

Lumbar Lateral Interbody Fusion (LLIF): Comparative Effectiveness and Safety versus PLIF/TLIF and Predictive Factors Affecting LLIF Outcome

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Evid Based Spine Care J 2014;5:28–37.

Abstract

Study Design Systematic review.

Study Rationale The surgical treatment of adult degenerative lumbar conditions remains controversial. Conventional techniques include posterior lumbar interbody fusion (PLIF) or transforaminal lumbar interbody fusion (TLIF). A new direct approach known as lumbar lateral interbody fusion (LLIF), or extreme lateral interbody fusion (XLIF[®]) or direct lateral interbody fusion (DLIF), has been introduced.

Objectives The objective of this article is to determine the comparative effectiveness and safety of LLIF, at one or more levels with or without instrumentation, versus PLIF or TLIF surgery in adults with lumbar degenerative conditions, and to determine which preoperative factors affect patient outcomes following LLIF surgery.

Materials and Methods A systematic review of the literature was performed using PubMed and bibliographies of key articles. Articles were reviewed by two independent reviewers based on predetermined inclusion and exclusion criteria. Each article was evaluated using a predefined quality rating scheme.

Results The search yielded 258 citations and the following met our inclusion criteria: three retrospective cohort studies (all using historical cohorts) (class of evidence [CoE] III) examining the comparative effectiveness and safety of LLIF/XLIF[®]/DLIF versus PLIF or TLIF surgery, and one prospective cohort study (CoE II) and two retrospective cohort studies (CoE III) assessing factors affecting patient outcome following LLIF. Patients in the LLIF group experienced less estimated blood loss and a lower mortality risk compared with the PLIF group. The number of levels treated and the preoperative diagnosis were significant predictors of perioperative or early complications in two studies.

Conclusion There is insufficient evidence of the comparative effectiveness of LLIF versus PLIF/TLIF surgery. There is low-quality evidence suggesting that LLIF surgery results in fewer complications or reoperations than PLIF/TLIF surgery. And there is insufficient evidence that any preoperative factors exist that predict patient outcome after LLIF surgery.

Keywords

- ▶ XLIF[®]
- ▶ DLIF
- ▶ LLIF
- ▶ PLIF
- ▶ TLIF
- ▶ minimally invasive
- ▶ extreme lateral interbody fusion
- ▶ direct lateral interbody fusion

received
September 3, 2013
accepted after revision
December 17, 2013

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Stuttgart · New York

DOI <http://dx.doi.org/10.1055/s-0034-1368670>.
ISSN 1663-7976.

Study Rationale and Context

The surgical treatment of adults degenerative lumbar conditions remains very controversial. Lumbar interbody arthrodesis, with or without instrumentation, provides better fusion rate but not better clinical results.

To reduce surgical morbidity and achieve satisfactory, long-standing results, a new direct approach to the lumbar spine, known as lumbar lateral interbody fusion (LLIF), direct lateral interbody fusion (DLIF), or extreme lateral interbody fusion (XLIF®; Nuvasive, San Diego, CA, United States), has been introduced.

A comparative analysis of this new approach versus conventional posterior lateral interbody fusion (PLIF) or transforaminal lumbar interbody fusion (TLIF) techniques is the aim of this study.

Objectives

The objective of this article is to determine the following:

- The comparative effectiveness and safety of LLIF, XLIF, or DLIF surgery at one or more levels with or without instrumentation versus PLIF or TLIF surgery, in adults with lumbar degenerative conditions including degenerative scoliosis
- What preoperative factors, if any, affect patient outcomes following LLIF, XLIF, or DLIF surgery.

Materials and Methods

Study design: This study is a systematic review.

Search: The databases included PubMed, Cochrane, and National Guideline Clearinghouse Databases, as well as bibliographies of key articles.

Dates searched: The dates were searched till November 2013.

Inclusion criteria: The inclusion criteria of the study were as follows: (1) patients 18 years or older, (2) lumbar degenerative disc disease (DDD) (with or without canal stenosis and with or without degenerative spondylolisthesis) or lumbar degenerative scoliosis, (3) studies with at least 10 patients per treatment group (comparative effectiveness) or studies with at least 20 patients total (predictive factors), and (4) comparison of LLIF/XLIF/DLIF with PLIF/TLIF surgery (comparative effectiveness).

