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The Effect of Brace Treatment on Large Curves of 40° to 55° in Adolescents With Idiopathic Scoliosis Who Have Avoided Surgery: A Retrospective Cohort Study

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Objective: To evaluate the effect of Milwaukee brace treatment on adolescents with idiopathic scoliosis (AIS) with large curves (40° to 55°) who refuse to do surgery.
Methods: In this retrospective cohort study, we gathered the clinical records of all adolescents with AIS with an initial curve of 40° to 55°. They had been referred to our center from December 1990 to January 2017. Although they had been advised to do surgery, they had all refused to do it. Their clinical data were recorded, such as sex, age, Risser sign, scoliosis, and kyphosis curve magnitude (at the beginning of brace treatment, weaning time, brace discontinuation, and minimum of 2 years after the treatment). Based on treatment success, the patients were divided into 2 groups: progressed and nonprogressed.
Results: Sixty patients with an average initial Cobb angle of 44.93° ± 4.86° were included. The curve progressed in 57%, stabilized in 25%, and improved in 18% of the patients. In the progressed group (34 patients), 31 patients had undergone surgery. There was no significant association between the age of beginning the brace treatment and the final Cobb angle of nonprogressed group ($p > 0.05$). However, in-brace correction and initial Risser sign had a significant correlation with curve magnitude at the final follow-up ($p < 0.05$).
Conclusion: Brace treatment seems to be effective in controlling the further curve progression in AIS with 40° and 55° curves. Our results can help physicians make sound decisions about the patients with larger curves who refuse to do surgery.

Keywords: Adolescent idiopathic scoliosis, Spine, Brace, Surgery, Outcome

INTRODUCTION

Adolescent idiopathic scoliosis (AIS) is the most prevalent type of spinal deformity. It is the frontal plane displacement of the spine more than 10° plus vertebral rotations. Its incidence is 0.47% to 5.2% among people aged 10 to 16 years old.[1]

Bracing is the most effective nonsurgical treatment for AIS.[2,3] Based on the Scoliosis Research Society (SRS) Committee and the International Scientific Society on Scoliosis Orthopedic and Rehabilitation Treatment (SOSORT), if the scoliosis curvature is 25° to 40° at the beginning of wearing a brace, the treatment result can be optimal.[4,5] For patients with more than 40° curves, brace's effectiveness decreases and surgery is often recommended.[6-8] However, despite the recommendation for doing surgery, some patients strongly refuse to do it and prefer to wear a brace.

The effectiveness of brace treatment on AIS cases with > 40°

curves is still in argue. Nevertheless, some reports in the literature show that brace treatment can have 35% to 91% effectiveness.[9-14] A reason for this vast difference is the heterogeneity of the inclusion criteria and brace type. Therefore, this study investigated the effectiveness of brace treatment on AIS with 40° to 55° curves who had refused to do surgery. Assessment of potential risk factors which can be associated with brace treatment failure such as prebrace Cobb angle,[15] curve type,[16] Risser sign,[17] and in-brace curve improvement[8] had been the secondary objectives of our study. We hypothesized that these parameters have a role in-brace treatment effectiveness in AIS with 40° to 55° curves.

MATERIALS AND METHODS

The ethics committee of Iran University of Medical Sciences approved this study (No. 1397.751). We gathered the clinical records of all AIS with an initial curve of 40° to 55° who had been referred to our center from December 1990 to January 2017. During the initial review, we found 117 cases that had more than 40° initial curve magnitude (Fig. 1). They had all been advised to undergo surgery at the first visit, but they had refused to do so. Thus, they had been recommended to do brace treatment.

Among them, 57 were excluded as they had not continued the treatment until the end of skeletal maturity. Therefore, 60 patients met the inclusion criteria of the study. The inclusion criteria were having: (1) AIS with at least one curve ≥40°, (2) Risser sign 0–2 at the beginning of brace treatment, (3) no history of treatment or surgery, and (4) being older than 10 years old.[4]

All patients received a Milwaukee brace (Fig. 2). The Milwaukee brace is a cervicothoracic-lumbosacral orthosis that has a custom-made pelvic section (to delordosing the lumbar spine) and a superstructure that attaches to the pelvic section. The superstructure has an anterior and 2 posterior uprights, and a neck ring. It provides an end-point control system to increase load-carrying capacity of the spinal column and, more importantly, a location for the attachment of the spinal pads to be positioned over the most displaced ribs on the convex side of the curvature. The brace pads had been maintained at the most tolerable pressure during treatment.

