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Clinical outcomes of minimally invasive transforaminal lumbar interbody fusion via a novel tubular retractor

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Abstract

Objective: To assess the feasibility and clinical results of microscopic minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF) using a novel tapered tubular retractor that preserves the multifidus.

Method: A total of 122 patients underwent MIS-TLIF using a tapered tubular retractor system from March 2016 to August 2017. Perioperative parameters and follow-up outcomes were reviewed.

Results: The follow-up period was 23.95 ± 1.43 months. The operative time averaged 130.48 ± 34.44 minutes. The estimated blood loss was 114.10 ± 96.70 mL. The mean time until ambulation was 16.33 ± 6.29 hours. The average visual analogue scale (leg/waist) and Oswestry Disability Index scores (preoperative to last follow-up) improved from 4.93 ± 2.68/3.74 ± 2.28 to 0.34 ± 0.77/0.64 ± 0.74 and from 59.09% ± 22.34 to 17.04% ± 8.49, respectively. At the last follow-up, 98.36% of the patients achieved solid fusion. Cerebrospinal fluid leakage occurred in two cases. The asymptote of the surgeon's learning curve occurred at the 25th case. There were no significant differences between the preoperative qualitative and quantitative analyses of multifidus muscle fatty infiltration and those at the final follow-up.

Conclusion: MIS-TLIF can be performed safely and effectively using this tapered tubular retractor system, which helps preserve the multifidus.

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Introduction

With the advent of modern imaging guidance and sophisticated instrumentation, the transforaminal lumbar interbody fusion (TLIF) procedure has been adapted as a minimally invasive technique, which over the past years has been suggested to be more advantageous than traditional open surgery.[1–5] This approach was first introduced by Foley et al.[6] in 2003 with the aim of reducing tissue damage associated with exposure and surgery while maintaining the ability to achieve neural decompression and adequate interbody fusion. To date, a number of minimally invasive TLIF (MIS-TLIF) techniques have been performed through the use of cylindric retractors and expandable retractors.[2,5,7,8] However, these retractors still have the problem of poor operability and causing excessive retraction of the paravertebral muscles.[3,7,9] In this article, the MIS-TLIF procedure was successful performed with a tapered tubular retractor to create less disruption of the muscle. The authors describe the surgical technique and clinical results for a series of 122 patients. In particular, we propose a three-dimensional (3D) computer reconstruction model based on a subtle MRI examination for preoperative and postoperative multifidus muscle fatty infiltration analyses (20 selected patients).

Method

Ethics and consent statement

This study was approved by the ethics committee of the Third Military Medical University and conducted by its affiliated hospital (Xinqiao Hospital). All patients provided written informed consent.

Study design

Patients who underwent the microscope-assisted MIS-TLIF procedure via a tapered tubular retractor at the authors' institution between March 2016 and August 2017 were included in this series. All procedures were performed at the L3-L4, L4–L5, and L5–S1 levels, and the fusion length was restricted to one segment. The patient outcomes were scored based on such measures as operative time, intraoperative blood loss, drainage amount, and time to ambulation. The visual analogue scale (VAS) score was recorded preoperatively and at 3 days and 24 months postoperatively for waist and leg pain. The Oswestry Disability Index (ODI) according to Fairbank et al.[10] was used to assess function (preoperatively and at 24 months postoperatively). Radiographs, computed tomography (CT), and magnetic resonance imaging (MRI) were performed both before and approximately 24 months after the operation for each patient. Twenty selected patients underwent specialized MRI for multifidus muscle fatty infiltration analysis. Fusion was graded based on a previously published grading system (Table 1).[11] Major and minor complications were also recorded.

Surgical procedure

After administering general anesthesia, the patient was placed in a prone position on a radiolucent operating table with a

Table 1. Classification of fusion based on postoperative computed tomography imaging.

Grade I	Complete fusion: trabecular bone was seen bridging the disc space, with accompanying remodeling of the cortical end plates.
Grade II	Partial fusion: trabecular bone seen extending from the end plate into the disc space, but forming an incomplete bridge.
Grade III	No fusion: no evidence of trabecular bone formation extending from the end plates.

