The Association Between Brace Compliance and Outcome for Patients With Idiopathic Scoliosis

Tariq Rahman, PhD, J. Richard Bowen, MD,* Masakazu Takemitsu, MD,*† and Claude Scott, MD*‡*

Abstract: This was a prospective study on the association of brace compliance and curve progression in idiopathic scoliosis. Compliance was measured electronically by embedding a temperature sensor and logger in the Wilmington scoliosis brace. To date there have been no studies that relate objective measures of compliance in a scoliosis brace to treatment outcomes. Thirty-four subjects with idiopathic scoliosis were monitored over the duration of their brace wear. Compliance data were downloaded and analyzed. The compliance rate for the patients whose curve progressed (>5 degrees) was 62%; the compliance rate for the patients who did not progress was 85% (P = 0.004). In the group that had high compliance (>90%), one of the nine subjects' curves progressed (11%). In the group with low compliance (<90%), 14 of the 25 subjects' curves progressed (56%, P = 0.0075). Results indicate that the more patients comply with brace treatment, the better their chances of a favorable outcome.

Key Words: idiopathic scoliosis, brace, compliance monitor

(*J Pediatr Orthop* 2005;25:420–422)

There are numerous articles evaluating the efficacy of brace treatment. Factors such as gender, age, bone maturity, prescribed hours, and curve pattern and magnitude have been shown to affect brace usage.[1–11] These studies assumed that the reported compliance by patients was reliable. Some authors did not exclude noncompliant patients from their studies[2,6,9,12] because of the difficulty in distinguishing between compliant and noncompliant patients.

Retrospective studies, such as those by Karol[3] and Gurnham,[13] relied on clinic notes and department records to assess compliance. The authors acknowledged an incomplete assessment of compliance by this method. Noonan et al[6] considered a patient compliant if he or she returned for most of the scheduled appointments, had no mention of noncompliance, and stated in a questionnaire that the treatment guidelines had been followed. Lonstein and Winter[4] measured compliance by sending a questionnaire to patients asking about their brace wearing times. They reported that 89% of patients wore their Milwaukee brace for 20 or more hours and were considered compliant. Wiley et al[10] interviewed patients and parents at each visit to assess compliance and set 18 hours of brace wear as the compliance threshold. They reported that 48% complied with treatment using the Boston brace. DiRaimondo and Green[14] used neutral, in-person, and phone interviews to ascertain compliance retrospectively. They showed that on average patients wore their braces 65% of the time they were instructed to do so.

The lack of objective compliance data has made it difficult to assess brace efficacy in idiopathic scoliosis. This is one of the major reasons why there has been considerable debate concerning efficacy. To this end, several groups have developed objective compliance measures.[15–19] Lou et al[18] used a pressure pad on a Boston brace to measure force distribution and compliance. Results showed 76% compliance for limited tests with 16 subjects. Havey et al[15] developed a pressure sensor and tested it with normal subjects for reliability. Houghton et al[16] used a pressure switch and Lavelle et al[12] employed a timer/temperature sensor. However, there are no reports of a relation between objective compliance and brace efficacy. These studies have not related compliance to outcomes, which is what is performed in this study.

We hypothesized that patients with higher brace compliance would have a better outcome in terms of halting curve progression. The aim of this study was to prove this hypothesis using an objective electronic compliance monitor for patients with idiopathic scoliosis. The monitoring was continued up to bony maturity or to the point when surgery was required, and curve progression was measured throughout brace treatment. This is the first study to evaluate the efficacy of brace treatment prospectively using an objective measure of compliance.

MATERIALS AND METHODS

This prospective study, aimed at measuring brace compliance, was carried out between February 2000 and May 2003 with full Institutional Review Board approval. An electronic compliance monitor was fitted to each patient's Wilmington jacket during routine clinical brace treatment. Fifty-two subjects were enrolled in the study. Data are reported on 34 patients; 18 subjects did not fall into the inclusion criteria (7 had initial curves <25 degrees, 4 were juveniles, 5 did not complete the brace-wearing protocol, 1 developed ulceration due to improper brace use, and 1 had a sensor

From *Alfred I. duPont Hospital for Children, Nemours Children's Clinic, Wilmington, Delaware; †Asahikawa Medical College, Asahikawa, Japan; and ‡Downstate Medical Center, Brooklyn, New York.

Study conducted at the Alfred I. duPont Hospital for Children, Nemours Children's Clinic, Wilmington, Delaware.

None of the authors received financial support for this study.

Reprints: Tariq Rahman, PhD, Pediatric Engineering Research Lab, Alfred I. duPont Hospital for Children, P.O. Box 269, Wilmington, DE 19899, (e-mail: trahman@nemours.org).

failure). All 34 patients completed their brace treatment. The same attending doctor, who was blinded to the compliance data being gathered, treated all patients. Of the 34 subjects, 4 were male and 30 were female. Average age at beginning of brace treatment was 12 years (range 10–16 years). In 8 of the 34 patients, the initiation of the monitor and brace did not coincide; the monitor was placed on the brace at a later date. In these cases, the compliance data were extrapolated over the entire brace-wearing period. Average brace treatment duration was 23 months.