Exclusion criteria: The exclusion criteria of the study were as follows: (1) patients younger than 18 years, (2) those involving traumatic onset, fracture, thoracic disc disease, infection, or neoplasms; (3) case reports, comparative studies with fewer than 10 patients per treatment group; and (4) cadaveric studies, nonhuman in vivo, in vitro, and biomechanical studies.

Outcomes: The outcomes of the study include the following: (1) perioperative complications, (2) reoperation risk, (3) complications or adverse events, (4) postoperative pain, (5) neurological improvement, and (6) sagittal and coronal balance.

Analysis: Descriptive statistics. Pooling of data was not done due to concerns regarding heterogeneity of treatments and populations as well as study quality.

Overall strength of evidence: Risk of bias for individual studies was based on using criteria set by *The Journal of Bone and Joint Surgery*¹ modified to delineate criteria associated with methodological quality and risk of bias based on recommendation from the Agency for Healthcare Research and Quality.^{2,3} The overall strength evidence across studies was based on precepts outlined by the Grades of Recommendation Assessment, Development and Evaluation Working Group⁴ and recommendations made by the Agency for Healthcare Research and Quality.^{2,3}

Details about methods can be found in the online supplementary material.

Results

From 258 citations, 11 citations were evaluated for full-text review. Three retrospective cohort studies (all using historical cohorts) (class of evidence [CoE] III) examining the comparative effectiveness and safety of LLIF/XLIF/DLIF versus PLIF/TLIF surgery and one prospective cohort study (CoE II) and two retrospective cohort studies (CoE III) reporting predictive factors following XLIF surgery met the inclusion criteria and form the basis for this report (►Fig. 1). Characteristics of studies investigating the comparative effectiveness of the surgical techniques are outlined in ►Table 1 and those examining predictive factors following LLIF/XLIF/DLIF are outlined in ►Table 2. Refer to the online supplementary material for critical appraisal, a list of excluded articles, and detailed outcome tables.

Comparative Effectiveness of LLIF/XLIF/DLIF versus PLIF/TLIF

None of the included studies reported radiographic or patient-reported outcomes for both treatment groups.



Fig. 1 Flow chart showing results of literature search.

Table 1 Characteristics of studies comparing LLIF/XLIF/DLIF with PLIF/TLIF for lumbar degenerative disease

Investigator (y) Study design CoE	Population	Condition	LLIF/XLIF/DLIF	PLIF/TLIF	Follow-up (% followed)
Deluzio et al (2010) Retrospective cohort (using historical cohort from same institution) CoE: III	<ul style="list-style-type: none"> N = 211 Age (mean): 55.5 y Male: 65% 	<ul style="list-style-type: none"> Degenerative spine conditions (details NR) Symptom duration: NR 	<ul style="list-style-type: none"> XLIF from L1-L2 to L4-L5 and MIS TLIF/transsacral fusion at L5-S1 Type of graft: NR n = 109 Number of levels: 2 2006-2009 	<ul style="list-style-type: none"> Open PLIF (historical cohort) Type of graft: NR n = 102 Number of levels: 2 Prior to 2006 	Follow-up period NR (% NR)
Rodgers et al (2010) Retrospective cohort (using historical cohort from same institution) CoE: III	<ul style="list-style-type: none"> N = 60 Age (mean): 83.4 y Male: 42% 	<ul style="list-style-type: none"> Degenerative spine conditions (stenosis, spondylolisthesis, scoliosis, postlaminectomy) Symptom duration: NR 	<ul style="list-style-type: none"> XLIF with unilateral or bilateral pedicle screws, percutaneous (n = 39) Type of graft: composite of demineralized bone matrix, cancellous allograft, local bone source, and bone marrow aspirate n = 40 1-level (n = 25), 2-level (n = 7), 3-level (n = 8); mean 1.6 levels from L1-L5 (62.5% including L4-L5) 	<ul style="list-style-type: none"> Open PLIF (historical cohort) with unilateral or bilateral pedicle screws, open exposure Type of graft: composite of demineralized bone matrix, cancellous allograft, local bone source, and bone marrow aspirate n = 20 1-level (n = 4), 2-level (n = 7), 3-level (n = 7), 5-level (n = 1), 7-level (n = 1); mean 2.6 levels from T10-S1 (80.0% including L4-L5) 	≥ 3 mo (% NR)
Knight et al (2009) Retrospective cohort (using historical cohort from senior author's practice) CoE: III	<ul style="list-style-type: none"> N = 98 Age (mean): 61 y Male: % NR 	<ul style="list-style-type: none"> Degenerative spine conditions (details NR) Symptom duration: NR 	<ul style="list-style-type: none"> XLIF or DLIF Type of graft: NR n = 58 1-level (n = 38), 2-level (n = 19), 3-level (n = 1); from T12-L5 2004-2006 	<ul style="list-style-type: none"> Open PLIF (historical cohort) Type of graft: NR N = 40 Number of levels: NR, excluded L5-S1 1992-1998 	XLIF or DLIF: 15 mo (3-34 mo) (% NR) PLIF: follow-up period NR (% NR)

