

# An Innovative Percutaneous Endoscopic Transforaminal Lumbar Interbody Fusion for the Treatment of Lumbar Spinal Stenosis with Degenerative Instability: a prospective cohort study

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## Research

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# Abstract

Lumbar spinal stenosis (LSS) is most common lumbar degenerative diseases for people with low back pain. Endoscopic lumbar fusion technique was considered as a promising treatment for LSS with degenerative instability. 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. Between April 2019 and December 2019, 40 patients with single-segment LSS were prospectively included in our study. 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. 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 ( $P > 0.05$ ). 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. (A multicenter non-randomized controlled study for percutaneous endoscope transforaminal lumbar interbody fusion (PE-TLIF) and traditional open surgery for the treatment of degenerative diseases of the lumbar spine;2019/4/13; <http://www.chictr.org.cn/showproj.aspx?proj=38002>; ChiCTR1900022492)

## Introduction

It is reported that low back pain is the leading cause of elder people lived with disability from 1990 to 2017[1], and lumbar spinal stenosis (LSS) is most common lumbar degenerative diseases for people with low back pain[2]. Although most of patients with LSS could be treated effectively by conservative method, there still are some patients require surgical treatment due to the failure to alleviate the severe pain by conservative treatment[3].

Spine fusion surgery has been considered as an effective method in improving pain, segment stability, function and quality of life in patients with LSS, especially the patients with degenerative instability [4, 5]. Most of surgeons consider posterior lumbar interbody fusion (PLIF) as the standard operation for LSS with degenerative instability, and the PLIF demonstrated a satisfactory clinical effect and a higher fusion rate[4]. Nevertheless, extensive destruction of posterior muscular-ligamentous complex usually leads to muscular atrophy, tremendous postoperative pain, and functional disability[6, 7]. Therefore, minimally invasive surgeries gradually gained popularity in order to overcome the disadvantages of traditional open surgeries in the past twenty years.

Recently, endoscopic lumbar fusion techniques have been attempted successfully in the treatment of patients with LSS[8–11], however, some drawbacks still exist, including nerve root injury, cage-related complication, long learning curve and so on. To overcome the aforementioned disadvantages, we developed an innovative percutaneous endoscopic transforaminal lumbar interbody fusion (PE-TLIF) with oriented superior articular process (SAP) resection device, and showed a good clinical result in a preliminary report[12]. As best we know, all the studies on endoscopic lumbar fusion technique for the treatment of patients with LSS were retrospective, so the clinical evidence is relative lower. Hence, we conducted a prospective cohort study on PE-TLIF for the treatment of patients with LSS in order to provide a high-level evidence for clinical practice. Meanwhile, we compared the injury degree of lumbar multifidus muscle between PLIF and PE-TLIF for the treatment of LSS with degenerative instability. We hypothesized that the clinical effects on PE-TLIF for the treatment of LSS with degenerative instability was not inferior than PLIF.

## Materials And Methods

Between April 2019 and December 2019, 40 patients diagnosed as single-segment LSS with degenerative instability were prospectively included in our study (ChiCTR1900022492). The eligible criteria were: (1) patients were treated by PLIF or PE-TLIF; (2) no history of lumbar surgery; (3) no obvious multifidus muscle injury certified by ultrasound. (4) no lumbar scoliosis or deformity. Our study was approved by the institutional review board of Beijing Chaoyang Hospital. All patients were told all possible results on these two surgeries and signed written consent before operation.

Appropriate clinical and radiological assessments were performed for all patients before a decision of operation. 18 patients were operated by PE-TLIF technique. There were 4 males and 14 females, with an average of  $60.50 \pm 9.56$  years. 22 patients were operated by PLIF technique. There were 6 males and 16 females, with an average of  $60.64 \pm 7.42$  years. Operative level was L4/5. The Bridwell criteria was used to evaluate the intervertebral fusion via CT at 6 months after operation. Visual Analogue Scale (VAS) on lumbar and leg pain (VAS-LBP, VAS-LP), Oswestry Disability Index (ODI), serum Creatine Kinase (CK) were evaluated preoperatively, post-operatively and at regular follow-up. We also employed contrast-enhanced ultrasonography to calculate 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 to present the multifidus muscle condition (**Figure 1**). More demographic characteristics data of the two groups are listed in **Table 1**. There was no statistical significance between the two groups before the operation in age, sex distribution, operative level, VAS-LBP, VAS-LP, ODI, CK (U/L), Max-CSA, and PI (**Table 1**).

