



Providence nighttime bracing is effective in treatment for adolescent idiopathic scoliosis even in curves larger than 35°

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Abstract

Summary of Background Data Since 2006, the Providence nighttime brace has been used for a conservative treatment for scoliosis. Previous studies comparing the outcomes after full-time bracing and nighttime bracing have reported a comparable outcome with curves < 35°. The aim of this study was to report the outcome after treatment in a cohort of adolescent idiopathic scoliosis patients, with curves between 20° and 45°.

Methods One hundred and twenty-four patients with adolescent idiopathic scoliosis were included in this study with Cobb > 20°, remaining growth potential and no previous scoliosis treatment. Providence nighttime treatment, 8 h nightly, was initiated. Treatment was continued until 2 years post-menarcheal for females and until 6-month growth arrest for males. The patients were evaluated using standing radiographs during treatment and 6 and 12 months after termination of bracing.

Results One hundred and twenty-four patients were included; 80 patients terminated brace treatment and were available for follow-up. Mean in-brace correction was 82%, and curve progression was observed in 9 patients. Brace treatment was successful in 89% of the patients, 88% of the patients braced with curves 20°–29°, 93% of the patients braced with 30°–39° and 77% of the patients braced with curves 40°–45°. Five of the 80 AIS patients were referred to surgery: 4 due to progression and 1 due to cosmetic concerns.

Conclusions Providence nighttime braces are an effective treatment for adolescent idiopathic scoliosis patients. This study reports a success rate of 89%, and the results are comparable to full-time treatment with the Boston brace. In-brace correction is crucial in part-time bracing, and we recommend at least 70% curve correction, if part-time bracing should be considered.

Graphical abstract

These slides can be retrieved under Electronic Supplementary Material.

Key points

1. Adolescent Idiopathic Scoliosis
2. Providence Night-time Bracing
3. Conservative treatment

Table 1

Effect Demographics	20° to 29°	30° to 39°	40° to 45°	p-value
n	25	42	13	
Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	
Age (years) at start	13.56 (0.99)	13.36 (1.21)	13.54 (1.45)	0.822
Monthly post-treatment	3.04 (0.28)	3.08 (0.32)	3.30 (0.13)	0.059
Correction factor	83% (14%)	84% (14%)	73% (16%)	0.000
In-brace correction	89% (14%)	88% (14%)	77% (16%)	0.017
Change Cobb	33.20 (4.56)	27.70 (6.77)	44.50 (6.92)	0.280
Cobb End	22.04 (8.92)	30.40 (7.69)	41.34 (5.48)	0.000
Progression > 5°	0	1	4	0.000
Surgery	0	1	4	0.000
n	8	24		p-value
Mean (SD)	Mean (SD)			
Correction factor	5.65 (1.96)	5.18 (1.49)		0.066

Take Home Messages

1. Providence night-time braces are effective, as a treatment in adolescent idiopathic scoliosis patients even in curves > 35° before treatment is initiated.
2. This study reports a success rate of 88.7% and the results are comparable to fulltime treatment with Boston braces or other TLSO.
3. In brace correction is crucial in part time bracing, and we recommend an initial 70% curve correction, if part time bracing should be considered.

Keywords Adolescent idiopathic scoliosis · Providence nighttime bracing · Conservative treatment · In-brace correction · Outcome

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Extended author information available on the last page of the article

Introduction

Scoliosis is a three-dimensional deformity of the spine, and the most common subgroup is adolescent idiopathic scoliosis (AIS), and the etiology of the disease is still unknown. Girls are affected 5–10 times more than boys. Of the 1–2% of all school-children diagnosed with AIS, only 0.3–0.5% of the patients progress and require treatment [1]. AIS is often diagnosed during the rapid growth of the spine, usually from 11 to 14 years of age.

Patients are often diagnosed by their gym teacher, school nurse or parents, who notice trunk shift, shoulder imbalance or deformity of the spine. Patients are diagnosed after screening with the Adams forward bending test and standing radiographs of the spine. If the patient presents with a Cobb angle $> 25^\circ$ and has remaining growth potential, brace treatment is recommended to avoid progression. Untreated AIS can progress to severe deformation of the spine, with pulmonary complications, back pain and reduced health-related quality of life [2].