U-shaped cushion to free the abdomen. Two paramedian skin incisions were made based on the desired pedicle screw angle (radiographically projected onto the skin surface). The incision into the fascia allowed for blunt dissection between the longissimus and multifidus muscles in a standard Wiltse muscle splitting approach.[12] Then, four K-wires were placed in the bilateral pedicles immediately superior and inferior to the index disc under fluoroscopic guidance. Then, the fixed tube approach began with placement of the smallest-grade dilator down to the lamina via the muscle bundle of the multifidus, and was aligned with the index vertebral disc. Following placement of sequential dilators, the tapered working tubule (Zista, Bosscom Technology, Chongqing, China) was appropriately fixed (Figure 1c, d, e). Because of the small diameter of this tubular retractor, resection of the superior and inferior facets was performed in the restricted surgical field by adjusting the direction of the retractor, and an ultrasonic osteotome (XD860A, SMTP Technology, Zhangjiagang, Jiangsu, China) was used in this procedure. This bone was removed and kept for use as an autograft for interbody fusion. Moreover, sufficient decompression, disc space and endplate preparation, and cage insertion were performed with standard TLIF techniques. The entire procedure was carried out under a high definition surgical microscope with variable magnification and focalization. For patients who had canal stenosis with bilateral radiculopathy, a previously described contralateral decompression option was executed.[3] After wound irrigation was performed, percutaneous pedicle screws were inserted along with the guidewires. Finally, the wound was closed in layers.

Qualitative and quantitative analysis of the multifidus muscle

The MRI was obtained with an MRI system (SIGNA HDxt 1.5T, GE Healthcare, Milwaukee, Wisconsin, USA) preoperatively and at the final follow-up. 3D T2-weighted sequences (Cube) were performed with an 8-channel CTL coil. The continuous sequences included 60 sections that were acquired in 4 minutes with the following parameters: repetition time/echo time (TR/TE), 2000/24.4 ms; receiver bandwidth, 62.5 Hz; matrix, 384×288; field of view, 24 cm; section thickness, 1.2 mm; slice gap, 0 mm; and echo train, 64.

For the qualitative analysis, we adopted a visual grading system (Table 2) for the axial T2-weighted MRI images to assess fatty infiltration of the multifidus muscle, and this method was modeled after that from Goutallier et al.,[13] which was later improved by Fan and colleagues.[14]

For the quantitative analysis, 20 selected patients (age, 50–60 years; BMI, 22–26; no diabetes) were enrolled. The bilateral multifidus was included in the analysis. The upper endplate of the superior vertebrae and lower endplate of the inferior vertebrae in the sagittal plane were used to approximately define the superior and inferior margins of the region of interest for segmental muscle evaluation. All axial scanning planes were parallel to the horizontal middle line