### Surgical Techniques

#### PE-TLIF

The patient was in a prone position under general anesthesia or low dose epidural anesthesia combining with local anesthesia. The aimed lumbar segment was confirmed under the C-arm fluoroscope. The

primary guide pin was inserted into pedicle on the symptomatic side under the guidance of fluoroscope, and the secondary guide pin was positioned at SAP through a specially designed SAP guider (**Figure 2**). Then dilating cannulas were inserted progressively via the secondary guide pin. A hook-shaped front of the cannula was employed to be a protection cannula in order to excise the majority of SAP safely by trepan (**Figure 3**). The working channel was placed through Kambin's triangle, and the endoscope system was connected. The complete endplate preparation was performed after the canal and nerve root were decompressed, and then an expandable cage was then inserted through the working tube after iliac bone autograft was implanted (**Figure 4-5**). The spinal canal was examined via endoscope to confirm the nerve root was totally relieved. 4 pedicle screws and 2 rods were inserted percutaneously. A drainage tube was placed in the decompression working channel, and the incisions were sutured. More details on PE-TLIF technique were reported in our previous study[12] (**Supplemental Video**).

## PLIF

The patient was in a prone position under general anesthesia. The symptomatic segment was confirmed by the C-arm fluoroscope. The posterior middle approach was

performed, and subperiosteal stripping was adopted until reaching bilateral facet joints. Bilateral pedicle screws were inserted and then interlaminar fenestration was performed bilaterally. The complete endplate preparation was performed after the nerve root were decompressed. Then a proper cage was inserted after intervertebral bone grafting. The loosening of the nerve root was inspected again, and a drainage tube was placed, and finally the incision was sutured.

## Post-operative protocol

The operation time, intraoperative bleeding volume, Incision length, postoperative drainage volume, postoperative bedridden time, and complications were recorded. VAS, ODI, CK, Max-CSA, and PI were evaluated preoperatively, post-operatively and at regular follow-up. The data were analyzed by SPSS 17.0 software with chi-square and Fisher's exact test in nominal data and independent t-test in continuous data.

## Results

The mean operation time was  $204.17 \pm 47.90$  minutes in PE-TLIF group, and  $99.77 \pm 30.02$  minutes in PLIF group. The average of postoperative drainage volume was  $41.94 \pm 28.65$  ml in PE-TLIF group, and  $285.23 \pm 142.17$  ml in PLIF group. The mean postoperative bedridden time was  $23.11 \pm 6.15$  hours in PE-TLIF group, and  $51.64 \pm 13.65$  hours in PLIF group. The average of intraoperative bleeding volume was  $105.56 \pm 76.79$  ml in PE-TLIF group, and  $241.82 \pm 129.64$  ml in PLIF group. The mean incision length was  $8.44 \pm 2.15$  cm in PE-TLIF group, and  $10.50 \pm 1.85$  cm in PLIF group. There was significant difference in the operation time, postoperative drainage volume, postoperative bedridden time, intraoperative bleeding volume and the incision length between the two groups ( $P < 0.05$ , **Table 2**). There was no significant

difference on the intervertebral fusion rate at 6 months after operation between these two groups ( $P>0.05$ , **Table 2**). More details were listed in **Table 2**.

All patients were followed up, and the average of follow-up period was  $15.33\pm 3.07$  months in PE-TLIF group, and  $15.82\pm 2.95$  months in PLIF group. The VAS-LBP and VAS-LP at 1 week, 3 months, 6 months after operation and at final follow-up were improved significantly compared to these data before operation in all the patients ( $P<0.05$ , **Table 3**). The ODI at 3 months, 6 months after operation and at final follow-up were improved significantly compared to the data before operation in all patients ( $P<0.05$ , **Table 3**). There was significant difference on VAS-LBP at 1 weeks, 3 months after operation between these two groups ( $P<0.05$ , **Table 3**). There was no significant difference on VAS-LP and ODI after operation between these two groups ( $P>0.05$ , **Table 3**). More details were listed in **Table 3**. (**Figure 6**)

