. This difference can explain the slight flexion in the dose–response curve for the outcomes "avoiding surgery" and, in some subgroups, "avoiding progression" too. Another difference could be that we used the entire treatment BWT, whereas BrAIST considered the first 6 months [8]. While the first 6 months of treatment results are very good predictors of the final results [24], we preferred to use the whole treatment BWT because it better represents what was performed by the patient and takes into account our gradual weaning protocol [11], which could impact the final results.

This study confirms once more that compliance is a main determinant factor in achieving results with bracing [25, 26]. Similar to BrAIST [8], the minimum prescription was 18 h/d in our population. Nevertheless, in our study, in the long-term whole treatment observation, more than 75% of the population wore the brace for 18 h or more, while this was true for less than 25% of the BrAIST study population within the first 6 months [8], confirming what found in other

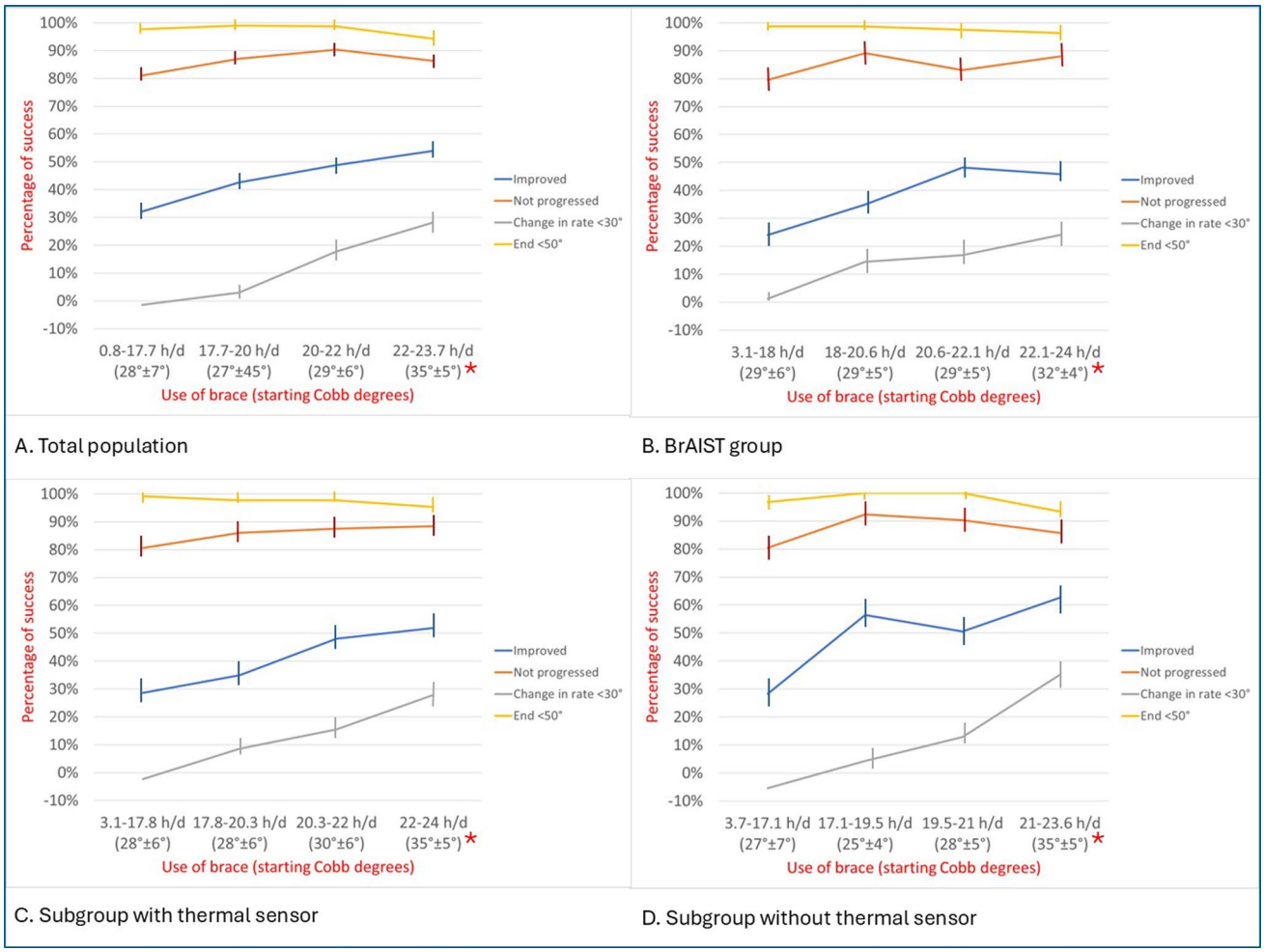

Fig. 2 Dose–response curves for the SOSORT outcomes for all groups. *Cobb degrees statistically significantly different from the other brace-wearing time (BWT) quartiles