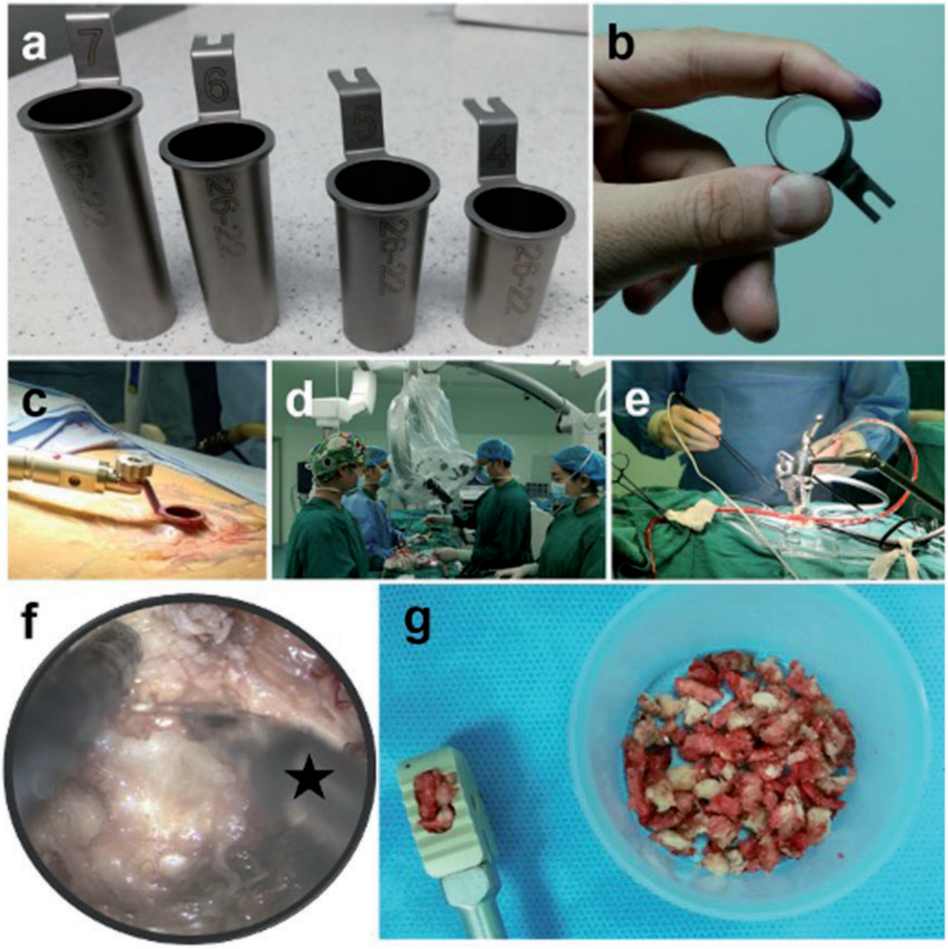

Figure 1. (a) Display of tapered tubular retractors of different sizes. (b) The dimensions of this tubular retractor are close to the size of the thumbnail of an adult male. (c) The working retractor has been installed. (d, e) View of the surgical field looking from the caudal and left aspect of the patient. (f) An ultrasonic osteotome (asterisk) was used to resect the ipsilateral facet joint. (g) Enough bone autograft is obtained through the tapered retractor using an ultrasonic osteotome and a fusion cage is ready for insertion.

Table 2. Qualitative analysis for fatty infiltration of the multifidus muscle.

Grade I	Normal muscle
Grade II	Fat tissue sparsely distributed between muscle fibers
Grade III	Fat tissue almost equal to muscle fibers
Grade IV	More fat tissue than muscle fibers in the quantitative analysis of the multifidus muscle

of the index intervertebral disc. To analyze the multifidus volume, we used Mimics software (Materialise, Leuven, Flemish Brabant, Belgium) to generate the 3D geometry of the multifidus and identified the muscle via contrast thresholding (Figure 2); a volumetric analysis of fatty and muscle tissue was performed. Percent fatty infiltration (%FI) was calculated

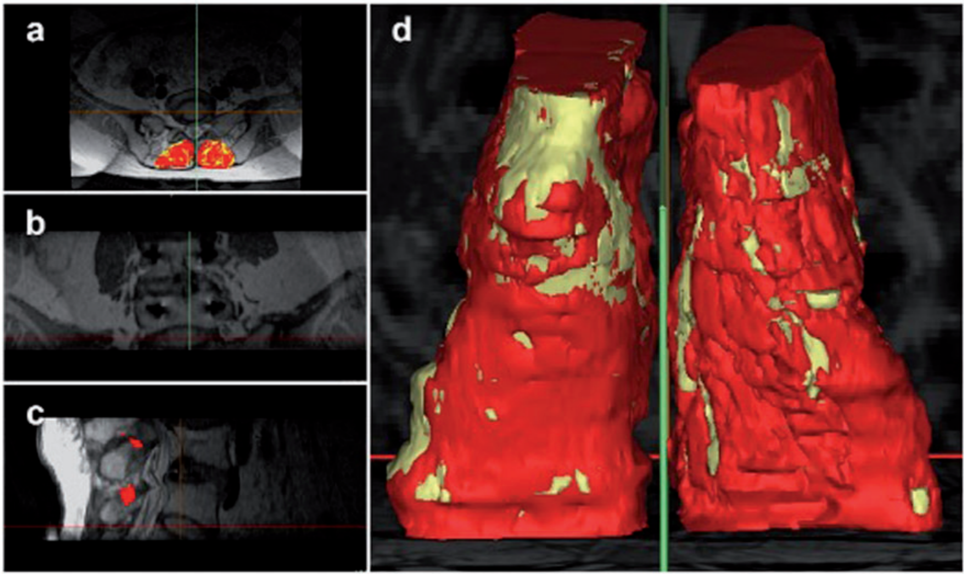

Figure 2. MRI segmentation and 3D reconstruction of the bilateral multifidus (d). Axial (a), coronal (b), and sagittal (c) plane lumbar MRI slices (coronal and sagittal planes were reconstructed from axial images). Muscle tissue is stained red, and fat tissue is stained yellow.

with the following formula:

$$\%FI = \frac{V_{Fat}}{V_{Fat} + V_{Muscle}}$$

Learning curve

The operative time trend was evaluated using piecewise regression analysis. The breakpoint estimate and its 95% confidence limits were estimated using the mathematical algorithm described by Muggeo.[15]

Statistical evaluation

Statistical analyses were performed using IBM SPSS Statistics for Windows, version 19.0 (IBM Corp., Armonk, NY, USA). The quantitative data are shown as the mean $\pm$ SD, and data from different time points were compared using Student's t-test. $P < 0.05$ indicated a statistically significant difference. A Learning curve analysis was performed using R statistical software (version 3.5.0, www.r-project.org).

