A Comparison of Thoracolumbosacral Orthoses and SpineCor Treatment of Adolescent Idiopathic Scoliosis Patients Using the Scoliosis Research Society Standardized Criteria

Steven R. Gammon, MD, Charles T. Mehlman, DO, MPH,* Winston Chan, BS,* Jonathan Heifetz, CPO,† Gregory Durrett, LO,‡ and Eric J. Wall, MD**

Background: SpineCor is a relatively new bracing system that uses dynamic bracing concepts in the treatment of adolescent idiopathic scoliosis (AIS). Limited data are available regarding its effectiveness. This study compared treatment outcomes of 2 groups of AIS patients treated via either a conventional rigid thoracolumbosacral orthoses (TLSO) or a SpineCor nonrigid orthosis.

Methods: We identified 2 scoliosis patient cohorts: 35 patients treated with a TLSO and 32 patients treated with a SpineCor orthosis. All patients included in these groups conformed with the Scoliosis Research Society (SRS) standardized criteria for AIS bracing: (1) Risser ≤ 2, (2) curve magnitude 25 to 40 degrees, (3) age ≥ 10 years. Outcomes were SRS standardized with failure being defined as curve progression ≥ 6 degrees, or ever exceeding 45 degrees, or having surgery recommended before skeletal maturity. All patients were followed through the completion of brace treatment or attainment of other treatment end points. The Yates corrected χ^2 test and unpaired t test were used for data analysis.

Results: The 35 patients (32 girls, 3 boys) in the TLSO group had an average age of 13 years (range: 11.1-16.8) and an average primary curve magnitude of 33 degrees (range: 25-40 degrees). Follow-up averaged 2 years (range: 8-61 m) from the beginning of brace treatment. The 32 patients (28 girls, 4 boys) in the SpineCor group had an average age of 13 years (range: 11-15.2) and an average primary curve magnitude of 31 degrees (range: 25-40 degrees). Follow-up for this group averaged 2 years and 6 months (range: 13-73 mo) from the beginning of brace treatment. No significant difference ($P = 0.75$) was found using the more strict outcome measure (≤ 5-degree curve progression) as the success rates were 60% (21/35) for TLSO and 53% (17/32) for SpineCor. Similarly, no significant difference ($P = 0.62$) was found using the more liberal outcome measure (never reached 45 degrees) as the success rates were 80% (28/35) for TLSO and 72% (23/32) for SpineCor.

Conclusions: We were unable to identify any significant differences in brace treatment outcomes when comparing TLSO and SpineCor treated patients.

Key Words: scoliosis, TLSO, SpineCor, Sainte-Justine brace, outcomes

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Adolescent idiopathic scoliosis (AIS) is a structural, lateral, and rotational curvature of the spine that arises in 1% to 3% of adolescents between 10 and 16 years of age.[1–3] Controversy exists today regarding the most effective nonoperative treatment of AIS.[4–9] Bracing is the mainstay of nonoperative treatment of AIS. However, the type of brace to be administered is a decision all AIS-treating clinicians must consider. In 1958, Blount first used the Milwaukee brace.[10] Thoracolumbosacral orthoses (TLSO) were later developed, which eliminated the cervical component from the Milwaukee brace. TLSOs were customized to improve comfort, cosmesis, and compliance.[1] Newer bracing modifications now include flexible, dynamic bracing systems (SpineCor, Triac, and Lycra orthoses) that may be worn under clothes and apply dynamic corrective forces to the trunk to counter the derotational and translation aspect of typical idiopathic scoliosis.[11–14] The dilemma remains as to which of these options is the ideal nonoperative treatment of AIS.

Only recently has the strict criteria been applied in the design and standardization of scoliosis bracing studies.[15] Early attempts have been made to compare the newer, dynamic SpineCor bracing system with traditional, rigid TLSO bracing, but the results are conflicting based on whether the reporting institution had any

From the *Cincinnati Children's Hospital Medical Center and University of Cincinnati, Cincinnati, OH; †Presque Isle Orthopedic Laboratory, Erie, PA; and ‡Hanger Prosthetics and Orthotics, Bethesda, MD.