The CK at 1 day after operation was higher compared to this item before operation in these two groups ( $P<0.05$ , **Table 4**), and there was no significant difference on CK at 1 week after operation in PE-TLIF group compared with this before operation ( $P>0.05$ , **Table 4**), but the CK at 1 week after operation still higher in PLIF group ( $P<0.05$ , **Table 4**). The CK at 1 days, 1 weeks after operation in PE-TLIF group was significantly lower than these in PLIF group ( $P<0.05$ , **Table 4**). The Max-CSA at 1 week after operation was higher compared to this item before operation in these two groups ( $P<0.05$ , **Table 4**), and there was no significant difference on Max-CSA at 3 months, 6 months, and final follow-up after operation in PE-TLIF group compared with these before operation ( $P>0.05$ , **Table 4**). The Max-CSA at 1 week after operation in PE-TLIF group was significantly lower than that in PLIF group ( $P<0.05$ , **Table 4**), but the Max-CSA at 3 months, 6 months and final follow-up after operation in PE-TLIF group was significantly higher than these in PLIF group ( $P<0.05$ , **Table 4**). The PI at 1 week after operation was higher compared to this item before operation in these two groups ( $P<0.05$ , **Table 4**), and there was no significant difference on PI at 3 months, 6 months and final follow-up after operation in PE-TLIF group compared with these before operation ( $P>0.05$ , **Table 4**). The PI at 3 months, 6 months and final follow-up after operation in PE-TLIF group was significantly higher than these in PLIF group ( $P<0.05$ , **Table 4**). More details were listed in **Table 4**.

There was no significant difference on the complication rate between these two groups ( $P>0.05$ , **Table 2**). In PE-TLIF group, 1 patient suffered temporary knee tendon hyperreflexia after surgery, and recovered within 24 hours after surgery. In PLIF group, 2 patients experienced incision infection, and were cured by intravenous antibiotics.

## Discussion

This was the first prospective cohort study on the clinical effects between lumbar endoscopic fusion surgery and PLIF for the treatment of LSS with degenerative instability at present. Our present results showed that the clinical effects on PE-TLIF for the treatment of LSS with degenerative instability was not inferior than PLIF, and the muscle injury degree in PE-TLIF technique was superior to PLIF operation, and

the postoperative drainage volume, postoperative bedridden time, and postoperative VAS-LBP was significantly better for the patients treated by PE-TLIF surgery.

PLIF demonstrated a satisfactory clinical effect for the treatment of lumbar spinal stenosis[4, 13, 14]. Nevertheless, extensive destruction of posterior muscular-ligamentous complex usually leads to muscular atrophy, tremendous postoperative pain, and functional disability[6, 7]. Some researchers found that bilateral stripping of the multifidus on PLIF was related to paraspinal muscle atrophy, and about 20% patients with failed back surgery syndrome was associated with paraspinal muscle atrophy[15, 16]. Kalichman et al found that there was a causal relationship between changes in the paraspinal muscles and low back pain, and a higher density of paraspinal muscles could decrease the symptom of low back pain[17]. In addition, Ranger et al showed that the extent of paraspinal muscle atrophy was associated with postoperative low back pain[18]. In addition, Khan et al described that back-muscle morphometry should be included as a predictor of clinical outcomes in order to improve postoperative functional results and reduce the surgery-related complications[19]. Hence, more and more surgeons believed that decreasing the injury extent of paraspinal muscles was very important to improve the postoperative functional outcomes and reduce the surgical complication rate.

Minimally invasive spine surgeries (MISS) gained popularity to overcome the drawbacks on traditional open surgeries. There are some advantages on MISS, including minimal soft tissue injury, satisfactory clinical effects, reduced the occurrence rate of surgical complication, and better cost-effectiveness[20]. Schwender et al firstly introduced the minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF), and MIS-TLIF technique presented the potential advantages over traditional open techniques[21]. Then, the MIS-TLIF became popular, and obtained satisfactory clinical improvement and fusion rate[22, 23]. Although the MIS-TLIF could minimize the injury to normal anatomic structures, the technique still requires an open incision of the posterior muscular-ligamentous complex for tube placement. Therefore, some surgeons have attempted endoscopic lumbar fusion techniques. Said et al. firstly reported endoscopic fusion techniques for the treatment of lumbar degenerative diseases. The technique could acquire good clinical outcomes, but the complication rate was relative higher[10]. Then Jacquot et al did not recommend the kind of technique because of the 36% complication rate[11]. Hence, decisive technical improvements have been made to reduce the complication rate, including cage improvement, approach modification, and intraoperative visualization enhancement. We also developed our technique named PE-TLIF, and initial clinical results was favorable[12].

