Pediatric Pedicle Screws: Comparative Effectiveness and Safety

A Systematic Literature Review from the Scoliosis Research Society and the Pediatric Orthopaedic Society of North America Task Force

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Background: Pedicle screws are widely used in spinal surgery. There is extensive published literature concerning the use of pedicle screw instrumentation for spinal surgery in adults. Now there is a trend to use pedicle screws in pediatric patients, including the very young. A systematic review of the current English-language literature on the use of pedicle screw instrumentation in the pediatric age group was performed to specifically determine (1) the pedicle screw placement accuracy in patients with spine deformity and (2) the effect size of all-pedicle screw constructs compared with other methods of spinal instrumentation in terms of the percentage of scoliosis correction.

Methods: English-language studies of pedicle screw use in pediatric patients (defined as those younger than eighteen years of age) were included. Descriptive statistics synthesized the accuracy of pedicle screw placement. Accuracy rates were compared between pediatric and adult patients. The effect of pedicle screw instrumentation on scoliosis correction was calculated with use of Cobb angle measurements.

Results: On the basis of the literature search, 1181 articles were screened, 320 abstracts were examined, and ninety full-text articles representing 5761 patients were reviewed in detail. Seventeen studies met the inclusion criteria for the analysis of pedicle screw placement accuracy. A total of 13,536 pedicle screws were placed in 1353 pediatric patients. The overall placement accuracy rate in pediatric patients was 94.9%, which was higher than the rate of 91.5% reported for adults. The weighted, geometric, and 5% trimmed mean accuracy rates of pedicle screw placement were 91.9%, 88.5%, and 89.1%, respectively (standard deviation = 10%; interquartile range = 10%). Sixteen comparative studies met the inclusion criteria for the analysis of the effect of pedicle screw instrumentation on scoliosis correction. Pedicle screw constructs had a significantly larger percentage of Cobb angle correction compared with hooks (Cohen's d = 1.14) and hybrid constructs (Cohen's d = 0.49).

Conclusions: The accuracy of pedicle screw placement in the pediatric spine exceeds the accuracy rate reported in adults. Pedicle screw instrumentation constructs are significantly more effective for scoliosis correction, as determined on the basis of Cobb angle measurements, than are hook constructs and hybrid constructs.

Level of Evidence: Therapeutic Level IV. See Instructions to Authors for a complete description of levels of evidence.

The introduction of pedicle screws for the treatment of scoliosis has been an important technological addition to spinal implant systems. By providing rigid, three-column fixation at multiple levels, pedicle screw instrumentation has allowed surgeons to provide improved correction of spinal deformity[1-7]. When this study was initiated, pedicle screws were not approved for marketing for pediatric use in the United States. In other parts of the world, this is variable. Since the

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submission of the original paper, one company has received approval for marketing in the United States for the use of pedicle screws in patients with adolescent idiopathic scoliosis.

While pedicle screws represent a substantial innovation, spinal instrumentation has long been a part of the treatment of spinal deformity in children. Since the introduction of Harrington instrumentation fifty years ago, many changes in instrumentation have led to improvements in the treatment of pediatric spinal deformities[8,9]. One advance occurred with the introduction of "segmental fixation" with use of sublaminar wires[10-13], which further obviated the need for postoperative casting and provided better coronal and sagittal curve correction and control. Although generally safe, the passage of sublaminar wires carried some added risk of neurological injury to the spinal cord[14,15]. Cotrel and Dubousset introduced an instrumentation system that involved the use of hooks instead of sublaminar wires, providing greater and safer three-dimensional correction of spinal deformities[16-18]. Gradually, lumbar spine hooks were replaced by the use of pedicle screws, which produced and maintained improved curve correction[19,20].

Because of growing evidence of their biomechanical superiority and greater correction of spinal deformity, the use of pedicle screws has increased throughout the entire thoracic and lumbar spine[2,20-24]. However, concern has been expressed about the safety of pedicle screw usage, particularly with regard to screw misplacement[25,26]. Nevertheless, pedicle screws are widely used in both young and adult patients, with numerous articles documenting a favorable risk-to-benefit profile for spinal deformity treatment[2,20,27-42].