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Reprints: Charles T. Mehlman, DO, MPH, Division of Pediatric Orthopaedic Surgery, Cincinnati Children's Hospital Medical Center, 3333 Burnet Avenue, Mail Location 2017, Cincinnati, OH 45229-3039. E-mail: Charles.Mehlman@cchmc.org.

affiliation with the development of SpineCor.[16–19] The purpose of our study was to independently compare SpineCor bracing with traditional TLSO bracing in the treatment of AIS by using standardized criteria of the Scoliosis Research Society (SRS).[15]

METHODS

All patients with AIS who were treated primarily with bracing between 2001 and 2009 at the Cincinnati Children's Hospital Medical Center (CCHMC) were included in this retrospective cohort study. The SRS standardized criteria[15] were used as the inclusion criteria as well as end points for our study. Patients were included into the study if they met the following SRS inclusion criteria for AIS:

- Age 10 years or older when the orthosis was prescribed
- Risser 0, 1, or 2
- Primary curve magnitude of 25-40 degrees
- No prior treatment
- If female, either premenarchal or less than 1 year postmenarchal

The qualifying patients were assessed using the SRS standardized end point criteria:

- Percentage of patients who have 5 degrees or less curve progression and the percentage of patients who have 6 degrees or more progression at skeletal maturity
- Percentage of patients who progress beyond 45 degrees
- Percentage of patients who have either been recommended for surgery or have undergone surgery before skeletal maturity

Skeletal maturity was defined by < 1 cm of vertical height over 12 months. If these measurements were not avialable, skeletal maturity was considered complete when Risser 4 is present and, in females, when the patient is 2 years postmenarchal.

Patients and their families self-selected which brace to wear, and were thus not randomized. The physician and orthotist who administered SpineCor braces both received SpineCor certification training. All TLSOs were custom made and were not "off-the-shelf." Brace wear protocol for full-time wear was 23 hours per day for TLSO and 20 hours per day for SpineCor. Compliance was assessed by review of information available in the patients' medical records.

Patient information was directly recorded from their respective charts except for the Risser, curve magnitude, curve levels, and curve type, which were

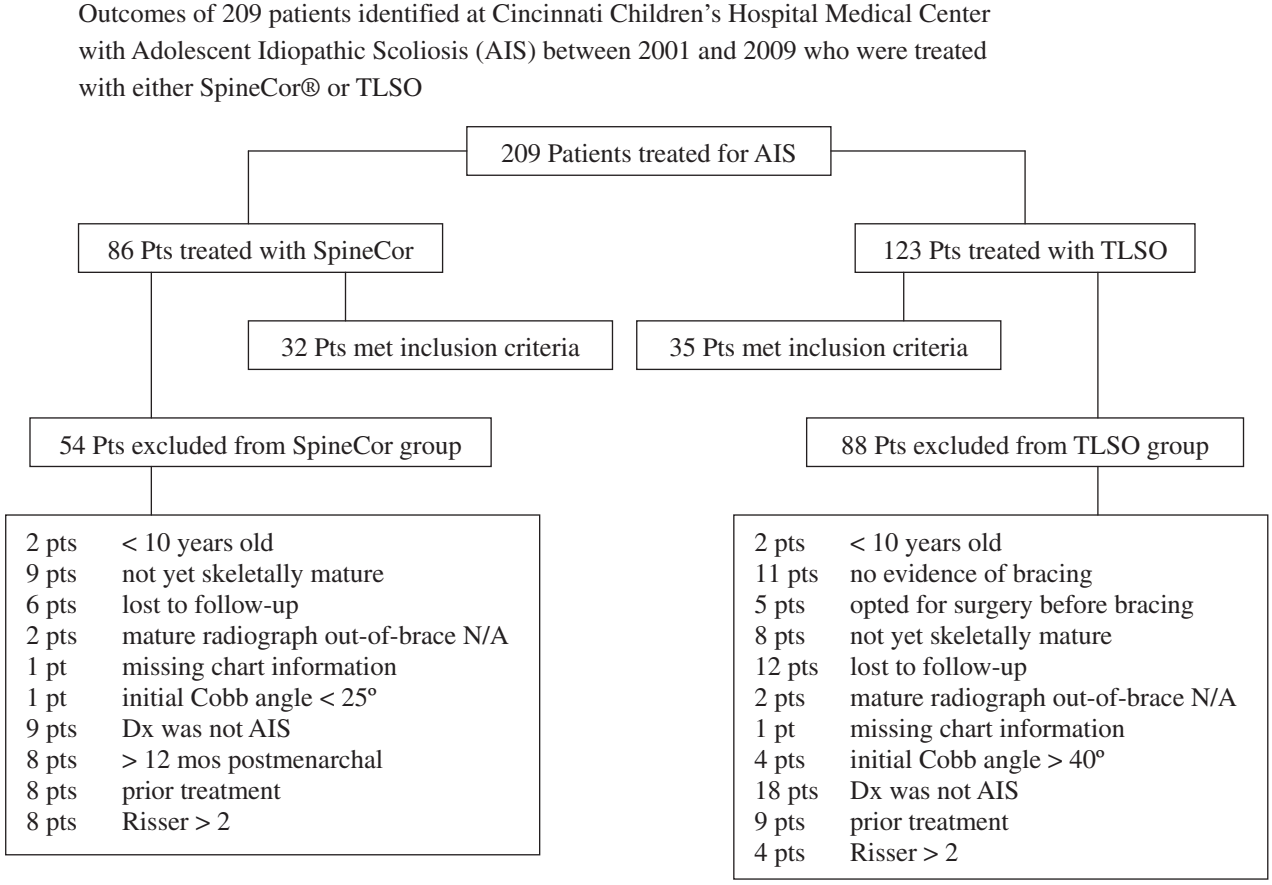

FIGURE 1. Outcomes of 209 patients identified at Cincinnati Children's Hospital Medical Center with adolescent idiopathic scoliosis (AIS) who were treated with either SpineCor or TLSO between 2001 and 2009. TLSO indicates thoracolumbosacral orthoses.

