

Patient-Reported Outcomes of Minimally Invasive versus Open Transforaminal Lumbar Interbody Fusion for Degenerative Lumbar Disc Disease: A Prospective Comparative Cohort Study

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Background: Comparative outcomes of minimally invasive transforaminal lumbar interbody fusion (MI-TLIF) and traditional open TLIF (O-TLIF) for degenerative lumbar disc disease have been poorly studied. The purpose of this study was to prospectively compare the outcomes between MI-TLIF and O-TLIF for patients with a degenerative disc disease, focusing on the functional capacity of patients in daily life.

Methods: A prospective cohort study was performed, comparing 54 patients who underwent O-TLIF and 55 patients who underwent MI-TLIF with a follow-up of 4 years. Clinical evaluation was performed using the Oswestry Disability Index (ODI), 36-item short form survey (SF-36), and a visual analog scale for pain (VAS pain). Radiological evaluation was also performed.

Results: At the final follow-up, compared with O-TLIF, MI-TLIF was associated with significantly better intraoperative results, including similar operative time (p = 0.246), lower estimated blood loss (p = 0.001), and shorter hospital stay (p = 0.001). The final ODI score was significantly better in the MI-TLIF group (p = 0.031). The SF-36-physical (p = 0.023) and VAS pain (p = 0.024) scores were significantly better in the MI-TLIF group. There was no significant difference in the fusion rate (p = 0.747).

Conclusions: The MI-TLIF technique is an effective and safe procedure for degenerative lumbar disc disease. Compared to traditional O-TLIF, MI-TLIF was associated with less disability and higher quality of life, with a low rate of intraoperative and postoperative complications.

Keywords: Lumbar vertebrae, Percutaneous pedicle screws, Transforaminal lumbar interbody fusion, Minimally invasive surgical procedures, Adverse effects

Transforaminal lumbar interbody fusion (TLIF) is a wellestablished surgical procedure used to treat several spinal

Received July 28, 2022; Revised September 5, 2022; Accepted October 5, 2022 Correspondence to: Alejandro Lizaur-Utrilla, MD Department of Traumatology and Orthopaedics, Faculty of Medicine, Miguel Hernandez University, Ctra Valencia 23C, 03550 San Juan Alicante, Spain Tel: +34-9-6697-5024, Fax: +34-9-6697-5148 E-mail: lizaur1@telefonica.net disorders including degenerative diseases.¹⁾ The procedure allows a safe technique to achieve circumferential fusion with minimal retraction of neural elements through a single posterior approach. Successful outcomes have been obtained with conventional open TLIF (O-TLIF) for degenerative lumbar diseases.²⁾ Despite its advantages compared to the traditional posterior lumbar interbody fusion, O-TLIF has also been associated with significant morbidities due to extensive muscle dissection and retraction.³⁾

Minimally invasive TLIF (MI-TLIF) was developed

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to reduce iatrogenic soft-tissue and muscle injury associated with traditional O-TLIF, using small incisions and tubular retractors inserted serially under radiological guidance via a muscle-dilating approach and a percutaneous pedicle screw-rod fixation system.⁴⁾ Potential clinical advantages of the MI-TLIF include less intraoperative blood loss, postoperative pain, time to discharge, and faster recovery.⁵⁾ MI-TLIF is currently a well-established procedure for lumbar degenerative diseases and has improved clinical outcomes and decreased perioperative morbidity.⁶⁾

Several studies have compared both procedures.⁶⁻⁸⁾ However, most of those studies involved retrospective designs, small sample sizes, short follow-up, and heterogeneity in surgical indications and case complexity. Among the prospective comparative studies, most focused on costs⁹⁾ and selected groups of patients such as obese people¹⁰⁾ or included mixed pathologies such as degenerative discs and spondylolisthesis.^{11,12)} The clinical outcome of lumbar fusion is known to be dependent on primary diagnosis.¹³⁾ To our knowledge, only two prospective studies have focused exclusively on the outcomes in patients with degenerative disc disease.^{14,15)} Thus, there is little evidence on the comparative outcomes of both procedures for that condition.

The purpose of this study was to prospectively compare the outcomes between MI-TLIF and O-TLIF for patients with degenerative disc disease, focusing on the functional capacity of patients in daily life. The hypothesis was that MI-TLIF should provide better patient-reported outcomes than O-TLIF.

