Axial interbody arthrodesis of the L5–S1 segment: a systematic review of the literature

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OBJECT The object of this study was to determine the fusion rate and safety profile of an axial interbody arthrodesis of the L5–S1 motion segment.

METHODS A systematic search of MEDLINE was conducted for literature published between January 1, 2000, and August 17, 2014. All peer-reviewed articles related to the fusion rate of L5–S1 and the safety profile of an axial interbody arthrodesis were evaluated.

RESULTS Seventy-four articles were identified, but only 15 (13 case series and 2 retrospective cohort studies) met the study inclusion criteria. The overall pseudarthrosis rate at L5–S1 was 6.9%, and the rate of all other complications was 12.9%. A total of 14.4% of patients required additional surgery, and the infection rate was 5.4%. Deformity studies reported a significantly increased rate of complications (46.3%), and prospectively collected data demonstrated significantly higher complication (36.8%) and revision (22.6%) rates. Lastly, studies with a conflict of interest reported lower complication rates (12.4%).

CONCLUSIONS A systematic review of the literature indicates that an axial interbody fusion performed at the lumbosacral junction is associated with a high fusion rate (93.15%) and an acceptable complication rate (12.90%). However, these results are based mainly on retrospective case series by authors with a conflict of interest. The limited prospective data available indicate that the actual fusion rate may be lower and the complication rate may be higher than currently reported.

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KEY WORDS axial interbody arthrodesis; systematic review; Axialif; L5–S1 fusion; lumbar

ARTHRODESIS of the lumbosacral junction is a common surgical procedure used successfully in the treatment of multiple spinal diseases such as scoliosis and spondylolisthesis. Several techniques to fuse this segment have been described; however, an interbody technique is commonly used. This method has a large surface area for new bone formation, provides anterior column support, and can reestablish the disc height, which can both indirectly decompress the nerve roots and aid in the

correction of local and global sagittal alignment.¹³ While this procedure can be performed from several different approaches, each requires significant mobilization of either neurovascular structures or abdominal viscera, which can lead to significant morbidity.^{6,7,12,14,22,25,28,32}

An understanding of the morbidity associated with traditional spinal exposures led to the emergence of newer minimally invasive techniques.^{20,21,23,34} With their newly developed instrumentation and image guidance, such tech-

ABBREVIATIONS ALIF = anterior lumbar interbody fusion; GLMM = generalized linear mixed model; rhBMP-2 = recombinant human bone morphogenetic protein 2.

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niques theoretically allowed surgeons to perform similar procedures with less iatrogenic damage to surrounding soft tissues and an associated decrease in blood loss, post-operative pain, and length of hospitalization.^{20,21,23,34} However, these new techniques were not without problems, such as an increased risk of retrograde ejaculation with laparoscope-assisted anterior lumbar interbody fusions (ALIFs)²⁸ or inadequate restoration of foraminal height and lordosis with transforaminal interbody fusion.¹³

Given the aforementioned advantages of an interbody fusion at L5–S1 and the complications associated with traditional approaches, a new minimally invasive technique was designed to use the anatomical tissue plane separating the sacrum from the peritoneal contents.^{5,19,33} Through a 2-cm paracoccygeal incision, a cannulated drill from the sacral promontory is passed through the sacrum to create a path to the L5–S1 disc. After the discectomy and bone grafting are performed, an axial-directed cylindrical implant (AxiaLIF, Baxano Surgical) is inserted.^{4,9} Cadaveric studies have demonstrated the biomechanical efficacy of such an implant^{1,17} and have further shown that the intact annulus and anterior longitudinal ligament allow for indirect decompression of the neural foramen from ligamentotaxis.^{1,17} Currently, the literature on the clinical application of this technique is limited almost exclusively to case series and case reports, so this systematic review was designed to answer the questions, What are the fusion rate and safety profile for an axial interbody arthrodesis of the L5–S1 motion segment?

Methods

Electronic Database Search

Two authors (G.D.S. and C.K.K.) independently performed a systematic MEDLINE search via PubMed for

literature published between January 1, 2000, and August 17, 2014. Peer-reviewed articles related to an axial interbody arthrodesis of the lumbosacral junction were identified using combinations of the following search terms: “Axialif,” “axial transsacral fusion,” “axial transsacral arthrodesis,” “presacral lumbar interbody fusion,” “presacral lumbar interbody arthrodesis,” “paracoccygeal fusion,” “paracoccygeal arthrodesis,” “paracoccygeal transsacral fixation,” and “minimally invasive fusion of L5/S1.” Only clinical studies on human subjects and in the English language were included. The reference lists of identified articles were also systematically reviewed, and any other eligible articles were incorporated. Included articles were chosen based on the inclusion and exclusion criteria listed in Table 1. All studies in which more than 10% of a cohort met the exclusion criteria were excluded.