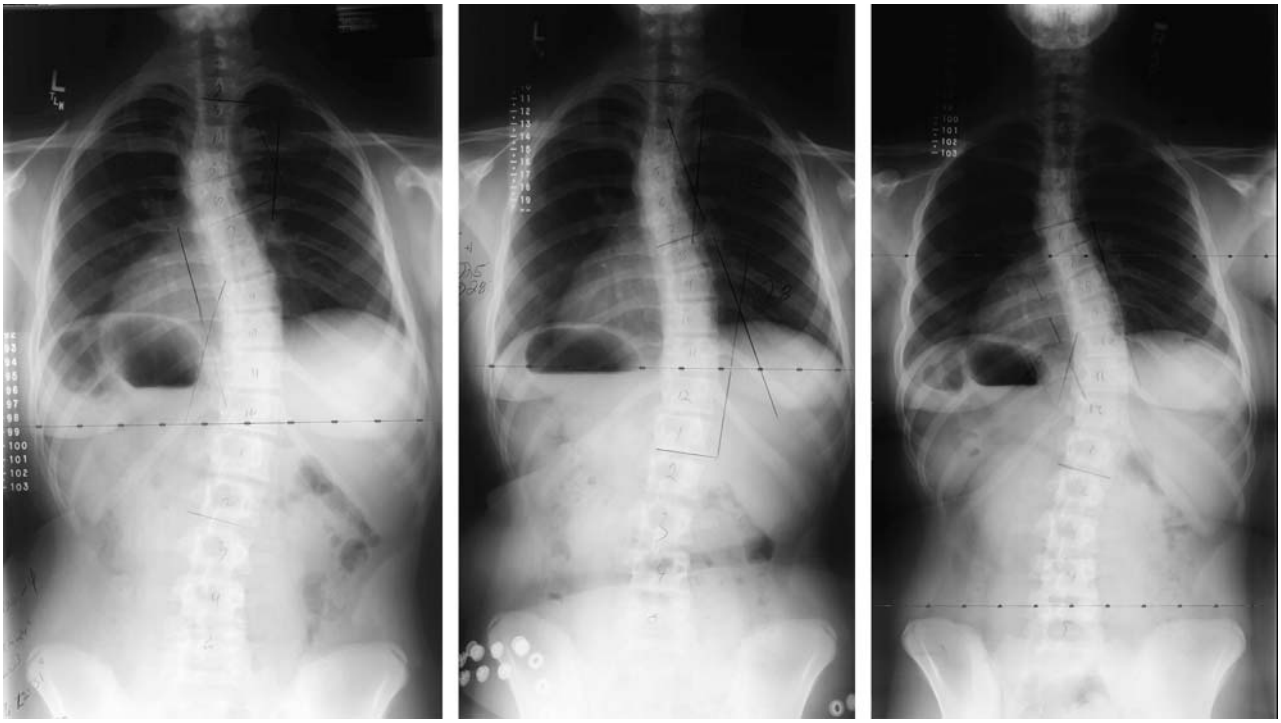

FIGURE 2. Radiograph pretreatment, in-brace, and out-of-brace at 26.4 months of a 13-year-old female with AIS successfully treated with SpineCor orthosis with − 3 degrees of curve progression. AIS indicates adolescent idiopathic scoliosis.

obtained radiographically from computerized radiographs. The values were measured by 2 authors and by a third author if there were still any disagreement. Previous reports have validated the reproducibility of electronic Cobb angle measurement.[20,21] If a radiograph was not available for direct viewing and measurement, radiologist's measurements were obtained from the patient's chart.

A patient's brace was usually discontinued once skeletal maturity has been reached. However, a few patients were lost to follow-up before the end of treatment. These patients were still included if they met the inclusion criteria, were skeletally mature at the last follow-up visit, and had an out-of-brace radiograph on their last visit. All surgery indications were documented.

Statistical significance for the results were determined using either the Yates corrected 2-tailed χ^2 analysis or the unpaired 2-tailed t test. Power analysis showed 80% power to recognize a large difference ($\geq 35\%$ difference) if one exists based on the number of patients in each of our cohorts.