Abbreviations: CoE, class of evidence; DLIF, direct lateral interbody fusion; f/u, follow-up; LLIF, lumbar lateral interbody fusion; MIS, minimally invasive surgical techniques; NR, not reported; PLIF, posterior lateral interbody fusion; TLIF, transforaminal lumbar interbody fusion; XLIF, extreme lateral interbody fusion.

Table 2 Characteristics of studies evaluating predictive factors affecting outcomes following LLIF/XLIF/DLIF for lumbar degenerative disease

Investigator (y) Study design CoE	Population ^a	Condition	Surgical procedure	Follow-up (% followed)	Predictive factors evaluated	Outcomes evaluated
Kepler et al (2012) Retrospective cohort CoE: III	<ul style="list-style-type: none"> N = 29 Age (mean): 69 y (45–87) Male: 41% 	<ul style="list-style-type: none"> DDD, spondylolisthesis, or degenerative scoliosis 	<ul style="list-style-type: none"> LTIF from L1–L5, with posterior instrumentation or standalone Number of levels: mean 2.3 levels/patient 	≥ 6 mo (% NR)	<ul style="list-style-type: none"> Demographic factors: age, sex, BMI Surgical factors: none Other factors: preoperative sagittal alignment at instrumented levels (degrees) 	Postoperative lumbar lordosis
Isaacs et al (2010) Prospective cohort CoE: II	<ul style="list-style-type: none"> N = 107 Age (mean): 68.4 y (45–87) Male: 27% 	<ul style="list-style-type: none"> Adult thoracolumbar scoliosis, with back pain, radicular pain, combined back/leg pain, or neurologic deficits Symptom duration: > 2 y (78% of patients) 	<ul style="list-style-type: none"> XLIF from T11–L5 or direct anterior/ AxILIF/posterior interbody approach at L5–S1 either standalone or with instrumentation (percutaneous posterior pedicle screws or lateral fixation) Number of levels involved: mean 4.4 levels/patient 	6 wks (% NR)	<ul style="list-style-type: none"> Demographic factors: age, sex, BMI, comorbidities, severity of deformity Surgical factors: inclusion of specific levels, number of levels treated, additional posterior decompression, type of fixation Other factors: none 	Perioperative complications
Rodgers et al (2010) Retrospective cohort CoE: III	<p>N = 313</p> <p>Obese group</p> <ul style="list-style-type: none"> N = 156 Age (mean): 58.9 y (30–87) Male: 41% BMI (mean): 36.0 kg/m² <p>Nonobese group</p> <ul style="list-style-type: none"> N = 157 Age (mean): 62.9 y (24–88) Male: 45% BMI (mean): 25.7 kg/m² 	<ul style="list-style-type: none"> Degenerative spine disease in lumbar and thoracic spine, including stenosis, spondylolisthesis, DDD, scoliosis, HNP, or postlaminectomy instability 	<ul style="list-style-type: none"> XLIF, range of levels NR Number of levels involved: NR 	3 mo (% NR)	<ul style="list-style-type: none"> Demographic factors: BMI, age, sex, height and weight, smoking, comorbidities (including diabetes mellitus, coronary artery disease, chronic obstructive pulmonary disease, chronic steroid use) Surgical factors: number of levels treated Other factors: preoperative diagnosis 	Early complications (within first 3 mo), including wound, nerve, cardiac, renal, GI, respiratory, vertebral body-related, and hardware-related

Abbreviations: AxILIF, axial lumbar interbody fusion; BMI, body mass index; CoE, class of evidence; DDD, degenerative disc disease; GI, gastrointestinal; HNP, herniated nucleus pulposus; NR, not reported; LTIF, lateral transpoas interbody fusion; XLIF, extreme lateral interbody fusion.