In our study, we compared the effectiveness of PE-TLIF and PLIF for the treatment of LSS with degenerative instability. PE-TLIF could obtained similar clinical effects and less muscle injury degree. CK, Max-CSA, and PI were employed to investigate the muscle injury in our study. In the follow-up after operation, these muscle injury related indicators was significantly better in PE-TLIF group than these in PLIF group. The postoperative rehabilitation was significantly improved in PE-TLIF, such as postoperative bedridden time and postoperative VAS-LBP. The compilation rate was low, and only 1 patient suffered temporary knee tendon hyperreflexia. Nerve root injury and cage migration was not included in our study. Our technique made decisive technical improvements, including innovative expandable cage and

modified approach. The learning curve on our technique is not very steep, and the technique is easy to be popularized.

The major advantage of our technique is that we innovatively develop some instruments such as guided SAP resection device and parallel expandable cage. We also improved the diameter of working channel to protect the exiting nerve root and the traversing nerve root, and to the benefit of cage insertion via percutaneous surgery. In our clinical experience, the standard operation procedure of guided SAP resection device is very important on our technique, and the SAP device has the ability to ensure the SAP sufficient and safe resection. We also used the innovative hook-shaped front of the cannula to restrict the depth of trepan-cutting SAP to protect the exiting nerve root and dura mater. Endplate preparation played an important role in the fusion aspect, the appearance of hemorrhagic exudation from bone endplate was acceptable under the endoscopic visualization. We also recommend iliac bone autograft and adequate bone graft ( $\geq 5\text{mm}^3$  per intervertebral space).

To the best of our knowledge, this is the first prospective cohort study on percutaneous endoscopic transforaminal lumbar interbody fusion for the treatment of LSS with degenerative instability. The muscle injury evaluation between endoscopic lumbar fusion surgery and traditional open surgery was firstly reported in our study. All surgeries were performed by one senior surgeon. A number of data on the characteristics of patients, treatment results and complications were reported in our study. However, certain limitations need be addressed. The number of patients is relatively small. More prospective randomized controlled trials are needed to overcome the limitations of our study.

## **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.

## **Declarations**

### **Ethics approval and consent to participate**

Our study was approved by the institutional review board of Beijing Chaoyang Hospital. All patients were told all possible results on these two surgeries and signed written consent before operation.

### **Consent for publication**

Not applicable.

### **Availability of data and materials**

These were included in our manuscript.

## Competing interests

The authors declare that they have no competing interests.

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## Authors' contributions

PY performed the design and conception of the research, collected and analyzed the data, and drafted the manuscript. YD joined the design and conception of the research and revised the manuscript critical for important content. LJZ joined the design of the research, and collected the data and underwent data analysis. CYX joined the design and conception of the research. LMZ underwent data analysis. HFG underwent data analysis. JCY performed operations, joined the design and conception of the research and drafted the manuscript. YH performed the design and conception of the research, analyzed the data, drafted the manuscript, and gave some precious comments in revising the manuscript. All authors read and approved the final manuscript.

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## Tables

**Table 1** Comparison of the demographic characteristics data between two groups

Indicators	PE-TLIF group	PLIF group	P
Number	18	22	-
Age (years)	60.50±9.56	60.64±7.42	0.958
Sex (Male/Female)	4/14	6/16	0.722
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 <sup>2</sup> )	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

**Table 2** Comparison of the clinical effects of patients in two groups

Indicators	PE-TLIF	PLIF	<i>P</i>
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)			0.757
Infection	0	2	
Nerve injury	1	0	
Intervertebral fusion rate (case)			0.861
I	1	2	
II	13	15	
III	4	5	
IV	0	0	

**Table 3** Comparison of Indicators related to efficacy evaluation between two groups

Indicators	PE-TLIF	PLIF	<i>P</i>
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
Post-last	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

**Table 4** Comparison of Indicators related to multifidus injury between two groups

Indicators	PE-TLIF	PLIF	<i>P</i>
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 <sup>2</sup> ∅			
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