METHODS

This study was designed and approved by the Institutional Ethics Committee (No. PI2014-181), and informed consent was obtained.

The O-TLIF procedure has been traditionally used in our center. Because of the promising results described in the literature, the use of MI-TLIF was started with a series of 10 patients as a learning curve, obtaining satisfactory early outcomes, and these patients were not included in this study. Thus, a comparative analysis of both procedures performed under usual practice conditions for the degenerative lumbar disease was conducted. Both procedures were performed alternately according to surgery date to minimize bias in the surgery selection.

Consecutive patients undergoing TLIF between January 2015 and December 2017 were candidates for the study. The indication for surgery was persistent or recurrent back pain or leg pain lasting at least 6 months despite conservative therapy such as physical therapy and pain management. The inclusion criterion was degenerative lumbar disc disease, such as severe degenerative disc disease and degenerative disc with stenosis. Exclusion criteria were isthmic or posttraumatic spondylolisthesis, prior spinal surgery, spinal trauma, active infection, malignancy, and severe osteoporosis.

Surgical Protocol

A single surgeon (ADJM) performed all the surgeries. In both groups, standard decompressions, placement of a peeking interbody cage (AVS navigator system; Stryker, Allendale, NJ, USA) with autologous bone graft obtained from the removed facet, and fixation with pedicle screws and rods were carried out. Specific magnifying lenses for spinal surgery were used for both groups.

The conventional O-TLIF was performed in the technique described by Lowe and Tahernia¹⁶⁾ with a midline incision, and paraspinal muscles were retracted with self-retaining retractors. The bilateral pedicle screws were inserted under fluoroscopy control. Standard facetectomies and decompression were carried out in the levels requiring decompression. After discectomy and end plate preparation, the interbody fusion cage with autologous was placed. Demineralized bone matrix (Grafton; Medtronic, Minneapolis, MN, USA) was added in 8 patients. Cage position was checked under fluoroscopy. Then, the screws were connected to rods (Xia3 system; Stryker), and compression was applied using a dynamometer. Finally, an autologous bone graft was applied to the transverse processes.

The MI-TLIF procedure was performed according to the technique described by Wiltse et al.¹⁷⁾ with small incisions on the lateral pedicle lines for placement of the pedicle cannulated screws under fluoroscopy control. The minimally invasive system used was the Lite system (Stryker). Using small paramedian incisions and sequential tubular dilators, facetectomies, decompression, discectomy, and endplate preparation were done. Cage insertion was carried out with an autologous bone graft. Screws and rods (ES2 spinal system; Stryker) were placed percutaneously on both sides and compression was applied using a dynamometer. Finally, an autologous bone graft was applied to the transverse processes. Demineralized bone matrix was added in 10 patients. The fluoroscope was only used during the placement of the tubular retractor system and at the end of the surgery to check pedicle screw placements or in case of doubt.

All patients received preoperative antifibrinolytic prophylaxis with tranexamic acid. Antibiotics were intravenously administered 24 hours after surgery and thromboembolic prophylaxis with low-molecular-weight heparin for 30 days. Patients were allowed to sit and walk with a thermoplastic corset at 24 hours after surgery. Rehabilitation was started around the second day and continued in the outpatient clinic after discharge.

Evaluations

The protocol included preoperative and postoperative clinical and radiological assessments at 1, 3, 6, and 12 months and yearly thereafter up to 4 years. At the final follow-up, assessments were performed by two independent surgeons who were blinded to the surgical procedure (ALU and FALP). The primary outcome was the Oswestry Disability Index (ODI) score¹⁸⁾ expressed in percentage, with higher scores indicating more disability related to back pain. ODI scores were presented in absolute value and dichotomized into satisfactory outcome (greater than 30 points) and unsatisfactory outcome (equal to or less than 30 points) according to Park et al.¹⁹⁾ Patients were also assessed for quality of life using the 36-item short form survey (SF-36).²⁰⁾ For this study, SF-36 was summarized in two components, physical and mental components, and then they were transformed to 0 (worst health) to 100 (best health) scale. A visual analog scale (VAS)²¹⁾ for low back pain was used at discharge and the final follow-up. Comorbidity at the time of admission was assessed using the American Society of Anesthesiologists score (ASA).

