SPINE Volume 30, Number 18, pp 2068–2075
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# Standardization of Criteria for Adolescent Idiopathic Scoliosis Brace Studies

## SRS Committee on Bracing and Nonoperative Management

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**Study Design.** Literature review.

**Objective.** To establish consistent parameters for future adolescent idiopathic scoliosis bracing studies so that valid and reliable comparisons can be made.

**Summary of Background Data.** Current bracing literature lacks consistency for both inclusion criteria and the definitions of brace effectiveness.

**Methods.** A total of 32 brace treatment studies and the current bracing in adolescent idiopathic scoliosis proposal were analyzed to: (1) determine inclusion criteria that will best identify those patients most at risk for progression, (2) determine the most appropriate definitions for bracing effectiveness, and (3) identify additional variables that would provide valuable information.

**Results.** Early brace studies lacked clarity in their inclusion criteria. In more recent studies, inclusion criteria have narrowed considerably to include primarily those patients most at risk for curve progression who may benefit from the use of a brace. Brace effectiveness was usually defined by various degrees of curve progression at maturity. Less frequently, it was defined by the resultant curve magnitude at maturity, whether or not surgical intervention was needed, or if there was change to another brace.

**Conclusions.** Optimal inclusion criteria for future adolescent idiopathic scoliosis brace studies consist of: age is 10 years or older when brace is prescribed, Risser 0–2, primary curve angles 25°–40°, no prior treatment, and, if female, either premenarchal or less than 1 year postmenarchal. Assessment of brace effectiveness should include: (1) the percentage of patients who have ≤5° curve progression and the percentage of patients who have ≥6° progression at maturity, (2) the percentage of patients with curves exceeding 45° at maturity and the percentage who have had surgery recommended/undertaken, and (3) 2-year follow-up beyond maturity to determine the percentage of patients who subsequently undergo surgery. All patients, regardless of subjective reports on compliance, should be included in the results (intent to treat). Every study should provide results stratified by curve type and size grouping.

**Key words:** scoliosis, bracing, nonoperative treatment. **Spine 2005;30:2068–2075**

Brace treatment has been used for the nonoperative treatment of adolescent idiopathic scoliosis (AIS) for nearly 45 years. During this period, there have been numerous studies in the literature that summarize the results of treatment.[1–35] Many of these reports support the effectiveness of an orthosis in preventing curve progression and the need for surgical intervention.[1–4,7–10,13–15,17–24,26–30,32–35] However, there are other studies that suggest bracing may not be effective.[6,11,12,16,25,31] A review of the literature on the effectiveness of an orthosis for AIS shows that inclusion criteria vary greatly from one study to the next. The age range, inclusion of both males and females, Risser sign, curve magnitude, and lack of stratification of results regarding curve pattern, curve size, and maturity can be quite different, which makes comparisons among studies difficult. These studies are summarized in Table 1.

As a greater understanding of the natural history of AIS has been gained, patients who are most at risk for curve progression have been better identified.[36–42] Subsequently, reports over the past decade have improved, primarily through the exclusion of patients who are known to have a low risk for progression. Patients who were skeletally mature at orthotic initiation, those with curves so small that progression was unlikely, those who had curves so large that nonoperative treatment would be ineffective, those who have had prior treatments, and nonidiopathic (such as congenital or neuromuscular deformities) should be excluded. Unfortunately, more recent studies still differ significantly among their inclusion criteria, thus making comparisons difficult.

Furthermore, there has been even less uniformity among the studies in defining what represents a success or failure of orthotic treatment. Some studies consider treatment a success only if curve progression does not exceed 5° by the time patients reach skeletal maturity. For others, it is less than 10°. Still others consider orthotic treatment successful if the curve is less than 45° at skeletal maturity, or if surgery was not necessary regardless of the amount of curve progression. This variation in

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Acknowledgment date: October 13, 2004. First revision date: December 30, 2004. Second revision date: February 15, 2005. Acceptance date: February 15, 2005.

The manuscript submitted does not contain information about medical device(s)/drug(s).

