



Patient-Reported Outcome Instruments in Pediatric Deformity Surgery: A Bibliometric Analysis

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Received 15 July 2014; revised 20 August 2014; accepted 25 August 2014

Abstract

Study Design: Bibliometric analysis.

Objectives: To identify patient-reported outcomes instruments (PROIs) used in pediatric deformity surgery research over the past decade and their frequency and usage trends.

Summary of Background Data: The emphasis on PROIs is increasing along with the demand for evidence-based medicine and cost-effectiveness research. Therefore, investigators and PROI consensus writers should be aware of the PROIs used in pediatric deformity and usage trends.

Methods: Five top orthopedics journals were reviewed from 2004 to 2013 for clinical studies of surgical intervention in pediatric deformity that report PROIs. Publication year, level of evidence (LOE), and PROIs were reported for each article. Mean and range scores for the most frequently used PROIs were analyzed at 2-year follow-up.

Results: A total of 79 studies using PROIs were published in the pediatric deformity literature over the period studied. The researchers identified 21 named PROIs and 6 additional custom questionnaires. The Scoliosis Research Society (SRS)-22 was the most frequently used instrument (32.9%), followed by the SRS-24 (29.1%), Oswestry disability index (17.7%), visual analog scale (12.7%), SRS-30 (10.1%), and Short Form-36 (6.3%). Level of evidence III was most common (39.2%) and 1 LOE I study was identified. Mean preoperative and postoperative SRS instrument scores were 4.0 (95% confidence interval, 3.8–4.1) and 4.5 (95% confidence interval, 4.4–4.6), respectively, in SRS-22r equivalents. No studies met the criteria for mean and range calculation for the other top instruments.

Conclusions: Scoliosis Research Society instruments are used in 74.7% of pediatric deformity studies reporting PROIs. Therefore, there is a consensus that SRS instruments should be used in pediatric deformity outcome studies; yet, consistent use of the most up-to-date version, the SRS-22r, is still needed. General health questionnaires are currently underused in pediatric deformity research. Version reporting and use of the latest versions of PROIs need to be improved in future studies.

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Keywords: Patient-reported outcomes; Pediatric spinal deformity; SRS questionnaire; Quality of life

Introduction

Recently, interest in patient-reported outcome instruments (PROIs) has grown considerably in medicine. As investigators incorporate PROIs in their studies more frequently, the number of unique PROIs appearing in the literature also has increased. It is generally accepted that the Scoliosis Research Society (SRS) questionnaires are the most common

instruments among pediatric deformity studies; yet, their frequency of use has not been measured or compared with other commonly used instruments. Moreover, the frequency of use of the 4 versions of the SRS—the SRS-24, 23, 22, and 22r—is not known.

Children with spinal deformity are unique in that often they do not have pain or significant functional disability, which are the main points of interest when PROIs are used in spine patients. For example, outcomes of patients treated for degenerative lumbar conditions are commonly measured with the Oswestry disability index (ODI) for pain and functional limitation or the visual analog scale (VAS) for back and leg pain. By contrast, newly developed instruments in pediatric deformity have focused on body image (Spinal

Author disclosures: HSC (none); JZG (none); JC (none); MAM (none); AKA (none); SKC (none).

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Appearance Questionnaire [1] and Trunk Appearance Perception Scale [2]) and the psychological impacts of body image concerns (Body Image Disturbance Questionnaire [3]). To provide a foundation for consensus building and standardization of PROI use in pediatric spinal deformity research, the current authors conducted a bibliometric analysis of the spine literature over the past 10 years, identifying the most frequently used PROIs, trends in their use, and reporting methods.