A radiological evaluation was done regularly during the follow-up visits with anteroposterior and lateral views. The last radiological evaluations were performed by two independent surgeons who had not participated in the surgery (ALU and MFVM). The fusion status was radiologically assessed according to the Bridwell et al.'s grading system in four grades,²²⁾ and the fusion was defined as grade I or II in this study. When the fusion status was difficult to confirm by radiographs, computed tomography (CT) scans were performed.

Statistical Analysis

A priori power analysis was performed to determine the needed sample size based on a relevant difference of 15 points (standard deviation, 17) in the ODI score.¹¹⁾ A minimum of 51 patients in each group was estimated to be necessary to find a significant difference between groups with an 80% power and 0.05 significance level. After assuming a drop-out rate of 5%, at least 53 patients were required per group.

Statistical analyses were conducted with IBM SPSS ver. 21 software (IBM Corp., Armonk, NY, USA). Normality was tested using the Shapiro-Wilk test. For categorical variables, chi-square or Mantel-Haenszel test was used, and Student *t*-test or Mann-Whitney test was used for continuous variables. Paired Student *t*-test or Wilcoxon signed-rank test was used to compare preoperative and postoperative continuous variables. The Spearman test was carried out to assess the correlation between continuous variables. A backward multivariate logistic regression model was used to study the effect of the independent variables on the outcomes. The adjusted risk was presented as an odds ratio (OR) with a 95% confidence interval (CI). Survival was assessed using the Kaplan-Meier method with revision for any reason as the endpoint, and comparison between groups was done using the log-rank test. Statistical significance was considered for *p*-values less than 0.05 in all tests.

RESULTS

Initially, 114 patients were included in the study, 57 in each group. In the O-TLIF group, 1 patient died during the follow-up for a reason not related to the surgery, and 2 patients were lost to follow-up. In the MI-TLIF group, there were 2 patients lost to follow-up. Thus, 54 patients in the O-TLIF group and 55 in the MI-TLIF group were available for the study. Baseline data of both groups are shown in Table 1. There were no significant differences between groups in the demographic data, body mass index, or comorbidities. Prior to surgery, the mean length of symptoms was 10.7 months in the O-TLIF group and 9.6 months in the MI-TLIF group. All patients had been managed conservatively, without prior instrumented or non-instrumented surgery. Regarding the perioperative data (Table 2), the mean operative time was not significantly different (p = 0.246), but the fluoroscope use time

Table 1. Preoperative Patient Data				
Variable	0-TLIF (n = 54)	MI-TLIF (n = 55)	<i>p</i> -value	
Age (yr)	63.3 ± 11.0	59.9 ± 13.7	0.188	
Sex (female : male)	30 : 24	31 : 24	0.542	
BMI (kg/m ²)	30.1 ± 13.4	27.8 ± 11.3	0.393	
ASA score (I – II : III – IV)	40:14	38 : 17	0.358	
Tobacco history	25 (46.2)	23 (41.8)	0.390	

Values are presented as mean ± standard deviation or number (%). O-TLIF: traditional open transforaminal lumbar interbody fusion, MI-TLIF: minimally invasive transforaminal lumbar interbody fusion, BMI: body mass idex, ASA: American Society of Anesthesiologists.

Table 2. Perioperative Data			
Variable	0-TLIF	MI-TLIF	<i>p</i> -value
Fusion level			0.147
L2-3	19	21	
L3-4	23	22	
L4-5	49	48	
L5 — S1	3	2	
Simultaneous level			0.170
1	16	18	
2	35	36	
3	3	1	
Operative time (min)	132.0 ± 51.9	143.2 ± 46.5	0.246
Radiation time (sec)	62.7 ± 6.6	81.9 ± 9.3	0.001
Hemoglobin (g/dL)			
Preoperative	14.3 ± 1.3	13.9 ± 1.3	0.144
At discharge	33.2 ± 4.3	34.7 ± 4.5	0.118
Blood loss (mL)	521.2 ± 221.2	261.8 ± 216.9	0.001
Transfused blood unit	9	1	0.007
Hospital stay (day)	3.7 ± 1.6	2.7 ± 0.9	0.001

Values are presented as mean ± standard deviation.

