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ORIGINAL RESEARCH

Innovative Percutaneous Endoscopic Transforaminal Lumbar Interbody Fusion of Lumbar Spinal Stenosis with Degenerative Instability: A Non-Randomized Clinical Trial

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Purpose: Lumbar spinal stenosis (LSS) with instability is most common lumbar degenerative diseases for people with low back pain. The objective of this study was to compared the clinical effects for the treatment of lumbar spinal stenosis (LSS) with degenerative instability between the innovative percutaneous endoscopic transforaminal lumbar interbody fusion (PE-TLIF) technique and posterior lumbar interbody fusion (PLIF) technique.

Patients and Methods: Between April 2019 and April 2020, 114 patients with single-segment LSS were prospectively included in our study (ChiCTR1900022492). Visual Analogue Scale (VAS) on lumbar and leg pain (VAS-LBP, VAS-LP), Oswestry Disability Index (ODI), serum creatine kinase (CK), the maximal cross-sectional area of multifidus muscle (Max-CSA) and the peak intensity of sulphur hexafluoride microbubble contrast agent (PI) around the surgical incision by contrast-enhanced ultrasonography were evaluated preoperatively, post-operatively and at regular follow-up.

Results: All patients were followed up. The VAS-LBP, VAS-LP, ODI after operation were improved significantly compared to these data before operation in all the patients ($P<0.05$). The VAS-LBP at 1 weeks, 3 months after operation in PE-TLIF group were significantly lower than these in PLIF group ($P<0.05$). The injury degree of multifidus muscle evaluated by MAX-CSA and PI was significantly less in PE-TLIF group after operation ($P<0.05$). There was no significant difference on the complication rate between these two groups ($P>0.05$).

Conclusion: Our results presented PE-TLIF technique could obtain comparable effective outcomes as conventional PLIF for the treatment of LSS with degenerative instability. The patients with PE-TLIF had less muscle injury, less pain and quicker postoperative rehabilitation.

Keywords: pain, minimally invasive surgery, percutaneous, spinal endoscope, transforaminal lumbar interbody fusion, lumbar spinal stenosis

Introduction

Low back pain was reportedly the leading cause of disability in elderly people from 1990 to 2017,[1] while lumbar spinal stenosis (LSS) is the most common lumbar degenerative disease in people with low back pain.[2] Although most patients with LSS can be treated conservatively, some still require surgery due to persistent severe pain.[3,4]

Spinal fusion surgery effectively improves the pain, segment stability, function, and quality of life of patients with LSS, especially those with degenerative instability.[5,6] Most surgeons consider posterior lumbar interbody fusion (PLIF)

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the standard treatment for LSS with degenerative instability, and PLIF demonstrated a satisfactory clinical effect and higher fusion rate.[5] Nevertheless, extensive destruction of the posterior musculoligamentous complex usually leads to muscular atrophy, tremendous postoperative pain, and functional disability.[7,8] Therefore, over the past 20 years, minimally invasive surgeries have gradually gained popularity for overcoming the disadvantages of traditional open surgeries.[9]

Endoscopic lumbar fusion techniques have successfully treated patients with LSS,[10–13] however, some drawbacks persist, including nerve root injury, cage-related complications, long learning curves, and others. To overcome the aforementioned disadvantages, we developed an innovative percutaneous endoscopic transforaminal lumbar interbody fusion (PE-TLIF) method using an oriented superior articular process (SAP) resection device, which showed good clinical results in a preliminary report.[14] To our knowledge, all other studies to date of the endoscopic lumbar fusion technique for treating patients with LSS were retrospective; thus, available clinical evidence is relatively low.

Hence, this prospective cohort study of PE-TLIF for treating patients with LSS aimed to provide high-level evidence for clinical practice. Meanwhile, we compared the degree of injury to the lumbar multifidus muscle induced by PLIF versus PE-TLIF for treating LSS with degenerative instability. We hypothesized that the clinical effects of PE-TLIF would not be inferior to those of PLIF.

Patients and Methods

114 patients diagnosed with single-segment LSS and degenerative instability between April 2019 and April 2020 were prospectively included (ChiCTR1900022492). The study was conducted in accordance with the Declaration of Helsinki.

The inclusion criteria were as follows: (1) The operative level was L4/5; (2) no history of lumbar surgery; (3) no obvious multifidus muscle injury certified on ultrasonography; and (4) no lumbar scoliosis, deformity, or tumor. The exclusion criteria were as follows: (1) inability to complete follow-up, (2) presence of other comorbidities that could affect lumbar fusion, and (3) presence of other comorbidities that could affect serum creatine kinase (CK) level. The choice of surgical method (PE-TLIF or PLIF) mainly depends on the patients' opinions and the surgeons' preferences. The institutional review board of Beijing Chao-Yang Hospital affiliated China Capital Medical University approved the study. All patients were informed of all possible results of these two surgeries and preoperatively provided written consent. The type of operation was selected by every patient's opinion before signing the consent.