Methods

Five top orthopedics journals (*Journal of Bone and Joint Surgery, Bone and Joint Journal, Spine Journal, Spine, and European Spine Journal*) that are read for information on spine surgery were identified by readership and impact factor. The titles of all clinical articles published in these journals over the past 10 years (2004–2013) were screened on PubMed. If the title referred to a clinical study of a surgical intervention in which outcomes were measured by a PROI, the article was included for analysis (Fig. 1). If the inclusion criteria could not be assessed from the title, the abstract was reviewed. Review articles were excluded. For included articles, the variables recorded were title, author, year, level of evidence (LOE), sample size, general diagnosis, and PROIs used. Level of evidence was assigned according to the definitions provided by the Oxford Center for Evidence-Based Medicine [4]. Only articles with LOE I to IV were included in this study; any LOE V articles were excluded.

This study included articles with the general diagnosis of pediatric spinal deformity, which included specific diagnoses of adolescent idiopathic scoliosis (AIS), early-onset scoliosis, congenital scoliosis, Scheuermann kyphosis, congenital

Table 1

Mean and range calculation exclusions.

Articles excluded for:
1. Not reporting numerical data (eg, graphical or statistical reporting of PROI scores)
2. Reporting only change in scores without preoperative or postoperative scores
3. Failing to report preoperative or postoperative scores
4. Significantly modifying a standard PROI
5. Reporting only domain or component scores rather than total score for a PROI

PROI, patient-reported outcome instrument.

kyphosis, congenital kyphoscoliosis, adolescent kyphoscoliosis, acquired kyphoscoliotic deformity, proximal junction kyphosis, and isthmic spondylolisthesis. Trends in PROI usage, number of PROI studies published by journal, and frequency of each LOE were reported.

The researchers identified the 3 most frequently used PROIs and analyzed articles using these measures for mean preoperative and mean 2-year postoperative scores. Only studies with complete preoperative and postoperative data were included. A 2-year minimum follow-up was chosen because it was most common and therefore yielded the largest sample size for the mean score analysis. Weighted average scores were calculated by weighting individual study scores by the sample size of the study. Studies that reported data for 4 or more treatment groups without overall averages were excluded. In addition, articles were excluded from the mean and range analysis for 1 or more of the reasons listed in Table 1. These articles were included in all other analyses of trends in PROI use.

Data analysis

Data were recorded and analyzed in Microsoft Excel 2011. The analysis included counts of articles by type, weighted averages of preoperative and postoperative means, and calculation of the 95% confidence interval (CI) of mean PROI scores.

Results

From 2004 to 2013, *Spine, European Spine Journal, Spine Journal, Journal of Bone and Joint Surgery American Volume, and Journal of Bone and Joint Surgery British Volume* published 19,736 articles. (In September 2011, *Journal of Bone and Joint Surgery British Volume* changed its name to *Bone and Joint Journal*. For convenience, articles from both journals are reported under *Journal of Bone and Joint Surgery British Volume* in this study.) The authors identified 1,079 clinical studies of surgical interventions that made use of 1 or more PROI. Of these, 79 articles focused on pediatric deformity surgery research. Yearly PROI use over the past 10 years did not show a consistent upward trend; however, an overall increase from 3 studies published in 2004 to 12 in 2013 is evident (Fig. 2). *Spine* published the most studies using PROIs, with 44 (55.7%) of the 79 total articles in this study (Fig. 3). Within

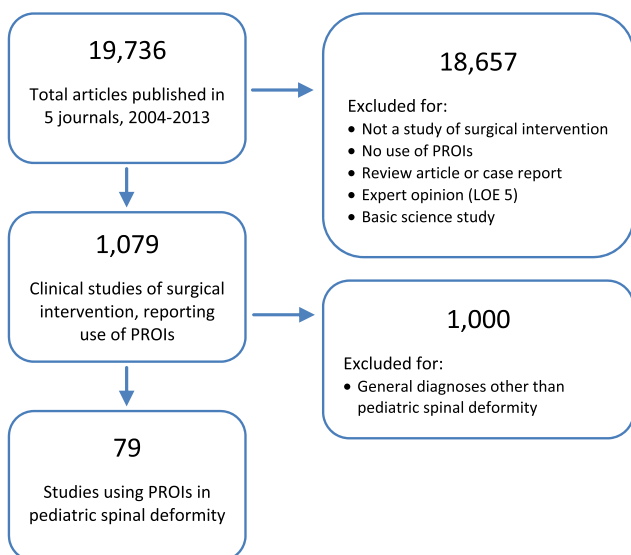


Fig. 1. Flow diagram depicting literature search strategy used to screen and identify clinical studies of surgical interventions in pediatric spinal deformity that report use of patient-reported outcomes instruments (PROIs). LOE, level of evidence.

