A Comparison of the Thoracolumbosacral Orthoses and Providence Orthosis in the Treatment of Adolescent Idiopathic Scoliosis

Results Using the New SRS Inclusion and Assessment Criteria for Bracing Studies

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Abstract: This is a retrospective cohort study comparing the effectiveness of the thoracolumbosacral orthosis (TLSO) and the Providence orthosis in the treatment of adolescent idiopathic scoliosis (AIS) using the new Scoliosis Research Society (SRS) Committee on Bracing and Nonoperative Management inclusion and assessment criteria for bracing studies. These new criteria will make future studies comparable and more valid and accurate.

Methods: We have used a custom TLSO (duration, 22 hours/day) and the Providence orthosis (duration, 8–10 hours/night) to control progressive AIS curves. Only 83 of 160 patients met the new SRS inclusion criteria: age of 10 years and older at initiation of bracing; initial curve of 25 to 40 degrees; Risser sign 0 to 2; female; premenarcheal or less than 1 year past menarche; and no previous treatment. There were 48 patients in the TLSO group and 35 in the Providence group. The new SRS assessment criteria of effectiveness included the percentage of patients who had 5 degrees or less and 6 degrees or more of curve progression at maturity, the percentage of patients whose curve progressed beyond 45 degrees, the percentage of patients who had surgery recommended or undertaken, and a minimum of 2 years of follow-up beyond maturity in those patients who were thought to have been successfully treated. All patients are evaluated regardless of compliance (*intent to treat*).

Results: There were no significant differences in age at brace initiation, initial primary curve magnitude, sex, or initial Risser sign between the 2 groups. In the TLSO group, only 7 patients (15%) did not progress (≤5 degrees), whereas 41 patients (85%) progressed by 6 degrees or more, including the 30 patients whose curves exceeded 45 degrees. Thirty-eight patients (79%) required surgery. In the Providence group, 11 patients (31%) did not progress, whereas 24 patients (69%) progressed by 6 degrees or more, including 15 patients whose curves exceeded 45 degrees. Twenty-one patients (60%) required surgery. However, when the initial curve at initiation of bracing was 25 to 35 degrees, the results improved. Five (15%) of 34 patients in the TLSO group and 10 (42%) of 24 patients in the Providence group did not progress, whereas 29 patients (85%) and 14 patients (58%), respectively, progressed by 6 degrees or more, and 26 patients (76%) and 11 patients (46%), respectively, required surgery.

Conclusions: Using the new SRS bracing criteria, the Providence orthosis was more effective for avoiding surgery and preventing curve progression when the primary initial curves at bracing was 35 degrees or less. However, the overall success of orthotic management for AIS in both groups was inferior to previous studies. Our results raise the question of the effectiveness of orthotic management in AIS and support the need for a multicenter, randomized study using these new criteria.

Key Words: adolescent idiopathic scoliosis, providence orthosis, Scoliosis Research Society inclusion and assessment criteria, surgery, thoracolumbosacral orthosis

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An orthoses is the only potentially effective nonoperative treatment for preventing curve progression in adolescent idiopathic scoliosis (AIS).[1] Several types of orthoses have been used with varying degrees of success, including the cervicothoracolumbosacral orthosis or Milwaukee brace, the thoracolumbosacral orthosis (TLSO), and the nighttime orthoses, such as the Providence and the Charleston orthoses. All of these orthoses with variable treatment criteria have been studied, usually retrospectively, for their effectiveness in the treatment of AIS.[1–21] As a consequence, the effectiveness of orthotic management remains controversial.