No funds were received in support of this work. No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this manuscript.

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**Table 1. Inclusion Criteria at Brace Prescription**

| Investigators | No. Patients | Idiopathic Only | Age at Brace Initiation | Risser | Curve Size | No Prior RX (documented) | Gender | Type of Brace |
|---|---|---|---|---|---|---|---|---|
| Moe and Kettleson[22] | 169 | Yes | Infantile thru adolescence | From 0 to "capped" | <20°–>70° | | Mixed | Milwaukee |
| Mellencamp *et al*[21] | 47 | Yes | 9.5–17.5 | | 17°–75° | | Mixed | Milwaukee |
| Carr *et al*[2] | 133 | Yes | 10.0–16.2 | | 12°–68° | | Mixed | Milwaukee |
| McCollough *et al*[20] | 100 | No* | 3–17 | | <20°–>40° | | Mixed | Miami TLSO |
| Emans *et al*[7] | 295 | Yes | 4–18 | 0–4 | 20°–59° | | Mixed | Boston |
| Green[13] | 44 | Yes | 9.7–15 | 0–2 | 23°–49° | | Mixed | Boston/Milwaukee |
| Hanks *et al*[14] | 100 | Yes | 7.5–15.0 | 0–>2 | <20°–>40° | | Female | Wilmington |
| Peltonen *et al*[27] | 162 | Yes | 10–17 | | 25°–40° | | Mixed | Boston |
| Montgomery and Willner[23] | 244 | Yes | | 0–3 | >25° | | Female | Boston/Milwaukee |
| Piazza and Bassett[28] | 67 | Yes | 9.4–14.9 | 0–1 | 20°–39° | | Mixed | Wilmington |
| Willers *et al*[35] | 25 | Yes | 8–16 | | 20°–55° | | Mixed | Boston |
| Goldberg *et al*[11] | 42 | Yes | 11.9–15 | 0 | 15°–35° | | Female | Boston |
| Lonstein and Winter[19] | 1020 | Yes | 10–17 | 0–>2 | 8°–82° | No Rx | Mixed | Milwaukee |
| Olafsson *et al*[26] | 64 | Yes | 9.8–17.2 | 0–>2 | 22°–44° | No Rx | Mixed | Boston |
| Fernandez-Feliberti *et al*[8] | 69 | Yes | 8–15 | | 20°–42° | No Rx | Mixed | TLSO |
| Nachemson *et al*[24] | 286 | Yes | 10–15 | 0–>2 | 25°–35° | | Female | TLSO |
| Upadhyay *et al*[33] | 85 | Yes | 8–15 | 0–3 | 20°–45° | | Mixed | Milwaukee/TLSO |
| Allington and Bowen[1] | 188 | Yes | ≥9 | 0, 1 | 10°–40° | | Mixed | Wilmington |
| Noonan *et al*[25] | 102 | Yes | ? | 0–3 | ≤45° | | Mixed | Milwaukee |
| Price *et al*[29] | 98 | Yes | 10–14.7 | 0–2 | 25°–49° | No Rx | Mixed | Charleston |
| Katz *et al*[17] | 319 | Yes | 10.2–16.9 | 0–2 | 25°–45° | No Rx | Mixed | Boston/Charleston |
| Howard *et al*[15] | 170 | Yes | ≥10 | 0–4 | 19°–66° | No Rx | Mixed | TLSO/Milwaukee/Charleston |
| Wiley *et al*[34] | 50 | Yes | 10–16 | 0–2 | 35°–45° | No Rx | Mixed | Boston |
| Karol[16] | 112 | Yes | 10.6–16.9 | 0–3 | 18°–45° | No Rx | Male only | Milwaukee/Charleston/Boston |
| Katz and Durrani[18] | 51 | Yes | ≥10 | 0–2 | 36°–45° | No Rx | Mixed | Boston |
| d'Amato *et al*[4] | 102 | Yes | 10–16.5 | 0–2 | 20°–42° | | Female | Providence |
| Danielsson and Nachemson[5] | 127 | Yes | 10.9–18.4 | | 12°–60° | | Mixed | Milwaukee/Boston |
| Trivedi and Thomson[32] | 42 | Yes | 10–15.1 | 0, 1 | 25°–40° | No Rx | Female | Charleston |
| Gepstein *et al*[10] | 122 | Yes | 10–16 | 0–4 | <25°–>39° | | Mixed | Charleston/Boston |
| Coillard *et al*[3] | 195 | Yes | 6–14 | 0–3 | 15°–50° | | Mixed | SpineCor |
| Spoonamore *et al*[31] | 71 | Yes | 10–16 | 0–3 | 25°–45° | | Mixed | Rosenberger |
| Gabos *et al*[9] | 55 | Yes | ≥10 | 0, 1 | 20°–45° | | Female | Wilmington |
| Weinstein *et al* (written communication, August 2004) | | Yes | 10–15 | 0–2 | 25°–39° | | Mixed | |