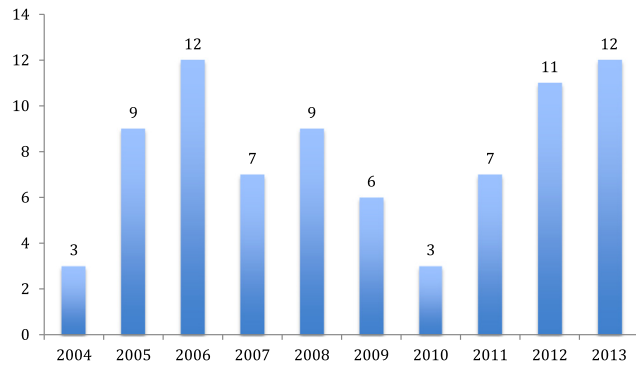


Fig. 2. Number of patient-reported outcome instruments used per year.

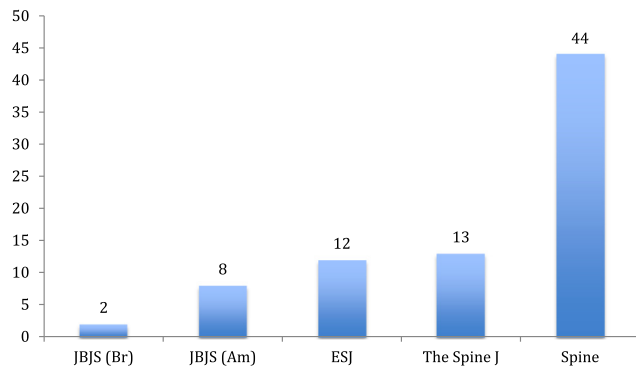


Fig. 3. Number of patient-reported outcome instruments used by journal. JBJS, *Journal of Bone and Joint Surgery*; ESJ, *European Spine Journal*.

pediatric deformity, AIS was the most commonly studied specific diagnosis ($n = 55$), followed by spondylolisthesis ($n = 10$) and kyphosis ($n = 7$).

Distinct outcome instruments, frequency, and LOE

A total of 21 named PROIs and 6 custom, single-use questionnaires were identified in this search. Only 8 PROIs were used more than once (Table 2). The top 6 PROIs in order of frequency of use were SRS-22 (26; 32.9% of articles), SRS-24 (23; 29.1% of articles), ODI (14; 17.7% of articles), VAS (10; 12.7% of articles), and Short Form (SF)-36 (5; 6.3% of articles) (Fig. 4). Taken in

Table 2
Patient-reported outcome instruments used more than once (2004–2013)

Instrument	Uses
SRS-22	26
SRS-24	23
Oswestry Disability Index	14
Visual analog scale	10
SRS-30	8
36-Item Short Form	5
Quality of Life for Spinal Disorders	3
SRS-22r	2
Scoliosis Quality of Life Index	2

SRS, Scoliosis Research Society.

