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ORIGINAL ARTICLE

The effect of Providence night-time bracing on the sagittal profile in adolescent idiopathic scoliosis

Martin Heegaard[1] · Niklas Tøndevold[1] · Benny Dahl[1] · Thomas B. Andersen[1] · Martin Gehrchen[1] · Søren Ohrt-Nissen[1]

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Abstract

Purpose Adolescent idiopathic scoliosis (AIS) is characterized by coronal scoliosis and often a sagittal hypokyphosis. The effect of bracing on the sagittal profile is not well understood. The aim of this study is to assess the effect of night-time bracing on the sagittal profile in patients with AIS.

Methods We retrospectively included AIS patients with a main curve of 25–45° treated with a night-time brace in our institution between 2005 and 2018. Patients with estimated growth potential based on either Risser stage, hand X-rays, or menarchal status were included. Coronal and sagittal radiographic parameters were recorded at both brace- initiation and -termination. Patients were followed until surgery or one year after brace termination. Results were compared to a published cohort of full-time braced patients.

Results One hundred forty-six patients were included. Maximum thoracic kyphosis (TK) increased 2.5° (±9.7) ($p = 0.003$), corresponding to a 3.5-fold relative risk increase post bracing in TK compared to a full-time brace cohort. Twenty-seven percent ($n = 36$) of the patients were hypokyphotic (T4/T12 < 20°) at brace initiation compared with 19% ($n = 26$) at brace termination ($p = 0.134$). All other sagittal parameters remained the same at follow-up. We found no association between progression in the coronal plane and change in sagittal parameters.

Conclusion This is the first study to indicate that night-time bracing of AIS does not induce hypokyphosis. We found a small increase in TK, with a substantially lower risk of developing flat back deformity compared to full-time bracing. The coronal curve progression was not coupled to a change in TK.

Keywords Adolescent idiopathic scoliosis · Night time brace · Sagittal profile · Coupled motion · Thoracic kyphosis

Introduction

Bracing is considered the standard treatment for skeletally immature patients with adolescent idiopathic scoliosis (AIS) and curves ≥ 20° [1]. Full- and part-time braces are both viable treatment options in terms of coronal correction and to some extent derotation [2]. In AIS, a relative sagittal hypokyphosis is often present that is not addressed in the design of the brace [3]. The effect of bracing on the hypokyphosis is not well described, but a few recent studies have suggested that full-time bracing (Boston, Cheneau, Milwaukee, Lyonnais braces) can lead to flat back deformity [4, 5]. In 2016, Cheung et al. conducted a retrospective cohort study on 265 AIS patients demonstrating the hypokyphotic effect of the full-time brace [4]. A linked mechanism between the coronal, axial and sagittal deformities is well described [6–8]. Luk et al. observed a natural coupling between coronal correction and kyphosis restoration on fulcrum bending radiographs [9]. An association between abnormal pre-brace sagittal spinopelvic parameters and coronal curve progression has been found but no studies have previously assessed the sagittal profile following night-time brace treatment [10]. The sagittal profile has shown significant clinical importance in the adult population and kyphosis restoration, after surgical treatment of AIS, has gained increased attention in recent years [11].

✉ Martin Heegaard
martin.heegaard@regionh.dk

1 Spine Unit, Department of Orthopedic Surgery, Rigshospitalet, Copenhagen University Hospital, Inge Lehmanns Vej 6, 2100 Copenhagen, Denmark

The aim of the study was to assess the sagittal profile along with the coupling between coronal correction and sagittal restoration after Providence night-time bracing.