In this study, the Milwaukee brace had been customized for each patient. The treating physician had confirmed its standards. The patients had been asked to wear their braces full-time (23 hours a day). They had been asked to carry out the Moe and Blount protocol exercise[18] for 2 hours per day (i.e., 1 hour while wearing the brace and 1 hour while not wearing it). These exercises aim to keep the strength of the trunk muscles and maintain the patient in the right posture. They include pelvic tilt and active trunk shifts away from the thoracic pad of the brace. Then, we ask the patient to do a deep inhalation and chest expansion and reach back next to the posterior bars of the brace. The patients were asked to do pelvic tilt in the supine position with the knees in flexion and extension, during sit-up motion,

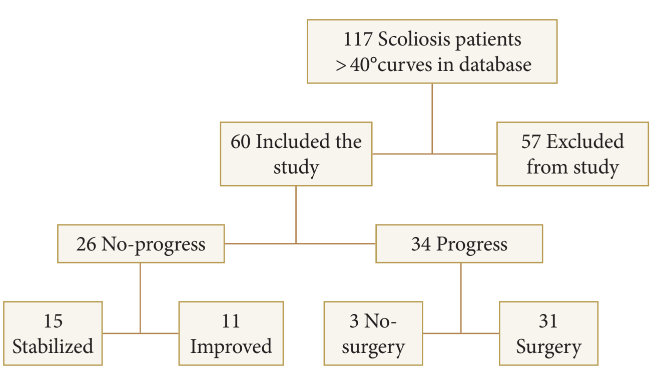

Fig. 1. Flowchart of the study's selection process.

Fig. 2. The Milwaukee brace.

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push-ups, and standing position. The details of the exercises had been given in a brochure to each patient.

The clinical data of the patients were recorded, including sex, age, Risser sign, scoliosis, and kyphosis curve magnitude (at the beginning of brace treatment, weaning time, brace discontinuance, and a minimum of 2 years after cessation of brace treatment). The brace compliance was evaluated subjectively and via questioning the patients and based on their braces' appearance.

Weaning from the brace had been initiated after growth cessation and reaching the Risser stage 4 (for girls) or 5 (for boys). At the end of skeletal maturity, the curve stability had been assessed by a radiographic image that was obtained 4 hours after removing the brace. If the curve magnitude had increased to less than 5°, the patient could not wear the brace 4 hours a day. After 4 months, the next radiographic image had been obtained 8 hours after removing the brace. If the curve was stable, the patient had been allowed not to wear the brace for 8 hours a day. This process was reiterated with taking the next radiographic image 12 hours after removing the brace. Again, if the curve was further stable, the patient had been allowed to wear the brace only at night for 6 to 12 months. Afterward, the patient did not wear the brace at all (Fig. 3).

In each visit, the clinical and radiological information of the patients were recorded. An experienced spinal surgeon (MSG) had measured and recorded all the radiographic parameters. Successfully treated patients were followed up for a minimum of 2 years after cessation of brace treatment. We used the modified Lenke (mLenke) categorization method to classify the curve pattern. Sanders et al.[19] first introduced the mLenke classification system in 2007 for the nonsurgical curves. However, they had not clearly expressed the rigidity of the secondary curves. Therefore, Thompson et al.[20] considered a secondary curve as a