^aObese group included patients who were obese (BMI ≥ 30 kg/m² and ≤ 40 kg/m²) or morbidly obese (BMI > 40 kg/m²) (Rodgers et al, 2010).

Table 3 Studies comparing LLIF/XLIF/DLIF with PLIF/TLIF: perioperative outcomes

	LLIF/XLIF/DLIF	PLIF/TLIF	p Value
Length of hospital stay			
Deluzio et al (2010)	1.2 d	3.2 d	NR
Rodgers et al (2010)	1.3 d	5.3 d	< 0.0001
Knight et al (2009)	5 d (1–12)	5 d	NS
Estimated blood loss			
Rodgers et al (2010) ^a	1.4 g	2.7 g	< 0.0001
Knight et al (2009)	136 mL	489 mL	0.0000

Abbreviations: DLIF, direct lateral interbody fusion; LLIF, lumbar lateral interbody fusion; NR, not reported; NS, not significant; PLIF, posterior lateral interbody fusion; TLIF, transforaminal lumbar interbody fusion; XLIF, extreme lateral interbody fusion.

^aBlood loss measured by average preoperative to postoperative hemoglobin change (Rodgers et al, 2010).

Comparative Safety of LLIF/XLIF/DLIF versus PLIF/TLIF

Perioperative Outcomes

- Length of hospital stay was reported by all three studies and found to be shorter in the LLIF group compared with the PLIF group in two studies (►Table 1, ►Supplementary Table 1, ►Table 3, ►Fig. 2).^{5,6}
- Estimated blood loss measured by two different methods was reported by two studies and found to be significantly less in the LLIF group compared with the PLIF group in both studies.^{6,7}

Reoperation Risks

- Only one study reported reoperation risks for both treatment groups, with the LLIF group experiencing a lower reoperation risk compared with the PLIF group (►Table 4).⁶

- Only one study⁸ reported early reoperation for complications after XLIF; however, no specific reoperation time-frame is reported in the available studies.
- Five studies^{7–11} reported data on reoperations either following posterior open procedures⁹ or lumbar lateral interbody fusion.^{7,8,10,11}

Complications

- Overall, complication risks ranged from 7.5 to 22.4% in the LLIF group and from 22.5 to 60.0% in the PLIF group in two studies (►Table 4, ►Figs. 3 and 4).^{6,7}
- Neurological complications following LLIF were reported in three studies,^{7–9} ranging from 0.9% of treated cases in one study⁷ to 13.8% in another study.⁹
- Mortality was higher in those with open PLIF (mean age, 84.2 years) compared with XLIF (mean age, 82.6 years) in one study (30 vs. 2.5%)⁶ but not different in another.⁷ The patient population experiencing the higher mortality risk were older compared with patients in the other study. In addition, the study with higher mortality risk was conducted at the same institution⁶ but not necessarily by the same surgical group as in the study with the lower mortality risk.⁷

Factors Affecting Patient Outcome after LLIF/XLIF/DLIF Surgery

Three factors were found to be associated with various poor outcomes following surgery (►Table 2, ►Supplementary Table 2, ►Table 5).

- Number of levels treated.** There was 59% increase in the complication risk for each additional level treated (odds ratio, 1.59; $p = 0.0105$).⁹
- Preoperative diagnosis.** Higher complication risks were reported in patients with a diagnosis of DDD or recurrent disc herniation (vs. scoliosis, spondylolisthesis, stenosis, or postlaminectomy instability) ($p = 0.0075$).⁸
- Preoperative alignment.** Preoperative alignment was significantly correlated with postoperative lordosis and increase in lordosis ($p = 0.003$, $p < 0.001$, respectively).¹² The levels with the least preoperative lordosis gained the most lordosis after surgery.