Materials and methods

Subjects and radiographs

This retrospective cohort study was approved by The National Health and Medical Authority and The National Data Protection Agency (May 20, 2020 #31–1521-327; Oct 21, 2021 #P-2021–779). "All AIS patients treated with a night-time brace from January 1, 2005—December 31, 2018 at a single center were identified. Indications for bracing were:

1. Main curve between 25–45°
2. Risser stage < 3 or Risser stage 3–4 with signs of progression.
3. Sanders stage < 5 or Sanders stage 5–6 with signs of progression.
4. < two years post-menarche

Patients with noncompliance or missing sagittal radiographs were hereafter excluded (Fig. 1). Patient demographics were obtained using electronic medical records. We gathered the following standing anteroposterior radiographic parameters: Risser stage, Cobb angle and Lenke curve type. We assessed sagittal parameters and Abelin-Genevois curve type on standing whole spine X-rays before and after brace treatment. Absolute change in maximum thoracic kyphosis (TK) post bracing was defined as ≥ 6° and were stratified in groups of increased, unchanged or decreased. All radiographic images were taken after one night out-of-brace and analyzed using the validated software system KEOPS (SMAIO, France) [12]. Patients wore the night-time brace until either skeletal maturity or surgery and had a minimum of one-year follow-up post-brace. Skeletal maturity was defined as either two-year post-menarche, less than 1 cm height change at in-hospital visits with more than six months apart or closed ulnar epiphyseal plate on wrist radiographs (Sanders stage 7).