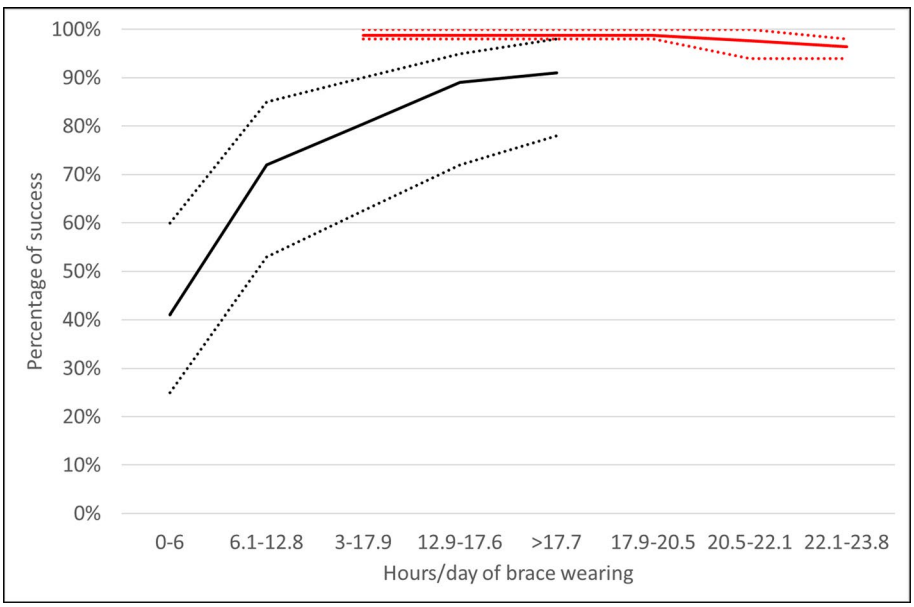

Fig. 3 The dose–response curve obtained by combining the results of the current with the BrAIST study [8]. Red lines: current study; black lines: BrAIST study. Dotted lines: 95% confidence intervals

papers [10]. There could be multiple explanations for this result, including the shared decision-making approach [11] and implementing all the strategies reported in the literature to increase compliance [26]. Other factors that could play a role include the type of brace (more or less visible), social aspects (Italy vs. USA), settings (surgical vs. conservative), and the implementation of the SOSORT Guidelines on bracing treatment management [27], among others. Future qualitative and quantitative research should carefully examine all these factors to enhance our understanding and ultimately improve the efficacy of brace treatment in various locations.

Another potentially important factor to consider is that patients are not treated surgically at the Institute where the data were collected, despite some surgeons serving as consultants and being included in the team. This factor could play a role in two directions. On one side, it could drive a patient's self-selection in favour of those who prefer and engage in conservative treatment. On the other hand, it could testify to the importance of a team completely devoted and committed to conservative treatment, whether autonomous, as in this case, or within surgical environments. These factors could be explored in future studies. Nevertheless, the main point of this paper remains: the more patients use the brace, the better the results they can achieve. The characteristics of the Institute can ultimately contribute significantly to explaining the high compliance achieved and the quality of results obtained through the implemented treatments.

The expertise of the treating team and the shared decision-making evidence-based approach [11] could be another confounding factor. Physicians prescribed more hours and higher brace rigidity according to their prognosis (expertise) and the level of agreement with patients (shared decision-making). This approach explains why patients who used the brace for more hours (in the first BWT quartile) were also those with the worst curves (statistically significant difference). Additionally, these patients demonstrated the highest compliance, which could be attributed to their motivation due to the importance of the curve. Finally, this factor may explain the slight but statistically significant increase in most subgroups of END > 50 and scoliosis progression rates in the highest BWT quartile. Nevertheless, also the improvement rate and the percentage of patients < 30° increased in the first quartile. All in all, this factor reinforces the study's message that the more patients use the brace, the better the results they can achieve.