RESULTS

Between 2001 and 2009, 209 patients were identified at CCHMC who were treated for AIS primarily with a brace. Of these, 86 were treated with SpineCor and 123 with TLSO. Of the 86 SpineCor patients, 32 met the SRS standardized inclusion criteria and 54 patients were excluded for various reasons (Fig. 1). Of the 123 TLSO patients, 35 met the SRS standardized inclusion criteria and 88 patients were excluded (Fig. 1).

The number of patients, age, initial Risser, initial Cobb angle, final Risser, final Cobb angle, and length of brace treatment follow-up were compared between the 32 SpineCor and 35 TLSO patients (Table 1). None of the initial or final parameters between the 2 groups were found to be significantly different by the unpaired 2-tailed t test. SpineCor patients had an average initial age of 13.2 years and TLSO patients had an average initial age of 13.0 years ($P = 0.59$). The average initial Cobb angles for SpineCor and TLSO were 31.0 and 32.7 degrees, respectively ($P = 0.16$). After an average follow-up of 30.5 months for SpineCor and 24.5 months for TLSO ($P = 0.08$), the average final Cobb angle magnitudes were 37.7 and 37.5 degrees, respectively ($P = 0.95$). Tables 2 and 3 list the individual characteristics, initial curve magnitude, final curve magnitude, and follow-up period for each of the patients in the SpineCor and TLSO cohorts, respectively. The SRS standardized end point criteria are summarized in Table 4 and in the following paragraphs. On the basis of the number of patients we had in each cohort, our study was 80% powered to recognize a large difference ($\geq 35\%$ difference) if one exists.

Percentage of Patients Who Progressed $\leq$5 Degrees at Skeletal Maturity

Of the 32 SpineCor patients, 17 (53%) did not progress beyond 5 degrees at 30.5 months. This value is comparable ($P = 0.75$) to 21/35 (60%) of TLSO patients who did not progress beyond 5 degrees at 24 months (Figs. 2–5).

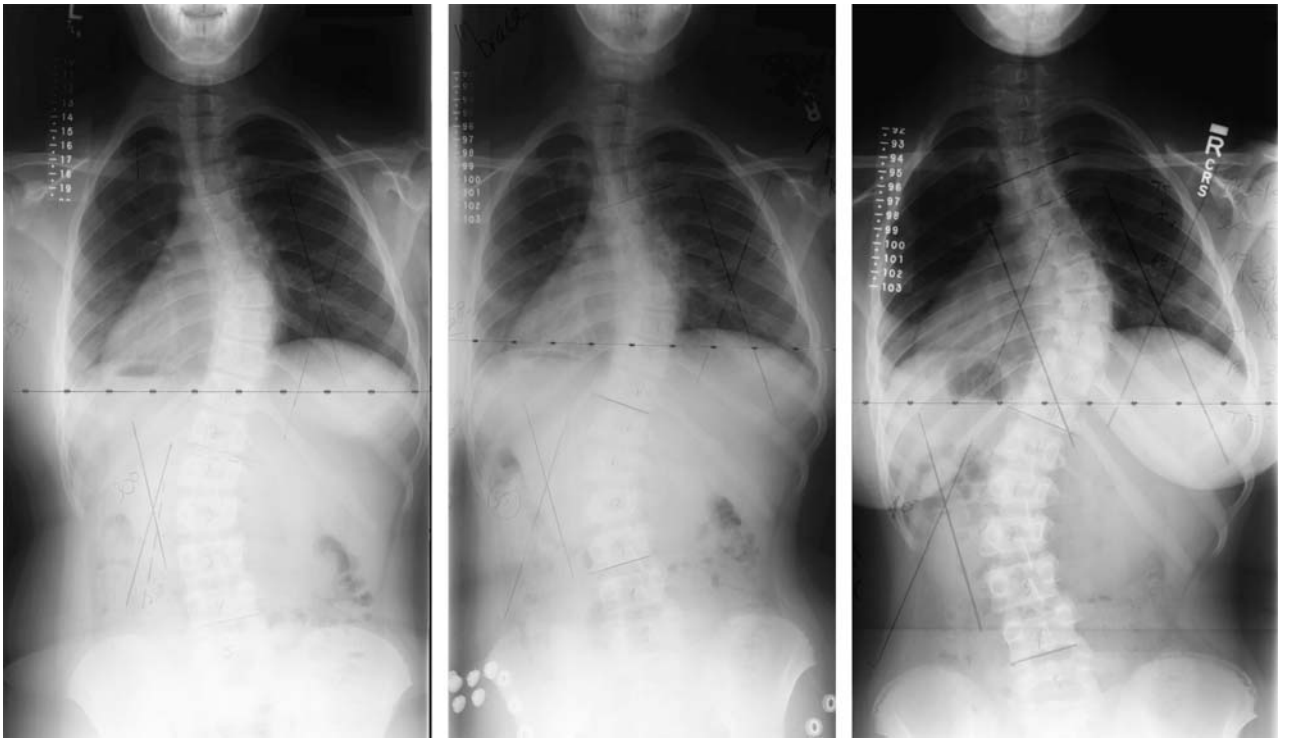

FIGURE 3. Radiograph pretreatment, in-brace, and out-of-brace at 28.4 months of an 11-year-old female with AIS unsuccessfully treated with SpineCor orthosis that resulted in 19 degrees of curve progression. AIS indicates adolescent idiopathic scoliosis.