The most experience is with the Milwaukee orthosis, which is worn 22 to 23 hours per day. Previous studies have indicated that it has the potential to alter the natural history of AIS and prevent curve progression and the need for surgical intervention.[4,12] However, a more recent study has questioned its effectiveness.[15] The TLSO was developed with the goal of equaling the initial results of the Milwaukee orthosis while decreasing the need for a suprastructure, which most patients find cosmetically objectionable.[1,5] Although protocols have generally recommended these orthoses to be worn full-time

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(duration, 22–23 hours/day) or part-time (duration, 12–18 hours/day), they have been found to be nearly as effective.[5,6,14]

Newer strategies have recommended correction and, sometimes, overcorrection of the deformity with aggressive molding.[16,19] These orthoses, of which the Charleston and the Providence orthosis are the most common, require 8 to 10 hours of nighttime wear. Although these orthoses seem to alter the natural history in retrospective studies, they are generally found inferior to or no different from full-time orthotic strategies in comparison studies.[17,21,22]

Although these previous studies have examined the effectiveness of various orthoses, the definition of success or who should be included in the analysis have never been universally agreed upon. Recently, the Scoliosis Research Society (SRS) Committee on Bracing and Nonoperative Management has attempted to standardize orthotic studies by recommending inclusion and assessment criteria for future bracing studies.[23] This is the first study to use these criteria.

Previously, we used a custom TLSO, worn 22 hours per day for progressive curves in AIS, but we changed to the Providence orthosis, worn 8 to 10 hours per night. This change was made because of our poor results with the TLSO and the suspicion that this was predominantly caused by a lack of compliance. This study compares the effectiveness of these 2 orthoses in AIS using the new SRS inclusion and assessment criteria.

FIGURE 1. Providence nighttime orthosis on a 13-year-old girl with adolescent idiopathic scoliosis. Observe the shape and cut of the orthosis that provides a corrective force over the apex of the curve, pushing it to the midline or past it.

METHODS

The new SRS inclusion criteria for bracing studies include diagnosis of idiopathic scoliosis, age of 10 years or older when the orthosis was prescribed, skeletal immaturity (Risser sign 0, 1, or 2), primary curve between 25 and 40 degrees, no previous treatment, and, if female, either premenarcheal or less than 1 year past menarche.[23] All patients are to be included, regardless of whether or not they were thought to be compliant with the orthotic treatment regime (intent to treat).

Orthotic management for AIS has been used at our institution in skeletally immature patients with AIS with progressive curves of 25 degrees or more. The TLSO has been used for more than 20 years. Beginning on a limited basis in 1994 and exclusively since 2001, the Providence nighttime orthosis (Fig. 1) has been used. This was initially based on surgeon preference. Patients were identified from the Pediatric Orthopaedic Spine Database from the years 1992 to 2004. If the follow-up data was inadequate for any patient, telephone calls were used and verbal reports were obtained from the parents with regard to the ultimate or current outcome, such as treatment at other facilities, including further bracing or surgery. Patients in need of follow-up were asked to return. The database review and telephone correspondence was completed by one of the authors (J.A.J.). The patients were treated either by the senior author, 3 other staff pediatric orthopaedists, all who are members of the SRS, and a pediatric orthopaedic nurse practitioner. The custom TLSO was manufactured from a plaster cast impression of the trunk and was fabricated by the same orthotists. The Providence orthosis was molded by the same orthotist and then manufactured in Providence, Rhode Island, using their computer assisted design/computer assisted manufacturing (CAD/CAM) technique.

Information obtained from the Pediatric Orthopaedic Spine Database included the patient's age, sex, menarcheal status, bracing dates, basic medical history, magnitude of the primary curve, curve types, Risser sign, results, and follow-up. Curve types were determined by the use of the curve magnitudes and levels. Patients were categorized as having one of the following curve patterns: single thoracic, double thoracic, double major, thoracolumbar, lumbar, or triple major.

The evaluation of orthotic effectiveness was determined using the new SRS assessment criteria. This includes the percentage of patients who had 5 degrees or less or 6 degrees or more of curve progression at maturity, the percentage of patients whose curve progressed beyond 45 degrees, the percentage of patients who had surgery recommended or performed, and a minimum of 2-year follow-up beyond skeletal maturity for those patients who were thought to have had successful brace treatment. Skeletal maturity was defined as less than 1-cm change in standing height on 2 consecutive measurements 6 months apart; Risser sign 4, and, in girls, when the patient is 2 years past menarche. It was also recommended that all studies be stratified according to curve magnitude and curve type. We could not strictly adhere to this recommendation because of the small number of patients. We used a minimum follow-up of 1 year beyond skeletal maturity to increase the number of patients available.