Results

Patient and clinical outcomes

A total of 122 patients were included in the study, and the mean age at surgery was 58.28 ± 9.65 (range, 34–85) years. The index diagnosis was degenerative lumbar spondylolisthesis with canal stenosis in 102 patients, degenerative canal stenosis in 17 patients, and a lumbar disc herniation in three patients. All procedures were performed by one senior surgeon (H.B.). There were no conversions to open surgery. The mean follow-up was 23.95 ± 1.43 months, with a range of 22 to 26 months. No instrumentation-related complications occurred. No wound infections or delayed wound healing were observed in any patients, and no revision surgeries were performed. Two patients experienced cerebrospinal fluid leakage because of dural tears, and they were strictly confined to bed rest for 1 week after surgery. The demographic data and mean values of the clinical results are shown in Table 3. Significant differences were found between the preoperative VAS and ODI scores and those at the final follow-up ($P < 0.05$).

CT reconstruction was performed to evaluate the bone fusion status (Figure 3i, j). According to Mannion's fusion grading scheme, at the final follow-up (mean 23.95 ± 1.43 months), 106/122 segments achieved a grade I fusion state, 14/122 segments achieved grade II fusion, and no trabecular bone formation (grade III) occurred in two cases. As a whole, segments with grade I and II fusion status accounted for 98.36% of all operated segments.

Qualitative and quantitative analyses of the multifidus muscle

The data from the qualitative assessment of the multifidus muscle are shown in Table 4.

In the quantitative assessment of the multifidus muscle (20 patients), the 3D MRI reconstruction-based volumetric evaluation revealed a nonsignificant increase in the percentage of fatty tissue, from $38.3 \pm 7.63\%$ preoperatively to $41.55 \pm 11.50\%$ after 24 months ($P > 0.05$). Moreover, there were no significant differences in fatty infiltration at the final follow-up

Table 3. Demographic data of the patients.

No. cases		122	
Sex (M/F)		45/77	
Age (y)		58.28±9.65	
Height (m)		1.58±0.09	
Weight (kg)		62.52±10.11	
BMI		24.83±3.17	
Hospital stay (d)		6.45±2.47	
Bilateral decompression		42	
Operation time (m)		130.48±34.44	
Blood loss (ml)		114.1±96.7	
Time to ambulation (h)		16.33±6.29	
Level	L3/L4	L4/L5	L5/S1
	8	105	9
Index diagnoses	Spondylolisthesis with canal stenosis	Spinal stenosis	LDH
	102	17	3
Drainage volume	Day 1	Day 2	Day 3
	66.92±69.41	33.59±15.09	16.75±10.44
VAS score (waist)	Preoperative	Postoperative (3d)	Follow-up(>1y)
	3.74±2.28	0.65±0.85*	0.64±0.74*
VAS score (leg)	Preoperative	Postoperative (3d)	Follow-up(>1y)
	4.93±2.68	0.36±0.83#	0.34±0.77#
ODI	Preoperative		Follow-up(>1y)
	59.09%±22.34		17.04%±8.49∮

*#∮ indicates a statistically significant difference compared with the preoperative value, $P < 0.05$.