*Included 3 congenital and 4 neuromuscular.
RX = prescription; TLSO = thoracolumbosacral orthosis.

the definition of success used to judge orthotic effectiveness makes it nearly impossible to compare the results of treatment. These differences that exist among studies emphasize the need to adopt consistent parameters for future brace studies. As yet, previous efforts to fulfill this need have not had much impact toward improving consistency in the literature.[30]

The purposes of our study are to define consistent parameters for inclusion criteria for orthotic treatment of patients with AIS and to define consistent parameters to assess the effectiveness (outcomes) of treatment. These parameters could then serve as guidelines for all future AIS bracing studies to make comparisons among studies more valid and reliable. It is not the intention of this study to determine the efficacy of orthotic treatment for AIS.

## ■ Materials and Methods

Natural history studies on skeletally immature patients with AIS were reviewed to identify the patient population most at risk for curve progression and those who are at relatively low risk for progression.[36–42] We identified 32 retrospective or prospective brace treatment studies and the current BrAIST study, which is a proposal by Weinstein *et al* (written communication, August 2004) for a randomized, prospective multicenter trial for bracing AIS *versus* no treatment.[1–5,7–11,13–29,31–35] To identify these studies, a MEDLINE search was performed using the key words "scoliosis," "brace," "orthosis," and "nonoperative treatment." To be included, the studies had to contain specific descriptions of their inclusion criteria. References from these pertinent articles were then examined to identify further relevant studies. The treatment inclusion criteria for each study were then recorded, including diagnoses, age range, gender, Ris-

**Table 2. Risk of Curve Progression Relative to Age***

| | Curve Magnitude | |
|---|---|---|
| Age (yrs) | 5°−19° | 20°−29° |
| ≤10 | 45% | 100% |
| 11−12 | 23% | 61% |
| 13−14 | 8% | 37% |
| ≥15 | 4% | 16% |

Risk of curve progression >5° for chronologic age relative to curve magnitude.
*Adapted with permission from *J Bone Joint Surg Br.*[39]

**Table 4. Risk of Curve Progression Relative to Skeletal Maturity**

| | Curve Magnitude | |
|---|---|---|
| Risser Sign | 5°−19° | 20°−29° |
| 0−1 | 22% | 68% |
| 2, 3, 4 | 1.6% | 23% |

Risk of curve progression >5° for skeletal maturity relative to curve magnitude.
*Adapted with permission from *J Bone Joint Surg Br.*[39]

ser sign, curve magnitude, curve patterns, type of orthosis, and recommended wear schedule. The definitions of orthotic success or failure were recorded as well as whether orthotic effectiveness was determined at skeletal maturity or at latest follow-up. Additional variables were recorded if they appeared to provide useful information. The aforementioned data were used to formulate recommendations for inclusion and exclusion criteria for future studies on the orthotic treatment of AIS.