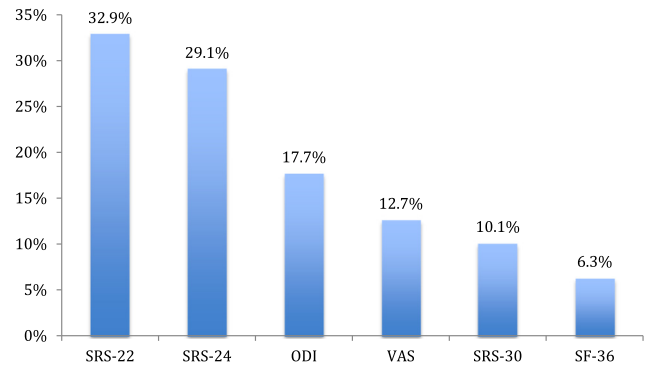


Fig. 4. Patient-reported outcome instrument prevalence as a percentage of total articles ($n = 79$). SRS, Scoliosis Research Society questionnaire; ODI, Oswestry Disability Index; VAS, visual analog scale; SF-36, Short Form-36.

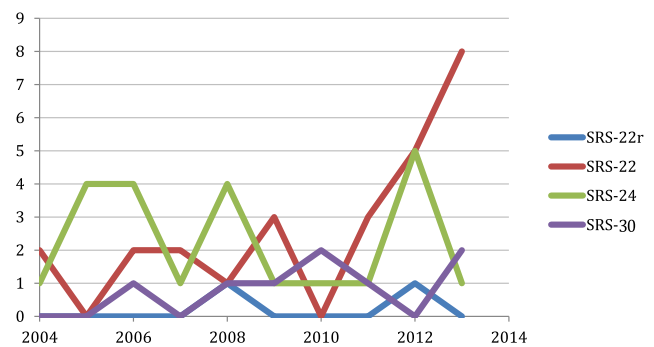


Fig. 5. Scoliosis Research Society (SRS) questionnaire version uses per year.

aggregate, SRS instruments were used in 74.7% of pediatric deformity studies. Use of the SRS-22 met or surpassed that of the original version, the SRS-24, in all of the past 3 years; however, wide adoption of the most up-to-date version, the SRS-22r, was not seen (Fig. 5). The PROIs not among the top 6 were used infrequently and appeared only 26 times (22.8% of all PROI uses). On average, 1.4 PROIs were used per study. There were 114 total uses of PROI.

Level of evidence III was most common among articles (39.2%) (Fig. 6). Level of evidence I was least common (1.3%), with only 1 LOE I article published in the past 10 years. *Spine* published the greatest number of studies with LOE II evidence, and the only LOE I study was published by *Journal of Bone and Joint Surgery American Volume* (Fig. 7).

Mean and range

Articles reporting SRS-22, SRS-24, and ODI scores were analyzed to calculate overall means and ranges because these were the 3 most frequently used PROIs. Although the ODI was used in 14 studies, none could be analyzed for mean and range because all were excluded for 1 of the reasons in Table 1. The SRS-22 was used in

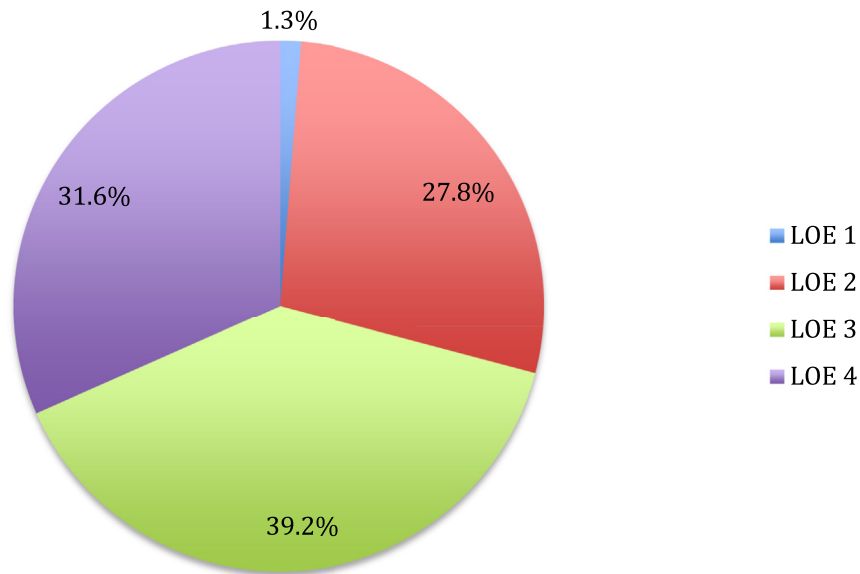


Fig. 6. Level of evidence (LOE) of articles using patient-reported outcome instruments as a percentage of total articles (n = 79).