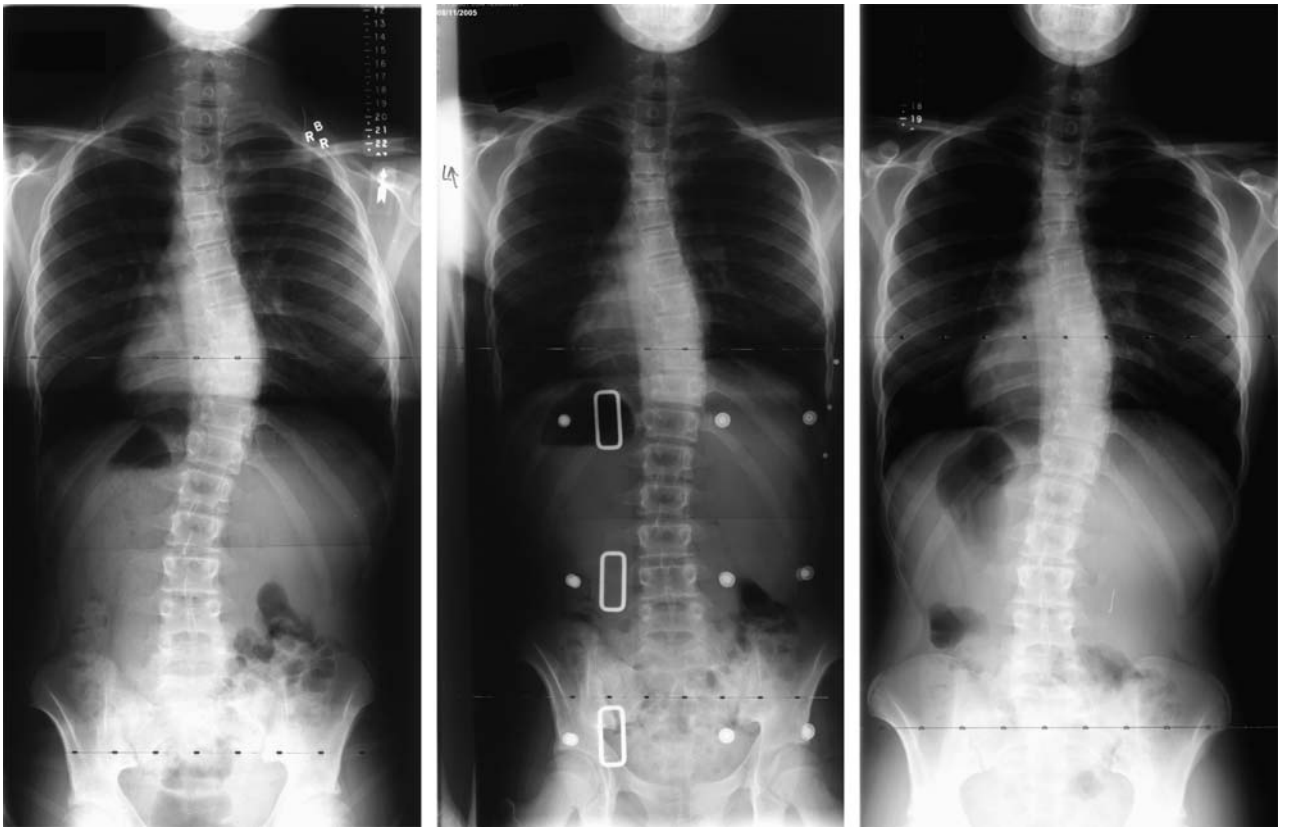

FIGURE 4. Radiograph pretreatment, in-brace, and out-of-brace at 23.3 months of a 15-year-old female with AIS successfully treated with TLSO with −1 degrees of curve progression. AIS indicates adolescent idiopathic scoliosis; TLSO, thoracolumbosacral orthoses.