Although there have been many studies examining the safety and efficacy of pedicle screws, no formal systematic literature review has been performed in this area, to our knowledge. The purpose of the present study was to review the available literature to determine the comparative effectiveness and safety of pedicle screws for the treatment of pediatric spinal deformity on the basis of two specific metrics: (1) the percentage curve correction with use of measurements of the Cobb angle (which is the most regularly reported outcome measure for scoliosis treatment), and (2) the accuracy of screw placement (which represents the best metric to evaluate device-related complications).

Materials and Methods

Search Strategy

A keyword search of the Cochrane, Ovid, MEDLINE, and PubMed databases for articles published from February 1986 to April 2009 was executed with use of the search term "pedicle screws." The limits that were applied on the search included "human clinical studies," "written in English," and "age range of 0-18 yrs." The specific aim of this review was to identify papers that described the use of pedicle screws in pediatric spine surgery. Abstracts of the resulting list of articles were independently reviewed, and the inclusion and exclusion criteria were applied. The reference list of the included papers was hand-searched, and the above criteria were applied to determine inclusion.

Inclusion Criteria

To determine the comparative effectiveness of pedicle screws with respect to other instrumentation constructs, articles were included if (1) they compared the use of pedicle screw constructs with other instrumentation constructs, such as hooks or hybrid systems, (2) the average age of the population in each study was eighteen years or less, and (3) the percentage of curve correction was measured with use of the Cobb method.

To determine the comparative safety of pedicle screw placement accuracy, articles that clearly mentioned the total number of pedicle screws that were used and the number of pedicle screws that were misplaced or malpositioned were included, similar to the methodology used in the meta-analysis of pedicle screw placement in adults by Kosmopoulos and Schizas[43]. The average age of the population in each study that was included was eighteen years or less.

Exclusion Criteria

Articles without pediatric patients; those without pedicle screw fixation; those in which pedicle screws were used in the cervical spine and in adults; and all cadaveric, basic science, and biomechanical studies were excluded.

Outcomes Metrics

The outcomes were divided into two categories. The effectiveness of pedicle screws in terms of scoliosis correction was determined on the basis of the mean percentage correction of the Cobb angle, which is the primary outcome measure for reports on scoliosis treatment. To conduct an effect-size analysis assessing the effectiveness of pedicle screws in comparison with other constructs, only articles that directly compared the use of pedicle screws, hooks, and hybrid instrumentation in patients with a mean age of eighteen years and below were included. For safety measures, the parameter that was used was the accuracy of pedicle screw placement as determined with postoperative imaging[41].

Statistical Methods

Tests of homogeneity were done on the age and preoperative Cobb angle measurements for populations that were included in studies in which pedicle screw constructs were compared with either hooks or hybrid systems. For comparisons between pedicle screw instrumentation constructs and other constructs in terms of the percentage correction of the Cobb angle, effect sizes were computed as Cohen's d, with a positive effect size representing improvement and a negative effect size representing worsening. The effect-size correlation coefficient (r) was computed directly as the point-biserial correlation between the dichotomous independent variable (treatment) and the continuous dependent variable (mean percentage correction). The point-biserial correlation represents a special case of the Pearson product-moment correlation that is used when one of the variables is dichotomous. Cohen's d can be converted to r, and vice versa[44].

For the evaluation of the accuracy of pedicle screw placement, descriptive statistics (including measures of central tendencies such as the weighted mean, geometric mean, 5% trimmed mean, median, and interquartile range) were used. The weighted mean takes into account the number of screws placed in each study to report a weighted average. The geometric mean is calculated using normally distributed transformed data and is useful for summarizing skewed data. The 5% trimmed mean was calculated by excluding the lowest and highest 2.5% of the data to address possible outliers. Other accuracy-based descriptive statistics that were used included the median, the standard deviation, the minimum and maximum values, and the 95% confidence interval for the mean. The box plots display the twenty-fifth and seventy-fifth percentiles (interquartile range) of the data set, the median, and possible outliers that extend past the whiskers, defined as 1.5 times the interquartile range. These measures as well as the inclusion and exclusion methodology are similar to those in the meta-analysis of the accuracy of pedicle screw placement in adult patients as reported by Kosmopoulos and Schizas[43].