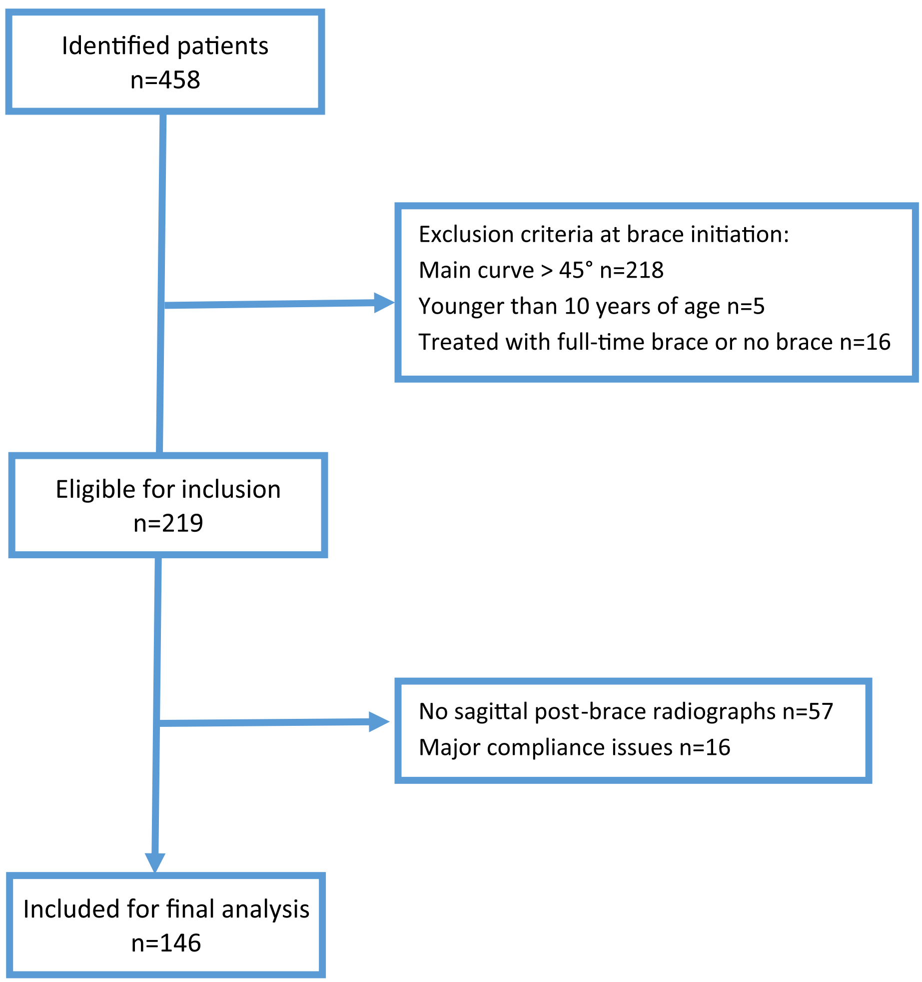

Fig. 1 Flowchart of patient selection

The Abelin-Genevois sagittal AIS types

Patients were grouped into four sagittal AIS spine types according to Abelin-Genevois et al. [13]. The four spine types were categorized as: Type 1 – normal kyphosis (T10/L2 > −10° and T4/T12 ≥ 20°); Type 2A – hypokyphosis (T10/L2 −10° to 10° and T4/T12 < 20°); Type 2B – hypokyphosis (T10/L2 > 10° and T4/T12 < 20°); Type 3 – cervicothoracic kyphosis and long thoracolumbar lordosis (T10/L2 ≤ −10°). The current study categorized Abelin-Genevois spine types into two groups of either normal kyphosis (Type 1) or hypokyphosis (Type 2A + 2B). Proportions of spine type 3 was not assessed.

The Providence night-time brace

All patients were treated with the Providence night-time brace, which is classified as a rigid brace with its primary action focused on bending [14]. The primary corrective plane is frontal, and the brace is constructed as a monocot with ventral closure [14]. Described by Amato et al. the Providence night-time brace applies direct correction, as controlled, lateral, and rotational forces are applied to the trunk to move the spine toward the midline [15]. Rotational correction is assessed in two different ways depending on curve location. For lumbar curves, a wedged pressure pad between the iliac crest and lowest rib creates a posterolateral pressure. For thoracic curves, a computerized model exclusively rotates the thoracic part of the brace.

Statistical analysis

All statistical analysis were assessed using R, Version 4.2.2 (R Development Core Team, Vienna, Austria, 2020). Data are reported as either means (± SD), medians [IQR], counts (%), coefficient [95% CI] or relative risk (RR). Normal distribution was assessed using histograms and Q-Q-plots. Paired *t*-test were used to compare normal distributed mean differences in radiographic parameters. We used Wilcoxon rank-sum test for non-normally distributed data. Pearson's X^2 were used to compare binary categorical data. Linear model analysis was used to compare association between radiographic parameters.

Results

One hundred forty-six patients were included for final analysis (Fig. 1 and Table 1). Overall, TK increased by a mean of 2.5° ($p = 0.003$) (Fig. 2) during bracing and the sagittal vertical axis (SVA) decreased 8.5 mm ($p = 0.025$) (Table 2). In our cohort, 38% of patients increased in TK, 42% remained unchanged and 20% decreased (absolute change ≥ 6°). We found a 3.5-fold (38% vs. 11%) increase in RR in patients with TK increase compared with the full-time brace cohort (Fig. 3). In the unchanged and decreased TK group, the full-time brace cohort exhibited a higher proportion, corresponding to a 1.1-fold (47% vs. 42%) and 2.1-fold (42% vs. 20%) RR, respectively (Fig. 3). There were no other significant differences in sagittal parameters at follow-up (Table 2). We found no significant differences in distribution of Abelin-Genevois spine types ($p = 1.000$) although we found hypokyphosis (Type 2A + B) in 27% vs 19% before and after bracing ($p = 0.134$).

Table 1 Patient demographics on entire cohort ($n = 146$)

Age (years)	13.4 (1.6)
Brace treatment (months)	25 [17–36]
Female	127 (87%)
Premenarchal status, $n = 114$	48 (33%)
Pre-brace Cobb angle (°)	37 [31–42]
Post-brace Cobb angle (°)	49 [40–57]
Progression > 45° at skeletal maturity	83 (57%)
Fusion surgery performed at skeletal maturity	65 (45%)
Lenke curve type	
1	80 (55%)
2	11 (8%)
3	9 (6%)
4	2 (1%)
5	36 (25%)
6	8 (5%)

Data are means (± SD), medians [IQR] or counts (%)

Stratified by coronal curve correction, we found no significant differences in sagittal parameters pre- or post-brace (Table 3). In the linear regression model there was no association between Cobb angle change and TK, SVA, sacral slope or pelvic incidence (PI) (Fig. 4 and Table 4). Maximum lumbar lordosis (LL) increased 0.21° [95%CI 0.01; 0.42] with every degree of Cobb angle progression (Table 4). We found no association between magnitude of coronal curve progression and change in TK.