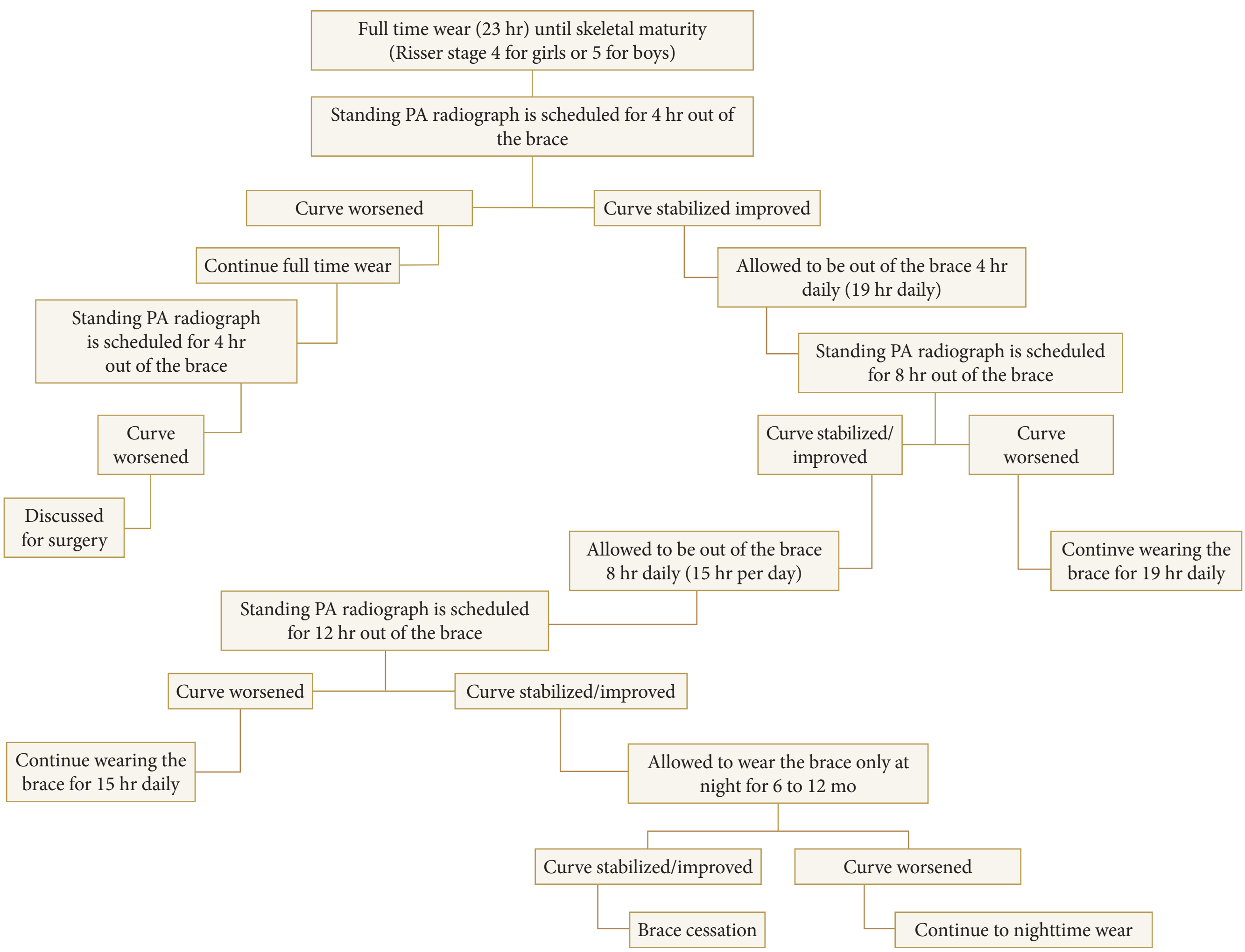

Fig. 3. Flowchart of the bracing course. PA, posteroanterior.

major curve when its size reached ≥80% of the major curve. According to them "using the simple mLenke categorizations, we can evaluate the relationship between curve morphology (main thoracic curve vs. main lumbar curve) and brace success in AIS."

According to the SRS committee,[4] progression is ≥6° increase in the curve magnitude. Stabilization refers to a change in curve by ±5°; and nonprogression is ≥6° reduction in the curve. We divided the patients into 2 groups based on treatment success: progressed and nonprogressed groups.

We used the SPSS ver. 17.0 (SPSS Inc., Chicago, IL, USA) to do the statistical analyses. The Kolmogorov-Smirnov test was used to evaluate the data normality. We used the independent sample t-test to compare the patient's characteristics regarding prebrace Cobb angle, Risser sign, age at initiation of brace treatment and menarche, Cobb angle at cessation of brace treatment, and in-brace curve correction between the progression and nonprogression groups. We used the Spearman correlation coefficient to assess the relationship between the prebrace Cobb angle, age, Risser sign, and in-brace curve correction with outcome of brace treatment in successfully treated patients. Chi-square test was used for categorical variables such as curve pattern and curve magnitude. We used the Friedman test to assess the changes in curve magnitude during the brace treatment process. The significance level was considered 0.05 for all tests.