This study possesses several strengths, including a large patient cohort that was prospectively collected, which enhances the statistical robustness of the findings. It utilises objective compliance measures across a significant portion of the population. The real-world clinical setting and personalised, shared decision-making approach augment the clinical applicability of the results. However, these factors may limit the generalisability of the results, along with the specialised conservative setting and the variability in brace types and prescription protocols. Despite the data being collected prospectively, the retrospective design permitted the inclusion of only those variables gathered during routine clinical practice. The absence of randomisation exposes the study to selection bias and confounding factors (e.g., patients with more severe curves were prescribed longer brace hours).

Conclusion

A BWT higher than 18 h/d is strongly associated with avoiding surgery (END < 50), significantly reduces the progression of cases, and enables positive outcomes (improving with BWT) regarding treatment completion below 30° Cobb angle, which is particularly relevant as it diminishes the risk of issues in adulthood. These results can aid in resolving the debate about daily BWT, which should rest on the desired outcomes and a candid discussion with patients and parents.

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Author contributions SN conceived the study, collected and controlled all the data, and drafted the paper; FN, FF, GJ, CP and FZ collected data, and provided important contributions to the paper; TB performed the statistical analysis, contributed to writing the paper also providing important contributions; AN provided an important conceptual contribution to the study development and conduct, and to the paper writing. All authors approved the final text.

Data availability The data presented in this study are openly available in Zenodo at https://doi.org/https://doi.org/10.5281/zenodo.5517156.

Declarations

Conflicts of interest AN and SN own stock of ISICO. FN is related to AN and SN. The other authors have no conflict of interest to declare.

Ethics Committee approval and trial registration The local Ethical Committee (Comitato Etico Milano Area B, Via F. Sforza 28, 20,122 Milan Italy—parere 801_2015bis, 15–12-2015) approved the study protocol available in clinicaltrials.gov.

Patient involvement statement: Study participants were not involved in the design, conduct, interpretation, or translation of the current research.