## Results

### Patients Most at Risk for Curve Progression

Most natural history studies that have examined curve progression involved females, primarily with thoracic curves. These patients' ages and initial curve magnitudes were factors closely related to the likelihood of curve progression (Tables 2, 3). Those patients with curves between 20° and 29° were significantly more likely to have more than 5° curve progression when compared with those in similar age groups with curves 5°−19°. This result was particularly true for younger females. Skeletal maturity, as determined by the Risser sign, was also important when considering the risk of curve progression. The likelihood of more than 5° progression is significantly higher for those patients who are skeletally immature (Table 4).

### Inclusion Criteria

The inclusion criteria in early studies were inconsistent and characterized by wide variations in patient's age at orthotic initiation, curve magnitude, and skeletal maturity (Table 1). Frequently, data were included from patients now known to be at low risk for curve progression or who were already beyond the point when surgery is now commonly recommended. Patient ages ranged from 4 to nearly 19 years, and those with advanced skeletal maturity (Risser sign 3 and 4) and curves as small as 12° or as large as 68° were included in the data.

**Table 3. Risk of Curve Progression Relative to Age***

| | Age (yrs) | | |
|---|---|---|---|
| Curve Magnitude | 10−12 | 13−15 | ≥16 |
| <19° | 25% | 10% | 0% |
| 20°−29° | 60% | 40% | 10% |
| 30°−59° | 90% | 70% | 30% |
| >60° | 100% | 90% | 70% |

Risk of curve progression >5° for chronologic age relative to curve magnitude.
*Adapted with permission from Nachemson *et al.*[43]

In more recent studies, inclusion criteria for patients considered brace candidates have become more consistent. Most patients are 10 years of age or older at brace initiation (fitting with the definition of AIS). Most patients are those who are most at risk for progression (*i.e.*, skeletally immature with Risser sign of 0, 1, or 2), although some recent reports still included more skeletally mature patients (Risser 3). The majority of studies include patients whose curve magnitudes were in the range of 20° to 45°. Of these, curves 20°−25° usually had documentation of progression. Nevertheless, during the last decade, some studies have still included curves as small as 10° or as large as 66°.

Although most reports include both females and males, the number of male patients generally has represented a small percentage of the patients. In a study by Karol[16] that reported on males only, bracing was found ineffective as a result, in part, of their increased curve stiffness and consistently poor brace compliance. Several reports have limited their population studies to females, avoiding any potentially confounding data introduced by the inclusion of male patients.[4,9,11,14,23,24,32]

Many studies specifically showed that there had been no previous treatment before initiation of the orthoses in their patients.[8,15–19,26,29,32,34] This factor is important because previous treatment could impact the patient's willingness to wear an orthosis or may have impacted the size and flexibility of the curve before the reporting. Only one report, from 1981, included patients with diagnoses other than idiopathic scoliosis.[20] All others were limited to idiopathic scoliosis.

### Definitions of Brace Effectiveness

Most commonly, orthotic effectiveness has been defined by the amount of curve progression that occurred up to the time of brace discontinuation (at skeletal maturity) (Table 5). Occasionally, effectiveness has been determined by the amount of curve progression that has occurred until the time of most recent followup, this usually being 1−3 years beyond skeletal maturity. The most frequent definition of bracing success was 5° or less curve progression at orthotic discontinuation (skeletal maturity). Conversely, if a curve progressed 6° or more, bracing was considered a failure. Less frequently, other studies have considered 10° or less curve progression to be