Discussion

The current study aimed to describe the sagittal profile after night-time brace treatment in AIS patients. We observed a slight mean increase in TK, along with a 3.5-fold RR in patients increasing TK, ultimately lowering the risk of flat back development compared to full-time bracing [4]. We found a decrease in the number of patients with hypokyphosis post bracing. Patients had decreased SVA measurements but remained within normal sagittal balance of ± 50 mm [4,

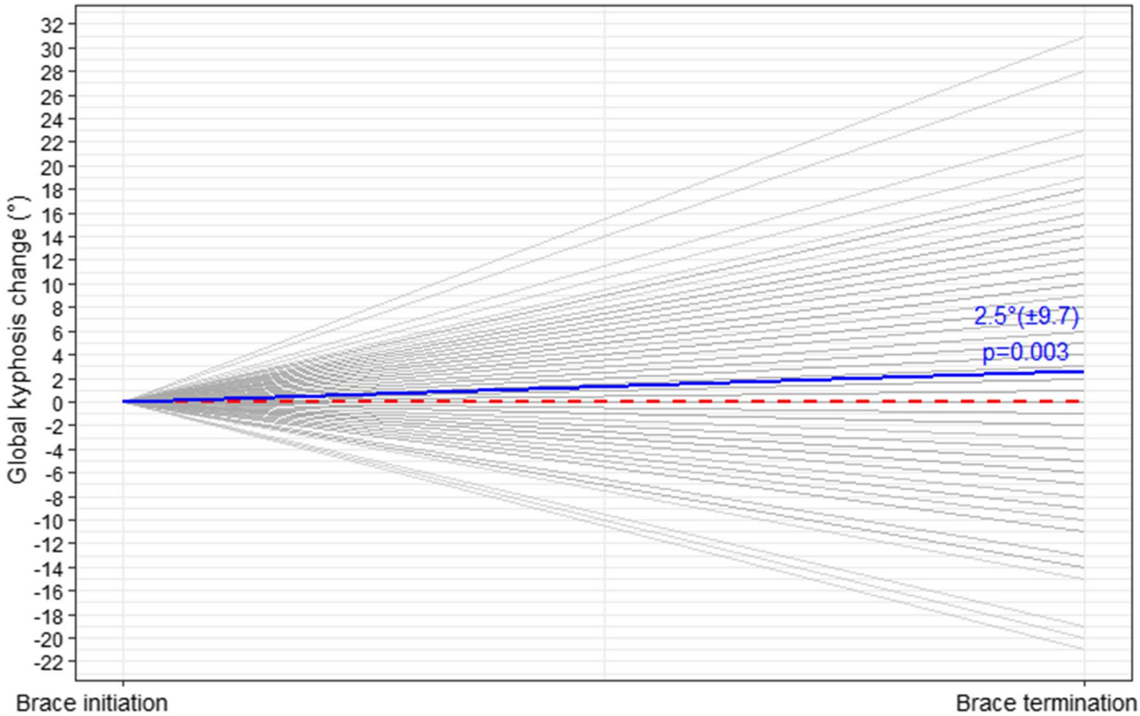

Fig. 2 Change in maximum thoracic kyphosis after night-time brace treatment. Gray-lines: Individual patients. Blue-line: Trendline. Dashed-red-line: Zero-degree change

Table 2 Radiographic sagittal parameters on entire cohort ($n = 146$)

	Pre-brace	Post-brace	*p*-value
Pelvic incidence (°)	46.3 (12.8)	46.3 (12.5)	0.757
Pelvic tilt (°)	5.4 (10.9)	6.7 (7.5)	0.131
Sacral slope (°)	41.1 (10.8)	39.5 (9.5)	0.054
Maximum lumbar lordosis (°)*	63.0 (12.4)	62.5 (11.8)	0.520
L1-S1 lordosis (°)	58.6 (14.4)	57.8 (14.4)	0.709
Maximum thoracic kyphosis (°)**	36.8 (14.3)	39.4 (15.1)	0.003
T1-T12 kyphosis (°)	30.3 (14.0)	33.1 (15.4)	0.009
T10-L2 (°)	−0.6 (9.9)	−1.8 (11.9)	0.242
SVA (mm)	−19.0 (39.7)	−28.1 (32.4)	0.025

Data are means (SD) or medians [IQR]. *SVA* sagittal vertical axis

*Calculated as the largest lordotic angle between any two vertebrae

**Calculated as the largest kyphotic angle between any two vertebrae

16]. We found no association between coronal correction and sagittal radiographic parameters.