Our retrospective analysis identified 160 patients treated orthotically for idiopathic scoliosis between 1992 and 2004. This included 110 patients treated using a TLSO and 50 patients treated using a Providence orthosis. From this cohort of 160 patients, 83 patients (TLSO, 48; Providence, 35) met the new SRS inclusion criteria and had complete data. Seventy-seven patients (TLSO, 62; Providence, 15) did not

meet the study criteria and were excluded from the study. The reasons for exclusion were inadequacy of initial data (16 patients [all TLSO]); inadequacy of follow-up data (7 patients [TLSO, 5; Providence, 2] whose ultimate outcome could not be determined); inadequacy of age (19 patients [TLSO, 18; Providence, 1] who were aged 9 years or younger when orthotic management commenced); previous orthotic treatment (11 patients [TLSO, 7; Providence, 4]); excluded Risser sign (9 patients [TLSO, 6; Providence, 3] who were braced despite being staged at Risser sign 3 or 4); excluded initial curve magnitude (13 patients [TLSO, 9; Providence, 4] with an initial curve magnitude of 41 degrees or greater); and other diagnoses (1 patient [Providence] with a later diagnosis of neuromuscular scoliosis and 1 patient (TLSO) with a spinal cord syrinx discovered during the course of treatment.

Statistical Analysis

The student *t* test was used for continuous data, whereas the χ^2 test was used for noncontinuous data. The Fisher exact test was used for small ($n < 5$) subsets of data. A *P* value of less than 0.05 was required for statistical significance.

RESULTS

The summary of the initial clinical and radiographic data for all 83 patients is presented in Table 1. The mean age at initial orthotic treatment for the 48 patients in the TLSO group and for the 35 patients in the Providence group was 12.7 ± 1.5 years (range, 10.3–17.2 years) and 12.8 ± 1.1 years (range, 10.5–14.9 years), respectively. The mean curve at the beginning of orthotic management was 33.6 ± 4.0 degrees (range, 25–40 degrees) and 33.7 ± 4.1 degrees (range, 25–40 degrees), respectively, in the 2 treatment groups. Curve types were classified as follows: in the TLSO group, there were 22 thoracic, 17 double major, 6 thoracolumbar, and 1 each for double thoracic, triple major, and lumbar. In the Providence group, there were 16 thoracic, 8 double major, 6 double thoracic, 4 thoracolumbar, and 1 triple major. In the TLSO group, there were 33 patients who were staged at Risser sign 0, 9 at Risser sign 1, and 6 at Risser sign 2 at initiation of orthotic managements. In the Providence group, 19 patients were staged at Risser sign 0, 6 at Risser sign 1, and 6 at Risser sign 2 at the beginning of bracing. Initial Risser signs for 4 patients in the Providence group could not be accurately determined because the pelvis was partially obscured on the anteroposterior radiograph at the time the brace was prescribed. However, they were definitely less than Risser sign 2 and were therefore included in the study group. All 4 patients eventually required surgery. In the TLSO group, there were 40 girls and 8 boys, whereas the Providence group consisted of 30 girls and 5 boys. There were no significant differences in initial age, initial curve magnitude, curve type (except double thoracic curves), skeletal maturity, or sex between the 2 groups. In the Providence group, there was a higher percentage of double thoracic curves, which are typically resistant to orthotic management.

TABLE 1. Initial Clinical and Radiographic Data

	TLSO	Providence	*P*
No. patients	48	35	
Age, mean (range), y	12.7 (10.3–17.2)	12.8 (10.5–14.9)	NS
Sex			
Female	40	30	NS
Male	8	5	NS
Initial curve (degrees)	33.6 (25–40)	33.7 (24–40)	NS
Curve distribution			
Thoracic	22	16	NS
Double thoracic	1	6	$P < 0.05$
Double major	17	8	NS
Thoracolumbar	6	4	NS
Lumbar	1	0	NS
Triple major	1	1	NS
Risser sign			
0	33	19	NS
1	9	6	NS
2	6	6	NS
Unknown	0	4	
Time in brace, mean (range), mo	16.5 (1–36)	16.2 (1–38)	NS

NS indicates statistical nonsignificance.