Appropriate clinical and radiological assessments were performed of all patients before surgery was planned. 56 patients (10 men, 46 women; mean age, 60.50 ± 9.56 years) were treated with the PE-TLIF technique. The other 58 patients (10 men, 48 women; mean age, 60.64 ± 7.42 years) were treated with the PLIF technique. The operative level was L4/5. The Bridwell criteria were used to evaluate intervertebral fusion via computed tomography at 6 months postoperative. Visual Analog Scale (VAS) scores for lumbar and leg pain (VAS-LBP, VAS-LP), Oswestry Disability Index (ODI), and serum CK level were evaluated preoperatively, postoperatively, and at regular follow-up intervals. We also employed contrast-enhanced ultrasonography to calculate the maximal cross-sectional area of the multifidus muscle (Max-CSA) and the peak intensity of the sulfur hexafluoride microbubble contrast agent (PI) around the surgical incision to document the multifidus muscle's condition (Figure 1). The demographic characteristics of the two groups are listed in Table 1. There were no statistically significant intergroup differences in age, sex distribution, operative level, VAS-LBP, VAS-LP, ODI, CK level (U/L), Max-CSA, or PI (Table 1).

Surgical Techniques

Percutaneous Endoscopic Transforaminal Lumbar Interbody Fusion

The patient was placed in a prone position under general anesthesia or low-dose epidural anesthesia combined with local anesthesia. The lumbar segment was confirmed using C-arm fluoroscopy. The primary guide pin was inserted into the pedicle on the symptomatic side under fluoroscopy guidance, while the secondary guide pin was positioned at the SAP through a specially designed guider (Figure 2). Dilating cannulas were then progressively inserted via the secondary guide pin. The hook-shaped front of the cannula was employed for protection and the majority of the SAP was safely excised by trepanning (Figure 3). The working channel was placed through Kambin's triangle, and the endoscope system was connected. Complete endplate preparation was performed after the canal and nerve root were decompressed, and an expandable cage was inserted through the working tube

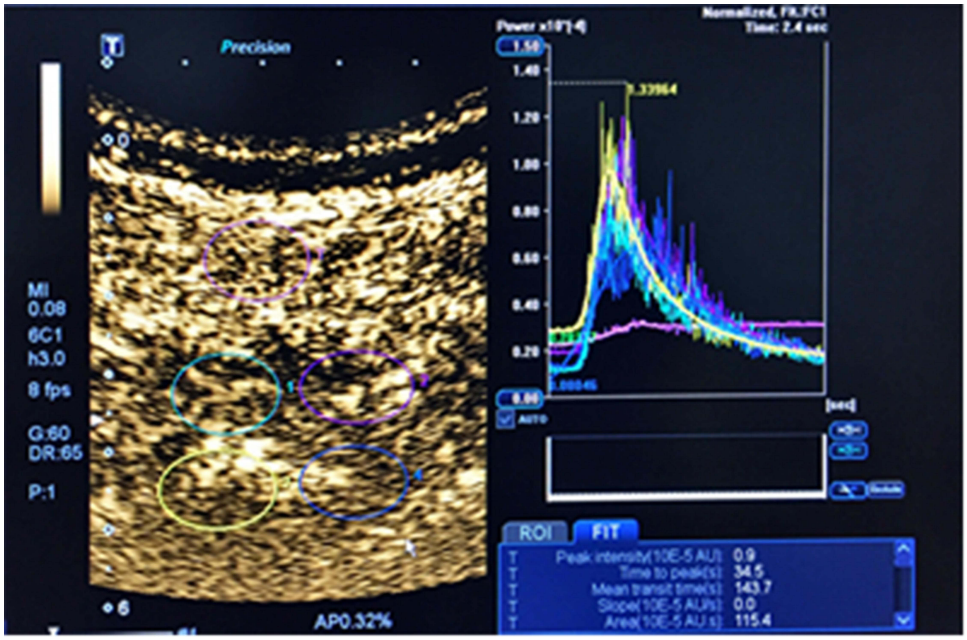

Figure 1 Contrast-enhanced ultrasonography demonstrates the blood perfusion of the multifidus muscle microcirculation.