A previous study by Lonstein and Carlson reports the risk of curve progression without treatment of up to 68% in Risser 0–1 patients with initial curves 20° – 29° [3]. The BRAIST trial conducted in 2015 provided evidence that brace treatment decreases the progression of the scoliosis and can reduce the rate of surgical treatment [4]. Skin problems, poor patient compliance and psychological stress have been a concern for many years [5], and nighttime bracing was introduced as an alternative to full-time bracing. The Providence nighttime brace (PNB), which corrects the spine by applying lateral and rotational forces on the trunk to move the spine toward the midline, was developed in the 1990s [6]. A biomechanical study of the PNB describes how the curve correction is achieved by combining the supine position with pads inside the brace, so the trunk is derotated and the deformity is corrected at nighttime, when the mechanical loading of the spine is relieved and the growth of the vertebrae peaks [7, 8]. A study by Yrjönen et al. [9] compared the outcome after Boston and Providence bracing and reported the same outcome after treatment. The purpose of this study is to report outcomes, after treatment with PNB in a cohort of AIS patients braced with curves from 20° to 45° .

Methods

Since 2006, the PNB has been the only available nonsurgical treatment modality for AIS in the region of Southern Denmark. We included all patients, diagnosed with AIS who fulfilled the following criteria, age > 10 years at time

of diagnosis, less than 12 months post-menarcheal, Cobb 20° – 42° , no prior scoliosis treatment, initial in-brace curve correction $> 60\%$ and follow-up including radiographs at least 12 months after brace termination. The patients were braced according to the SRS criteria [10].

All patients were diagnosed based on standing postero-anterior radiographs and clinical examination. If brace treatment was recommended, the patient was placed in supine position on a measurement table, allowing the orthopedist to gradually apply pressure to the trunk and evaluate the flexibility of the spine. The BNP is produced in the USA by SpineTech, as described by D'Amato et al., using a CAD/CAM model based on the measurements [6]. Once manufactured, the brace was adjusted by the orthopedist and brace wear initiated at home, as described by Al-Aubaidi et al. [11]. Bracing was started with wearing the brace as long as tolerated by the patient, gradually increasing to 8 h a night by 2 weeks. After the initial 2 weeks of brace wear, the in-brace correction was evaluated using an in-brace radiograph, with the patient in lying supine in the brace 30 min. Adjustments were made to the brace to achieve a minimum of 60% curve correction. Overcorrection of the curves was often seen in the young patients, and in these cases, the in-brace correction was recorded as 100%. Clinical examination and standing radiographs were performed every 6 months during treatment. To ensure the best evaluation of curve progression during treatment, the patients and parents were instructed not to wear the brace, the night before the radiographic evaluation. To avoid unnecessary radiation exposure to the patients, no prebending radiographs or Risser radiographs were obtained. Brace treatment was terminated 2 years after menarcheal for the girls, and when no increase in standing height was measured in the boys in the 6-month interval between clinical examinations [12]. Compliance was recorded by the orthopedist during the clinical visit. Thermal sensors were not used in this study since these were not available at the beginning of this study. Patients were re-evaluated 6 and 12 months after termination of brace treatment. All Cobb measurements were taken by 2 independent observers, and if difference was seen, the observers made a third evaluation together to ensure the correct evaluation. Harrington factor was calculated, as described by Korovesis et al. [13], at the radiograph 1 year after termination of brace treatment.

Curves were classified according to a modified Lenke classification, as lateral radiographs were not available, to reduce radiation exposure to the patients [14]. Brace treatment was successful if no progression occurred, or a slight reduction of the curve was observed.

To evaluate the effect of bracing in curves larger than 35° when treatment was initiated, the patients were divided into groups according to the Cobb at the start of treatment: Cobb 20° – 29° , Cobb 30° – 39° and Cobb 40° – 45° . Failure

was defined as a curve progression of 5° or more, during or after termination of brace treatment. The rate of patients referred to surgery was also recorded.

Results

One hundred and twenty-four consecutive patients were included in this study; 14 patients were excluded due to lack of compliance. Seventeen patients were diagnosed with a neurologic disease, genetic malformation or other disease shortly after initiating brace treatment. Thirteen patients have completed brace treatment but had not reached one-year follow-up. A total of 80 patients completed bracing and follow-up, 68 females and 12 males, and were included in the analysis. Patient demographics are summarized in Table 1.

The mean treatment time in brace was 18 months (10–36 months), and 2 patients were braced < 12 months. The mean in-brace correction was 83% (57–100%), and in-brace correction was significantly different between the groups, due to curve stiffness observed in curves > 40° . Curve progression > 5° during brace treatment was

observed in 9 patients (11.3%) of the patients (Table 2). Five patients were referred for surgical management, 1 patient progressed from 38° to 50° , and 3 patients with Cobb 40° progressed. One patient was referred to surgery due to cosmetic concerns. The Harrington factor, previously thought of to be a prognostic factor for progression, was not statistically significantly different among the three groups. Brace treatment was effective in prevention of curve progression in 71 of 80 patients. 88% of the patients were braced with Cobb 20° – 29° , 93% of the patients braced with Cobb 30° – 39° , and 77% of the patients braced with Cobb > 40° .