## Figures

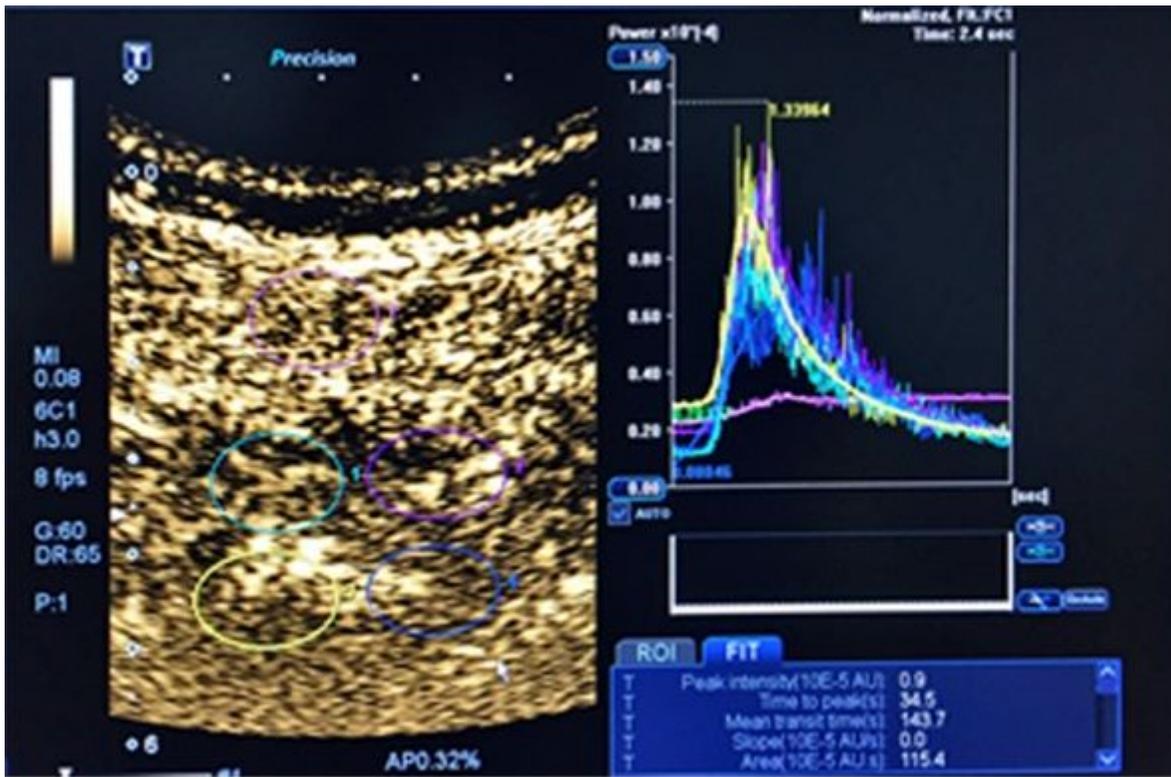


Figure 1

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

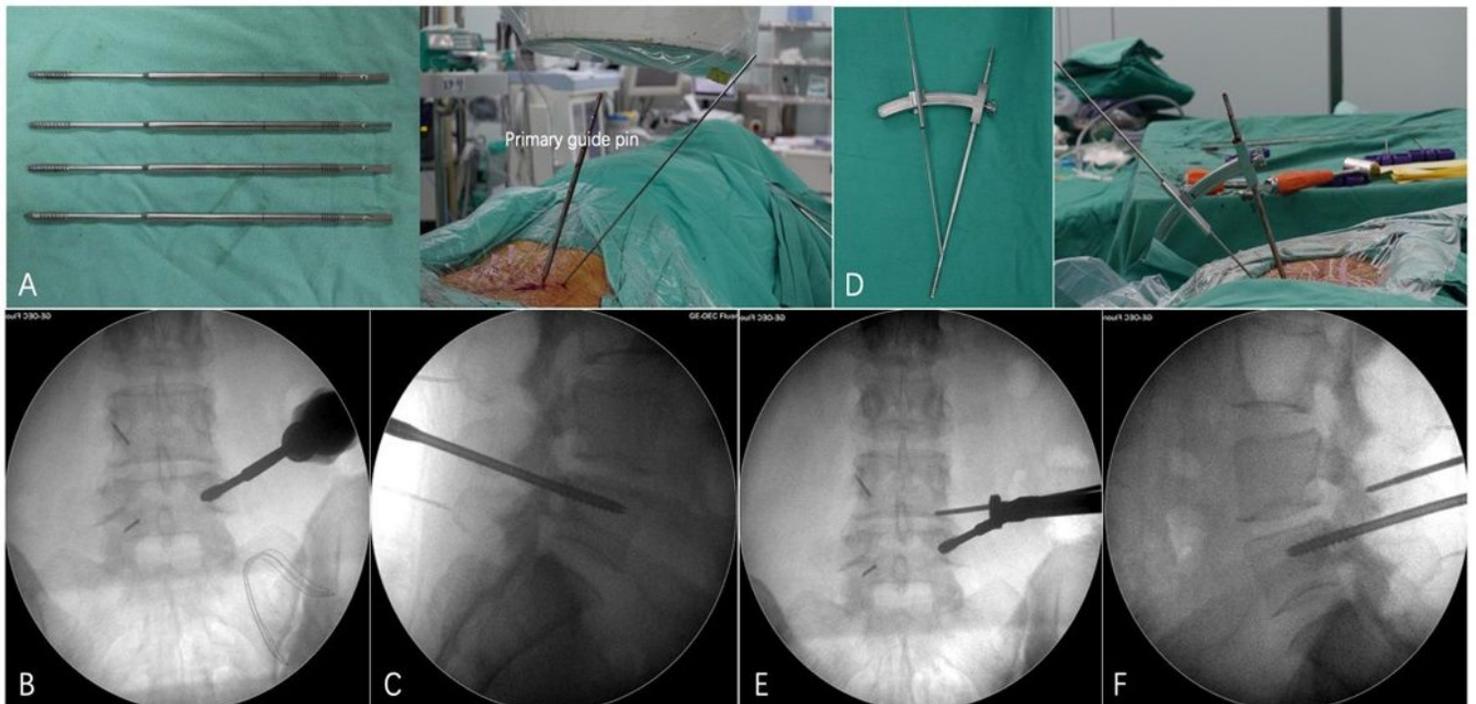


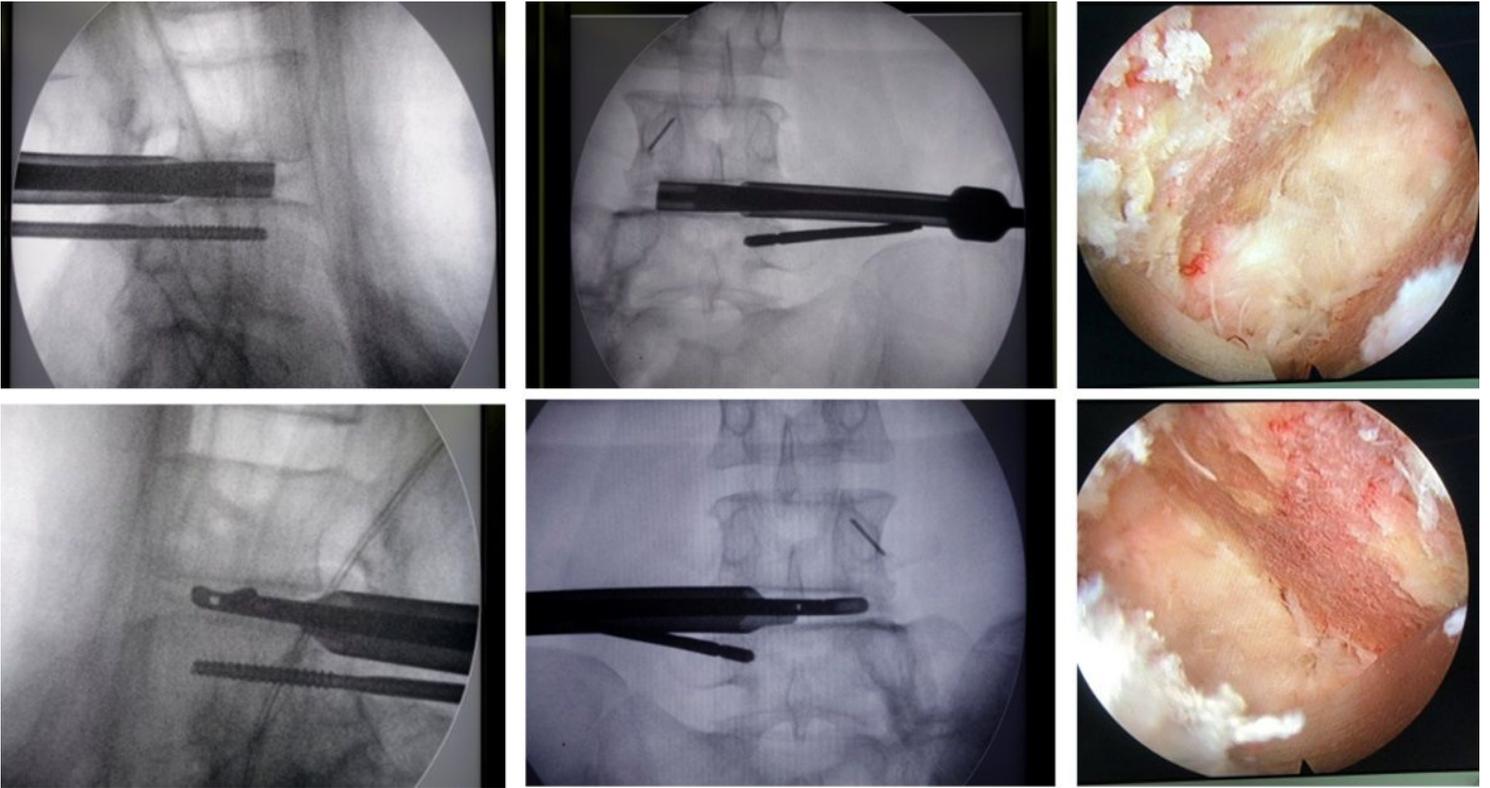
Figure 2

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-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-F, C-arm anteroposterior and lateral fluoroscopy confirms that the second guide pin is fixed to the posterior aspect of the superior articular process.