Table 1 Comparison of the Demographic Characteristics Data Between Two Groups ($\bar{x} \pm s$)

Indicators	PE-TLIF Group	PLIF Group	*P*
Number	56	58	-
Age (years)	60.50±9.56	60.64±7.42	0.958
Sex (Male/Female)	10/46	10/48	0.812
VAS-LBP (points)	7.17±0.92	6.86±0.94	0.313
VAS-LP (points)	6.44±1.42	6.86±0.99	0.280
ODI (%)	60.17±12.04	57.32±9.70	0.412
CK (U/L)	78.06±25.66	87.23±29.84	0.310
Max-CSA (mm^2)	509.28±79.75	515.27±80.82	0.816
PI	2.82±0.59	2.81±0.65	0.948
Follow-up time (months)	15.33±3.07	15.82±2.95	0.615

after the iliac bone autograft was implanted (Figures 4 and 5). The spinal canal was examined via endoscopically to confirm complete relief of the nerve root. Four pedicle screws and two rods were inserted percutaneously. A drainage tube was placed in the decompression working channel and the incisions were sutured. The PE-TLIF technique was described in detail in our previous study[12] (Supplemental Video).

Posterior Lumbar Interbody Fusion

The patient was placed in a prone position under general anesthesia. The symptomatic segment was confirmed using C-arm fluoroscopy. The posterior middle approach was employed with subperiosteal stripping until the bilateral facet joints were reached. Bilateral pedicle screws were inserted, and interlaminar fenestration was performed bilaterally. Complete endplate preparation was performed after nerve root decompression. A proper cage was inserted after intervertebral bone grafting. Loosening of the nerve root was confirmed, a drainage tube was placed, and the incision was sutured.

Postoperative Protocol

The surgical time, intraoperative bleeding volume, incision length, postoperative drainage volume, postoperative bedridden time, and complications were recorded. VAS, ODI, CK level, Max-CSA, and PI were evaluated preoperatively, postoperatively, and regular follow-up intervals. The data were analyzed using SPSS 19.0, with the chi-square and Fisher's exact tests for nominal data and independent *t*-tests for continuous data.

Results

The mean operation time was 204.17 ± 47.90 minutes in the PE-TLIF group versus 99.77 ± 30.02 minutes in the PLIF group. The mean postoperative drainage volume was 41.94 ± 28.65 mL in the PE-TLIF group versus 285.23 ± 142.17 mL in the PLIF group. The mean postoperative bedridden time was 23.11 ± 6.15 hours in the PE-TLIF group versus 51.64 ± 13.65 hours in the PLIF group. The mean intraoperative bleeding volume was