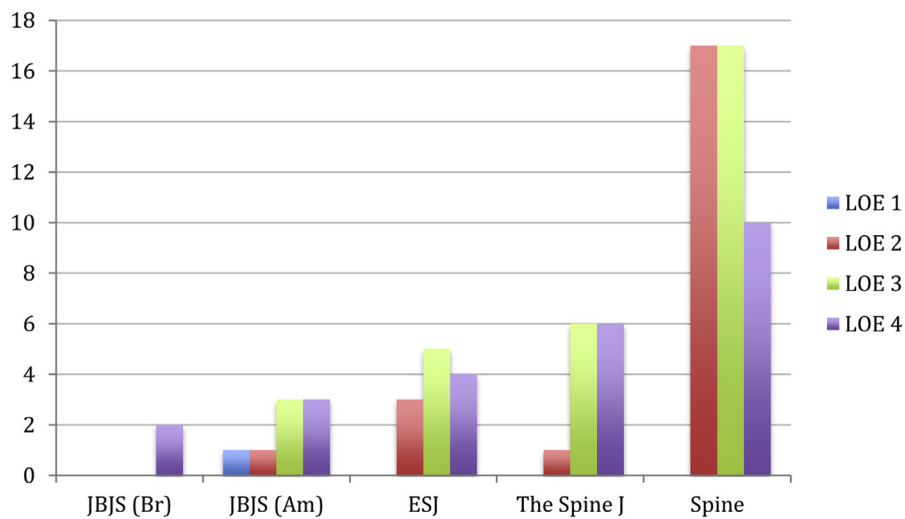


Fig. 7. Level of evidence (LOE) of articles by journal. ESJ, *European Spine Journal*; JBJS, *Journal of Bone and Joint Surgery*.

Table 3
Patient-reported outcome instrument score.

	Before surgery (mean [95% CI])	2 years after surgery (mean [95% CI])	SRS-22 studies	SRS-24 studies	Total studies
SRS-22r equivalent scores	4.0 (3.8–4.1)	4.5 (4.4–4.6)	4	3	7

SRS, Scoliosis Research Society; CI, confidence interval.

Preoperative and postoperative scores reported with SRS-22 and SRS-24 were converted to SRS-22r equivalent scores using conversion equations developed by Lai et al. [5].

4 studies that reported preoperative and 2-year postoperative scores, and the SRS-24 was used in 3 studies. The equations established by Lai et al. [5] to convert SRS-24, SRS-23, and SRS-22 scores into SRS-22r equivalents were applied so that valid comparisons could be made across all SRS data. Mean preoperative and postoperative SRS instrument scores were 4.0 (95%

CI 3.8–4.1) and 4.5 (95% CI 4.4–4.6), respectively, in SRS-22r equivalents (Table 3).

Discussion

Bibliometric analysis is an important tool used to analyze the content or citations of published research

studies to highlight trends or direct readers to key studies in a field. Murry et al. [6] and Lefavre et al. [7] performed bibliometric analyses of citations in spine and orthopedic research to point readers to the 100 most frequently cited articles in these fields. Hunt and Hurwit [8] and Zaidi et al. [9] performed bibliometric analyses of the content of articles in foot and ankle research to point out trends and impacts of PROI and LOE. The current study explored trends in PROI use over the past 10 years by bibliometric analysis to highlight the need for consensus on PROIs and standardization of their use and reporting in pediatric spine deformity research.