**Table 5. Outcome of Brace Effectiveness**

| Investigators | Definition of Brace Effectiveness: Success | Definition of Brace Effectiveness: Failure | Definition of Maturity (brace discontinued/ weaned at this time) | Noncompliant Patients | Average f/u After Maturity (when brace was discontinued) |
|---|---|---|---|---|---|
| Moe and Kettleson[22] | Not defined | | Bone age, Risser sign, height, menarche | | |
| Mellencamp *et al*[21] | Not defined | | | | >5 yrs |
| Carr *et al*[2] | Not defined | | | Excluded | 8 yrs |
| McCollough *et al*[20] | Not defined | | 2 yrs after menarchal | | None |
| Emans *et al*[7] | ≤5° Progression | ≥6° Progression | Cessation of growth, Risser 4 or 5 | | 1.4 yrs |
| Green[13] | <5° Progression | ≥5° Progression | Bone age, Risser 4 | | 1.8 yrs |
| Hanks *et al*[14] | <10° Progression | ≥10° Progression | Risser 4 | Included | 3.3 yrs |
| Peltonen *et al*[27] | ≤5° Progression | ≥6° Progression | "When growth stopped" | | None |
| Montgomery and Willner[23] | <45° Curve | Progression of curve to >45° | Risser 4+ | | None |
| Piazza and Bassett[28] | <40° Curve | >40° Curve with ≥5° progression <u>or</u> surgery | | | 5–13 yrs |
| Willers *et al*[35] | Not defined | | 2 yrs after menarchal | Excluded | 8.5 yrs |
| Goldberg *et al*[11] | <10° Progression <45° curve size No surgery | ≥10° Progression <u>or</u> <u>≥</u>45° curve size <u>or</u> need for surgery | | | None |
| Lonstein and Winter[19] | <5° Progression | ≥5° Progression <u>or</u> surgery2 | No change in height on consecutive visits; Risser 4 or 5; 18 mos after menarchal | | 6 yrs (54% patients) |
| Olafsson *et al*[26] | Not defined | | Risser 4 or bone age | | 4.8 yrs |
| Fernandez-Feliberti *et al*[8] | <40° Curve | ≥40° Curve at end of Rx <u>or</u> surgery | | Excluded | 3.3 yrs |
| Nachemson *et al*[24] | ≤5° Progression | ≥6° Progression | Bone age | | None |
| Upadhyay *et al*[33] | ≤45° Curve <u>and</u> within 5° of the prebrace curve | ≥6° Progression <u>or</u> surgery | Bone age or Risser | | >2 yrs |
| Allington and Bowen[1] | <5° Progression | ≥5° Progression | Risser 4 and 2 yrs after menarchal (boys: Risser 5) | | 1.5 yrs |
| Noonan *et al*[25] | (1) <5° Progression by maturity, (2) no surgery, (3) <10° progression at f/u | (1) ≥5° Progression by maturity, (2) surgery or 50° curve at f/u, (3) ≥10° progression at f/u | | | 6.3 yrs |
| Price *et al*[29] | ≤5° Progression at end of treatment | **Failures:** good->5° but ≤10°; fair->10° but no surgery or Δ brace; poor-surgery or Δ brace | | Included | 1.1 yrs |
| Katz *et al*[17] | ≤5° Progression at end of Rx | ≥6° Progression curve <u>or</u> surgery (subset) | "Skeletal maturity" | Included | 1.6 yrs |
| Howard *et al*[15] | | >6° Progression or >10° progression or surgery | Risser 4+ | | 1.5 yrs |
| Wiley *et al*[34] | ≤5° Progression | ≥6° Progression <u>or</u> need for surgery | Risser 4–5 | | 3.1 yrs |
| Karol[16] | ≤5° Progression | ≥6° Progression <u>or</u> curve size ≥50°/ surgery | | Included | 1.2 yrs |
| Katz and Durrani[18] | ≤5° Progression | ≥6° Progression <u>or</u> surgery (subset) | "Skeletal maturity" | | 2.7 yrs |
| d'Amato *et al*[4] | ≤5° Progression | ≥6° Progression (at f/u) <u>or</u> surgery performed | No growth at 2 consecutive visits 6 mos apart; Risser 4; 18 mos after menarchal | Included | 2.6 yrs |
| Danielsson and Nachemson[5] | Not Defined | | Risser 4 | | 22 yrs |
| Trivedi and Thomson[32] | ≤5° Progression at f/u | ≥6° Progression <u>or</u> surgery necessary <u>or</u> changed brace | Risser 4 or no change in height over 2 consecutive visits 6 mos apart | Included | 3 yrs |
| Gepstein *et al*[10] | ≤5° progression by maturity | ≥6° progression <u>or</u> surgery | | | 1.9 yrs |

(*Table Continues*)