Pre-brace sagittal profile

While AIS patients often present with a relative hypokyphosis and increased pelvic tilt (PT), this is not the case for all AIS patients [3, 17]. Our patient population exhibited radiographic sagittal parameters (TK and PT) closer to that of normal adolescents, similar to previous studies [16, 18, and19]. The sagittal profile is influenced by both coronal curve magnitude and curve apex which may explain differences between studies [3, 4, 13, 17, and20]. The distribution of Abelin-Genevois spine types in our cohort were similar to previous studies [13, 21].

Night-time versus fulltime brace treatment

Very few studies have previously assessed the sagittal profile post bracing [4, 22]. Cheung et al. recently found that full-time brace treatment leads to thoracic hypokyphosis and lumbar hypolordosis in AIS patients [4]. This study is one of the largest of its kind and was used for comparison to our results. The main finding of our study is that night-time bracing does not induce hypokyphosis as it is seen in full-time bracing. We found a marginal mean increase in TK and a substantially lower proportion of patients with a decrease in TK post night-time bracing compared with full-time bracing [4]. The two studies are comparable in terms of sex and curve type distribution, but our patients were older (Δ0.9 years) and more often post-menarchal (77% vs. 49%). Radiographically, we found a larger pre bracing TK in our cohort (Δ15), which could be explained by a higher Cobb angle (Δ18°) and a greater skeletal maturity. For this reason, we focused on changes in TK in our comparison rather than

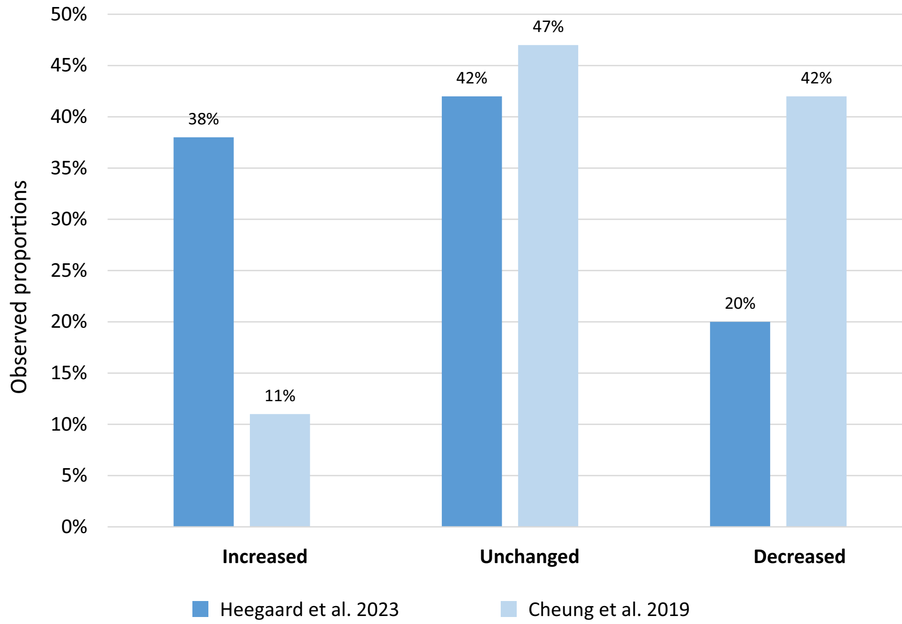

Fig. 3 Distribution of change in maximum thoracic kyphosis after night-time bracing (146 AIS patients) compared with Cheung et al.'s full-time brace cohort (265 AIS patients), stratified by ≥ 6° absolute change into increased, unchanged and decreased groups