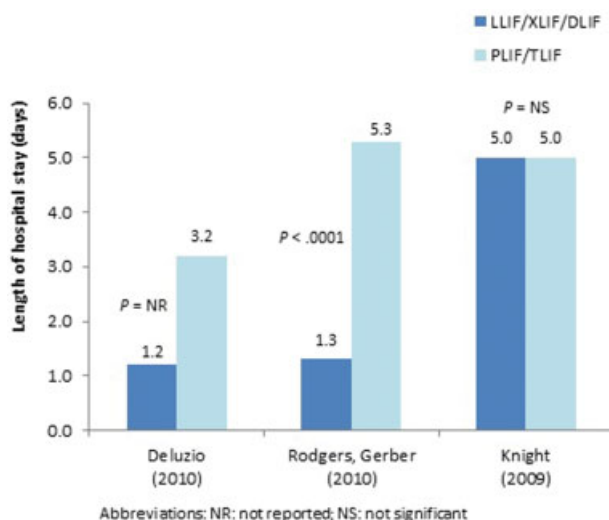


Fig. 2 Length of hospital stay for XLIF versus PLIF studies. NR, not reported; NS, not significant; DLIF, direct lateral interbody fusion; LLIF, lumbar lateral interbody fusion; PLIF, posterior lateral interbody fusion; TLIF, transforaminal lumbar interbody fusion; XLIF, extreme lateral interbody fusion.

Table 4 Studies comparing LLIF/XLIF/DLIF with PLIF/TLIF: reoperation risks and adverse events

	LLIF/XLIF/DLIF, %	PLIF/TLIF, %	p Value
Reoperation risks and cause			
Rodgers et al (2010)	5.0 (2/40) compression fracture or NR	15.0 (3/20) deep wound infection or compression fracture	NS
Knight et al (2009)	1.7 (1/58) loss of fixation at L2–L3 for acute subsidence	NR	
Overall complication risk			
Rodgers et al (2010)	7.5 (3/40)	60.0 (12/20)	< 0.0001
Knight et al (2009)	22.4 (13/58)	22.5 (9/40)	NR
Mortality risk			
Rodgers et al (2010)	2.5 (1/40)	30 (6/20)	0.0018
Knight et al (2009)	0 (0/58)	2.5 (1/40)	NR

Abbreviations: DLIF, direct lateral interbody fusion; LLIF, lumbar lateral interbody fusion; NR, not reported; NS, not significant; PLIF, posterior lateral interbody fusion; TLIF, transforaminal lumbar interbody fusion; XLIF, extreme lateral interbody fusion.

Clinical Guidelines

None found.

Evidence Summary

Overall, there is insufficient evidence of the comparative effectiveness of LLIF surgery versus PLIF surgery. There is low-quality evidence suggesting that LLIF surgery results in fewer complications or reoperations than PLIF surgery. And there is insufficient evidence that any factors exist that predict patient outcome after LLIF surgery (► **Table 6**).

Illustrative Case

A 65-year-old woman, with no significant medical history, presented with a long history of severe pain in the lumbar spine. No radicular pain was present. Symptoms made her ambulation difficult, as well as performing daily domestic activities.

Imaging revealed a degenerative thoracolumbar, left-sided convex scoliosis with apex at L2–L3 and L1–L2 (► **Figs. 5 and 6**).

She was initially treated with conservative care and medical drugs but without clinical benefit. Surgery was performed

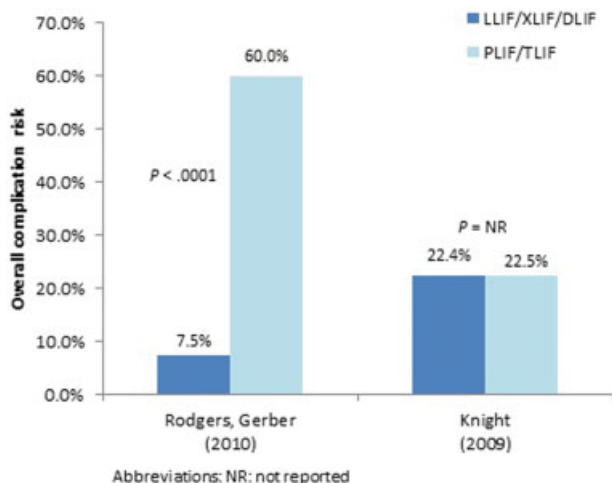


Fig. 3 Overall complication risks for XLIF versus PLIF studies. NR, not reported; DLIF, direct lateral interbody fusion; LLIF, lumbar lateral interbody fusion; PLIF, posterior lateral interbody fusion; TLIF, transforaminal lumbar interbody fusion; XLIF, extreme lateral interbody fusion.