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Results

The literature search with the keyword "pedicle screw" yielded 1181 articles. These articles were cross-referenced with PubMed, MEDLINE, and Cochrane searches with the same keywords, and duplicates were discarded. Next, limits of "human clinical studies," "written in English," and "age range of 0-18 yrs" were applied, which resulted in 320 articles that were eligible for review. The abstracts of these 320 articles were then reviewed in detail. Case reports, review articles, articles pertaining to adult populations, articles pertaining to the use of pedicle screws in the cervical spine, and articles pertaining to biomechanical and cadaveric studies were excluded, resulting in ninety articles that were eligible for this study (Fig. 1). Of the ninety articles, two types of studies were most common: (1) comparative studies evaluating the

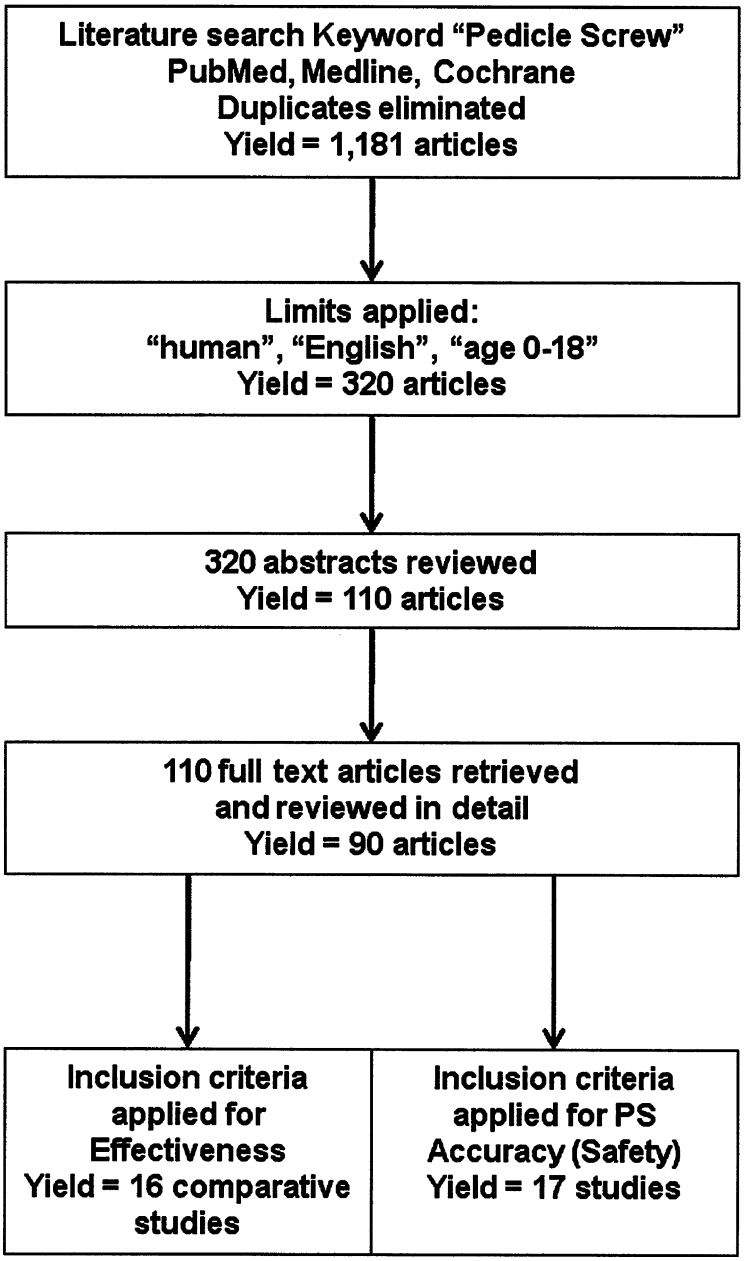

Fig. 1

Flow chart of literature search. PS = pedicle screw.