O-TLIF: traditional open transforaminal lumbar interbody fusion, MI-TLIF: minimally invasive transforaminal lumbar interbody fusion.

was significantly longer in the MI-TLIF group (p = 0.001). However, the mean estimated perioperative blood loss (p = 0.001), the number of transfused units of packed red blood cells (p = 0.007), and length of hospital stay (p = 0.001) were significantly lower in the MI-TLIF group.

Clinical Results

All patients were followed up for 4 postoperative years. There was no significant preoperative difference in the mean ODI score between groups (Table 3), and the score significantly improved in both groups (p = 0.001) from preoperative to final follow-up. ODI scores showed more important improvements in the first postoperative year and then slower improvements in both groups (Fig. 1). At the final follow-up, the mean ODI score was significantly better in the MI-TLIF group than in the O-TLIF

Table 3. ODI Scores over Time			
Follow-up	0-TLIF	MI-TLIF	<i>p</i> -value
Preoperative	44.6 ± 13.4	47.4 ± 12.9	0.331
1 mo	29.2 ± 4.1	26.5 ± 4.6	0.012
3 mo	27.5 ± 3.9	22.4 ± 3.6	0.001
6 mo	21.7 ± 6.4	17.8 ± 3.9	0.003
12 mo	16.8 ± 6.3	12.0 ± 4.2	0.001
2 yr	16.4 ± 7.6	12.8 ± 6.9	0.010
3 yr	16.1 ± 8.1	12.9 ± 7.6	0.035
4 yr	15.6 ± 7.2	12.4 ± 6.3	0.031

Values are presented as mean ± standard deviation.

ODI: Oswestry Disability Index, O-TLIF: traditional open transforaminal lumbar interbody fusion, MI-TLIF: minimally invasive transforaminal lumbar interbody fusion.

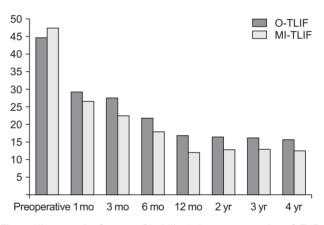


Fig. 1. Histogram for Oswestry Disability Index score over time. O-TLIF: traditional open transforaminal lumbar interbody fusion, MI-TLIF: minimally invasive transforaminal lumbar interbody fusion.

group (12.4% vs 15.6%, respectively; p = 0.031). Regarding the quality of life at the final follow-up (Table 4), SF-36-physical was significantly better (p = 0.023) in the MI-TLIF group, but there was no significant difference in SF-36-mental (p = 0.214). Mean VAS pain was significantly lower in the MI-TLIF group at discharge (p = 0.001) and final follow-up (p = 0.024). In the multivariate analysis (Table 5), only the MI-TLIF procedure (OR, 4.1; 95% CI, 1.2–13.9; p = 0.022) was a significant predictor of satisfactory ODI outcome.

Radiological Results

Radiologically, fusion status at the final follow-up in the MI-TLIF group was Bridwell grade I–II in 54 patients (98.2%) and grade-III in 1 patient (0.8%), while in the O-

Table 4. Clinical Outcomes			
Variable	0-TLIF	MI-TLIF	<i>p</i> -value
SF-36 physical			
Preoperative	25.3 ± 12.1	28.8 ± 13.4	0.211
Final follow-up	46.8 ± 18.3	55.0 ± 12.6	0.023
p-value (pre vs. final)	0.001	0.001	
SF-36 mental			
Preoperative	34.0 ± 18.6	38.2 ± 19.2	0.319
Final follow-up	53.2 ± 21.0	58.5 ± 16.5	0.214
p-value (pre vs. final)	0.001	0.001	
VAS pain			
At discharge	1.7 ± 1.7	0.5 ± 0.7	0.001
At final follow-up	2.6 ± 1.8	1.8 ± 1.2	0.024

Values are presented as mean ± standard deviation.

O-TLIF: traditional open transforaminal lumbar interbody fusion, MI-TLIF: minimally invasive transforaminal lumbar interbody fusion, SF-36: 36item short form survey, VAS: visual analog scale.

TLIF group, there were 53 (98.1%) grade I–II, and 1 (0.9%) grade III, with no statistical difference between groups (p = 0.747).