TABLE 2. Summary of Clinical and Radiographic Results (Initial Curve, 25–40 Degrees)

	TLSO, No. (%)	Providence, No. (%)	*P*
No. patients	48	35	
No progression (≤5 degrees)	7 (15)	11 (31)	0.065
Progression ≤6 degrees	41 (85)	24 (69)	0.065
Progression >45 degrees	30 (56)	15 (45)	0.22
Progression to surgery	38 (79)	21 (60)	0.057

The mean curve at the time the orthoses was discontinued was 46.8 ± 10.6 degrees (range, 24–85 degrees) in the TLSO group and 43.4 ± 9.9 degrees (range, 26–70 degrees) in the Providence group. The higher curves occurred in patients who discontinued their orthosis on their own and did not return for follow-up until curve progression was quite obvious. The mean time of wearing the orthosis was 16.5 ± 9.0 months (range, 1–36 months) and 16.2 ± 10.4 months (range, 1 to 38 months) in the TLSO group and the Providence group, respectively.

The results for the curves of 25 to 40 degrees at initial bracing are presented in Table 2. In the TLSO group, only 7 patients (15%) showed no curve progression (≤5 degrees), whereas 11 patients (31%) in the Providence group did not progress ($P = 0.065$). Forty-one patients (85%) in the TLSO group and 24 patients (69%) in the Providence group progressed by 6 degrees or more ($P = 0.065$). Thirty patients (56%) and 15 patients (45%) in the 2 study groups had curve progression beyond 45 degrees ($P = 0.22$). There were only 11 patients in the TLSO group and 9 patients in the Providence group who progressed by 6 degrees or more and did not ultimately exceed 45 degrees. Overall, 38 patients (79%) and 21 patients (60%) in the TLSO and Providence

groups underwent surgery ($P = 0.057$). Progression of curve magnitude and the need for surgical intervention between the 2 groups approached but did not meet the criteria for statistical significance ($P \leq 0.05$). Our usual criteria for recommending surgery was a progressive curve of 45 degrees or more or a rapidly progressing curve in noncompliant patients in whom the curve was being approached and expected to exceed 45 degrees.

Thus, only 10 patients (21%) in the TLSO group and 14 patients (40%) in the Providence group were felt to have had successful orthotic management. The mean follow-up beyond skeletal maturity in these patients was 24.7 ± 12.9 months (range, 12–49 months) in the TLSO group and 20 ± 19 months (range, 12–52 months) in the Providence group. There were only 4 TLSO and 6 Providence patients with orthosis who had less than 2 years of clinical and radiographic follow-up after skeletal maturity.

The 58 patients who had initial curves at brace initiation of 25 to 35 degrees were examined separately, thereby eliminating the curves of greater magnitude. There were 34 patients in the TLSO group and 24 patients in the Providence group for this analysis (Table 3). In the TLSO group, 5 patients (15%) did not progress (≤5 degrees) compared with 10 patients (42%) in the Providence group ($P = 0.017$). Twenty-nine patients (85%) and 14 patients (58%) in the TLSO and Providence groups, respectively, progressed by 6 degrees or more ($P = 0.017$). The curve progressed to 45 degrees or more in 18 patients (52%) and 7 patients (29%), respectively, in the 2 groups. This did not reach statistical significance ($P = 0.07$). There were 11 patients in the TLSO group and 7 patients in the Providence group that progressed 6 degrees or more but did not exceed 45 degrees. Overall, 26 patients (76%) and 11 patients (46%), respectively, in these 2 groups required surgery ($P = 0.02$). This was a statistically significant reduction in the progression of curve magnitude and the need for surgery in patients who used the Providence orthosis.