RESULTS

Sixty AIS (7 boys and 53 girls) with 40° to 55° curves were included in this study. The means of age and scoliosis Cobb angle at the beginning of brace treatment were 12.63±1.44 years old, and 44.93°±4.86°, respectively. The average of Risser sign was 1.73±0.57. The average of brace-wearing time was 37.23±20.70 months (16 to 84 months). The average of age at menarche was 12.32±0.84 years old. All the studied patients had had full compliance. The average follow-up duration for the patients successfully treated with brace was 27.92±10.03 months (24 to 60 months). Based on the treatment results, we divided the patients into 2 groups: nonprogressed (n=26) and progressed (n=34) groups. If the final Cobb angle had decreased (n=11) or stabilized (n=15), the patients were categorized in the nonprogressed group. However, if the curve magnitude had increased (n=34), they were placed in the progressed group.

Generally, the scoliosis curve had increased in 57% of patients, stabilized in 25%, and improved in 18% of the patients. There was a significant difference between the 2 groups in terms of the curve magnitude at the initiation of brace treatment (Table 1) ($p<0.001$). The mean of age at the beginning of brace treatment was significantly higher in the nonprogressed group compared to the progressed group ($p<0.05$). In the nonprogressed group, the average duration of wearing the brace was 37.23±20.70 months (16 to 84 months) and the average follow-up period was 27.92±10.03 months (24 to 60 months). At the beginning of brace treatment, there were 8 cases with >50° curve magnitude. The other 52 cases had a major Cobb angle of 40° to 50°. At the final follow-up session, there were 21 patients with a major Cobb angle of ≤40°, 15 patients with a Cobb angle of 40° to 50°, and 24 patients with a Cobb angle of >50°. Among them, 31 patients had undergone surgery before skeletal maturity. The mean age at the time of surgery was 14.16±1.26 years old (12 to 17 years old). The average Cobb angle at the time of spinal fusion was 54.45°±6.78° (40° to 69°).

Fig. 4 summarizes the average of Cobb angle in different phases of brace treatment (at the beginning of brace treatment, weaning time, brace discontinuation, and final follow-up). There were significant differences in Cobb angle values across these phases

Table 1. The patient's characteristics

Variable	All patients (n=60)	Nonprogression (n=26)	Progression (n=34)	p-value
Age at initiation of bracing (yr)	12.63±1.44	13.4±1.34	12.32±1.47	0.04
Age at menarche (yr) (n=53)	12.32±0.84	12.45±0.85	12.22±0.84	0.33
Brace wearing time (mo)	37.23±20.70	55.62±13.74	23.18±12.37	<0.001
Initial Risser sign	1.73±0.57	1.69±0.61	1.76±0.55	0.60
Scoliosis Cobb angle at initiation of bracing (°)	44.93±4.84	42.94±3.69	46.47±5.13	<0.001
Kyphosis Cobb angle at initiation of bracing (°)	46.30±10.94	42.17±9.79	49.06±11.04	0.09
Scoliosis Cobb angle at cessation of bracing (°)	47.29±10.58	38.15±6.89	54.48±6.68	<0.001
In-brace curve correction (%)	15.73±13.78	24.79±16.40	8.80±4.64	<0.001

Values are presented as mean±standard deviation.

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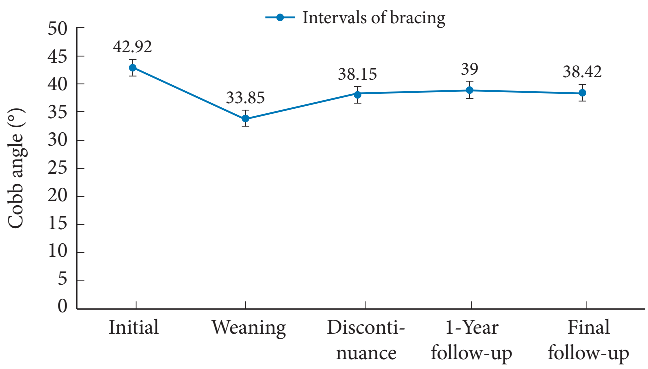

Fig. 4. The average of Cobb angle at different intervals of brace treatment in the nonprogressed group.