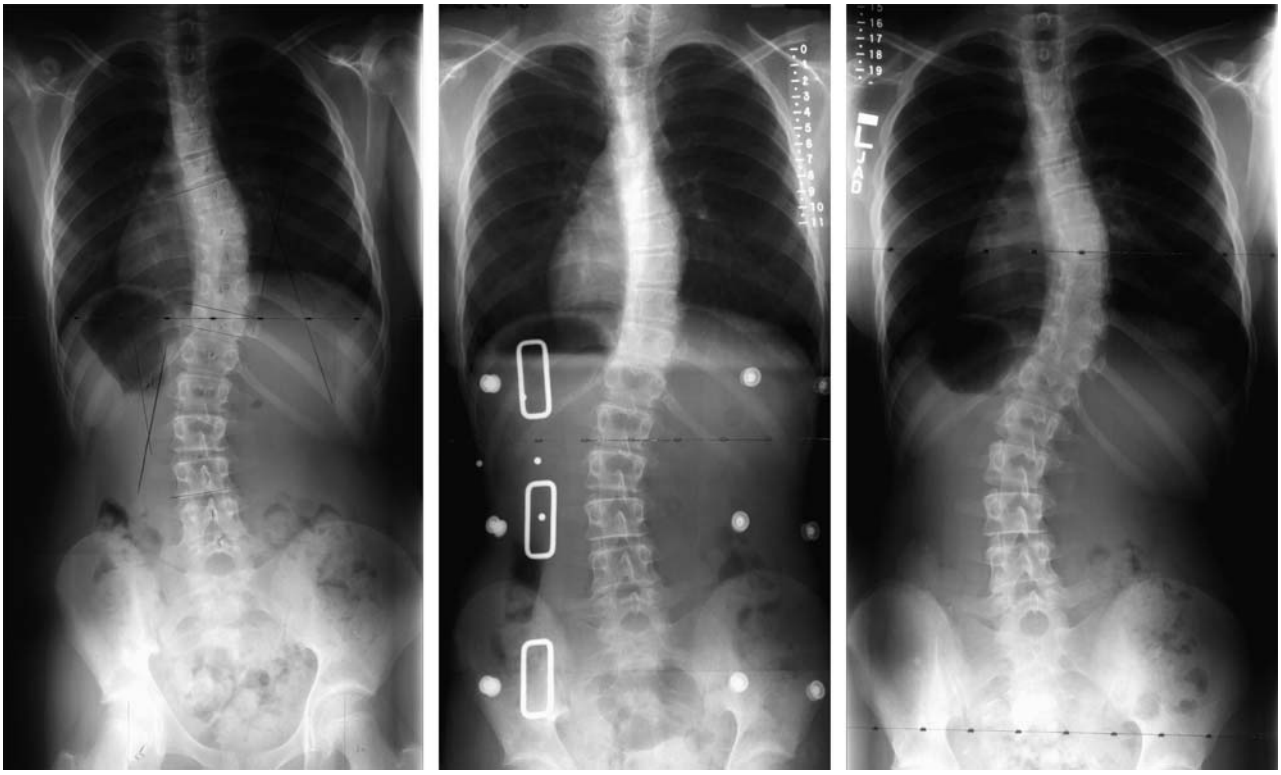

FIGURE 5. Radiograps pretreatment, in-brace, and out-of-brace at 22.3 months of a 14-year-old female with AIS unsuccessfully treated with TLSO that resulted in 7 degrees of curve progression. AIS indicates adolescent idiopathic scoliosis; TLSO, thoracolumbosacral orthoses.

Percentage of Patients Who Progressed Beyond 45 Degrees

With this less stringent outcome measurement, 23 of 32 SpineCor patients (72%) did not ultimately progress beyond 45 degrees. Likewise, 28 of 35 TLSO patients (80%) did not progress beyond 45 degrees. These success rates were not significantly different ($P = 0.45$) when using a 2-tailed χ^2 test with Yates correction.

Percentage of Patients Who Have Been Recommended for Surgery or Have Undergone Surgery Before Skeletal Maturity

One (3.1%) of 32 SpineCor patients received posterior spinal fusion before skeletal maturity due to rapid progression of her scoliosis from 37 degrees at her initial visit to 55 degrees. Two (5.7%) of 35 TLSO patients had surgery before reaching maturity due to increasing scoliosis. The rates of surgery before maturity for the 2 groups were not significantly different ($P = 0.61$) when using a 2-tailed χ^2 test with Yates correction. An additional non-SRS end point noted was that an additional 4 SpineCor and 4 TLSO patients underwent surgery after skeletal maturity. This value was also not statistically significant ($P = 0.87$).