Table 3 Sagittal parameters stratified by Cobb angle curve progression > 5° and no progression

	Pre-brace			**Post-brace**		
	No progression (*n* = 54)	Progression (*n* = 92)	*p*-value	No progression (*n* = 54)	Progression (*n* = 92)	*p*-value
Pelvic incidence (°)	46.2 (12.6)	46.4 (13.1)	0.923	46.1 (12.5)	46.4 (12.6)	0.892
Pelvic tilt (°)	5.9 (9)	5.1 (12)	0.644	7.5 (5.8)	6.3 (8.4)	0.320
Sacral slope (°)	40.8 (10.3)	41.2 (11.2)	0.821	38.7 (9.7)	40 (9.4)	0.434
Maximum lumbar lordosis (°)*	63.5 (12.9)	62.7 (12.1)	0.749	61.4 (12.5)	63.1 (11.4)	0.404
L1-S1 lordosis (°)	57.8 (14.3)	59.1 (14.6)	0.614	57 (14)	58.3 (14.7)	0.585
Maximum thoracic kyphosis (°)**	37.5 (12.5)	36.4 (15.4)	0.623	39 (14.6)	39.7 (15.4)	0.788
T1-T12 kyphosis (°)	30.7 (13.4)	30.1 (14.5)	0.817	32.7 (14.6)	33.3 (15.9)	0.804
T10-L2 (°)	−1.7 (10.2)	0.1 (9.8)	0.317	−2 (10.6)	−1.7 (12.7)	0.905
SVA (mm)	−27.1 (38.8)	−13.3 (39.6)	0.052	−28.1 (33.5)	−28.1 (31.9)	0.997

Data are means (SD) or medians [IQR]. *SVA* sagittal vertical axis

*Calculated as the largest lordotic angle between any two vertebrae

**Calculated as the largest kyphotic angle between any two vertebrae

absolute post bracing values. Cil et al. and Mac-Thiong et al. found TK to increase with age in pediatric asymptomatic subjects suggesting natural evolution of sagittal alignment during childhood [18, 23]. Cil et al. found a TK decrease in age group 10–12 years explained by anterior vertebral growth exceeding posterior growth leading to a decrease in TK [23]. These findings imply that at least two factors significantly contribute to the variation in TK observed between night-time and full-time brace treatments. Firstly, the later brace initiation allows for a more natural kyphosis evolution, hence less hypokyphotic patients. We do not ascribe the later initiation to be solely responsible for the differences in TK between the two treatment modalities. Hence, the second significant factor we consider is the variation in brace designs and treatment intensity. We propose that the utilization of a night-time brace, as opposed to a full-time brace, entails a gentler treatment approach, potentially reducing the likelihood of patients developing flat back deformity.

Coupled motion

The strong association between coronal- and sagittal parameters have been suggested in previous studies [10, 17]. In particular, abnormal sagittal parameters were associated