Complications

Regarding intraoperative complications, there were 4 patients with small dural tears in the MI-TLIF group, and 6 patients in the O-TLIF group. All these tears were repaired intraoperatively with no influence on the outcomes. Postoperative complications occurred in 3 patients (5.4%) in the MI-TLIF group and 9 patients (16.6%) in the O-TLIF group (p = 0.057). Two patients in the MI-TLIF group had screw breakages at 19 and 26 postoperative months, respectively, but none required reoperation. In the O-TLIF group, 1 patient presented cage migration at 7 postoperative months, which did not require reoperation. Another patient, who had a Von Willebrand coagulopathy, developed a hematoma postoperatively and presented with sacral and bilateral leg numbness, requiring reoperation with complete recovery. Other 7 patients in the O-TLIF group presented failed back syndrome between 5 and 22 postoperative months, requiring reoperation in 4 of them.

Thus, reoperation was needed in none of the patients in the MI-TLIF group and in 5 patients (9.2%) in the O-TLIF group (p = 0.091). TLIF survivorship at final follow-up was 94.5% (95% CI, 84.8%–100%) in the MI-TLIF group and 90.5% (95% CI, 82.5%–98.4%) in the O-

Table 5. Multivariate Analysis for Final Satisfactory ODI

Variable	Satisfactory (n = 88)	Unsatis- factory (n = 21)	OR (95% CI)	<i>p</i> -value
Age (yr)	59.9 ± 10.2	63.4 ± 11.4	0.8 (0.2–3.0)	0.862
BMI (kg/m ²)	28 ± 9.9	30.8 ± 11-6	1.0 (0.3–3.1)	0.892
Fusion level < 2	19	15	1.8 (0.4–7.2)	0.371
No complication	81	14	0.2 (0.02–3.1)	0.302
MI-TLIF	45	10	4.1 (1.2–13.9)	0.022

Values are presented as mean \pm standard deviation unless otherwise indicated.

ODI: Oswestry Disability Index, OR: odds ratio, CI: confidence interval, BMI: body mass idex, MI-TLIF: minimally invasive transforaminal lumbar interbody fusion.

TLIF group (p = 0.471).

DISCUSSION

The present study showed that compared with O-TLIF, MI-TLIF was associated with significantly better intraoperative results, including shorter operative time, lower estimated blood loss, and shorter hospital stay. Likewise, the outcomes at 4 postoperative years were significantly better in the MI-TLIF group, including ODI, SF-36-physical, and VAS pain scores. The ODI scores showed slow improvements at 1 postoperative year, but significant differences between groups at 4-year follow-up. Nevertheless, the difference between groups could be considered not clinically relevant. There was no significant difference in the fusion rate.

Comparing present study's findings with those of the literature is difficult because only 2 prospective studies focused on patients diagnosed with degenerative lumbar disc disease.^{14,15)} Other prospective studies comparing MI-TLIF and O-TLIF procedures have been published, but most of them included mixed conditions, such as isthmic spondylolisthesis or other spinal deformities.⁶⁻⁸⁾ Another study focused on low-grade degenerative spondylolisthesis,²³⁾ and three other studies included degenerative lumbar disc and degenerative spondylolisthesis patients.^{6,12,24)}

Gu et al.,¹⁴⁾ in a comparative study focused on degenerative lumbar disc patients, reported no significant difference between the two groups, but the authors performed a fusion of only two levels. As in the present study, intraoperative blood loss and transfused patient rates were significantly lower in the MI-TLIF group than in the O-TLIF group. Likewise, the length of hospital stay was significantly shorter for MI-TLIF patients. Unfortunately, another similar study did not report data on perioperative results.¹⁵⁾