DISCUSSION

This study used SRS standardized criteria in evaluating outcomes of AIS treatment with either TLSO or SpineCor orthoses. Of the 67 patients identified, no

TABLE 1. Characteristics of 67 Patients With Adolescent Idiopathic Scoliosis Who Met Scoliosis Research Society Inclusion Criteria and Were Treated With Either SpineCor or Thoracolumbosacral Orthoses Between 2001 and 2009

	SpineCor	TLSO	*P*
No. of patients	32 (28 girls, 4 boys)	35 (32 girls, 3 boys)	0.90
Average initial age	13.2 ± 1.3 y (range: 11-15.2)	13.0 ± 1.3 y (range: 11.1-16.8)	0.59
Average initial Risser	0.53 (range: 0-2)	0.63 (range: 0-2)	0.62
Average primary curve	31.0 ± 5.02 degrees (range: 25-40 degrees)	32.7 ± 4.97 degrees (range: 25-40 degrees)	0.16
Average final Risser	3.72 (range: 1-4)	3.71 (range: 0-4)	0.63
Average final curve	37.7 ± 9.4 degrees (range: 25-57 degrees)	37.5 ± 10.8 degrees (range: 21-65 degrees)	0.95
Average follow-up	30.5 ± 14.6 mo (range: 13-73 mo)	24.5 ± 11.5 mo (range 8-61 mo)	0.08

TLSO indicates thoracolumbosacral orthoses.

TABLE 2. Characteristics of 32 Patients With Adolescent Idiopathic Scoliosis Treated With SpineCor Orthosis

Patient	Age (y)	Sex	Initial Curve (degrees)	Final Curve (degrees)	Follow-up (mo)
1	13.9	F	37	36	36.5
2	14.3	M	26	29	16.3
3	14.3	F	27	27	20.3
4	14.2	F	27	27	29.4
5	12.1	F	27	25	27.3
6	15.3	M	25	37	17.5
7	13.9	F	35	47	31.3
8	11.2	F	31	50	28.4
9	11.4	F	25	28	43.2
10	13.1	F	35	57	32.3
11	12.4	F	37	37	14.5
12	11.0	F	37	33	24.0
13	11.2	F	30	43	26.6
14	11.7	F	37	47	33.1
15	15.2	M	38	47	21.2
16	11.8	F	25	30	53.9
17	12.8	F	25	25	37.6
18	13.2	F	36	41	22.2
19	12.4	F	40	55	13.8
20	12.3	F	31	36	13.1
21	12.7	F	25	25	45.5
22	15.2	M	30	43	69.8
23	13.5	F	26	48	31.5
24	13.9	F	37	34	26.4
25	14.7	F	35	35	21.0
26	13.3	F	30	41	23.7
27	11.8	F	26	34	42.7
28	13.9	F	33	27	17.7
29	11.2	F	37	55	27.3
30	13.7	F	26	36	38.6
31	14.9	F	26	31	15.2
32	14.9	F	30	41	72.8

TABLE 3. Characteristics of 35 Patients With Adolescent Idiopathic Scoliosis Treated With Thoracolumbosacral Orthoses

Patient	Age (y)	Sex	Initial Curve (degrees)	Final Curve (degrees)	Follow-up (mo)
1	13.9	F	32	25	15.9
2	14.1	F	38	44	8.0
3	11.1	F	40	39	37.6
4	11.8	F	30	35	22.6
5	13.8	F	29	26	30.1
6	13.9	F	40	44	18.5
7	12.4	F	25	29	22.9
8	13.4	F	37	42	29.5
9	14.4	F	31	38	22.3
10	15.1	F	29	28	23.3
11	12.6	F	40	61	36.1
12	13.2	F	36	45	28.5
13	13.0	M	31	36	35.2
14	12.2	F	30	41	46.5
15	12.7	F	35	41	14.0
16	12.2	F	30	31	23.3
17	12.8	F	36	47	16.3
18	12.1	F	25	21	15.9
19	10.3	F	40	27	61.1
20	12.2	F	37	57	20.7
21	12.6	M	40	46	15.6
22	16.8	M	39	41	18.8
23	13.6	F	34	42	12.4
24	12.9	F	25	28	44.3
25	12.3	F	32	38	21.1
26	13.6	F	26	26	14.4
27	12.6	F	28	28	25.0
28	13.0	F	38	45	26.2
29	11.0	F	28	28	28.9
30	14.4	F	31	30	18.4
31	13.8	F	27	22	20.3
32	15.3	F	32	31	13.6
33	13.4	F	31	36	42.0
34	11.3	F	27	52	16.9
35	10.9	F	37	65	11.5

statistically significant differences were found in the 2 groups or their treatment outcomes. These data conflict with previous reports by independent institutions comparing TLSO and SpineCor.[17,18] Consequently, this study provides the first independent evidence that flexible, dynamic bracing has a role in the nonoperative treatment of AIS.[16]