Standardization of PROI use within pediatric deformity surgery has important implications for evidence-based medicine and cost-effectiveness studies in the field. It provides a common language for reporting the findings of individual studies, which then strengthens meta-analyses and inter-study comparisons, and ultimately evidence in the field as a whole. The current review of the literature over the past 10 years demonstrates in quantitative terms that the SRS questionnaires [10] are standard among PROIs in pediatric deformity research. Unfortunately, investigators have yet to adopt the most up-to-date version, the SRS-22r, despite its publication in 2006 [11].

Having a standard, widely used PROI in pediatric deformity empowers clinical researchers to design studies around PROIs and incorporate PROIs early in the study design process. These benefits are evident in the quality of evidence, which is high among PROI studies in pediatric deformity literature. Nearly a third of PROI studies (29.1%) over the past 10 years were prospectively conducted. The current authors expected that standardization of PROI use would drive an upward trend in the number of studies using PROIs published per year; however, the number of articles climbed to 12 in 2006 and fell back to 3 in 2010, giving no indication of an upward linear progression. The periodicity seen may reflect the introduction of new PROIs, which generate waves of prospective studies that are published several years later, or it may reflect changes made by the Affordable Care Act that are driving renewed interest in measuring patient outcomes [12,13]. The influence of these factors may be more evident in the years to come.

It is difficult for a single PROI to meet the competing demands of being specific enough to detect small changes in outcomes of a given disease and general enough to enable outcomes comparisons across other diseases. For this reason, investigators often use more than 1 PROI in a given study. This analysis showed many studies using multiple instruments. On average, 1.4 PROIs were used per article. However, these were frequently redundant measures of pain and functional domains, such as an SRS questionnaire with ODI or VAS. A more advantageous application of PROIs would be to complement a disease-specific questionnaire with a general health questionnaire, as recommended by McCormick et al. [14] and Hunt and Hurwit [8]. Greater incorporation of general health questionnaires will enable economic

evaluations of pediatric deformity treatments, which are needed to address rising costs [15–17].

A handful of general health questionnaires have been developed specifically for children, including the Child Health Utility–9D (CHU-9D), Child Health Questionnaire, American Academy of Orthopedic Surgeons Pediatrics Outcome Data Collection Instrument, and EuroQol–5-Dimensions Youth (EQ-5D-Y) [18–22]. In the long run, these PROIs are designed to facilitate economic analysis, although further studies of normative data in pediatric populations are currently needed.

The challenge of studying patient-reported outcomes in pediatric populations is the reliability of responses from very young patients. Studies have shown reliability of SRS-22r responses for patients as young as age 8 years [18]. For younger patients and other PROIs, proxies are relied on for quality-of-life assessments [21,23]. Rinella et al. [24] showed that parents reported lower scores on self-image and overall satisfaction domains on the SRS-24 than their children, with greater differences in satisfaction scores seen for younger patients. Nonetheless, proxies are often the best available option.

As PROI use in pediatric deformity matures, these challenges will have to be considered by investigators choosing among PROIs for a study, revising existing PROIs, or designing new PROIs. The SRS-22r appears to meet the current needs of a disease-specific PROI in pediatric deformity; greater adoption of this instrument is needed. The top 6 PROIs are discussed below along with their development, structure, ease of use, and current issues.

Scoliosis Research Society questionnaire

In response to the fragmented system of patient satisfaction assessment in AIS surgery, Haheer et al. [25,26] conducted rigorous testing of pain, function, self-image, and satisfaction questions to develop of the SRS-24 in 1999. Their goal was to provide a uniform assessment of patient well-being, which was beyond the capacity of process measures (ie, radiographs), the standard at the time. The psychometric properties of the SRS-24 were sequentially improved in the SRS-23, SRS-22, and SRS-22r revisions of the original instrument and a mental health domain was added [11,27]. Although similar, these instruments differ in their validation, reliability, and responsiveness. Therefore, clear reporting of the instrument version is needed as well as separate reporting of SRS scores measured by different versions. Although this review revealed that the SRS-22 was used most frequently over the past decade, the researchers advise investigators to choose the SRS-22r for new studies. The limited use of SRS-22r found in this review may be a result of 1) its publication in 2006 and the time needed for investigators to conduct new studies and publish with the SRS-22r, 2) reluctance to conduct research with a new instrument that is not yet used widely by other investigators, and 3) authors failing to clearly distinguish between SRS-22 and SRS-22r in reporting which instrument