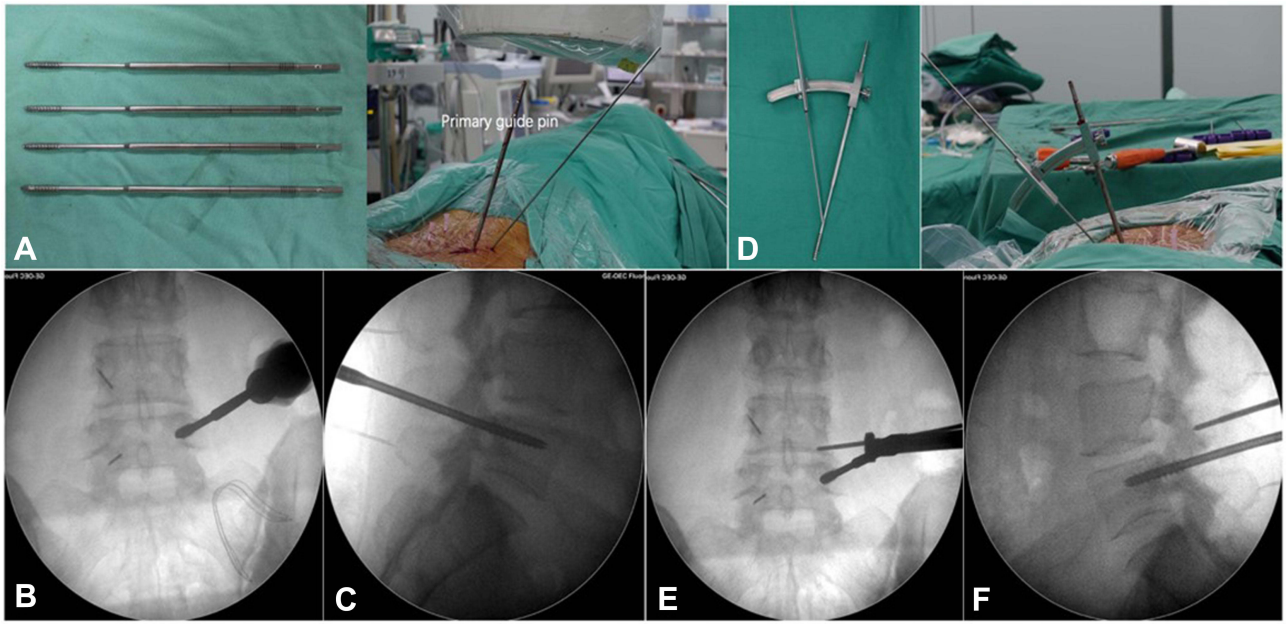

Figure 2 Fluoroscopic insertion of guide pins. (**A**) the primary guide pin (left), the front end of which is threaded design, which can be firmly fixed in the pedicle, and the position of the primary guide pin is easily recognized under fluoroscopy; the primary guide pin is percutaneously inserted into the vertebral pedicle, rotating to fix (right). (**B** and **C**) C-arm anteroposterior and lateral fluoroscopy confirms that the primary guide pin enters the pedicle, and the upper edge of the thread is lower than the dorsal lateral level of the superior articular process. (image from the other patient). (**D**) Physical view of the specially designed SAP guider, the first guide pin and the second guide pin are connected by the connecting arch, and the second guide pin puncture angle and depth can be adjusted on the connection arch. (**E** and **F**) C-arm anteroposterior and lateral fluoroscopy confirms that the second guide pin is fixed to the posterior aspect of the superior articular process.

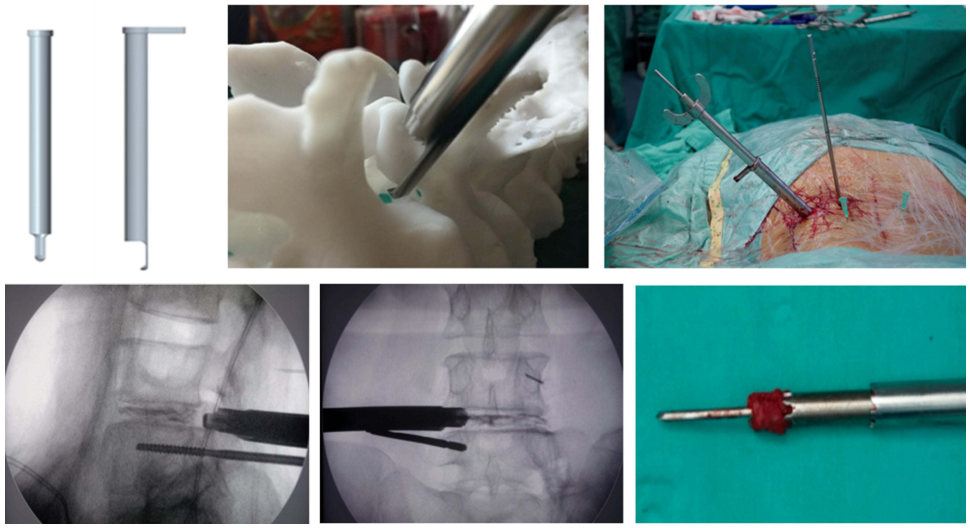

Figure 3 Resection method of the superior articular process. The hook-shaped protective sleeve clings to the lateral periosteum of the superior articular process, reaches the ventral side of the articular process, protects the exiting nerve root and can control the cutting depth of the trephine at the same time, protects the dura mater and nerve root, and rotates the trephine to remove the superior articular process.

105.56 ± 76.79 mL in the PE-TLIF group versus 241.82 ± 129.64 mL in the PLIF group. The mean incision length was 8.44 ± 2.15 cm in the PE-TLIF group versus 10.50 ± 1.85 cm in the PLIF group. There were significant intergroup differences in operation time, postoperative drainage volume, postoperative bedridden time, intraoperative bleeding volume, and incision length ($P < 0.05$, Table 2). In contrast, there was no significant intergroup difference in the intervertebral fusion rate at 6 months postoperative ($P > 0.05$, Table 2).