TABLE I Percentage Cobb Angle Correction

Construct	No. of Articles	No. of Patients	Percentage Cobb Angle Correction (%)			
			Mean	Standard Deviation	Minimum	Maximum
Hooks	8	243	46	14	20	68
Hybrid	8	221	56	10	42	68
Pedicle screw	16	393	61	11	35	72

effectiveness of pedicle screw constructs as compared with hooks and hybrid instrumentation constructs in pediatric patients, and (2) observational case series (retrospective or prospective) describing the results of treatment (Fig. 1). Most of the articles included patients with adolescent idiopathic scoliosis. All but one of the articles were Level-III or IV studies. The remaining study was a Level-I randomized clinical trial comparing pedicle screw insertion with and without the use of computer-aided navigation, but this study was treated as a case series.

Sixteen of the ninety articles compared pedicle screw systems with other instrumentation systems, whereas seventeen of the ninety articles described the accuracy of pedicle screw placement (see Appendix). The reference lists of these articles were hand-searched but yielded no additional articles meeting the inclusion criteria.

Seven thousand, one hundred and thirty-four patients had posterior spinal fusion in which pedicle screws, hooks, or hybrid instrumentation was used. Of these, 5761 patients had fusion in which all-pedicle-screw instrumentation or hybrid instrumentation was used. Overall, the mean Cobb angle percentage correction ranged from 20% to 75% for all constructs.

Effectiveness

Pedicle screws are utilized for many indications in skeletally immature patients, including adolescent idiopathic scoliosis, congenital scoliosis, neuromuscular scoliosis, and spondylolisthesis. To compare the effectiveness of pedicle screw constructs in a homogeneous population, we selected a subset of patients with adolescent idiopathic scoliosis for this analysis. Eight studies compared pedicle screw instrumentation with hook instrumentation, and eight studies compared pedicle screw instrumentation with hybrid instrumentation. Homogeneity tests were applied, and the results are described below.

Pedicle Screw Instrumentation versus Hook Instrumentation

The Levene test showed equal variances in age ($p = 0.242$) and preoperative Cobb angle ($p = 0.915$).

The t test with equal variances assumed showed no significant difference in terms of age ($p = 0.642$; two-tailed test) or preoperative Cobb angle measurement ($p = 0.753$; two-tailed test). The Mann-Whitney U test revealed that the distributions of age ($p = 0.564$) and preoperative Cobb angle measurement ($p = 0.793$) were the same across both constructs.

Pedicle Screw Instrumentation versus Hybrid Instrumentation

The Levene test showed equal variances in terms of age ($p = 0.444$) and preoperative Cobb angle measurement ($p = 0.983$). Consequently, the t test with equal variances assumed showed no significant difference in terms of age ($p = 0.572$; two-tailed test) or preoperative Cobb angle measurement ($p = 0.923$; two-tailed test). The Mann-Whitney U test revealed that the distributions of age ($p = 0.833$) and preoperative Cobb angle measurement ($p = 0.916$) were the same across both instrumentation groups.

Sixteen articles on adolescent idiopathic scoliosis were utilized to evaluate the effect size of the mean percentage correction in the Cobb angle by comparing pedicle screw instrumentation constructs with other constructs (see Appendix). All were Level-III retrospective analyses comparing the effectiveness of pedicle screw constructs with the effectiveness of hook or hybrid constructs in terms of the mean percentage Cobb angle correction. The mean percentage Cobb angle correction (and standard deviation) was 46% ± 14% for hooks, 56% ± 10% for hybrid constructs, and 61% ± 11% for pedicle screw constructs (Fig. 2 and Table I).

Using a pooled standard deviation to compute for Cohen's d, the effect size of percentage Cobb angle correction was 1.14 standard deviations apart when comparing pedicle screws and hooks. The mean average was 0.49 standard deviations apart when comparing pedicle screw and hybrid constructs. Although there are no well-accepted criteria for determining whether a given Cohen's d is large enough to be clinically important, Cohen made the reasonable recommendation that

TABLE II Cohen's d and Effect-Size Correlation Coefficient r*

Comparison Groups	Cohen's d	r
Pedicle screw versus hooks	1.14	0.50
Pedicle screw versus hybrid	0.49	0.24

*A Cohen's d of 0.20 is a small effect, 0.50 is a medium effect, and 0.80 is a large effect. An r value of 0.1 is a small effect size, 0.3 is a medium effect size, and 0.5 is a large effect size.