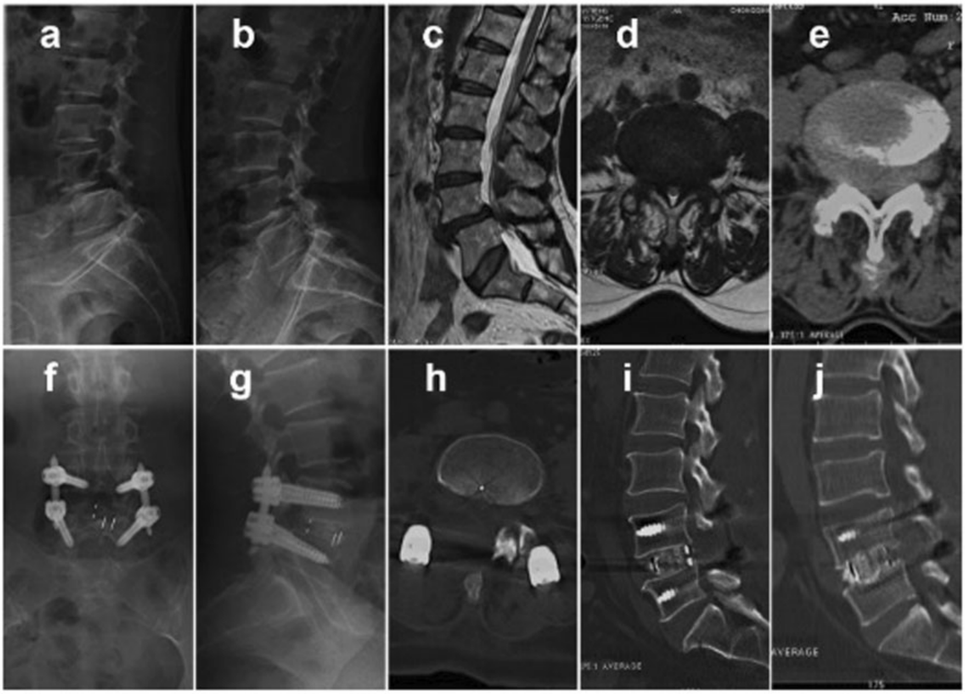

Figure 3. A representative case of a patient (female, 67 years old) with L4-L5 spondylolisthesis and canal stenosis. (a, b) A preoperative sagittal flexion–extension X-ray image showing L4-5 spondylolisthesis. (c, d) Preoperative axial and sagittal magnetic resonance imaging (MRI) showing dural sac compression at the L4-L5 level. (e) A preoperative axial CT scan showing the spinal canal size at the L4-L5 level. (f, g) A postoperative coronal and sagittal X-ray image showing the reduction of spondylolisthesis at the L4-5 segment. (h) Postoperative axial CT shows expansion of the spinal canal. (i) Sagittal computed tomography scan at 3 months postoperatively. (j) Sagittal computed tomography scan at the final follow-up shows solid bone graft fusion.

Table 4. Qualitative assessment of the multifidus muscle.

Grade	Preoperative (Tube side)	Preoperative (Normal side)	Postoperative (Tube side)	Postoperative (Normal side)
I	84	88	79	84
II	29	25	30	27
III	9	9	13	11
IV	0	0	0	0
Avg ± SD	1.39 ± 0.62	1.34 ± 0.60	1.47 ± 0.69*	1.40 ± 0.65#

*# indicates no statistically significance, with a $P > 0.05$ compared with the preoperative value.

on either side of the multifidus muscle. The percentage of fatty infiltration on the tube side and normal side were 42.35 ± 11.80% and 40.75 ± 11.44%, respectively (Table 5).

Learning curve

From the piecewise regression analysis, the surgeon's operative time for performing

Table 5. Qualitative assessment of the multifidus muscle.

	Preoperative (%)	Postoperative (%)	P value
Tube side	38 ± 7.67	42.35 ± 11.80	$P = 0.18$
Normal side	38.6 ± 7.77	40.75 ± 11.44	$P = 0.49$
Both sides	38.3 ± 7.63	41.55 ± 11.50	$P = 0.14$

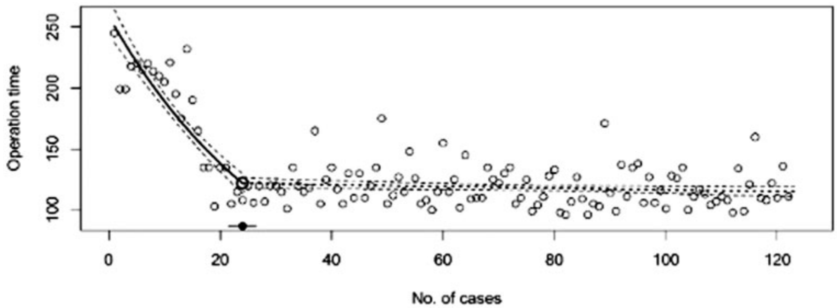

Figure 4. The procedure learning curve: the bar above the X-axis represents the breakpoint estimate (25) and its 95% confidence limits (22–28 patients).

MIS-TLIF was estimated to stabilize after performing the 25th operation (95% CI, 22–28) (Figure 4).