The patients were followed for a mean 15.33 ± 3.07 months in the PE-TLIF group and 15.82 ± 2.95 months in

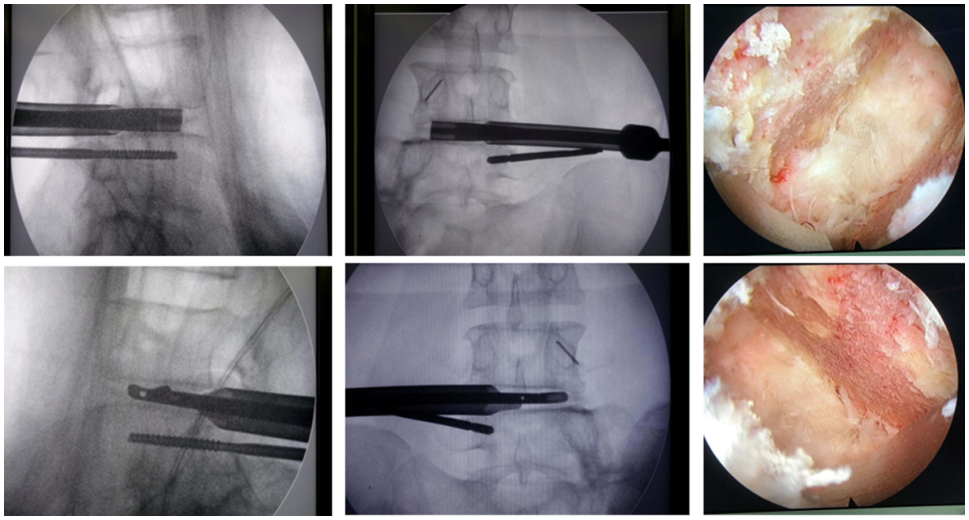

Figure 4 Bone graft bed preparation. The width adjustable reamer and endplate curette are used to prepare the cartilage endplate to adequately expose the bony endplate. Finally, Intervertebral space is fully prepared and the appearance of exudation from bone endplate is good, the bony endplate is fully exposed.

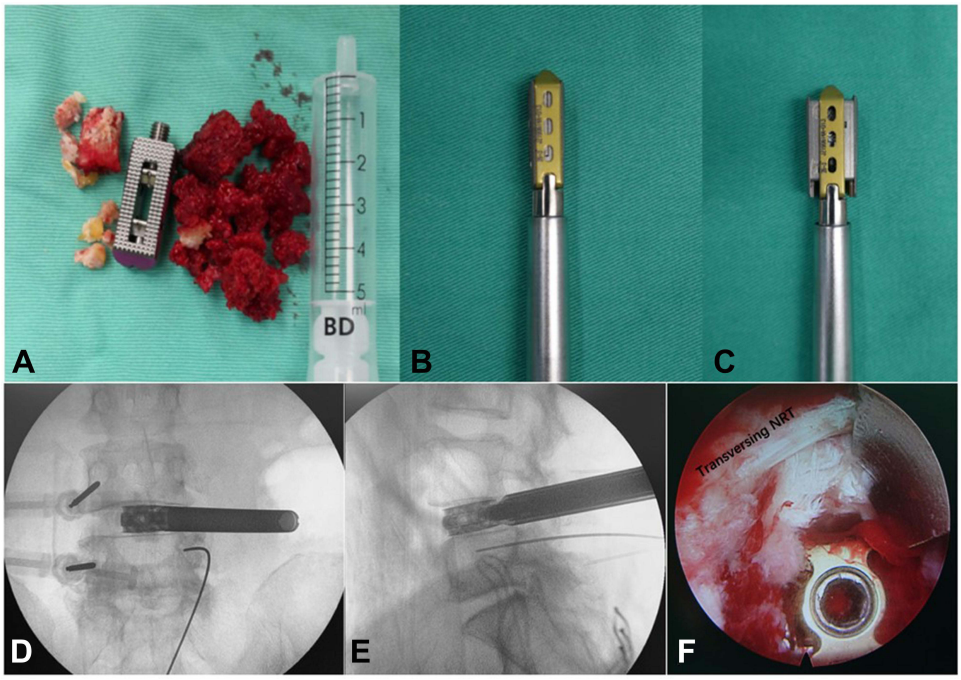

Figure 5 Intervertebral bone graft and interbody fusion device implantation. (**A**–**C**) Expandable cage, the autogenous bone, and allogenic bone are prepared for implantation. (**D** and **E**) The height-adjustable interbody cage is positioned at the center of the interbody space in the anteroposterior radiograph, and the leading edge reaches the position of the iliac crest. (**F**) The expandable cage is confirmed in a satisfactory position under endoscopy. Nerves are not compressed by bone graft particles.

the PLIF group. The VAS-LBP and VAS-LP at 1 week, 3 months, and 6 months postoperative and at the final follow-up were significantly improved compared to the preoperative values in all patients ($P < 0.05$, Table 3). The ODI at 3 and 6 months postoperative and at the final follow-up were significantly improved compared to the preoperative values in all patients ($P < 0.05$, Table 3). There was a significant intergroup difference in VAS-LBP at 1 and 3 months postoperative ($P < 0.05$, Table 3). In contrast, there were no significant intergroup differences in postoperative VAS-LP and ODI values ($P > 0.05$, Table 3, Figure 6).