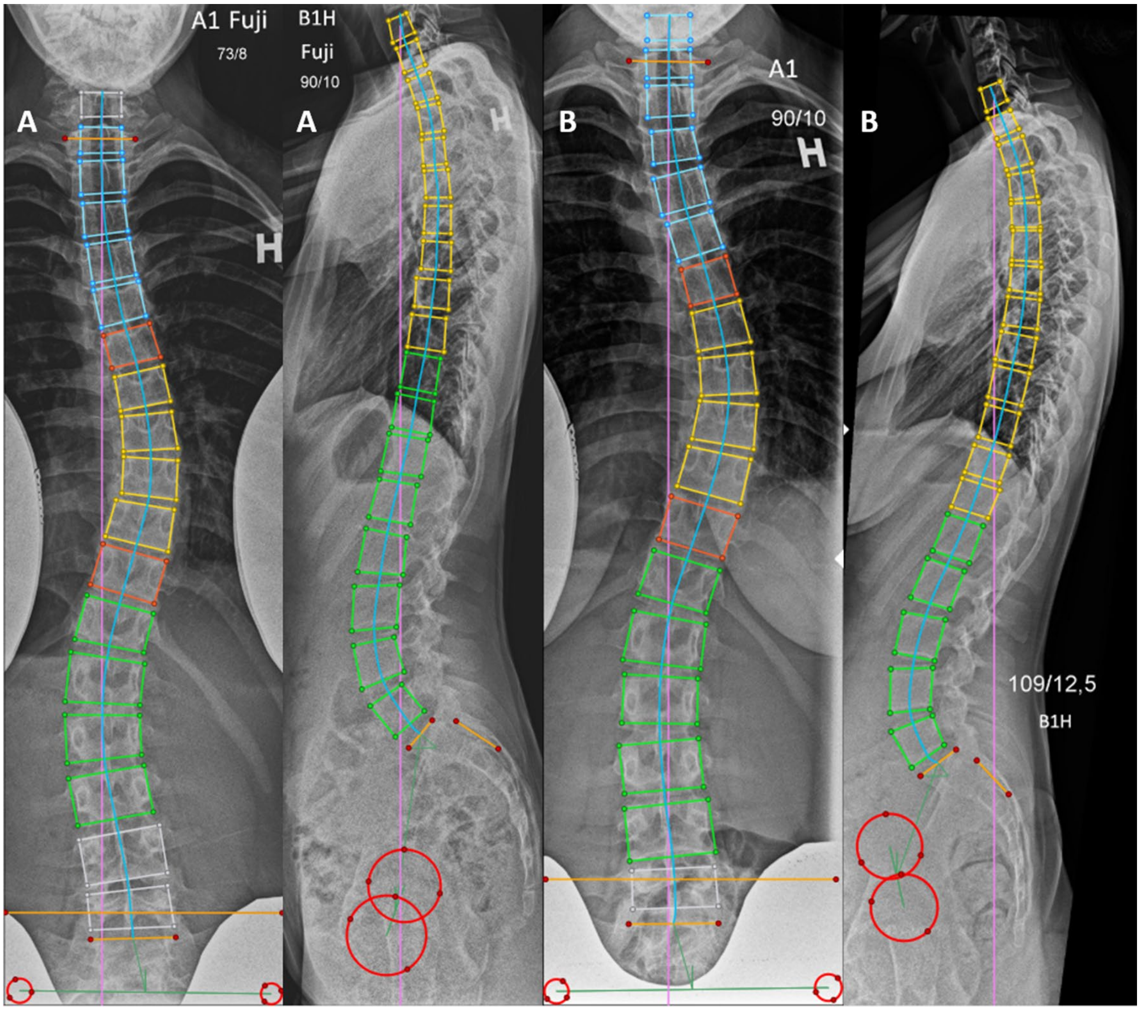

Fig. 4 A 13-year old girl suffering from adolescent idiopathic scoliosis with a coronal curve and thoracic kyphosis of 32° (**a**). Night-time bracing was initiated and at two-year follow-up, skeletal maturity was achieved with unchanged coronal curve (33°), but thoracic kyphosis had increased slightly to 39° (**b**)

Table 4 Linear regression analysis of Cobb angle change and change in sagittal parameters

	Univariable coefficient [95% CI]	*p*-value	Multivariable coefficient [95% CI]	*p*-value
Maximum lumbar lordosis (°)*	0.21 [0.01; 0.42]	0.045	0.11 [−0.27; 0.49]	0.558
Maximum thoracic kyphosis (°)**	0.10 [−0.06; 0.25]	0.217	0.20 [−0.06; 0.46]	0.131
SVA (mm)	−0.03 [−0.09; 0.02]	0.232	−0.04 [−0.11; 0.04]	0.333
Pelvic tilt (°)	−0.08 [−0.33; 0.16]	0.496	0.06 [−0.39; 0.51]	0.802
Sacral slope (°)	0.14 [−0.09; 0.37]	0.232	0.15 [−0.41; 0.71]	0.601

CI confidence interval

*Calculated as the largest lordotic angle between any two vertebrae

**Calculated as the largest kyphotic angle between any two vertebrae

with coronal curve progression. These findings support the idea of coupled motion. In the current study, we did not find an association between coronal curve correction and increased kyphosis. Mak et al. found similar hypokyphotic curves in nonbraced patients regardless of coronal curve magnitude, curve location and PI [3]. In full-time braced AIS patients, Cheung et al. found no association between TK change and coronal Cobb angle change [4]. Matsumoto found that AIS patients with pre-brace LL below 40° had three times increased risk of curve progression [10]. We found LL to increase with Cobb angle progression likely due to the small increase in TK post-brace.