Data Extraction

The abstract of every identified article was reviewed, and over half of the studies were excluded based on information in the abstract alone. The remaining articles could not be unequivocally dismissed based on the abstract, so a full review of each of these articles was performed. Approximately half of these articles were eventually excluded based on the criteria in Table 1. One retrospective cohort study by Gerszten et al. compared fusion rates in patients who had undergone an axial interbody fusion of L5–S1 with or without the use of recombinant human bone morphogenetic protein 2 (rhBMP-2).⁹ Because all of the patients underwent an axial interbody fusion at L5–S1 and because there was wide variability in the use of rhBMP-2 in other studies, the Gerszten et al. study was treated as a large case series. Only a single article comparing axial interbody fusions and another interbody fusion technique was identified.³¹ Because no other comparative

TABLE 1. Inclusion and exclusion criteria for studies on axial interbody fusion of the lumbosacral junction

Study Component		Inclusion	Exclusion
Participants	Age ≥18 yrs		Age <18 yrs
	A pathology of DDD, spondylosis, spondylolisthesis, scoliosis, pseudarthrosis, revision surgery		A pathology of tumor, infection, or trauma
Interventions	Patients undergoing axial interbody arthrodesis of lumbosacral junction		
Comparators	Patients undergoing ALIF, posterior lumbar interbody fusion, or transforaminal interbody fusion		
Outcomes	L5–S1 fusion rate		Radiographic outcomes that did not clearly define the fusion rate at L5–S1
	Complication rates: nonunion, revision surgery, infection, postop radiculopathy, neurological deficit, bowel perforation, retroperitoneal hematoma/vascular injury, hardware failure		Mean FU <12 mos
Study Designs	Study assessing L5–S1 fusion rate after an axial interbody arthrodesis of the L5–S1 segment		Nonclinical study
	Study assessing complications in patients with an L5–S1 fusion rate utilizing an axial interbody arthrodesis		Case report
Publication	Study published in English in a peer-reviewed, PubMed-indexed journal		Review articles, abstracts, editorials, letters, repeat publication of same patient group, and study reporting the technical feasibility of the surgery

DDD = degenerative disc disease; FU = follow-up.

studies were identified, that single comparative article was treated as a case series, and only patients from the Axialif arm were included in our systematic review.

All reported complications were noted, including pseudarthrosis at L5–S1, revision and/or subsequent surgery, infections, postoperative radiculopathy, neurological deficits, bowel perforations, retroperitoneal hematomas and/or vascular injury, and significant medical complications (for example, myocardial infarction, stroke, and so forth). In addition to the overall incidence of complications, prospective versus retrospective studies and studies with and without a reported conflict of interest were identified. Furthermore, a level of evidence was assigned to each study using the *Journal of Bone and Joint Surgery* level of evidence table (<http://jbjs.org/instructions-for-authors/#LevelofEvidence>), which is an adaptation of work published from the Centre for Evidence-Based Medicine.¹⁷ Lastly, studies were identified as comprising patients with either degenerative or deformity-based spinal disease according to the surgery performed and the underlying diagnoses. Studies were included in the degenerative group if less than 20% of patients underwent surgery at 3 or more levels or had a diagnosis of high-grade spondylolisthesis or scoliosis.

Statistical Analysis

Data amassed from individual articles were analyzed using the lme4 package in the R statistical platform (R Foundation for Statistical Computing). We performed a generalized linear mixed model (GLMM) to estimate the rate of outcomes by using conflict of interest (yes/no), prospective versus retrospective study, and degenerative versus deformity-based spinal disease as fixed effects and study as a random effect. The p values are based on the estimated parameter value and the standard error, and a p value < 0.05 was accepted as significant.

While we initially intended to perform a statistical analysis on the frequency of all complications, the reported number of postoperative radiculopathies, neurological deficits, bowel perforations, and retroperitoneal hematomas and/or vascular injuries was insufficient to allow for a formal analysis. We analyzed L5–S1 pseudarthrosis, all complications except for pseudarthrosis, revision and/or subsequent surgery, and postoperative infections. Estimated complication rates (with confidence intervals), averaged across studies, were reported based on the GLMM, both per predictor and overall.