Discussion

Tubular retractors are technically more challenging to apply, as the surgery involves much smaller operative fields to perform MIS-TLIF than expendable retractors. With the assistance of developed endoscopic or microscopic systems, several surgeons have reported their successful surgical experience and satisfactory outcomes using cylindrical tubular retractors. However, the main limitation of the commonly used cylindrical tubular retractor is that the retractor has the same diameter at the upper end and lower end and along the tube height, which reduces the operability and narrows the visual field. Hence, this retractor led to a high level of surgical difficulty, and only experienced surgeons could use this device competently. To overcome this situation, we adopted a tapered tubular retractor (Zista, Bosscom Technology, Chongqing, China) with various sizes to reduce the difficulty and risks as much as possible during MIS-TLIF (Figure 1a). The upper end of the working tubular retractor is 22–28 mm in diameter, which provides a larger angle for surgical tool movement and a larger insight angle and tapers to a diameter of 18–24 mm at the lower end to allow for a convenient decompression and fusion (Figure 5a). The operability of the surgical tool decreases with increasing tube height. Therefore, the length between the skin and facet joint must be determined from MRI or CT during the surgical planning period to choose a tube with the appropriate height for optimal surgical comfort and an individualized operation.

Some studies have shown that ultrasonic instruments can decrease the risk of damage to the surrounding soft tissues and critical structures such as nerves and vessels, especially during osteotomy procedures.[16,17] In our cases, an ultrasonic osteotome was successfully used to perform the needed osteotomies with high precision and assist with

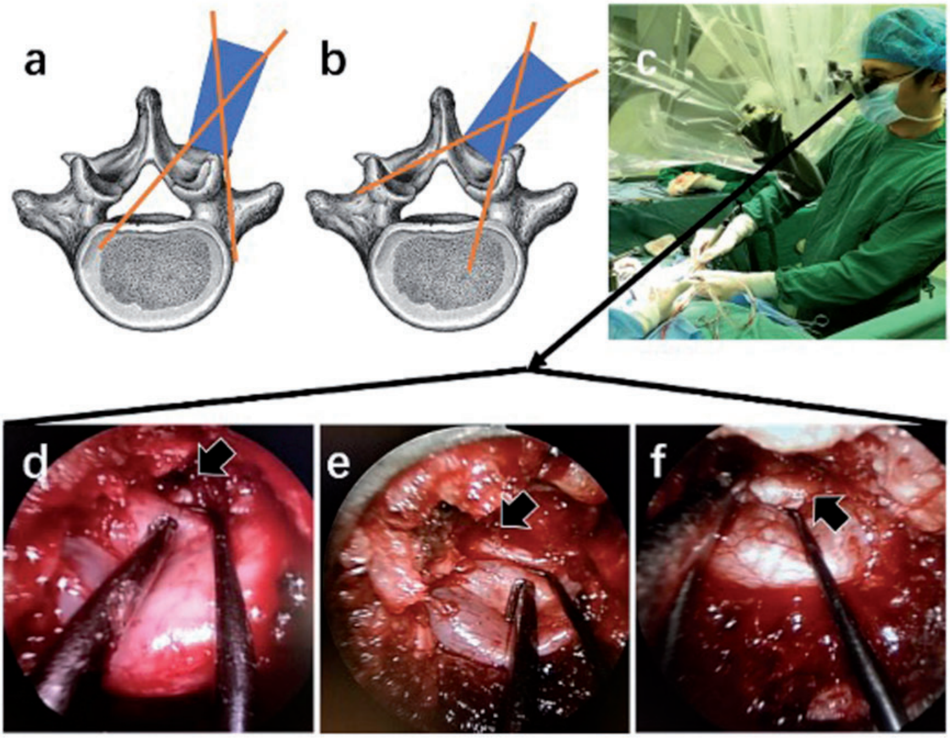

Figure 5. (a) Schematic diagram of the working tubular retractor placement process. A wide operating space ensured that the surgical tool could be delivered because of its inverted tapered design. The orange line represents the range of surgical tools available. (b) The retractor was moved medially so that a contralateral decompression procedure could be performed. (c) There was no need to tilt the bed when performing contralateral decompression. (d, e, f) The microscopic view of the decompressed contralateral nerve root (black arrow) in three cases.

the surgical procedure (Figure 1f–g). Our retractor not only overcame the shortcomings of an insufficient autograft harvest with a burr, but was also much safer than an osteotome. In our study, no allograft materials were used as a substitute for autografts, and this benefit contributed to a 98.36% fusion rate. Moreover, there were no osteotomy-related injuries to the critical nerves or blood vessels.