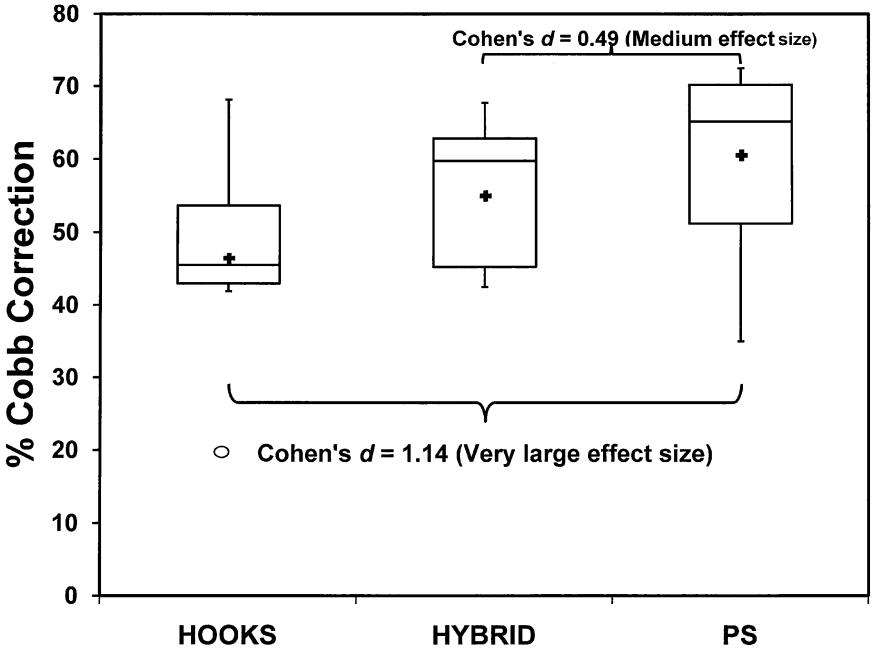

Fig. 2

Box plot of outcome by treatment. The whiskers are drawn to the most extreme points in the group that lie within the fences. The upper fence is defined as the third quartile (represented by the upper edge of the box) plus 1.5 times the interquartile range. The lower fence is defined as the first quartile (represented by the lower edge of the box) minus 1.5 times the interquartile range. Observations outside the fences (suspected outliers) are identified with a circle. The plus sign represents the group mean. The box-and-whisker plot widths are proportional to the group size. The box for pedicle screws (PS) clearly shows higher percentage Cobb correction than do the boxes for hooks and hybrid constructs. Values for Cohen's d illustrate the difference in effect sizes between pedicle screws and hooks and between pedicle screws and hybrid constructs.

a d of 0.20 is a small effect, 0.50 is a medium effect, and 0.80 is a large effect[44]. Hence, the effect of pedicle screws on the percentage Cobb angle correction was large in comparison with hook constructs and medium in comparison with hybrid constructs (Fig. 2 and Table II).

The effect-size correlation coefficient r is presented in Table II. According to Cohen, the effect size is low if the value of r varies around 0.1, medium if r varies around 0.3, and large if r varies >0.5[45,46]. Hence, the effect of pedicle screw instrumentation on percentage Cobb angle correction is large in comparison with hook constructs (r = 0.5) and medium in comparison with hybrid constructs (r = 0.24).

Accuracy of Pedicle Screw Placement

Seventeen studies met the inclusion criteria for the evaluation of the accuracy of pedicle screw placement. A total of 13,536 pedicle screws were placed in 1353 pediatric patients, the large majority of whom had spinal deformity (see Appendix). Six hundred and eighty-nine (5.1%) of 13,536 screws were reported to be misplaced, yielding an accuracy rate of 94.9% (12,847 of 13,536), which is better than the rate of 91.3% (34,107 of 37,337) reported for adults[43]. The weighted, geometric, and 5% trimmed mean accuracies of pedicle screw placement were 92%, 89%, and 89%, respectively (range, 70% to 99%; standard deviation, 10%; interquartile range, 10%) (Fig. 3) (see Appendix).