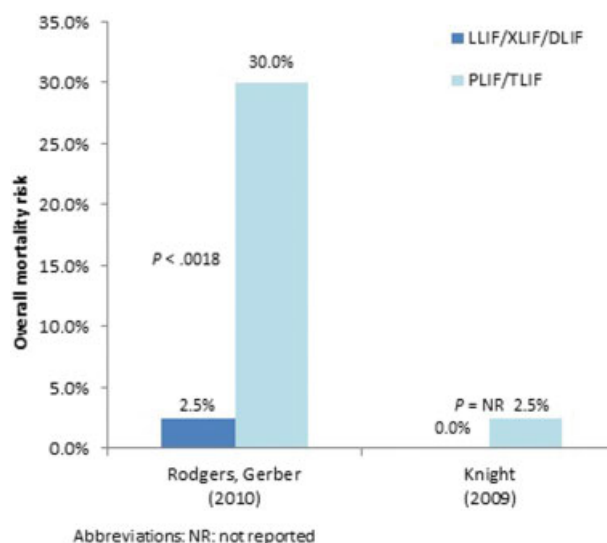


Fig. 4 Overall mortality risks for XLIF versus PLIF studies. NR, not reported; DLIF, direct lateral interbody fusion; LLIF, lumbar lateral interbody fusion; PLIF, posterior lateral interbody fusion; TLIF, transforaminal lumbar interbody fusion; XLIF, extreme lateral interbody fusion.

Table 5 Summary of demographic, surgical, and other factors evaluated as predictive factors for outcome following LLIF/XLIF/DLIF surgery

	Multivariate analysis to control for confounders		No multivariate analysis
	Isaacs et al (2010)	Rodgers et al (2010)	Kepler et al (2012)
Outcome evaluated	Perioperative complications	Early complications	Postoperative lumbar lordosis
Demographic factors			
Age	NS	NS	NS
Sex	NS	NS	NS
BMI	NS	NS	NS
Height/weight		NS	
Smoking		NS	
Comorbidities	NS	NS	
Severity of deformity	NS		
Surgical factors			
No. of levels treated	↑	NS	
Inclusion of specific levels	NS		
Type of fixation	NS		
Additional posterior decompression	NS		
Other factors			
Preoperative diagnosis		↑	
Preoperative sagittal alignment			↑

Abbreviations: BMI, body mass index; DLIF, direct lateral interbody fusion; LLIF, lumbar lateral interbody fusion; NS, not significant; XLIF, extreme lateral interbody fusion; ↑, increased risk of outcome.

Note: Empty cell indicates that factor was not evaluated.

Table 6 Evidence summary

	Strength of evidence	Conclusions/comments
In adult patients, what is the comparative effectiveness of LLIF/XLIF/DLIF surgery compared with PLIF or TLIF surgery?		
LLIF/XLIF/DLIF versus PLIF/TLIF		None of the studies reported the comparative effectiveness of radiographic or patient-reported outcomes.
In adult patients, what is the comparative safety of LLIF/XLIF/DLIF surgery compared with PLIF or TLIF surgery?		
LLIF/XLIF/DLIF versus PLIF/TLIF		Overall, the evidence on the comparative safety of LLIF compared with PLIF is low. The LLIF treatment group had less estimated blood loss and a lower mortality risk than the PLIF treatment group. However, results for other outcomes were inconsistent. Two studies reported a shorter length of hospital stay for the LLIF group, yet one study reported the same length of hospital stay for both treatment groups. One study reported a significantly lower complication risk for the LLIF group, but another study reported approximately the same risk for both treatment groups. And only one study reported the reoperation risk for both treatment groups.
In adult patients, are there any factors affecting patient outcome after LLIF/XLIF/DLIF surgery?		
LLIF/XLIF/DLIF		Overall, the evidence that factors predict patient outcome after LLIF surgery is insufficient. The three studies examined predictive factors for different outcomes. Two studies performed a multivariate analysis to control for confounders: one study found that number of levels treated was a significant predictor of

Table 6 (Continued)

	Strength of evidence	Conclusions/comments
		perioperative complications and one study found that preoperative diagnosis was a significant predictor of early complications. The third study found that preoperative sagittal alignment was a significant predictor of postoperative lumbar lordosis but did not control for confounders in the analysis. All three studies found that age, sex, and BMI were not predictors of outcome after LLIF.