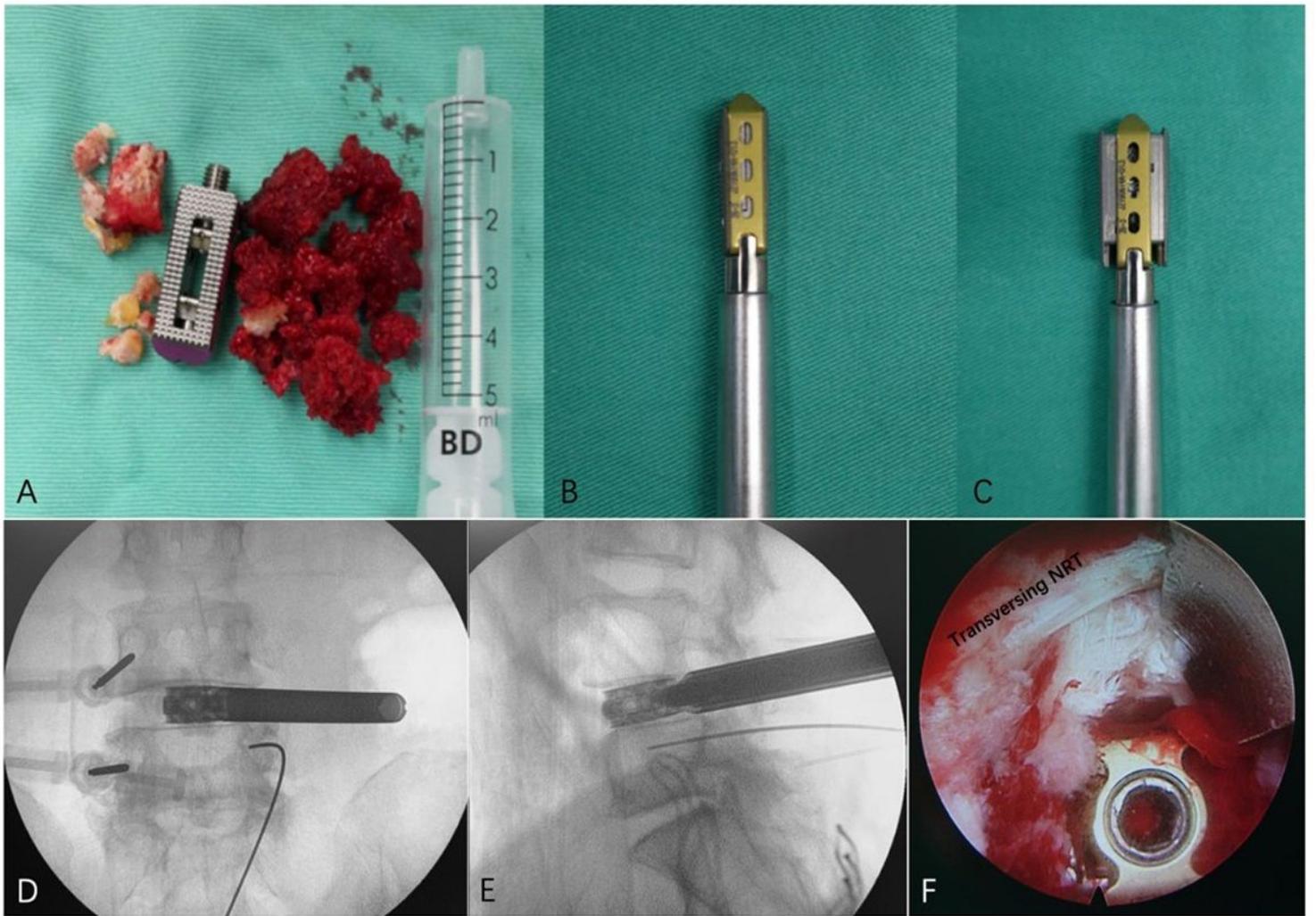
**Figure 3**

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.



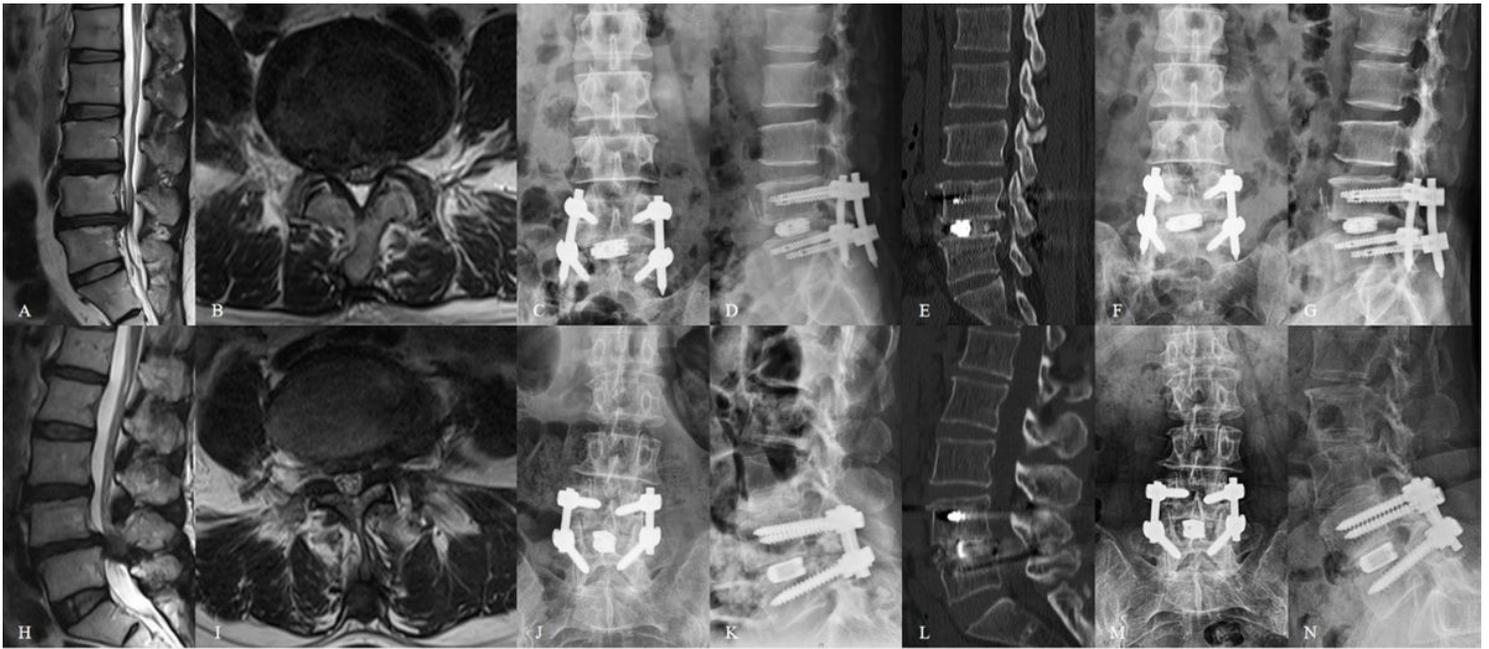
**Figure 4**

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-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.



**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-B) Preoperative MRI showed a lumbar spinal stenosis on L4/5. (C-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-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-I) Preoperative MRI showed a lumbar spinal stenosis on L4/5. (J-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-N) X-ray images showed a good implantation position at final follow-up.

## Supplementary Files

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