Discussion

The BrAIST study provided solid evidence that brace treatment can effectively prevent the progression of AIS [4]. Boston braces and other Thoraco Lumbar Sacral Orthosis (TLSO) studies reported good curve control but also reported compliance issues, due to skin problems, psychological issues and patients feeling “trapped” inside the brace during daytime [2, 5, 15, 16]. The PNB brace combines the supine position during nighttime as an additional

Table 1 Patient demographics

Gender	68 Females	12 Males		
BMI	18.28 (15.58–24.98)	18.41 (17.09–20.76)		
	Baseline Cobb angle			
	20°–29°	30°–39°	40°–45°	
<i>N</i>	25	42	13	
	Mean (SD)	Mean (SD)	Mean (SD)	<i>p</i> value
Age years start	13.16 (0.99)	13.38 (1.21)	13.54 (1.45)	0.612
Months post-menarcheal	3.04 (9.28)	3.68 (9.92)	3.90 (9.13)	0.959
Harrington factor	4.10 (1.07)	5.67 (1.47)	6.18 (1.56)	0.000
In-brace correction	89% (14%)	84% (16%)	73% (16%)	0.017
Change cobb	3.20 (8.24)	2.79 (6.77)	−0.38 (4.93)	0.293
Cobb end	22.04 (8.92)	30.40 (7.69)	41.54 (5.40)	0.000
Progression > 5°	3	3	3	–
Referred to surgery	0	1	4*	0.000
	Progression		No progression	
<i>N</i>	9	71		
	Mean (SD)	Mean (SD)		<i>p</i> value
Harrington factor	5.65 (1.96)	5.18 (1.49)		0.066

* 1 patient had surgery due to cosmetic concerns, not observed progression during treatment

Table 2 Brace failures

Age years	Curve type	Cobb start (°)	Cobb end (°)	Harrington factor	In-brace correction (%)
15	3	25	35	3.6	67
14	5	22	28	3.7	100
12	1	29	37	3.2	70
15	1	31	40	6.2	80
16	5	34	40	6.8	62
12	5	38	50	7.6	80
13	1	40	46	6.7	64
13	3	40	46	8	72
11	1	40	48	8	80

corrective force, as described by Sattout et al. [7]. Biomechanical studies by Villemure et al. [8] have suggested that slight distraction can increase the bone growth. This allows the AIS patients to grow during the nightly “over-correction” of their spine allowing the concave side of the spine to increase in length. The results of the current study are comparable to previous studies with Providence braces [9] but also comparable to the outcome reported by Katz and Durani [17] and Danielsson et al. [18]. Major limitations in our study are the lack of a control cohort treated with Boston braces, the lack of Risser grading prior to treatment and the lack of bending radiographs due to the concern of radiation exposure. All patients were treated according to the SRS Brace criteria and until full growth was completed. Furthermore, compliance was evaluated by “wear and tear,” since sensors were not available when the study was initiated.

The in-brace correction of 83% is comparable to the studies by D’Amato et al. [6] and Yrjönen et al. [9]. In our evaluation of the outcome of bracing, we chose to separate the patients in groups, according to the initial Cobb. The PNB was able to prevent progression in 71/80 patients, and even in the group braced with curves $>40^\circ$, the effect success was 77%, which can be explained by the good in-brace correction in all 3 groups. The rate of progression and need for surgical treatment were higher in the group braced with curves $>40^\circ$, which is explained by the curve stiffness and higher risk of progression during the growth.

Three patients were braced with curves $<30^\circ$ and progressed during treatment. The initial in-brace correction was 67%, 70% and 100%, and we suspect compliance issues as the explanation to the progression, which is not reported due to the lack of sensors included in this study. None of our patients experienced skin problems, but one patient developed a bursitis on the lower anterior costae the brace was adjusted. The majority of patients stayed active with sports throughout the brace treatment period, and no physiotherapy treatment or exercises was recommended.

Conclusion

PNB is effective in a conservative treatment for AIS in curves with apex at T7 or below, ranging from 20° – 40° . This study reports outcomes similar to previous studies with Boston Braces or other TLSO, with 8-h wear at nighttime and a success rate of 89% (range 77–93%) bracing curves from 20° to 29° , 30° – 39° and 40° – 45° . Progression during treatment was observed in 9 patients, 3 patients from each group. In-brace correction is a concern in part-time bracing, and we recommend aiming at minimum 70% in-brace correction in the Providence brace initially to ensure the best effect during treatment. Close attention is needed during treatment of patients with a Harrington factor $>6^\circ$ or an in-brace correction $<60\%$, since this might be associated with a high risk of progression during PNB treatment.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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