Results

We reviewed the abstract of every identified article (74; Fig. 1) and excluded 43 articles, including 20 review articles, 11 cadaveric studies, 7 non-English-language articles, and 5 articles establishing the feasibility of the procedure. The 31 remaining articles could not be unequivocally dismissed on the basis of the abstract, so each of these articles was fully reviewed. Sixteen additional articles were excluded at this time: 5 case reports, 5 articles in which the patient underwent multilevel fusions and there was no clearly reported fusion rate at L5–S1, 4 articles describing the technique but without follow-up, and 2 articles in which patients underwent lumbar fusion via multiple tech-

FIG. 1. Flowchart demonstrating the literature review results.

niques and there was no clearly described results of the L5–S1 axial interbody fusion.

Overall, 15 articles with 700 patients were included.^{2–4, 8–11,15,18,26,27,29–31,35} Thirteen of the 15 articles were case series (Level IV evidence),^{2–4,8,10,11,15,18,26,27,29,30,35} and 2 were retrospective cohort studies (Level III evidence).^{9,31} The overall pseudarthrosis rate at L5–S1 following axial interbody arthrodesis was 6.9% (95% CI 1.0%–16.2%). Failed fusion was verified by CT in 12 of the 15 studies and by radiography in the remaining 3 studies. The rate of all complications excluding pseudarthrosis was 12.9% (4.5%–27.5%). A total of 14.4% of patients (range 11.3%–20.1%) required additional surgery, and the infection rate was 5.44% (range 2.50%–9.66%). The unadjusted numbers of rare complications are listed in Table 2.

When the case series were categorized as degenerative or deformity studies, the deformity group had a significantly increased rate of complications compared with the degenerative group (46.3% vs 9.2%, $p = 0.004$; Table 3). Similarly, compared with retrospectively collected data, the prospectively collected data demonstrated a significantly higher complication rate (36.8% vs 8.7%, $p = 0.003$) and a higher rate of revision surgery (22.6% vs 12.9%, $p = 0.03$; Table 4). Lastly, industry-sponsored studies or studies in which the authors had a conflict of interest reported lower complication rates than the studies with no conflict of interest (12.4% vs 17.8%, $p < 0.0001$; Table 5).

Discussion

The use of an interbody fusion technique for the treatment of several different diseases affecting the lumbosacral junction has been well established in the litera-

TABLE 2. Unadjusted number of rare complications

Complication	Total Reported Occurrences
Postop radiculopathy	7
Broken Axialif	3
Retroperitoneal hematoma/vascular injury	2
Myocardial infarction	2
Stroke	2
Bowel perforation	1

TABLE 3. Subgroup analysis grouping studies according to type of disease

Parameter	Deformity-Based Disease	Degenerative Disease	p Value
No. of articles	4	11	
No. of patients	86	614	
Pseudarthrosis	7.08% (2.52%–18.31%)	5.87% (0.73%–34.50%)	0.87
All complications excluding pseudarthrosis	46.26% (16.21%–79.30%)	9.20% (6.70%–12.50%)	0.004*
Revision or subsequent surgery	28.21% (7.34%–66.30%)	15.54% (12.10%–19.72%)	0.35
All postop infections	13.82% (4.95%–33.07%)	4.42% (2.40%–8.02%)	0.06

* Statistically significant.

ture,^{13,24,36,37} however, significant complications have been associated with all approaches.^{6,7,12,14,22,25,28,32} Thus, a new technique using a minimally invasive paracoccygeal approach to perform axial interbody arthrodesis was developed. Our purpose in this systematic review was to determine the safety profile and fusion rate when an axial interbody technique was used for an L5–S1 arthrodesis. We found a low risk of complications and a fusion rate of 93.15%. The fusion rate was not significantly affected by any of the factors in the subgroup analyses.

The fusion rates for axial interbody fusion compare favorably with those following classic techniques for a fusion at L5–S1. In a prospective, randomized multicenter study of the ProDisc-L disc replacement versus circumferential fusion, the authors reported a fusion rate of 97% at 2 years for 75 patients undergoing an ALIF. However, one-third of the fusions were performed at the more biomechanically advantageous L4–5 or L3–4,^{36,37} and none of these patients were undergoing deformity surgery.

Similarly, the revision rate for axial interbody fusion is similar to that identified in the multicenter prospective, randomized, controlled investigational device exemption study of the FlexiCore artificial disc (Stryker Spine).²⁴ Sasso et al. reported a 35% revision rate at 2 years in patients who had undergone an ALIF, and in the current study only 14.42% of patients who had undergone axial interbody fusion required a revision. Even patients in the prospective subgroup analysis (22.56%) and the deformity analysis (28.21%) had revision rates less than 35%.