**Table 5. Continued**

| Investigators | Definition of Brace Effectiveness: Success | Definition of Brace Effectiveness: Failure | Definition of Maturity (brace discontinued/ weaned at this time) | Noncompliant Patients | Average f/u After Maturity (when brace was discontinued) |
|---|---|---|---|---|---|
| Coillard *et al*[3] | ≤5° Progression | ≥6° Progression | "Skeletal maturity" or 2 yrs after menarchal | Excluded | 2 yrs |
| Spoonamore *et al*[31] | (1) <5° Progression by maturity, (2) no surgery, (3) <10° progression at f/u | (1) ≥5° Progression by maturity, (2) surgery or 50° at f/u, (3) ≥10° progression at f/u | Risser 4 | | 2.3 yrs |
| Gabos *et al*[9] | | ≥5° Progression from time that brace was discontinued to f/u | Risser 4−5 | "Documented compliance" | 14.6 yrs |
| Weinstein *et al* (written communication, August 2004) | <45° Curve size | ≥45° Curve size | Maturity–cessation of growth in height (over 12 mos) | | No |

f/u = follow-up.

the threshold for success/failure. Most often, braces were discontinued, or the weaning process was begun, when the patients reached skeletal maturity. Maturity was defined in a variety of ways. Most commonly, radiographic parameters were used, such as the Risser sign 4 or "4+" (females) or 5 (males), or by bone age determined from wrist radiographs using the Gruelich and Pyle Atlas. Physiologic parameters were also used, but less frequently. If patients had either no change or <1 cm change in their standing height over 2 consecutive visits 6 months apart, they were considered mature. In females, maturity was considered achieved if the patient was either 18 months postmenarchal or 2 years postmenarchal. The median values of these maturity indicators (*i.e.*, Risser sign 4, <1 cm change in height, and 2 years postmenarchal) are closely related.[44]

Other parameters have also been used to assess the effectiveness of orthotic treatment. Instead of using skeletal maturity as the end-point for assessment, some studies examined the amount of curve progression that had occurred at latest follow-up, usually 1−3 years after skeletal maturity. Although it is obvious that curves would have a higher tendency to increase over this interval, the same thresholds defining brace failures were used (≥6° or ≥10° curve progression).

Still, other definitions of brace failure have been used. These definitions are not based on the degree of curve progression that may have occurred during treatment but rather focus on the magnitude that the curve has reached. Some investigators defined failure as the progression of a curve to a magnitude exceeding 45° either before or at skeletal maturity. This was considered the threshold when surgery is recommended. However, many patients do not undergo surgery at this point, and, for this reason, some studies considered an orthosis to have failed only when surgery was recommended or undergone.

Two studies have combined several of these parameters used to assess brace effectiveness.[25,31] They assessed the percentage of patients who had a progression of 5° or more by skeletal maturity, the percentage who had undergone surgery or had curves 50° or higher at the latest followup, and the percentage who had 10° or more progression by the latest followup. The data were then combined, and the resulting summation was used to report on the effectiveness of orthotic treatment. Obviously, as more parameters are combined in studies, an orthosis will be appear less effective when compared to reports using single parameters.

### *Additional Useful Variables*

Many studies reported on additional variables, many of which appeared to provide useful comparative information (Table 6). The data were often analyzed separately by curve pattern (thoracic only, thoracolumbar/lumbar, double curves), curve magnitude grouping (*i.e.*, 20°−29°, 25°−35°, 30°−39°, 35°−45°, and ≥40°), curve rotation, menarchal status, in-brace correction, and comparisons among Risser signs 0, 1, and 2 skeletal maturity. Only one study documented peak height velocity data.[18]

## ■ Discussion

Over the past 15 years, there have been numerous studies on the orthotic treatment of AIS. In addition to reports on the more established orthoses, such as the Milwaukee brace, Boston brace, Wilmington brace, and Charleston bending brace, newer orthoses, such as the Providence brace, SpineCor brace (The SpineCorporation Ltd., Chesterfield, UK) and Rosenberger brace, are being de-