There was no difference in the progression of curve magnitude or the rate of surgery between the 14 patients in the TLSO group and the 11 patients in the Providence group whose initial curves were between 36 and 40 degrees. Only 2 patients in the TLSO group (14%) and 1 patient in the Providence group (9%) did not progress. The curves of all 12 remaining patients in the TLSO group progressed beyond 45 degrees and required surgery. In the Providence group, the curves of 8 of 10 patients progressed beyond 45 degrees, but all 10 required surgery.

TABLE 3. Summary of Clinical and Radiographic Results (Initial Curve, 25–35 Degrees)

	TLSO, No. (%)	Providence, No. (%)	*P*
No. patients	34	24	
No progression (≤5 degrees)	5 (15)	10 (42)	0.017*
Progression ≤6 degrees	29 (85)	14 (58)	0.017*
Progression >45 degrees	18 (52)	7 (29)	0.07
Progression to surgery	26 (76)	11 (46)	0.02*

Asterisk (*) indicates statistical significance.

DISCUSSION

The goal of orthotic management in idiopathic scoliosis is to alter the natural history. Lonstein and Carlson[24] found that in skeletally immature patients with curves of 20 to 29 degrees, there was a 68% risk of curve progression. Factors associated with an increased risk of progression included curve magnitude, skeletal immaturity, and double curve patterns. Nachemson and Peterson[1] also reported that 66% of untreated patients with curves between 25 and 35 degrees will progress by 5 degrees or more. Bunnell[25] reported progression of at least 5 degrees in 68% of patients, 10 degrees in 34% of patients, and 20 degrees in 18% of patients in his series. To be considered an effective management method, we think that an orthosis must prevent progression in at least 70% of patients with AIS.

Orthotic management has been found to be the only potentially effective alternative to operative correction and fusion in the treatment of AIS. Initially, a full-time Milwaukee orthosis was used for correction and control. Lonstein and Winter[12] reported a 47% rate of failure (curve progression of ≥6 degrees or operative treatment) in skeletally immature patients (Risser sign 0 or 1) with initial curves of 30 to 39 degrees. Earlier, Carr et al[4] reported a 39% surgery rate in patients treated with the Milwaukee orthosis who had long-term follow-up. However, these and other studies[3,26] did not include *noncompliant* patients. The new SRS inclusion criteria requires that all patients to be included in bracing studies should belong to the *intent-to-treat* population and not merely be the *compliant* patients.[23] In addition, the Milwaukee orthosis has been found to have a negative effect on a patient's self-image.[27] Noonan et al[15] questioned the use of the Milwaukee orthosis and reported progression in 48% of patients after the brace had been stopped, which necessitated operative fusion in 42% of the series. The poor acceptance of the Milwaukee orthosis ultimately led to the development of underarm braces, such as the TLSO.

The results of the TLSO were found equivalent to and sometimes superior to those of the Milwaukee orthosis. In a prospective study, Nachemson and Peterson[1] reported a success rate of 74% in controlling curve progression with the use of a TLSO. Emans et al[5] also reported good results using the Boston brace, and surgery was avoided in 88% of their patient population. Montgomery and Willner[9] noted that the Milwaukee orthosis had 5 times greater risk of failure compared with the Boston Brace.

The next strategy at decreasing psychological morbidity and improving compliance was to decrease the amount of time the brace was worn on a daily basis. Allington and Bowen[14] found no statistical difference in full-time (duration, 23–24 hours/day) versus part-time (duration, 12–16 hours/day) use of the Wilmington brace. Emans et al[5] has also suggested that part-time bracing may be as effective as full-time bracing. This was in contrast to the study of Wiley et al[28] who found that compliant patients who wore the brace for

more than 18 hours per day had less progression than those who wore it 12 hours per day or less.