The mean CK level at 1 day postoperative was higher than the mean postoperative value in both groups ($P < 0.05$, Table 4). In the PE-TLIF group, there was no significant difference in CK level at 1 week postoperative

Table 2 Comparison of the Clinical Effects of Patients in Two Groups ($\bar{x} \pm s$)

Indicators	PE-TLIF	PLIF	P
Operation time (minutes)	204.17±47.90	99.77±30.02	<0.001
Intraoperative hemorrhage (mL)	105.56±76.79	241.82±129.64	<0.001
Incision length (cm)	8.44±2.15	10.50±1.85	0.002
Postoperative drainage volume (mL)	41.94±28.65	285.23±142.17	<0.001
Postoperative bedridden time (h)	23.11±6.15	51.64±13.65	<0.001
Complication(case)			0.666
Infection	0	2	
Temporary knee tendon hyperreflexia	1	0	
Residual numbness	4	2	
Cerebrospinal fluid leakage	0	2	
Intervertebral fusion rate (case)			0.973
I	6	9	
II	43	46	
III	7	3	
IV	0	0	

Table 3 Comparison of Indicators Related to Efficacy Evaluation Between Two Groups ($\bar{x} \pm s$)

Indicators	PE-TLIF	PLIF	P
VAS-LBP (points)			
Pre-operation	7.17±0.92	6.86±0.94	0.313
Post-1w	3.44±1.04	5.00±1.20	<0.001
Post-3m	1.39±0.61	2.41±0.91	<0.001
Post-6m	1.00±0.77	1.05±0.65	0.841
Final follow-up	0.61±0.61	0.64±0.58	0.894
VAS-LP (points)			
Pre-operation	6.44±1.42	6.86±0.99	0.280
Post-1w	2.33±1.19	2.00±1.02	0.346
Post-3m	1.11±0.83	1.18±0.66	0.767
Post-6m	0.83±0.79	0.86±0.71	0.899
Final follow-up	0.33±0.49	0.50±0.67	0.384
ODI (%)			
Pre-operation	60.17±12.04	57.32±9.70	0.412
Post-3m	25.94±12.67	26.59±7.50	0.842
Post-6m	13.83±7.56	13.91±6.59	0.973
Final follow-up	7.44±5.98	6.82±4.73	0.713

versus preoperative value (P > 0.05, Table 4). In the PLIF group, the mean CK level at 1 week postoperative remained higher than the preoperative value (P < 0.05, Table 4). The mean CK level of the PE-TLIF group at 1 day and 1 week postoperative was significantly lower than those of the PLIF group (P < 0.05, Table 4). The Max-CSA at 1 week postoperative was higher than the preoperative value in both groups (P < 0.05, Table 4). The Max-CSA of the PE-TLIF group did not differ at 3 and 6 months postoperative and at the final follow-up from the preoperative values (P > 0.05, Table 4). The Max-CSA at 1 week postoperative was significantly lower in PE-TLIF group than in the PLIF group (P < 0.05, Table 4), whereas the Max-CSA at 3 and 6 months postoperative and at the final follow-up were significantly higher in the PE-TLIF group than in the PLIF group (P < 0.05, Table 4). The mean PI was higher at 1 week postoperative than preoperative value in both groups (P < 0.05, Table 4), and no significant difference in mean PI values was noted in the PE-TLIF group at 3 and 6 months postoperative and at the final follow-up versus the preoperative values (P > 0.05, Table 4). The mean PI values of the PE-TLIF group were significantly higher at 3 and 6 months postoperative and at the final follow-up than preoperatively (P < 0.05, Table 4).

The complication rate did not differ significantly between the two groups (P > 0.05, Table 2). In the PE-TLIF group, one patient suffered temporary knee tendon hyperreflexia after surgery that resolved within 24 hours. Four patients complained of residual numbness, but with the related symptom improvement after the operation. In the PLIF group, two patients experienced an incision infection that was successfully treated with intravenous antibiotics. Two patients had cerebrospinal fluid leakage and treated by conservative treatment. Two patients complained of residual numbness, but with the related symptom improvement after the operation.

Discussion

This prospective cohort study compared the clinical effects of lumbar endoscopic fusion surgery and PLIF for the treatment of LSS with degenerative instability. The present results demonstrated that the clinical effects of PE-TLIF for the treatment of LSS with degenerative instability were not inferior to PLIF, whereas the PE-TLIF technique induced more severe muscle injury than the PLIF technique. However, the postoperative drainage volume, postoperative bedridden time, and postoperative VAS-LBP were significantly better for patients treated with the PE-TLIF technique.