Abbreviations: BMI, body mass index; DLIF, direct lateral interbody fusion; LLIF, lumbar lateral interbody fusion; PLIF, posterior lateral interbody fusion; TLIF, transforaminal lumbar interbody fusion; XLIF, extreme lateral interbody fusion.

Notes: Baseline strength: Risk of bias (including control of confounding) is accounted for in the individual article evaluations. High = majority of articles level I/II; low = majority of articles level III/IV.



Fig. 5 Preoperative anterior posterior radiograph of 65-year-old female with degenerative lumbar scoliosis.

with a two-level XLIF at the apex of the deformity (L2–L3, L1–L2), followed by a posterior open correction and fixation from Th11 down to L5 (► **Figs. 7** and **8**).

Following such procedure, a good balance and alignment of the spine were obtained as well as improvement of pain. Full recovery of her domestic activity as well of ambulatory ability was achieved.

Discussion

- This systematic review is limited by the following:
 - The majority of included studies were CoE III.
 - There was a paucity of studies comparing LLIF surgery with PLIF or TLIF surgery.
 - All three studies investigating the effectiveness of LLIF used historical controls who received PLIF or TLIF: two studies used a comparison group from the same institution^{5,6} and one study used a comparison group from the senior author's practice.⁷ Therefore, patients in the LLIF treatment group might have been subject to changes in policies or supportive care.
- The new direct lateral approach to the lumbar spine proves to be safe and effective, and at least comparable with the PLIF/TLIF techniques. This approach cannot be used for the L5/S1 level for anatomic limitations.
- The complications' rate shows to be inferior in the XLIF/DLIF/LLIF compared with the PLIF/TLIF studies.^{6,7}
- More studies with longer follow-up, including randomized trials, are necessary to evaluate the theoretical benefit of direct lumbar lateral approach and to assess whether the results of this strategy are superior and durable as the ones achieved by PLIF/TLIF technique performed in open or minimally invasive surgery.
- Potential limitations may also be related to some authors' conflicts of interest.^{6,7,9,10}

Disclosures

Analytic support for this work was provided by Spectrum Research, Inc. with funding from AOSpine.



Fig. 6 Preoperative lateral radiograph.



Fig. 7 Postoperative anterior posterior radiograph following two-level XLIF and posterior open correction and fixation.



Fig. 8 Postoperative lateral radiograph.

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Editorial Perspective

The EBSJ reviewers felt that this topic was an excellent and timely choice made by the authors. There are many variants of the same idea being offered by industry, all of them based on the premise to avoid the extensor backside of patients while finding the magic interval between the lumbar plexus and the large vessels for the sake of decreased muscle dissection. Although the timing of this systematic review may appear premature to the point of offering the predictable “need more research” conclusion, this study does provide a valuable overview of the current state of research on this largely industry-driven technique-based procedure variant. That said, there is no doubt that the findings of this systematic review strongly support a comparative effectiveness-based project.

Criticisms of the reviewers revolved around the uncontrolled variables—curve deformity and spondylolisthesis, previous surgery, and level of surgery. Access to the L4-5

level in particular can be difficult with lateral techniques due to the variable height of the pelvic crest and somewhat unpredictable bifurcation anatomy, leading to the question of how much “effectiveness” will mirror the rather positive “efficacy” results presented by experts in these early technique-based publications.

Finally, the reviewers raised the very critical point of potential for conflict of interest. As stated earlier, this technology is very clearly based on an industry “push.” The question of the relationship of the investigators and the implant manufacturers, who are commonly newer to the market and tend to be more aggressive than the more established manufacturers, certainly warrants careful review of the disclosures made.

Finally, this is a very helpful status check and hopefully will help the EBSJ community advance their insights into this emerging surgical technique.