was used. The SRS-22r is a self-administered questionnaire that takes patients 3 to 5 minutes to complete. Higher scores indicate better health status.

The SRS-30 [10] was developed from a combination of questions in the SRS-22 and SRS-24. It is not yet validated [20]. Its ability to evaluate patient perception of improvement makes the SRS-30 an attractive PROI for investigators. As discussed by Bago et al. [28], this information can be compared with the change in SRS scores from baseline to after surgery to calculate the minimal clinically important difference (MCID). Although a study may find statistical significance in the change of PROI scores over time, this improvement is not meaningful if it is too narrow to be perceived by patients [27,29,30]. Bago et al. measured the MCID of the SRS-22r after treatment of idiopathic scoliosis to be 0.6 for the average sum score.

The mean and range analysis in this study revealed average scores of 4.0 before surgery and 4.5 after surgery in SRS-22r equivalent terms. Scoliosis Research Society–24 and SRS-22 scores in the literature were converted to SRS-22r scores by applying the conversions equations established by Lai et al. [5]. Merola et al. [31] previously reported SRS-24 scores of 3.68 before surgery and 4.63 2 years after surgery from a large multicenter study of outcomes after surgical treatment of AIS. If the conversion equations by Lai et al. are applied to the data reported by Merola et al., the SRS-22r scores are 4.0 before surgery and 4.8 after surgery. This improvement of 0.8 is greater than the MCID proposed by Bago and colleagues [28], while the score improvement of 0.5 calculated in the current review is less than the MCID. This suggests that either there is no overall difference in preoperative and postoperative status or the SRS-22 and SRS-24 instruments are not sensitive to change. However, the score improvement below the MCID may also reflect error introduced by using conversion equations between SRS-24, -22, and -22r. This underscores the importance of establishing consensus regarding use of the most up-to-date SRS instrument, which would enable reliable comparisons among PROIs of different studies.

Although SRS questionnaire data are abundant in pediatric deformity, general health questionnaire data are lacking. This has fueled development of conversions centered on SRS questionnaires. Lai et al. [19] studied conversions between the SF-36 and SRS-22 in patients with AIS. In a recent review of the value of spine deformity surgery, Paulus et al. [32] discussed the need for a direct conversion from SRS scores to health utility scores, which would facilitate cost-effectiveness analyses. Conversions centered on SRS instruments will continue to be developed until investigators begin to use a general health questionnaire consistently.

Oswestry Disability Index

The ODI was introduced in 1980 to measure functional disability in patients with low back pain [33,34]. It is a 10-

question self-administered survey that takes patients approximately 2 minutes to complete. A higher ODI score indicates greater disability. Historically, investigators have done a poor job of reporting which version of ODI was used [35], which will confound meta-analyses of ODI outcomes. The most up-to-date version is the ODIv2.1a, which is freely available on-line [36].

Within pediatric deformity, the ODI is most frequently used in studies of isthmic spondylolisthesis because back pain is the main clinical symptom [37]. The ODI was used in 8 of 10 spondylolisthesis studies (80.0%) and only 5 of 55 AIS studies (9.1%). Use of the ODI to measure function and pain may be redundant if the SRS-22r, which also measures these domains, is used in the same study. The ODI may not be necessary for evaluation of isthmic spondylolisthesis treatment outcomes. In 2 studies of spondylolisthesis in pediatric populations, Bourassa-Moreau et al. [38] and Helenius et al. [39] published significant results using only the SRS questionnaire. Moreover, Bridwell et al. [40] suggested that improvements in SRS-22r pain questions 11 and 17 could make the SRS-22r pain domain a more attractive option for isthmic spondylolisthesis studies and thereby further standardize PROI use in pediatric deformity.