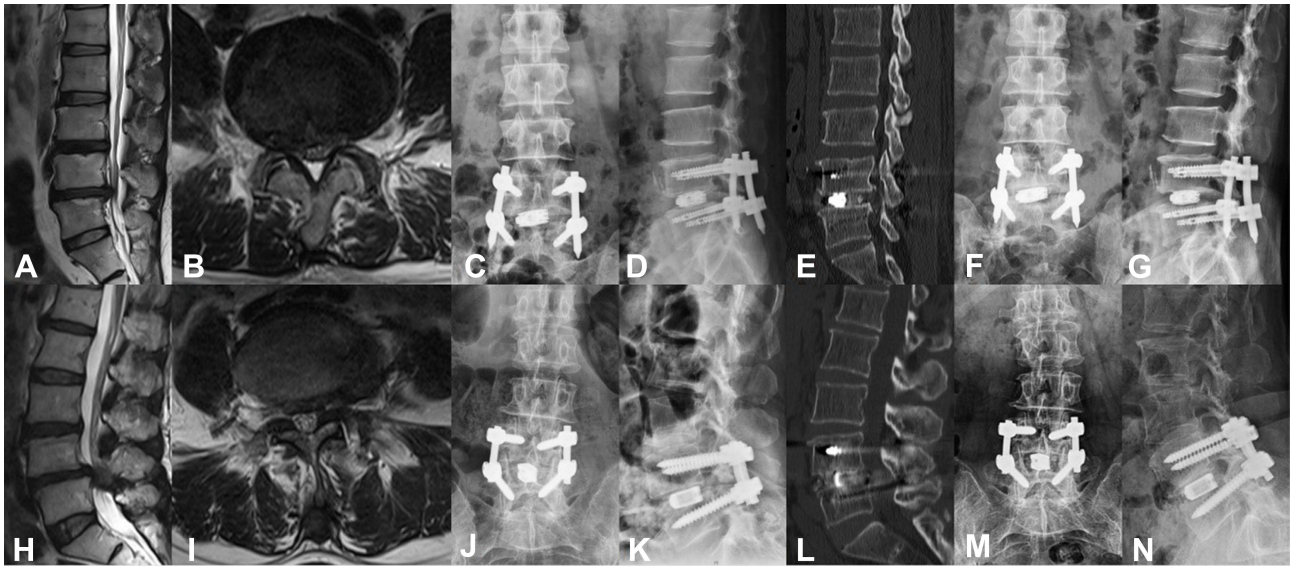

Figure 6 PE-TLIF group (**A**–**G**): A 63-year-old female patient who suffered low back pain with right leg pain and numbness for 3 years, intermittent claudication 50m, and was treated by PE-TLIF. (**A** and **B**) Preoperative MRI showed a lumbar spinal stenosis on L4/5. (**C** and **D**) X-ray images showed a good implantation position at 7 days after operation. (**E**) CT scan image showed a standard lumbar fusion at 6 months after operation. (**F** and **G**) X-ray images showed a good implantation position at final follow-up. PLIF group (**H**–**N**): A 52-year-old female patient who suffered low back pain with right leg pain and numbness for 2 years, intermittent claudication 100m, and was treated by PLIF. (**H** and **I**) Preoperative MRI showed a lumbar spinal stenosis on L4/5. (**J** and **K**) X-ray images showed a good implantation position at 7 days after operation. (**L**) CT scan image showed a standard lumbar fusion at 6 months after operation. (**M** and **N**) X-ray images showed a good implantation position at final follow-up.

Table 4 Comparison of Indicators Related to Multifidus Injury Between Two Groups ($\bar{x} \pm s$)

Indicators	PE-TLIF	PLIF	*P*
CK(U/L)			
Pre-operation	78.06±25.66	87.23±29.84	0.310
Post-1d	443.44±95.31	657.09±83.31	<0.001
Post-1w	92.33±18.22	130.32±37.54	<0.001
Max-CSA (mm^2)			
Pre-operation	509.28±79.75	515.27±80.82	0.816
Post-1w	621.83±84.87	724.36±85.28	<0.001
Post-3m	524.11±50.85	446.09±63.20	<0.001
Post-6m	491.28±62.27	374.36±56.11	<0.001
Final follow-up	476.28±62.95	358.72±52.39	<0.001
PI			
Pre-operation	2.82±0.59	2.81±0.65	0.948
Post-1w	4.57±1.18	4.83±0.74	0.399
Post-3m	2.97±0.400	2.47±0.51	0.002
Post-6m	2.58±0.36	1.86±0.48	<0.001
Final follow-up	2.35±0.47	1.74±0.49	<0.001