References

1. Negrini S, Donzelli S, Aulisa AG et al (2018) 2016 SOSORT guidelines: orthopaedic and rehabilitation treatment of idiopathic scoliosis during growth. Scoliosis Spinal Disord. https://doi.org/10.1186/s13013-017-0145-8
2. Hresko MT (2013) Clinical practice. Idiopathic scoliosis in adolescents. N Engl J Med 368:834–841. https://doi.org/10.1056/NEJMcp1209063
3. Li M, Nie Q, Liu J, Jiang Z (2024) Prevalence of scoliosis in children and adolescents: a systematic review and meta-analysis. Front Pediatr 12:1399049. https://doi.org/10.3389/fped.2024.1399049
4. Dolan LA, Weinstein SL (2007) Surgical rates after observation and bracing for adolescent idiopathic scoliosis: an evidence-based review. Spine 32:S91–S100. https://doi.org/10.1097/BRS.0b013e318134ead9
5. Freedman B (1987) Equipoise and the ethics of clinical research. N Engl J Med 317:141–145. https://doi.org/10.1056/NEJM198707163170304
6. Smith GCS, Pell JP (2003) Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials. BMJ 327:1459–1461. https://doi.org/10.1136/bmj.327.7429.1459
7. Dolan LA, Donnelly MJ, Spratt KF, Weinstein SL (2007) Professional opinion concerning the effectiveness of bracing relative to observation in adolescent idiopathic scoliosis. J Pediatr Orthop 27:270–276. https://doi.org/10.1097/01.bpb.0000248579.11864.47
8. Weinstein SL, Dolan LA, Wright JG, Dobbs MB (2013) Effects of bracing in adolescents with idiopathic scoliosis. N Engl J Med 369:1512–1521. https://doi.org/10.1056/NEJMoa1307337
9. Zaina F, Cordani C, Donzelli S et al (2022) Bracing interventions can help adolescents with idiopathic scoliosis with surgical indication: a systematic review. Children 9:1672. https://doi.org/10.3390/children9111672
10. Dolan LA, Donzelli S, Zaina F et al (2020) Adolescent idiopathic scoliosis bracing success is influenced by time in brace: comparative effectiveness analysis of BrAIST and ISICO cohorts. Spine 45:1193–1199. https://doi.org/10.1097/BRS.0000000000003506
11. Negrini S, Donzelli S, Negrini F et al (2021) A pragmatic benchmarking study of an evidence-based personalised approach in 1938 adolescents with high-risk idiopathic scoliosis. J Clin Med 10:5020. https://doi.org/10.3390/jcm10215020
12. Negrini S, Hresko TM, O'Brien JP et al (2015) Recommendations for research studies on treatment of idiopathic scoliosis: consensus 2014 between SOSORT and SRS non-operative management committee. Scoliosis 10:8. https://doi.org/10.1186/s13013-014-0025-4
13. Weinstein SL, Ponseti IV (1983) Curve progression in idiopathic scoliosis. J Bone Joint Surg Am 65:447–455
14. Danielsson AJ, Hasserius R, Ohlin A, Nachemson AL (2007) A prospective study of brace treatment versus observation alone in adolescent idiopathic scoliosis: a follow-up mean of 16 years after maturity. Spine 32:2198–2207. https://doi.org/10.1097/BRS.0b013e31814b851f
15. Weinstein SL, Dolan LA, Spratt KF et al (2003) Health and function of patients with untreated idiopathic scoliosis: a 50-year natural history study. JAMA 289:559–567. https://doi.org/10.1001/jama.289.5.559
16. Mayo NE, Goldberg MS, Poitras B et al (1994) The Ste-justine adolescent idiopathic scoliosis cohort study. Part III: Back pain. Spine 19:1573–1581. https://doi.org/10.1097/00007632-199407001-00005
17. von Elm E, Altman DG, Egger M et al (2007) The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. Lancet Lond Engl 370:1453–1457. https://doi.org/10.1016/S0140-6736(07)61602-X
18. Negrini S, Aulisa AG, Cerny P et al (2022) The classification of scoliosis braces developed by SOSORT with SRS, ISPO, and POSNA and approved by ESPRM. Eur Spine J 31:980–989. https://doi.org/10.1007/s00586-022-07131-z
19. Negrini S, Tessadri F, Negrini F et al (2022) Impact of the Free-Pelvis Innovation in Very Rigid Braces for Adolescents with Idiopathic Scoliosis: Short-Term Results of a Matched Case-Control Study. Child Basel Switz 9:871. https://doi.org/10.3390/children9060871
20. Aulisa AG, Mastantuoni G, Laineri M et al (2012) Brace technology thematic series: the progressive action short brace (PASB). Scoliosis 7:6. https://doi.org/10.1186/1748-7161-7-6
21. Coillard C, Circo AB, Rivard CH (2014) A prospective randomized controlled trial of the natural history of idiopathic scoliosis versus treatment with the SpineCor brace. Sosort Award 2011 winner. Eur J Phys Rehabil Med 50:479–487
22. Romano M, Negrini A, Parzini S et al (2015) SEAS (scientific exercises approach to scoliosis): a modern and effective evidence based approach to physiotherapic specific scoliosis exercises. Scoliosis 10:3. https://doi.org/10.1186/s13013-014-0027-2
23. Negrini S, Donzelli S, Di Felice F et al (2020) Construct validity of the Trunk Aesthetic Clinical Evaluation (TRACE) in young people with idiopathic scoliosis. Ann Phys Rehabil Med 63:216–221. https://doi.org/10.1016/j.rehab.2019.10.008
24. Negrini S, Di Felice F, Negrini F et al (2022) Predicting final results of brace treatment of adolescents with idiopathic scoliosis: first out-of-brace radiograph is better than in-brace radiograph-SOSORT 2020 award winner. Eur Spine J Off Publ Eur Spine Soc Eur Spinal Deform Soc Eur Sect Cerv Spine Res Soc. https://doi.org/10.1007/s00586-022-07165-3
25. Liu S, Ho LY, Hassan Beygi B, Wong MS (2023) Effectiveness of Orthotic Treatment on Clinical Outcomes of the Patients with Adolescent Idiopathic Scoliosis Under Different Wearing Compliance Levels: A Systematic Review. JBJS Rev 11:. https://doi.org/10.2106/JBJS.RVW.23.00110
26. Cordani C, Malisano L, Febbo F et al (2023) Influence of specific interventions on bracing compliance in adolescents with idiopathic scoliosis-a systematic review of papers including sensors' monitoring. Sensors (Basel) 23:7660. https://doi.org/10.3390/s23177660
27. Negrini S, Grivas TB, Kotwicki T et al (2009) Guidelines on "Standards of management of idiopathic scoliosis with corrective braces in everyday clinics and in clinical research": SOSORT Consensus 2008. Scoliosis 4:2. https://doi.org/10.1186/1748-7161-4-2