The curve magnitude was measured by Cobb angle in a whole-spine posteroanterior radiograph taken every 4 to 6 months out of the brace. Twenty-seven of the 34 patients ended their brace treatment when they reached bone maturity with Risser 4 or more; the remaining 7 patients went on to have spinal fusion surgery. Data collected after these patients were first made aware of the likelihood of surgery were not included because of the possibility of biased data.

Inclusion criteria of patients for this study were adolescent idiopathic scoliosis with curves greater than 25 degrees and less than 45 degrees of Cobb angle, immature skeleton with a Risser sign of 0 or 1 before the treatment, and treated with the Wilmington brace. Prescribed regimens for the brace-wearing schedule were 8 (nighttime) or 12 hours per day in the brace for patients with curves 30 degrees or less and 16, 20, or 23 hours per day for those with curves greater than 30 degrees. Psychosocial factors that would affect compliance were considered in six patients, and acceptable wearing hours were agreed upon by the patient, parents, and physician. Six patients with Risser sign of 2 or more were included in this study at their request.

Compliance was measured with a temperature sensor (Onset Computer Corporation, Bourne, MA) that was placed on the inside of the brace. The temperature sensor was connected to a HOBO data logger (Onset Computer Corp) that was fixed on the outside of the brace. Temperature was measured every 10 minutes and stored by the logger for a period of up to 9 months. The data were downloaded to a personal computer at every clinic visit. The raw temperature data and the corresponding time stamp were then analyzed to yield the average daily hours worn during the measurement period. A temperature threshold that determined brace-on and brace-off states was manually set. This temperature was approximately 83°F; however, it increased to 90°F during summer months. Reliability of the sensor was 97%.[20]

Compliance was measured as the ratio of time actually worn to prescribed time, expressed as a percentage.

RESULTS

Results on overall compliance and its relation to age and self-reported compliance are presented elsewhere.[20] This paper correlates curve progression to compliance during brace wear. Data were divided into two groups, a group whose curves did not progress more than 5 degrees between initial and final brace use and another group whose curves progressed more than 5 degrees. The compliance rate of the group whose curves did not progress was 85 ± 18.5%; that of the group whose curves progressed was 62% ± 24.3% (Fig. 1). The Student *t* test yielded a two-sided *P* value of 0.004. Subject age and Cobb angle before treatment were not significant co-variants.

An alternate way of analyzing the data is to divide the subjects into two groups, one with high compliance (>90%, n = 9) and the other with low compliance (<90%, n = 25). In the high compliance group, curves progressed more than 5 degrees in 1 of the 14 subjects (11%). In the less compliant group, curves progressed more than 5 degrees in 14 of the 25 subjects (56%). The two groups were significantly different as measured by the Student *t* test (two-sided *P* value of 0.008).

DISCUSSION

Results showed a statistically significant improvement in curve progression for subjects who complied with the treatment. This is in agreement with Winter et al's[11] finding that compliant patients had better results. This result suggests that brace compliance and indeed brace wearing has an effect on curve progression. From this, one could infer that the natural history is affected positively with brace wearing. Dividing the groups by relative compliance backs this inference: the patients with greater than 90% compliance were five times as likely to have a favorable outcome than those with less than 90% compliance. The threshold of 90% compliance was arbitrary; others have used dichotomous measures such as compliant/noncompliant[6] by seeing whether patients returned for most clinic visits. Lonstein and Winter[4] used a categorical scale (excellent, good, fair, and poor) to assess compliance, which was based on subjective patient feedback. Wiley et al[10] divided compliance into three groups: full-time compliant, part-time compliant, and noncompliant.

Some of the limitations of the study were that all curve patterns and prescribed times were grouped together. There were a relatively small number of patients, which did not allow grouping by level of risk, amount and level of curvature, gender, bone maturity, and prescribed regimen of hours.

Eight of the 34 children started their brace wear before the compliance sensor was placed on the brace. We decided to include these patients in the analysis by extrapolating over the initial part of brace wear. Observation of the patients whose entire compliance was recorded showed that compliance was the same as overall compliance in the initial phase. That withstanding, we feel that a multicenter study using this monitor may provide precise information on nonoperative treatment of

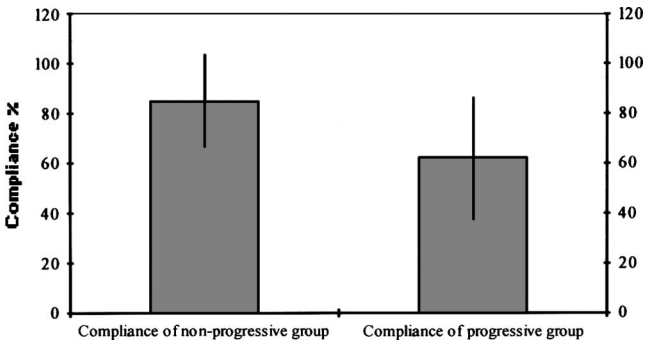

FIGURE 1. Compliance rates of the group whose curves did not progress and the group whose curves did progress.

scoliosis and address questions on the timing, dose, and duration of treatment. This is a starting point for further investigation into brace treatment based on scientific evidence.