**Table 6. Documentation of Potentially Useful Additional Variables**

| | | Stratifications | | | | |
|---|---|---|---|---|---|---|
| Investigators | Curve Patterns | Curve Magnitude Grouping (*i.e.*, 25–35, 36–45, 20–29, 30–39, >40) | Comparisons Among Risser Signs 0, 1, and ≥2 | In-Brace Correction (curve flexibility) | Curve Rotation (measured by Nash-Moe, Perdriolle, both, or other methods) | Menarchal Status |
| Moe and Kettleson[22] | Yes | Yes | No | Yes | No | No |
| Mellencamp *et al*[21] | No | No | No | Yes | No | No |
| Carr *et al*[2] | Yes | Yes | No | Yes | No | No |
| McCollough *et al*[20] | Yes | No | No | Yes | No | No |
| Emans *et al*[7] | Yes | Yes | No | Yes | Yes | No |
| Green[13] | Yes | No | No | No | No | No |
| Hanks *et al*[14] | Yes | Yes | No | Yes | No | Yes |
| Peltonen *et al*[27] | Yes | No | No | Yes | Yes | No |
| Montgomery and Willner[23] | Yes | Yes | No | No | No | Yes |
| Piazza and Bassett[28] | Yes | Yes | No | No | No | No |
| Willers *et al*[35] | Yes | No | No | Yes | Yes | No |
| Goldberg *et al*[11] | Yes | No | No | No | No | Yes |
| Lonstein and Winter[19] | Yes | Yes | Yes | Yes | Yes | No |
| Olafsson *et al*[26] | Yes | No | No | Yes | Yes | Yes |
| Fernandez-Feliberti *et al*[8] | Yes | No | No | No | No | No |
| Nachemson *et al*[24] | Yes | Yes | No | No | Yes | Yes |
| Upadhyay *et al*[33] | Yes | Yes | No | No | Yes | Yes |
| Allington and Bowen[1] | Yes | Yes | No | Yes | No | No |
| Noonan *et al*[25] | Yes | No | No | Yes | Yes | Yes |
| Price *et al*[29] | Yes | Yes | Yes | Yes | No | No |
| Katz *et al*[17] | Yes | Yes | Yes | Yes | No | No |
| Howard *et al*[15] | Yes | Yes | Yes | No | No | No |
| Wiley *et al*[34] | Yes | Yes | Yes | Yes | Yes | Yes |
| Karol[16] | Yes | Yes | Yes | Yes | No | N/A |
| Katz and Durrani[18] | Yes | Yes | Yes | Yes | Yes | Yes |
| d'Amato *et al*[4] | Yes | Yes | Yes | Yes | No | Yes |
| Danielsson and Nachemson[5] | Yes | No | No | Yes | No | Yes |
| Trivedi and Thomson[32] | Yes | Yes | No | Yes | No | No |
| Gepstein *et al*[10] | Yes | Yes | No | Yes | No | No |
| Coillard *et al*[3] | Yes | Yes | No | Yes | No | No |
| Spoonamore *et al*[31] | Yes | Yes | Yes | Yes | Yes | Yes |
| Gabos *et al*[9] | Yes | No | No | No | No | No |

veloped, tested, and reported on by various centers. To assess the effectiveness of each orthosis and how it may compare to other orthoses available to patients with scoliosis, the need for consistent study parameters is obvious. A review of Tables 1 and 5 confirms the importance of using more consistent parameters for both patient inclusion criteria and the assessment of the effectiveness of orthotic treatment (outcomes).

Fortunately, in the more recent literature there has been a trend toward including only patients who have completed treatment and who are now known to have a significant risk for curve progression if not treated. Based on this evolution and an appreciation of the risk of progression as determined from observations of untreated patients, this committee proposes the following guidelines for future studies of orthotic treatment for AIS. We believe that until more is known about AIS and the methods to predict curve progression, such as genetic or laboratory testing, adherence to the following recommendations will facilitate our interpretation of future clinical studies.