The bilateral decompression technique via a unilateral approach for MIS-TLIF had the benefits of preserving the stability of the contralateral bony, ligamentous, and muscular structures.[18] However, it is impossible for expandable retractors to complete this procedure due to their large size and inflexibility. If needed, the new tapered retractor could incline to the middle line easily (Figure 5b), then contralateral decompression can be performed by adjusting the microscopic lens angle (Figure 5c). Furthermore, the bevel angle of the tapered tube could compensate for some lens angles, so it was not necessary to tilt the bed. Prior to this technique, we used an endoscopic system to perform contralateral decompression, but later we preferred the use of a microscope. The reasons were as follows. First, the endoscope lens is often blurred by blood and bone debris, and extra time is required to clear these obstructions, but this is not an issue with a microscope. Second, the contralateral decompression site is much deeper than the ipsilateral site, and the microscope can deliver higher visual clarity and better stereoscopic sensation than the endoscope. In this series, 42 patients underwent contralateral nerve root decompression procedures effectively (Figure 5d–f) and no intraoperative complications occurred. We required 14.37 ± 2.16 minutes of extra time to complete the surgery, but there was no significant increase in blood loss ($P > 0.05$).

The VAS and ODI scores decreased significantly in all patients after surgery. In particular, the VAS scores significantly decreased at 3 days postoperatively, especially the waist scores (Table 3). Surprisingly we found that most of our patients progressed to walking early after surgery. The mean time to ambulation was 16.32 ± 6.29 hours, and 13 patients were ambulatory within 6 hours after surgery. These patients appeared to have less postoperative pain. Despite the use of drugs to relieve pain, we suspect that the reliable surgical procedure and minimal intraoperative trauma to the soft tissues allowed the patients to ambulate earlier.

Early papers reported longer operative times for MIS-TLIF. However, in the current study, the surgeon managed to achieve a shorter operative time for MIS cases.[2,19–22] Because we mastered the technique during the first 25 cases, the operative time decreased gradually and stabilized at approximately 120 minutes (Figure 5). This stabilization point is earlier than in other MIS-TLIF-related studies, such as at the 44th case reported by Lee et al.[22] and the 30th case reported by Lee et al.[21] After the breakpoint, we noticed a significant decrease in the operative time from 176.6 minutes in the early phase (1–25) to 118.6 minutes in the later phase (26–122). Therefore, MIS-TLIF via this new retractor system did not increase the operative duration or surgical difficulty.

There were few intra- and postoperative complications and symptom recurrences throughout the follow-up period. In the early phase of this technique, two patients experienced cerebrospinal fluid leakage because of dural tears. In one case, the K-wire accidentally penetrated the ligamentum flavum during the tube placement procedure, and created a pinhole in the dura mater. In the other case, there was an accidental laceration between the posterior longitudinal ligament and the ventral dura mater due to adhesions when performing intraspinal decompression. To avoid serious postoperative complications, such as infection and epidural hematoma, a drainage tube was necessary. In our experience, we usually removed the drainage tube on the third postoperative day, but the two following conditions have to be met. The drainage volume should be less than 10 mL in 24 hours, and the bloody fluid in the tube should become serous.

Although there are many potential benefits to MIS-TLIF, the technique still has its drawbacks and limitations. First, the surgeon must take the working distance of the surgical microscope into account to avoid accidental contamination of the surgical area. Second, this approach requires a certain period of time to become familiar with the longer and bayoneted surgical instruments. Finally, the tube is often forced out by the surrounding muscles due to its tapered shape when weakly held in place. In that case, the assistant needs to place an additional hand to hold the retractor in place.

The MIS-TLIF procedure can lead to reduced tissue injuries, while allowing the surgeon to perform the operation as effectively as conventional open surgery.[3,7,8,23,24] However, this technique still requires significant soft tissue dissection and retraction to access the disk space. Various retractors have been reported to be successful and can be approximately divided into two categories: expandable retractors and non-expendable retractors.[5,7,23,25] As reported by Stevens et al.,[9] the paraspinal intramuscular pressure (IMP) of the expandable retractor group was significantly higher than that of the non-expandable tubular retractor group. Moreover, excessive pressure to paraspinal muscle can lead to capillary perfusion damage, and may result in muscle degeneration, especially if the retraction time is more than 2 hours.[26–28] This was corroborated by Kawaguchi et al., who proved that retraction duration and pressure positively correlated with elevated serum levels of the creatine phosphokinase MM isoenzyme, a direct marker of muscle injury. Six months after surgery, Stevens et al. found that the expandable retractor group showed marked intramuscular edema on MRI, while patients treated with MIS-TLIF using a tube had nearly normal findings. Coincidentally, our 3D MRI reconstruction findings were similar; both bilateral multifidus muscles had a normal fat infiltration ratio, and there were no significant differences in fat infiltration at the final follow-up on either side of the multifidus muscle. Therefore, the trans-muscular approach using a non-expandable tubular retractor may lead to fewer iatrogenic soft tissue issues than an expandable retractor,