PLIF demonstrated a satisfactory ability to treat LSS.[6,15] Nevertheless, extensive destruction of the posterior musculoligamentous complex usually leads to muscular atrophy, tremendous postoperative pain, and functional disability.[8] Some researchers reported that bilateral stripping of the multifidus on PLIF was related to paraspinal muscle atrophy and that approximately 20% of patients with failed back surgery syndrome had paraspinal muscle atrophy.[16,17] Kalichman et al reported a causal relationship between changes in the paraspinal muscles and low back pain and that a higher density of paraspinal muscles could decrease the symptoms of low back pain.[18] In addition, Ranger et al showed that the paraspinal muscle atrophy extent was associated with postoperative low back pain.[19] In addition, Khan et al described that back muscle morphometry should be included as a predictor of clinical outcomes to improve postoperative functional results and reduce surgery-related complications.[20] Hence, an increasing number of surgeons believe that decreasing the extent of paraspinal muscle injury is very important to improving postoperative functional outcomes and reducing the surgical complication rate.

Minimally invasive spine surgery (MISS) has gained popularity for its ability to overcome the drawbacks of traditional open surgeries. Advantages of MISS include minimal soft tissue injury, satisfactory clinical effects, a reduced occurrence of surgical complications, and better cost-effectiveness.[21] Schwender et al first introduced minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF) and presented its potential advantages over traditional open techniques.[22] Its popularity increased, and satisfactory clinical improvements

and fusion rates were achieved.[23,24] Although MIS-TLIF can minimize injury to normal anatomic structures, it requires an open incision into the posterior musculoligamentous complex for tube placement. Therefore, endoscopic lumbar fusion techniques have been attempted by some surgeons. Osman et al first reported using an endoscopic fusion technique to treat lumbar degenerative diseases. The technique achieved good clinical outcomes but featured a relatively high complication rate.[11] In contrast, Jacquot et al did not recommend this technique because of its 36% complication rate.[13] Hence, decisive technical changes including cage improvement, approach modification, and intraoperative visualization enhancement have been made to reduce the complication rate. We also developed a technique called PE-TLIF, whose initial clinical results were favorable.[14]

In our study, we compared the effectiveness of PE-TLIF and PLIF for the treatment of LSS with degenerative instability and found that the former could have similar clinical effects and a lower degree of muscle injury. CK level, Max-CSA, and PI were used here to investigate muscle injury. During postoperative follow-up, these muscle injury–related indicators were significantly better in the PE-TLIF group than in the PLIF group. Moreover, postoperative rehabilitation factors including bedridden time and postoperative VAS-LBP were significantly improved in the PE-TLIF group. The complication rate was low; there was only one case of temporary knee tendon hyperreflexia. No cases of nerve root injury or cage migration occurred in the present study. Our technique involved decisive technical improvements, including innovative expandable cages and approach modification. Moreover, the learning curve of our technique is not very steep.

The major advantage of our study is that we developed an innovative guided SAP resection device and parallel expandable cage. We also improved the diameter of the working channel to protect the exiting and traversing nerve roots and enable cage insertion via percutaneous surgery. The use of the guided SAP resection device is very important for our technique since it ensures safety. We also used the innovative hook-shaped front of the cannula to restrict the trepanning depth and protect the exiting nerve root and dura mater. Endplate preparation played an important role in the fusion, and the appearance of hemorrhagic exudation from the bone endplate was acceptable under endoscopic visualization. We also recommend iliac bone autografting and adequate bone graft size (≥5 mm^3 per intervertebral space).

To the best of our knowledge, this is the first prospective cohort study of PE-TLIF for the treatment of LSS with degenerative instability. The current study was the first to evaluate muscle injury created during endoscopic versus traditional open surgery. All surgeries were performed by a single senior surgeon, and patient characteristics, treatment results, and complications were reported. However, certain limitations of this study must be addressed. First, the indications for PE-TLIF are relatively limited. For example, this technique is not suitable for treating severe canal stenosis. Second, the number of patients was relatively small, and the follow-up duration was relatively short. More prospective randomized controlled trials are needed to overcome these limitations.

Conclusions

Our results showed that the PE-TLIF technique could achieve effective outcomes comparable to those of conventional PLIF for the treatment of LSS with degenerative instability. Patients with PE-TLIF had less severe muscle injuries, less pain, and quicker recovery periods.

Data Sharing Statement

The data used to support the findings of this study are available from the corresponding author upon request.

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Disclosure

The authors report no conflicts of interest in this work.

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