Table 2. The relationship between the age, Cobb angle, in-brace correction, and Risser sign at initiation of brace treatment with Cobb angle at final follow-up in successfully treated patients (n = 26)

Variable	Cobb angle at final follow-up		
	r	95% CI	p-value
Age at initiation of brace treatment	-0.28	-046 to 0.24	0.15
Cobb angle at initiation of brace treatment	0.30	-0.13 to 0.66	0.12
In-brace correction	-0.40	-0.71 to 0.07	0.04
Initial Risser sign	-0.41	-0.74 to 0.00	0.03

CI, confidence interval.

($p < 0.05$). There was no significant association between the age of beginning to use the brace and the final Cobb angle of nonprogressed group (Table 2). However, in-brace curve correction and initial Risser sign had a significant correlation with curve magnitude at the final follow-up ($p < 0.05$). The progression rate was higher in mLenke thoracic curves compared to mLenke lumbar curves (Table 3).

There were 34 cases (56.6%) with main thoracic curve, 15 (25%) with main thoracolumbar curve, and 11 (18.3%) with main lumbar curve. For the cases with double curves, the largest curve was considered for statistical analysis. The least curve progression was in those with 40° to 45° curves and the most in those with 51° to 55° curves.

DISCUSSION

Natural history studies on adolescents with idiopathic scoliosis suggest that the progression rate is high in severe curves (≥ 40°).[4] Therefore, the physicians' advice for such cases is surgery. However, some patients completely refuse to do surgery

Table 3. The effect of initial curve pattern and curve severity on the outcome of brace treatment

Variable	Nonprogression	Progression	p-value
Curve pattern			
mLenke thoracic	14/34 (41)	20/34 (59)	0.30
mLenke lumbar	12/26 (46)	14/26 (54)	0.69
Curve severity			
40°–45°	23/40 (57.5)	17/40 (42.5)	0.34
46°–50°	2/12 (17)	10/12 (83)	0.02
50°–55°	1/8 (12.5)	7/8 (87.5)	0.03

Values are presented as number (%).
mLenke, modified Lenke.

and insist on using a brace. Our main finding is that the Milwaukee brace has 43% overall success rate for AIS cases with 40° to 55° Cobb angles. However, the subgroup analysis based on the curve severity reveals that the success rate is higher (57%) for 40° to 45° curves. This is consistent with the findings of Verhofste et al.[14] On the other hand, for patients with > 46° curve magnitude, the success rate of bracing is 15%.

Some high-quality studies, including a systematic review and a multicenter randomized clinical trial, have reported convincing evidence about the effectiveness of brace treatment for managing AIS curves < 40°.[2,21,22] Weinstein et al.[2] studied 242 AIS patients with 20° to 40° Cobb angles. They found out that the curve progression rate was only 7% to 10% if the patients wore their braces for a minimum of 12.9 hours per day. The success rate of brace treatment for AIS cases with curve magnitude of 20° to 40° has been 64% to 77% in 3.5 to 8 years follow-up periods.[23,24]

The Milwaukee brace is the first approved orthosis in halting the further progression of AIS curves worldwide. The largest case series study on its effectiveness on AIS was conducted by Lonstein and Winter[23] that involved 1,020 cases with 20° and 39° Cobb angle. They observed that this brace has 22% failure rate in treating AIS. However, its effect has not been thoroughly studied for patients with more severe curves (≥ 40°). This study evaluated the appropriateness of the Milwaukee brace for patients with ≥ 40° curves and its use in clinical decision-making.

The first report on brace effectiveness on AIS with ≥ 45° curves was published by Negrini et al.[11] In their study, curve progression up to > 50° occurred in only 2 patients. These findings provide valuable information about brace effectiveness for patients who avoid surgery. In this study, there were 16 patients with a low-risk of curve progression (Risser sign of 3 or 4) and 12 patients with a high-risk of curve progression (Risser 0–2). More-over, only 14 patients cooperated until the final follow-up of 2 years after cessation of brace treatment. Lusini et al.[10] studied 57 AIS patients with > 45° curve and Risser sign 0–4 who received Sforzesco brace treatment. Their results revealed that brace treatment has 23.5% failure rate. However, the number of patients who had undergone surgery before skeletal maturity was not reported. Furthermore, in 2 other studies, the success rate of bracing has been > 90%.[9,12] The progression rate in our study was significantly higher than these studies.