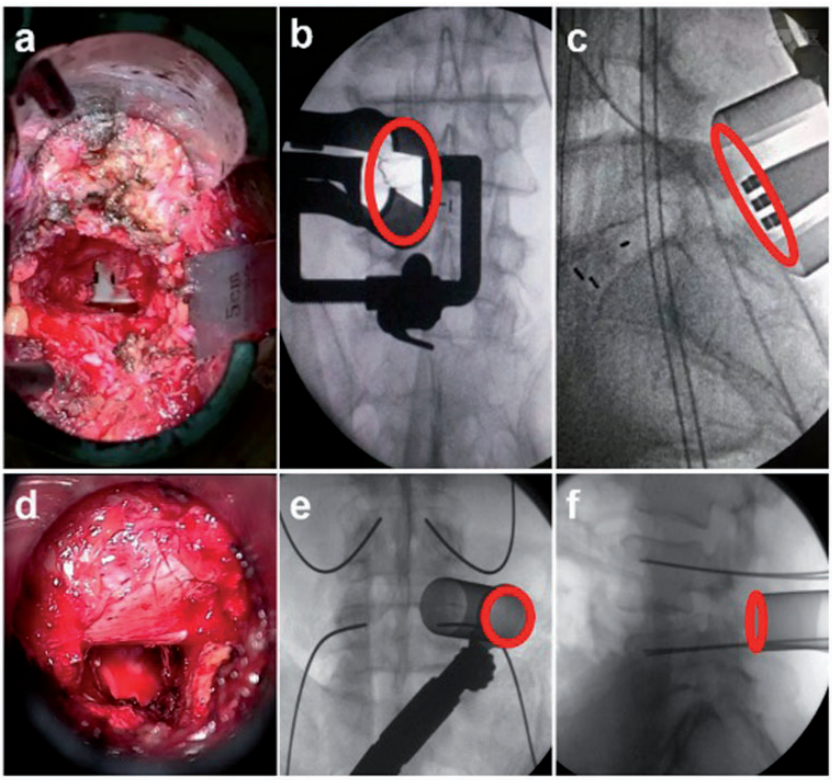

Figure 6. (a, b, c) Intraoperative image through an expandable retractor and radiograph (coronal and lateral views). (d, e, f) Intraoperative image through the tubular retractor and radiograph (coronal and lateral views) showing lower invasiveness compared with that obtained with an expandable retractor.

possibly because of the minimal retraction range and low retaining pressure to the paraspinal muscles (Figure 6d–f).

Two-dimensional MRI analyses and 3D CT descriptions for paraspinal muscles have been extensively demonstrated.[14,24,29] However, MRI 3D reconstruction quantitative assessments of paraspinal muscles for postoperative changes after MIS-TLIF surgery have not been described in the literature. In our research, section thickness and the slice gap of MRI scans were 1.2 mm and 0 mm, respectively. It was more precise than frequently-used MRI scans, and reconstruction from these data could reflect the muscle integrally. To avoid the interference of edema, fatty infiltration changes in our cases were evaluated 24 months postoperatively.[27]

The limitation of this study was the lack of a matched controlled group, especially for comparisons to expandable retractors or open approaches. This study was based on a patient series from one surgical team in a single institution with a short follow-up. Moreover, the 3D reconstruction by Mimics software was performed by one engineer, which may bias the conclusion. In the future, a prospective controlled study should be performed to determine the superiority of this tubular retractor over other methods.

Conclusion

Although the long-term results of this technique have yet to be determined, the results of the present study suggest that satisfactory clinical results and preservation of the multifidus can be achieved and that single-level microscope-assisted MIS-TLIF via this novel tubular retractor system is a safe and effective surgical technique.

Abbreviations

MIS-TLIF: minimally invasive transforaminal lumbar interbody fusion
VAS: Visual Analogue Scale
ODI: Oswestry Disability Index
CT: Computed tomography
MRI: magnetic resonance imaging
LDH: Lumbar disc herniation.
3D: three-dimensional
%**FI:** Fatty infiltration

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Declaration of conflicting interest

The authors declare that there is no conflict of interest.

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