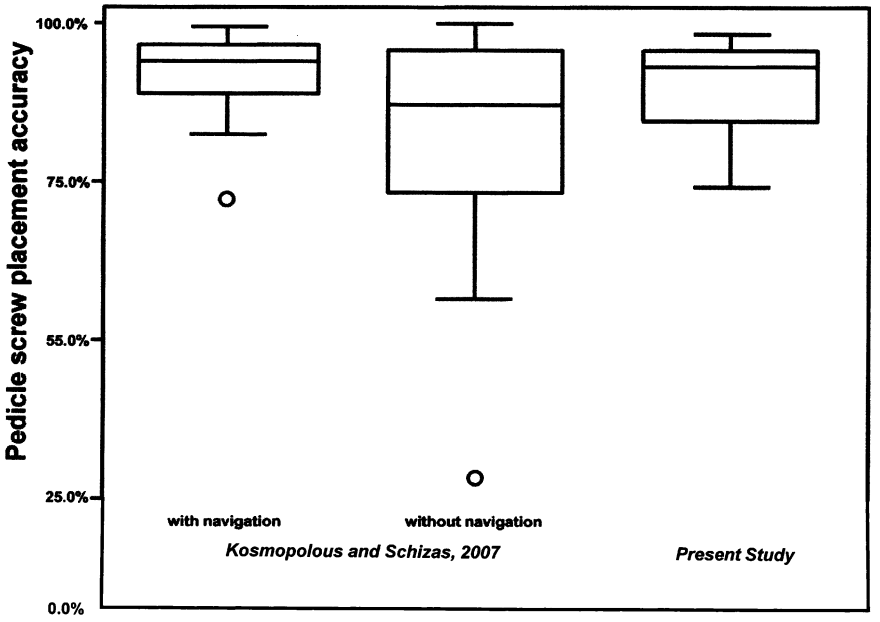

Fig. 3

Box plot of pedicle screw placement accuracy showing comparable rates in the adult population as described in the meta-analysis by Kosmopoulos and Schizas[43] and in the pediatric population as reported in the present study. The whiskers are drawn to the most extreme points in the group that lie within the fences. The upper fence is defined as the third quartile (represented by the upper edge of the box) plus 1.5 times the interquartile range. The lower fence is defined as the first quartile (represented by the lower edge of the box) minus 1.5 times the interquartile range. Observations outside the fences (suspected outliers) are identified with a circle.

Discussion

The current treatment of pediatric spinal deformity commonly involves the use of pedicle screw instrumentation to maximize three-dimensional spinal deformity correction. The use of pedicle screw instrumentation has been reported to decrease the number of fusion levels, to result in improved postoperative appearance, and to result in lower rates of reoperation for the treatment of implant migration and pseudarthrosis of the spinal fusion[2,20,23,24,40,47].

In this systematic literature review regarding the use of pedicle screws for the treatment of pediatric spinal deformity, we chose to focus the analysis on the two most widely reported and most easily comparable measures: frontal plane correction in patients with adolescent idiopathic scoliosis as determined by the major Cobb angle measurement, and the accuracy of pedicle screw insertion[41,48]. With use of the method of Cohen (d) for effect-size analysis, it was determined that pedicle screw constructs were clinically superior to hook constructs (large effect size) and to hybrid constructs (medium effect size) for correcting the major frontal plane scoliosis.

It is theoretically possible that pedicle screw use in an immature patient could result in altered spine growth. However, clinical reports of pedicle screw use in very young children have failed to identify this as a clinical problem yet[49-52]. The accuracy of pedicle screw placement is presumably more challenging in pediatric spines than in adult spines, given the smaller pedicle size in children, but the existing literature does not support this concern. We speculate that this observed phenomenon (similar pedicle screw placement accuracy rates in the adult and pediatric populations) may be due to the initial adoption of a pedicle screw placement technique in adults that was translated into use in children, obviating some of the learning curve.