In our study, all cases had a Risser grade of 0–2 at the beginning of bracing. They were followed up until the end of the skeletal maturity or spinal fusion. We found out that all patients were very motivated to use the braces because of their fear of surgery. We did the radiographic evaluations and brace checkups every 4 to 6 months. Nonetheless, the curve magnitude increased by more than 6° in 57% of the patients. In this study, there were 7 cases of < 50° major Cobb angle at the time of spinal fusion. A key factor on brace effectiveness in AIS is the flexibility across the scoliosis curves, where sufficient flexibility affords a satisfactory in-brace curve correction.[25] For these cases, flexibility across the scoliosis curves was insufficient and the degrees of in-brace curve corrections were minimal (with a mean of 9.29%, ranging between 6% and 12%). Therefore, they underwent spinal fusion.

Recently, Zhu et al.[13] reported the data of 54 AIS patients with 40° to 50° curves who were treated with a Boston bracing system or a Milwaukee brace. Our results are consistent with the findings of Zhu et al. in terms of the number of cases who had undergone spinal fusion before puberty. They had 35% success rate for bracing. In our case series, we found out that in the nonprogressed group, the curve magnitude had significantly reduced at all stages of brace treatment compared to the prebrace measures. The greatest in-brace curve correction occurred at the weaning phase of treatment (25%). At the final follow-up, 12% of the curve magnitude had increased by more than 5°.

The patient's age at the beginning of brace treatment, Cobb angle, curve location, Risser stage, and in-brace correction are important factors for predicting treatment effectiveness in AIS.[26-28] In our study, although the mean of age was noticeably different between the progressed and nonprogressed groups at the beginning of brace treatment, there was no significant relationship between the prebrace age and brace effectiveness. This is consistent with the findings of Zhu et al.[13]

We found out that the prebrace Cobb angle in the nonprogressed group was significantly lower than the progressed group. Furthermore, there was a significant relationship between the in-brace curve correction and initial Risser sign, and treatment effectiveness. These results suggested that prebrace curve magnitude, initial Risser sign and in-brace curve correction are prognostic factors for the effectiveness of brace treatment in AIS.[26,29] Katz and Durrani[26] observed that a threshold of 25% is required for in-brace correction to anticipate the positive long-term results of bracing on AIS cases with large curves. According to the findings of Zhang et al.,[27] the initial Risser sign is not a strong prognostic factor for brace treatment outcome in AIS unless it is considered with other parameters such as the initial curve magnitude, degrees of vertebral rotation, and the spinal height.

Thompson et al.[20] found out that curve type is significantly associated with brace treatment success. Accordingly, they saw that the curve progression rate was greater in cases with major thoracic curves than in cases with major lumbar curves. In our study, most of the cases had a major mLenke thoracic curves pattern (57%). Among them, the curves of 20 patients (59%) progressed to > 50°. However, Van den Bogaart et al.[30] found no significant relationship between curve patterns and treatment effectiveness.

Firstly, we had no control group (untreated cases). So, we cannot compare our outcomes with the natural history of the AIS cases with large curves (> 40°). Secondly, the number of male patients was too low to compare the outcome of brace treatment in terms of sex differences. A larger sample size is required to compare the effectiveness of brace treatment between the males and females with AIS with > 40° curves. Thirdly, the brace compliance was evaluated subjectively (reported by patients) and examining the brace's appearance. To measure the brace compliance objectively, reliable temperature or pressure data loggers are used which offer researchers more accurate information on in-brace pressure values and adherence of patients to the brace.[31,32] Due to the retrospective nature of our study, measuring the brace wear compliance objectively was not possible. However, at each follow-up during brace treatment, the treating physician had recorded the average hours of wearing the brace by evaluating the brace appearance and asking the patients and their parents.

Fourthly, it is important to consider patients' health-related quality of life as the clinical and radiological parameters to evaluate the impact of scoliosis and brace treatment.[33] We found out that all patients tolerated their braces well during the treatment periods. However, because of the retrospective nature of the study, we cannot evaluate the health-related quality of life of the studied patients. Further research is needed to evaluate the impact of brace treatment on health-related quality of life of patients with >40° scoliosis curves. Lastly, our results were limited to the available medical history in the clinical profiles. Still, the clinical examinations of all patients had been done in a uniform fashion.

CONCLUSIONS

Brace treatment seems to have a lower success rate in AIS with larger curves (40°–55°) than those with moderate curves (<40°). Still, if the patient's family refuses to do surgery, the physician can help them to make better decisions.

CONFLICT OF INTEREST

The authors have nothing to disclose.

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