Our findings question the correlation between coronal deformity and sagittal parameters. We do acknowledge that some abnormal pre-brace sagittal measurements might correlate with coronal curve progression. This is important to keep in mind when initiating brace treatment.

Strengths and limitations

There are some limitations to the current study. There are no school screening programs in Denmark and patients are typically referred in cases of more advanced scoliosis. Patients therefore tend to have bigger curves and be more skeletally mature [24]. As this was not a study on bracing efficacy on coronal curve progression, we chose to include patients outside the SRS and SOSORT guidelines to reflect daily clinical practice [1, 25]. We included patients with curves ≤ 45° with an estimated growth potential based upon Risser stage, hand x-rays, or menarchal status. This might influence the sagittal profile towards fewer hypokyphotic patients, since our patients follow the natural history of AIS for a longer period before brace initiation. The main limitation of the current study is the lack of a control group consisting of observational AIS patients. The group of noncompliant patients was considered as a control group, but the small sample size (16 patients) and the heterogeneity of the treatment duration negated this. It remains unclear whether the observed changes in the sagittal profile are attributed to the brace or the natural progression in AIS patients. Nonetheless, our findings do indicate potential disparities between full-time and night-time braces. In our study, AIS patients were included over a period of 14 years (January 1, 2005 through December 31, 2018). Possible changes in diagnostics, awareness in society and brace initiation/termination should be considered. We ascribe this to be a minor cofactor due to maintained principles of diagnostics and treatment of our AIS patients. The night-time brace did not undergo any design alterations. One-fourth of patients were excluded, due to missing sagittal radiographs increasing the risk of selection bias.

Overall, we find our results of significance to both clinicians and patients. This is one of the largest night-time brace studies to date and the first to assess the sagittal profile following night-time bracing. In light of our discoveries, we argue that selecting a night-time brace, in contrast to a full-time brace, facilitates a more natural progression of kyphosis, consequently reducing the probability of AIS patients developing flat back deformities. To further investigate, we suggest looking into changes of the sagittal profile amongst different brace types in AIS patients. Preferably with matched cohorts on parameters such as: age, menarchal status, Cobb angle.

Conclusion

Night-time bracing of AIS did not lead to hypokyphosis. We observed a slight increase in TK, with a substantially lower risk of developing flat back deformity compared to full-time bracing. We hypothesize that the night-time brace allows for a natural kyphosis evolution, which is not coupled to the coronal corrective effect of the brace. Whether night-time bracing provides better restoration/maintenance of sagittal parameters compared to full-time bracing could be a focus for future studies.

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Author contribution MH: Substantial contributions to the conception or design of the work, Substantial contributions to the acquisition, analysis and interpretation of data, Revising the work critically for important intellectual content, Final approval of the version to be published; NT, BD, TBA, MG: Substantial contributions to the conception or design of the work, Revising the work critically for important intellectual content, Final approval of the version to be published; SO-N: Substantial contributions to the conception or design of the work, Substantial contributions to the analysis and interpretation of data, Revising the work critically for important intellectual content, Final approval of the version to be published.

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Availability of data and material The datasets generated during and/or analyzed during the current study are not publicly available due to national data protection law.

Code availability Code can be made available upon reasonable request.

Declarations

Conflict of interest MG: Stryker (consultancy), institutional grants from Cerapedics, institutional grants from NuVasive; BD: Stryker (consultancy), supported by The Alfred Benzon Foundation; the remaining authors report no conflicts of interest.

Ethical approval This study was approved by the National Health and Medical authority and The National Data Protection Agency.

Informed consent This study includes no experimental investigation.

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