With regard to the safety of pedicle screw use in the pediatric population, there was an overall accuracy rate of 94.9% in the existing literature, which was significantly better than the rate reported by Kosmopoulos and Schizas (91.3%) in their meta-analysis of the adult spine literature[43]. The weighted, geometric, and 5% trimmed mean accuracies in this review compare favorably with the literature on insertional accuracy in the adult population (see Appendix). The accuracy of screw placement may be considered a surrogate for complications (safety) data[41]. Reports of complications resulting from the use of pedicle screws typically involve a description of malpositioned screws, with or without untoward effects. Complications that occur in the presence of optimal pedicle screw placement probably reflect the long-term failure of fusion rather than a problem with the screw placement.

Surgeons must rely on the best available information to guide patient management decisions in the absence of randomized clinical trials. Although evidence regarding the advantage of pedicle screw constructs remains limited to case series, biomechanical studies, and expert opinions, there appears to be a number of advantages of all-pedicle-screw constructs in the surgical treatment of pediatric spinal deformity. This literature review, which spans more than fifteen years and represents a cumulative experience with approximately 7000 patients in both included and excluded articles and 2169 patients in included articles only, documents widespread use of pedicle screws in the treatment of skeletally immature populations and suggests that pedicle screws have an equivalent or superior effectiveness and safety profile in comparison with their use in the adult population.

Limitations of the Present Study

The present study is based on the existing published literature. Heterogeneity existed among the sixteen comparative studies. Two studies compared pedicle screw instrumentation with hooks and hybrid instrumentation, seven studies compared pedicle screws with hooks, and seven compared pedicle screws with hybrid constructs. Four studies comparing pedicle screw constructs with hybrid constructs were matched, whereas three studies compared pedicle screws with hooks in the lumbar spine. Although subjects in all sixteen included articles were patients with adolescent idiopathic scoliosis, the curve classification and curve magnitude varied (see Appendix). However, all of the studies demonstrated the same effect direction that favored pedicle screw constructs. There can be debate about how useful correction of the Cobb angle is for the measurement of effectiveness, but these data seem compelling.

Similarly, the seventeen case series that were included in the analysis of pedicle screw placement accuracy had a relatively heterogeneous population, but most of the patients were adolescents who had idiopathic scoliosis with varied degrees of curve magnitude. The method that was used to determine pedicle screw malpositioning also varied, but computed tomography imaging was used in the majority of studies. Nevertheless, the overall accuracy of pedicle screw placement for the pediatric population in the present study was 95% (range, 72% to 99%). In one study, by Ruf and Harms[49], the average age was two years and the reported screw placement accuracy rate was 97%.

Learning-curve factors probably do exist and were not assessed with our study methodology. However, with clinical experience now exceeding fifteen years, the use of pedicle screw instrumentation can no longer be considered to be a new technique.

Factors other than Cobb angle correction are clearly important. These other factors include patient-reported outcomes, now evaluated with the Scoliosis Research Society questionnaire as developed by Haher[53] and modified by Asher[54-61]. Other important factors include sagittal contour, chest wall effects, pulmonary function, complication rates, and the cost of the instrumentation. Unfortunately, high-quality data sets with these outcomes are not available for comparison with the previous spinal instrumentation techniques and are only now emerging for the newest techniques[41].

There is extensive literature documenting the use of pedicle screws in pediatric patients. The cumulative literature experience indicates that the use of pedicle screws is associated with greater Cobb angle correction as compared with hooks (large effect size) and hybrid constructs (medium effect size). The accuracy of pedicle screw placement in the pediatric population is at least equivalent to or better than that reported in the adult population.

Appendix

eA Tables showing a list of the journal articles that were included in the effect-size analysis, a list of the journal articles that were included in the analysis of pedicle screw accuracy (including several articles not already cited in the text[62-74]), a comparison between the present study and the study by Kosmopoulos and Schizas[43] in terms of pedicle screw placement accuracy, details on the comparative studies, and details on articles with single cohorts assessing pedicle screw placement accuracy are available with the online version of this article at jbjs.org. ■

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