Newer strategies are now using the concept of part-time (nighttime only) orthotic use to correct or overcorrect the curve. Climent and Sanchez[29] found that nighttime-only bracing had the least negative effect on psychological functioning, sleep disturbance, back pain, body image, and flexibility. With aggressive bracing that often creates greater than 80% improvement of curve magnitude, these braces are thought to alter the factors affecting progression during their 10 to 14 hours a day of wear, usually at night. The Charleston and the Providence orthoses are the 2 most common orthoses worn only at night. The Charleston nighttime bending brace, which works by bending the spine, required the brace to be worn for a minimum of 8 hours per night and was found effective in preventing curve progression.[16] The Providence orthosis works by the application of opposing forces and, as opposed to bending the spine, pushes the curve apexes to the midline or past it (Fig. 1). In a recent study of 102 consecutive female patients, D'Amato et al[19] found excellent correction in the Providence orthosis, with a success rate of 79% if the apex was at or below T9. Because of limitations of sample numbers, the study was only able to state that the brace was effective in initial curves less than 35 degrees.

There have been 3 previous studies comparing a nighttime orthosis to more traditional methods.[17,21,30] Katz and Durrani[18] retrospectively recommended the use of the Boston brace in curves between 36 to 45 degrees because it prevented curve progression of 6 degrees or more in 57% of patients, as compared with only 17% success in using the Charleston orthosis. The Boston orthosis also controlled curves of 25 to 35 degrees more effectively than did the Charleston orthosis, preventing progression in 71% of patients versus 53% in using Charleston orthosis. Howard et al[30] likewise found that the TLSO was superior at preventing curve progression when compared with the Charleston brace (and Milwaukee). Gepstein et al,[21] however, found no statistical difference in the surgery rate of 13.5% using the TLSO and 11% using the Charleston Brace.

In our study, the Providence nighttime orthosis was more effective in avoiding surgery and preventing curve progression than a TLSO in a comparable population of patients with AIS having initial curves of 25 to 40 degrees. However, this comparison fell below the threshold for statistical significance ($P < 0.05$). Further analysis found a statistically significant difference in avoiding surgery and preventing curve progression in patients with initial curves of 25 to 35 degrees. The groups were comparable and had no difference in their initial patient characteristics, including age, curve magnitude, Risser sign, and sex. Curve types were also similar, with the only difference being a statistically higher percentage of the difficult to brace double thoracic curves in the Providence group. We hypothesize that the compliance with the Providence brace may be greater and leads to improved results. The staff who prescribed and monitored these orthoses were the same; thus, no bias in the *attitude* regarding orthotic management was likely. This is the first study in which part-time (nighttime) bracing has been found superior to a full time-brace.

The results of both orthoses were unfavorable when compared with previous studies and the natural history of the condition. Neither orthosis was effective, when compared with the natural history of AIS, at preventing progression to surgery in subset of patients with curves of 35 degrees or more. Although not included in this analysis, our patients with initial curves of 41 to 45 degrees also had poor results using either orthosis. The use of a TLSO did not prevent curve progression or the need for surgery in only 20% to 25% of our patients. This was true even when the initial curves of 25 to 35 degrees were evaluated separately. The Providence orthosis did not prevent curve progression or surgery in 40% to 55% of patients. The best results were obtained in curves of 25 to 35 degrees. On the basis of these results, we are reconsidering our guidelines and are considering orthotic management in skeletally immature patients with progressive curves of 20 to 24 degrees.

The reasons for our poor results when compared with those of previous studies is likely multifactorial and include demographic factors, genetic pool, referral patterns (tertiary center), and the current lack of acceptability toward bracing. Moreover, previous studies have eliminated noncompliant patients from the evaluation, which likely improved their results. Compliance is a major issue with orthotic management, but noncompliant patients should be included in an analysis, as recommended by the SRS assessment criteria. Previous studies have also been difficult to compare, which should improve with the use of standardized criteria. This is the first study using the new SRS inclusion and assessment criteria. Our results indicate that the use of bracing with the TLSO or the Providence brace in curves greater than 35 degrees in the control of AIS is questionable. The results using the Providence orthosis in smaller curves (25–35 degrees) were more favorable. These results support the need for a larger, multicenter randomized study using the new SRS inclusion and assessment criteria.

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