ACKNOWLEDGMENTS

The authors thank Whitney Sample and Jehan Defonseka for assistance in data collection and sensor preparation, Lawalls prosthetics for integrating the sensors into the brace, and Kaifen Wang for assistance with statistical analysis.

REFERENCES

1. Bassett GS, Bunnell WP, MacEwen GD. Treatment of idiopathic scoliosis with the Wilmington brace. Results in patients with a twenty to thirty-nine-degree curve. *J Bone Joint Surg [Am]*. 1986;68:602–605.
2. Emans JB, Kaelin A, Bancel P, et al. The Boston bracing system for idiopathic scoliosis. Follow-up results in 295 patients. *Spine*. 1986;11: 792–801.
3. Karol LA. Effectiveness of bracing in male patients with idiopathic scoliosis. *Spine*. 2001;26:2001–2005.
4. Lonstein JE, Winter RB. The Milwaukee brace for the treatment of adolescent idiopathic scoliosis. *J Bone Joint Surg [Am]*. 1994;76:1207–1221.
5. Nachemson AL, Peterson LE. Effectiveness of treatment with a brace in girls who have adolescent idiopathic scoliosis. A prospective, controlled study based on data from the Brace Study of the Scoliosis Research Society. *J Bone Joint Surg [Am]*. 1995;77:815–822.
6. Noonan KJ, Weinstein SL, Jacobson WC, et al. Use of the Milwaukee brace for progressive idiopathic scoliosis. *J Bone Joint Surg [Am]*. 1996; 78:557–567.
7. Peterson LE, Nachemson AL. Prediction of progression of the curve in girls who have adolescent idiopathic scoliosis of moderate severity. *J Bone Joint Surg [Am]*. 1995;77:823–827.
8. Price CT, Scott DS, Reed FR, et al. Nighttime bracing for adolescent idiopathic scoliosis with the Charleston bending brace: long-term follow-up. *J Pediatr Orthop*. 1997;17:703–707.
9. Rowe DE, Bernstein SM, Riddick MF, et al. A meta-analysis of the efficacy of non-operative treatment for idiopathic scoliosis. *J Bone Joint Surg [Am]*. 1997;79:664–672.
10. Wiley JW, Thomson JD, Mitchell TM, et al. Effectiveness of the Boston brace in treatment of large curves in adolescent idiopathic scoliosis. *Spine*. 2000;25:2326–2332.
11. Winter RB, Lonstein JE, Drogt J, et al. The effectiveness of bracing in the nonoperative treatment of idiopathic scoliosis. *Spine*. 1986;11: 790–791.
12. Lavelle JR, Smith K, Platts R, et al. An assessment of brace compliance in adolescent idiopathic scoliosis using a new brace timer. *J Bone Joint Surg [Br]*. 1996;78(Supp):162.
13. Gurnham RB. Adolescent compliance with spinal brace wear. *Orthop Nurs*. 1983;2:13–17.
14. DiRaimondo CV, Green NE. Brace-wear compliance in patients with adolescent idiopathic scoliosis. *J Pediatr Orthop*. 1988;8:143–146.
15. Havey R, Gavin T, Patwardhan A, et al. A reliable and accurate method for measuring orthosis wearing time. *Spine*. 2002;27:211–214.
16. Houghton GR, McInerney A, Tew A. Brace compliance in adolescent idiopathic scoliosis. *J Bone Joint Surg [Br]*. 1997;69:852.
17. Katz DE, Durrani AA. Factors that influence outcome in bracing large curves in patients with adolescent idiopathic scoliosis. *Spine*. 2001;26: 2354–2361.
18. Lou E, Raso JV, Hill DL, et al. The daily force pattern of spinal orthosis in subjects with adolescent idiopathic scoliosis. *Prosthet Orthot Int*. 2002; 26:58–63.
19. Nicholson GP, Ferguson-Pell MW, Smith K, et al. The objective measurement of spinal orthosis use for the treatment of adolescent idiopathic scoliosis. *Spine*. 2003;28:2243–2251.
20. Takemitsu M, Bowen RJ, Rahman T, et al. Compliance monitoring of brace treatment for patients with idiopathic scoliosis. *Spine*. 2004;29: 2070–2074.