This paper has significant limitations. Foremost, it is a systematic review of 13 case series and 2 retrospective cohort studies. No Level I or Level II studies on this technique have been published. Furthermore, only 4 available articles were prospective studies,^{8,10,28,29} and only 4 studies were completely independent.^{4,10,11,29} Additionally, the lead author of one of the independent studies²⁹ reported owning significant stock in TranS1 (currently Baxano Surgi-

cal) in an article published 2 months later.³⁰ Our subgroup analyses demonstrated that the limitations of the available literature should not be trivialized, as the prospective data revealed a statistically significant increase in complications and revisions and a nonsignificant increase in the rate of pseudarthrosis.

A second limitation of this study is that multiple variables, which could not be accounted for, may have affected the fusion rate. Not only was there variation between studies in the use of posterior instrumentation, but there was also significant heterogeneity of the overall constructs within the same studies; stand-alone constructs, bilateral or unilateral pedicle screws, and facet screws were all documented to varying degrees. However, one would expect this variation to lead to inferior fusion rates, and the overall fusion rate was quite high. Similarly, the choice of bone graft and biological enhancers varied both between and within the studies. Eight studies reported the use of rhBMP-2 in at least some of the cases,^{2–4,9,27,29–31} compared with 5 studies that reported not using rhBMP-2^{8,11,18,26,35} and 2 cases that did not report their choice of bone graft.^{10,15}

Lastly, this systematic review only establishes the fusion rate and safety profile of an L5–S1 axial interbody fusion. It does not address patient-reported clinical outcomes or radiographic parameters aside from fusion. Ideally, this review would have included health-related quality of life metrics; however, with significant heterogeneity in the surgical indications between as well as within studies, we believed that a meaningful interpretation of these results was not possible. One would expect a patient undergoing axial interbody fusion for spondylolisthesis with instability to have significantly improved clinical results, compared with the outcome in a patient undergoing axial interbody fusion for low-back pain and degenerative disc disease. Because there was no clear way to separate these patients, we elected not to report the clinical outcomes. Nonetheless, this information in the current study is sig-

TABLE 4. Subgroup analysis grouping studies according to type of data collection

Parameter	Prospective	Retrospective	p Value
No. of articles	4	11	
No. of patients	104	596	
Pseudarthrosis	12.09% (2.24%–45.22%)	5.4% (1.88%–14.57%)	0.40
All complications excluding pseudarthrosis	36.75% (14.35%–66.85%)	8.73% (6.55%–11.56%)	0.003*
Revision or subsequent surgery	22.56% (14.97%–32.53%)	12.92% (9.20%–17.83%)	0.03*
All postop infections	3.43% (0.44%–22.09%)	5.89% (3.44%–9.91%)	0.61

* Statistically significant.

TABLE 5. Subgroup analysis grouping studies according to conflict of interest

Parameter	Conflicts Reported	No Conflicts of Interest	p Value
No. of articles	11	4	
No. of patients	586	114	
Pseudarthrosis	5.40% (1.88%–14.57%)	16.41% (2.96%–55.80%)	0.25
All complications excluding pseudarthrosis	12.44% (8.20%–18.44%)	17.77% (11.96%–25.58%)	<0.0001*
Revision or subsequent surgery	16.36% (11.87%–22.12%)	17.09% (10.97%–25.66%)	0.87
All postop infections	3.79% (1.67%–8.38%)	7.60% (3.38%–16.20%)	0.26

* Statistically significant.

nificant: Even though the clinical outcomes of lumbar fusions vary significantly by surgical indication, it is clear that patients who develop pseudarthrosis after lumbar fusion have inferior long-term clinical results.¹⁶

This review highlights the weakness in the literature on an L5–S1 axial interbody fusion; high-level studies are required to determine how this technique can be best used. Keys for future investigators include prospective studies ideally randomizing patients to an axial interbody fusion and an alternative interbody fusion technique; non-industry-funded studies to remove any perceived author bias; and strict inclusion criteria such that included patients are only those who are undergoing lumbar fusion for an evidenced-based reason such as spondylolisthesis associated with instability.

Conclusions

A systematic review of the literature indicated that an axial interbody fusion performed at the lumbosacral junction is associated with a high fusion rate (93.15%) and an acceptable complication rate (12.90%). However, these results are based mainly on retrospective case series by authors with a conflict of interest, and the limited prospective data available indicate that the actual fusion rate may be lower and the complication rate may be higher than currently reported.

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Author Contributions

Conception and design: Vaccaro. Acquisition of data: Schroeder, Kepler. Analysis and interpretation of data: Schroeder. Drafting the article: Schroeder. Critically revising the article: Kepler, Vaccaro. Reviewed submitted version of manuscript: Kepler, Vaccaro. Administrative/technical/material support: Vaccaro. Study supervision: Vaccaro.

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