Weiss and Weiss[17] and Wong et al[18] recently reviewed treatment of AIS with TLSO and SpineCor and found unsatisfying results with SpineCor. Neither study used the SRS standardized criteria. Weiss and Weiss[17] compared 12 SpineCor patients with 15 TLSO patients and showed that the SpineCor patients on average progressed 10 degrees after 21 months of treatment compared with 0.2 degrees for TLSO patients. The groups were not well match controlled and the SpineCor patients began treatment with an average Cobb angle of 21 degrees compared with the TLSO group that started with an average Cobb angle of 33.7 degrees. Wong et al[18] compared 22 SpineCor patients with 21 TLSO patients and showed that only 68% of SpineCor patients maintained curve progression of ≤ 5 degrees at 45 months compared with 95% of TLSO patients maintaining curve

TABLE 4. Success and Failure Rates of 67 Patients After Treatment of Adolescent Idiopathic Scoliosis With SpineCor Versus Thoracolumbosacral Orthoses

	SpineCor	TLSO	*P*
Success ($\leq$5-degree progression)	17/32 (53.1%)	21/35 (60.0%)	0.75
Success (never reached 45 degrees)	23/32 (71.9%)	28/35 (80.0%)	0.62
Failure (surgery before maturity)	1/32 (3.1%)	2/35 (5.7%)	0.64
Failure (surgery after end of treatment)	5/32 (15.6%)	6/35 (17.1%)	0.87
Failure (> 5 degrees, $\geq$45 degrees, or surgery before maturity)	15/32 (46.9%)	20/35 (57.1%)	0.55

TLSO indicates thoracolumbosacral orthoses.

progression of ≤5 degrees at 45 months. These studies contrast with previously published positive reports by the brace's originators[12] who reported 93% success rate at 2 years posttreatment at maintaining ≤5-degree curve progression. These discrepancies in the literature led to the undertaking of the current study.

Our results for TLSO patients compare with previously reported TLSO success rates at preventing curve progression ≤5 degrees and preventing curve from ever reaching 45 degrees.[22–25] Nachemson and Peterson[22] in a nonrandomized cohort study of bracing compared with observation and electrical stimulation found bracing 74% successful compared with observation (34% effective), and electrical stimulation (33% effective) at maintaining ≤5-degree curve progression. This study claimed that bracing alters the natural history of AIS. This claim that bracing alters the natural history of AIS has been questioned recently[4–8] and has given way to a need for randomized clinical trials to evaluate bracing with observation.[26] Two such randomized clinical trials are currently underway: Bracing in Adolescent Idiopathic Scoliosis Trial[27] and Dutch Randomized Controlled Treatment Trial.[28] The results of these trials will be of great importance in the discussion of bracing patients with AIS.

The ability of a bracing regimen to help patients avoid surgical intervention is another end point for SRS standardized criteria in bracing studies. Previous reports comparing bracing to observation have been conflicting with bracing being reported as nearly 4 times as effective in 1 study (7.3% compared with 28%)[29] to being no more effective (23% compared with 22%)[9] than observation. This controversy[30] has led to the question whether bracing has any effect on incidence of surgery. The surgical rates before maturity in this study were low (3% SpineCor and 6% TLSO), but these values increased to 16% and 17%, respectively, after skeletal maturity. No significant difference was found between SpineCor and TLSO surgical rates before maturity ($P = 0.64$) or after maturity ($P = 0.87$).

Whether type of brace can predict quality of life or compliance is another important issue. Several studies have confirmed that brace wearing has minimum effects on self-image[31] or quality of life[32] on adolescents with AIS. In lieu of this, another study showed that the type of brace has a different effect on quality of life, and that in cases of different orthoses having proven similar effectiveness the use of bracing with the lowest impact on quality of life should be recommended.[33] Whether a flexible SpineCor brace that can fit under clothing improves quality of life or compliance has not been evaluated in the literature. Compliance is often overestimated[34] and difficult to objectively determine.[35] Compliance was evaluated retrospectively in this study and unfortunately was only mentioned in 12/32 SpineCor patients and in 8/35 TLSO patients. Of these groups, 5/12 SpineCor patients and 2/8 TLSO patients reported noncompliance.

The main limitations of this study include its relatively small sample size and follow-up period. A power analysis showed that our study had 80% power to detect a large difference (≥35% difference) in bracing effectiveness if one exists between the 2 systems. Our study must only be interpreted within the context of the study design. Electronic Cobb angle measurements were performed by 2 separate authors (S.R.G. and W.C.) and were confirmed by all other authors. Previous reports have established the reproducibility of electronic Cobb angle measurement, but some error is still apparent.[20,21] Additional data were collected from retrospective review of patient information and may be influenced by recall bias.

CONCLUSIONS

We were unable to find any significant differences in the treatment outcomes when comparing TLSO and SpineCor-treated patients. This is the largest study to date using SRS standardized criteria and directly comparing TLSO and SpineCor by an independent institution. Long-term, high-powered outcome studies as well as randomized controlled trials comparing bracing with observation are pending and will ultimately determine the future direction of bracing in AIS.

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