In prospective studies that included heterogeneous lumbar conditions, Shunwu et al.⁶⁾ compared 32 patients who underwent MI-TLIF and 30 who underwent O-TLIF. The authors reported that the MI-TLIF group had reduced blood loss, fewer transfusions, less postoperative back pain, and lower serum creatine kinase on the third postoperative day, a shorter time to ambulation, and a briefer hospital stay as compared with the O-TLIF group. Schizas et al.²⁵⁾ reported similar results. Conversely, Hey and Hee,²⁴⁾ in a prospective matched study of 25 pairs of patients, reported that operative time was significantly longer in the MI-TLIF group than in the O-TLIF group due to technical constraints, and no differences in estimated blood loss or length of stay were found. The mean age of their patients was 44 years. Peng et al.¹²⁾ in a prospective matched study of 29 pairs of patients, also reported a longer operative time in the MI-TLIF group, although they performed a single-level fusion in all the patients. However, they found less blood loss and shorter hospitalization in MI-TLIF compared with O-TLIF. Sulaiman and Singh,²³⁾ in a prospective study cohort of 57 MI-TLIF and 11 O-TLIF patients for degenerative spondylolisthesis grades 1–2, reported a longer operative time for MI-TLIF, even though most patients in the MI-TLIF group had a 1-level fusion, while most patients in the O-TLIF group had a 2-level fusion. They also reported that the mean estimated blood loss was significantly less in the patients receiving MI-TLIF. In the most recent meta-analysis, where all indications for TLIF were combined, Hammad et al.³⁾ found that MI-TLIF compared to O-TLIF had a shorter operative time, while others^{7,26)} found no substantial difference. However, all those meta-analyses also reported that MI-TLIF resulted in less perioperative blood loss and shorter length of stay than O-TLIF.

In the present study, MI-TLIF provided better functional outcome and quality of life and less residual pain than did O-TLIF. While some authors have reported better ODI and VAS pain scores for MI-TLIF,^{6,23)} others found no difference between both procedures in the midterm.^{14,15,27)} Peng et al.¹²⁾ reported no differences in ODI or SF-36 scores at 2-year follow-up, but MI-TLIF patients had faster recovery, ambulating earlier after surgery with less postoperative pain and analgesic use. Other studies have also reported better short-term ODI scores for MI-TLIF patients compared to O-TLIF patients.^{9,28)} Conversely, Hong et al.²⁹⁾ found that MI-TLIF provided better outcome at the early postoperative, but no significant differences at 7 years. Additionally, these authors reported similar rates of adjacent segment disease between groups. Jeong et al.³⁰⁾ also reported similar rates of adjacent segment disease at 10-year follow-up. Most meta-analyses reported no remarkable differences in functional scores at midterm follow-up,^{3,7)} except Miller et al.²⁶⁾ and Kim et al.,³¹⁾ who found lower ODI scores at short-term follow-up in MI-TLIF patients than in O-TLIF patients. However, the significant heterogeneity of diagnoses included in those meta-analyses limited their ability to apply the results to any specific patient population.

In agreement with our findings, most prospective studies and meta-analyses found no difference in the fusion rate according to the Bridwell criteria between both procedures.^{3,12,14,24)} In the present study, the risk of postoperative complications was lower in the MI-TLIF group compared to that in the O-TLIF group. While some studies found no difference in complication rates of both procedures,^{6,14)} others reported lower rates in MI-TLIF.^{23,32)} Other meta-analyses reported that the complication rate was lower in O-TLIF patients, but with no significant difference compared to MI-TLIF patients.^{3,26)} Our findings indicate that the MI-TLIF procedure is a safe and beneficial alternative to O-TLIF for degenerative lumbar disc disease, although the learning curve could be a potential limitation for the outcomes.³³⁾ Compared to O-TLIF, the MI-TLIF procedure is technically more challenging, because the operative field is much smaller and lacks visualization of the bony landmarks.

To our knowledge, this is the third prospective study focusing on degenerative lumbar disc disease that reported comparative perioperative data and outcomes between MI-TLIF and O-TLIF.^{14,15)} However, this study has several limitations. Firstly, the study did not have a randomized design, and the baseline characteristics of the cohorts were not controlled. The follow-up was only intermediate at 4 years. However, the main objective of this study was to compare the patient-reported outcomes, and that followup time seems sufficient to analyze it. On the other hand, prospective studies with a follow-up of at least 2 years are scarce.^{14,15)} The fusion status was radiologically assessed, and CT scan was only used when the fusion was difficult to confirm by radiographs. The postoperative sagittal alignment was not analyzed in the present study. Nevertheless, a recent study found a low correlation between the spinopelvic alignment and lumbar degenerative pathology.³⁴⁾ Further larger and well-designed prospective studies are required to confirm the findings of the current study.

In conclusion, the MI-TLIF technique can be an

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effective and safe procedure for single- and multi-level fusion in degenerative lumbar disc diseases. Compared to traditional O-TLIF, MI-TLIF was associated with less disability, higher quality of life, and a low rate of intraoperative and postoperative complications.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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