1. A stringent, uniform criteria for patient inclusion in bracing studies must be established. Optimal inclusion criteria for future AIS brace studies consist of age 10 years and older when the orthosis is prescribed, Risser 0–2, primary curve magnitude 25°–40°, no prior treatment, and, if female, either premenarchal or less than 1 year postmenarchal. The fact that some patients begin bracing shortly after they reach the age of 10 years signifies that they likely may have been noted to have scoliosis before age 10. An example of this would be a child who presents at age 7 years with a 15° curve but is not braced until 10 years of age. Such instances emphasize the need to include documentation of the patient's age when first diagnosed to categorize properly between juvenile and adolescent scoliosis. Menarchal status, curve patterns, and curve rotation should be recorded. Curve rotation can be measured using either the Nash-Moe method or the Perdriolle method, as both are reported in the orthotic literature. A template is required for Perdriolle measurements.
2. Assessment of brace effectiveness should include all of the following:
   a. The percentage of patients who have 5° or less curve progression and the percentage of pa-

tients who have 6° or more progression at skeletal maturity.

b. The percentage of patients who have had surgery recommended/undergone before skeletal maturity (*i.e.*, the time when the orthosis would normally have been discontinued). The surgical indications must be documented.

c. The percentage of patients who progress beyond 45°, indicating the possible need for surgery.

d. A minimum 2-year follow-up beyond skeletal maturity for each patient who was "successfully" treated with a brace to determine the percentage of patients who subsequently required or had surgery recommended. The surgical indications must be documented.

Efforts must be made to minimize radiographic measurement errors. Whenever possible, one observer familiar with scoliosis should make all the measurements using the same protractor. The importance of this process is clearly recognized when taking the first parameter, listed previously (2a), under consideration. Despite concerns about the accuracy of such measurements,[45,46] most investigators over the past decade have continued to use this parameter in their assessment of brace effectiveness.

3. Skeletal maturity should be considered achieved when <1 cm change in standing height has occurred on measurements made on 2 consecutive visits 6 months apart. If standing height measurements have not been obtained, skeletal maturity will be considered achieved when Risser 4 is present and, in females, when the patient is 2 years after menarche.
4. All patients, regardless of subjective reports on compliance, should be included in the results. This process makes "intent to treat" analysis possible (*i.e.*, all noncompliant patients who were supposed to be treated have their curve progression documented over the same time and are included in the results as if they were compliant with bracing). An "efficacy analysis," in which those noncompliant patients can be pulled out of the results to document the efficacy of the brace in those patients able to comply, should also be considered. For compliance data to be considered completely valid, it should be measured objectively.[47] Currently, the data loggers required to obtain these objective measurements are used as research tools. In the future, when temperature data loggers and pressure data loggers can be economically fabricated into orthoses, then objective evidence of compliance will be routinely available.
5. All studies should provide results stratified by curve type, curve magnitude grouping, and skeletal maturity (comparing Risser signs 0, 1, and 2) (Table 6). Subgroup analysis of these variables will strengthen the ability to compare and combine results across studies.
6. Consideration should be given to including functional and psychosocial outcome parameters in future brace studies. Only 2 of the 32 articles in this study addressed this issue, both of which were long-term follow-up studies.[5,9] A recommendation has been made to include the Child Health Questionnaire, the Self-image Questionnaire for Young Adolescents, and the PedsQL (Weinstein *et al* written communication, August 2004).

## ■ Key Points

• Optimal inclusion criteria for brace studies consist of: age is 10 years or older when the brace is prescribed, Risser 0–2, curves 25°–40°, and no prior treatment.
• Outcomes should be determined from: (1) the percentage of patients who have ≤5° curve progression and the percentage of patients who have ≥6° progression at maturity, (2) the percentage of patients with curves exceeding 45° at maturity and the percentage who have had surgery recommendation/undergone, and (3) 2-year follow-up beyond maturity to determine the percentage of patients who subsequently undergo surgery.
• All patients, regardless of subjective reports on compliance, should be included in the results (intent to treat).

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