The MCID estimates for the ODI range from 4 to 15 points [35]. The most accepted estimate of the MCID is 12.8, which was determined by Copay et al. [41] in a large cohort study of the adult population [14]. Unfortunately, the MCID has not been studied in pediatric populations.

Short Form–36

The SF-36 is a general health questionnaire that enables comparisons of quality-of-life outcomes across medical disciplines. It is composed of 8 sections that address function, pain, health perceptions, and mental health. First published in 1992 by Ware and Sherbourne [42], the SF-36 has been validated in several spinal conditions including back pain, spinal injury, and disk herniation [43,44]. The 36-question survey takes patients approximately 8 minutes to complete [45], making it the longest of the top 6 instruments. The most up-to-date version of the instrument is the SF-36v2, which can be licensed on-line [46]. If responder burden is a deterrent to using general health questionnaires, the much shorter SF-12 and EQ-5D-Y should be considered. Both instruments are used in the pediatric deformity literature.

Importantly, the SF-36 is the only PROI among the top 6 that is routinely used to study cost-effectiveness of treatments, yet it was used only 5 times in 79 studies. In a recent study of the cost of AIS surgery, Roach et al. [17] estimated cost increases of 100% from 1997 to 2006, which highlights the need for cost-effectiveness studies in pediatric deformity. Rihn et al. [47] recently detailed the methodology for studying cost-effectiveness in spine care. General health questionnaire scores are converted to utility scores, which are taken over time to estimate the quality-adjusted life-years gained from a given treatment. Unfortunately,

the normative data and preference weights needed to convert SF-36 scores into utility scores have not been established in pediatric populations as they have in adult populations [48–50], nor have they been established for the EQ-5D-Y, Child Health Questionnaire, CHU-9D, or American Academy of Orthopedic Surgeons Pediatrics Outcome Data Collection Instrument, the other general health questionnaires designed for children. This is a significant barrier to economic analysis in the field. Of the general health questionnaires, the CHU-9D is most actively being studied for use in economic evaluations. The CHU-9D is therefore a PROI to consider for investigators of pediatric deformity [51–56].

Visual analog scale

The VAS is a simple tool used primarily to measure pain. It is commonly a 100-mm line with the text “no pain” on the left and “severe pain” on the right, and patients are instructed to pick the position on the line that best describes their condition. The VAS can be completed in a matter of seconds, so use of the instrument does not place an unnecessary burden on patients. However, McCormick et al. [14] questioned the value of this tool in a recent review of spine surgery research, stating that “although these scales are simple methods for patients to report pain and are commonly used in musculoskeletal medicine, research has failed to consistently find meaningful and reliable use for these tools.”

This study has several limitations worth noting. First, the researchers limited this search to 5 top journals, yet additional relevant studies using PROIs has been published elsewhere. Second, additional studies within the 5 journals may have been missed during screening. Third, patient cohorts were heterogeneous with various spinal deformities and few data points were available for the mean analysis, which limits the reliability of the overall mean as an indicator of preoperative and 2-year postoperative scores in pediatric spinal deformity.

This review shows in quantitative terms the wide adoption of SRS questionnaires in studies of pediatric spinal deformity over the past 10 years. Consistent use of the most up-to-date version, the SRS-22r, is still needed. Clear, consistent version reporting is needed for multiple PROIs discussed in this article. To that end, the authors have highlighted the difference between versions and included references to the latest instrument versions. General health questionnaires were shown to be underused in pediatric spinal deformity research, and the authors recommend that investigators consider them as data become available to enable cost-effectiveness analyses.

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