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Comparative study between mini-open TLIF via Wiltse's approach and conventional open TLIF in lumbar degenerative diseases

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Abstract. – OBJECTIVE: To compare the clinical effects, operation safety and radiation exposure of mini-open TLIF via Wiltse's approach (MOTLIF) and conventional open TLIF (COTLIF) in the treatment of single-segment lumbar degenerative disease via the prospective control study.

PATIENTS AND METHODS: A total of 77 patients were enrolled from November 2012 to July 2014, including 42 patients in the mini-open group (MOTLIF) and 35 patients in the COTLIF group. Oswestry Disability Index (ODI) and Visual Analogue Scale (VAS) scores before operation, operation time, intraoperative blood loss, postoperative drainage volume, blood transfusion rates, postoperative bedridden time, postoperative hospital stays, intraoperative fluoroscopic time, levels of serum creatine phosphokinase (CPK) before operation, 3 days and 1 week after operation, VAS scores before operation, 3 days and 1 week after operation, and ODI and VAS scores in the last follow-up between the two groups were compared.

RESULTS: There were significant differences between the two groups in the operation time, intraoperative blood loss, postoperative drainage, blood transfusion rates, postoperative bedridden time, postoperative hospital stays and intraoperative fluoroscopic time; all indicators in MOTLIF group were superior to those in COTLIF group ($p<0.05$). There were no significant differences between the two groups in levels of serum CPK before operation and 1 week after operation ($p>0.05$). However, 3 days after operation, the level of serum CPK in COTLIF group was increased more significantly than that in MOTLIF group (647.4±178.6 vs. 467.4±189.4). There were no differences between the two groups in ODI and VAS scores before operation; ODI score in MOTLIF group in the last follow-up was significantly superior to that in COTLIF group ($p>0.05$). And VAS scores at 3 days and 1 week after operation and the last follow-up in MOTLIF group were superior to those in COTLIF group ($p<0.05$).

CONCLUSIONS: Compared with the conventional open TLIF, mini-open TLIF via Wiltse's approach using the self-designed operating apparatus is characterized by the convenient operation, small trauma and quick recovery after operation. At the same time, the radiation exposure is lower and long-term follow-up effect is superior. Its short-term and long-term effects in the treatment of lower lumbar degenerative disease are also superior.

Key Words
Lumbar degenerative disease, Mini-open surgery, Thoracolumbar spine, Minimally invasive, Pedicle screw, Open surgery.

Introduction

TLIF (transforaminal lumbar interbody fusion) technique was first reported by Harms and Rolinger[1] in 1982. It is characterized by the posterior approach and reaching the spinal canal from one side for bilateral interbody fusion. It does not need to interfere with the central canal, thus reducing the occurrence of cerebrospinal fluid leakage, and does not need to pull nerve root and dural sac too much, thus reducing the probability of nerve injury[2]. Moreover, it retains the contralateral lamina and facet joints, and increases the bone graft area, so 360° fusion is feasible[3]. Also, it retains the supraspinous liga-

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ment and interspinous ligament, thus retaining the posterior lumbar tension band structure. TLIF technique is gradually being accepted and widely used by clinicians. But the conventional open TLIF has been criticized for iatrogenic damage due to the extensive peeling of soft tissue and muscle[4-6]. In recent years, the surgical treatment of lumbar degenerative disease has showed the minimally-invasive trend, and TLIF technique has developed to mini-open incision. Expandable passage tube minimally-invasive system, such as Quadrant system, establishes the surgical channel using the step-by-step expansion method, exposing limitedly and minimizing the tissue damage in surgical approach and surgical procedures. Compared with the conventional open surgery, it can not only complete the operation, but also achieve the goal of smaller incision, better internal stability, less systemic and local responses, faster tissue healing, shorter functional recovery time and better psychological effect[7-9]. At present, sextant system-assisted percutaneous bilateral pedicle screw fixation and Quadrant channel-assisted TLIF have been extensively performed clinically and achieved better short-term effects as well as the same long-term effects as open TLIF[10].

Compared with conventional open surgery, Quadrant system-assisted minimally-invasive TLIF significantly reduces the risk of bleeding and surgical complications, postoperative serum CPK level is decreased, bedridden time is reduced, postoperative ODI and VAS scores are improved better and the recovery cycle is shortened[11]. Although Quadrant channel-assisted TLIF technique has the above advantages, but both Quadrant channel-assisted and Sextant system-assisted posterior minimally invasive surgery have the disadvantages of relatively difficult operation, too long learning curve, early cerebrospinal fluid leakage, high misplacement rate of pedicle screw[12], combination with percutaneous fixation technique[13], much radiation exposure required during operation, high cost of operating apparatus and supporting implantation materials and repeatedly slipped muscle in channel operation, so in order to ensure the clear surgical field sometimes, spine surgeons often choose cauterization and partial resection of muscle[14,15].

To solve the above problems, retain the "minimally invasive characteristics" of channel technique and overcome the shortcomings of channel technique, we modified the Wiltse approach a second time in the preliminary study. Our preliminary findings showed that the intermuscular space was reached through subfascial median incision, instead of the subcutaneous approach, which can effectively reduce the muscle pressure during operation, reduce the "osteofascial compartment-like effect" of multifidus muscle in bilateral incision approach, better protect the paraspinal muscles and avoid the skin necrosis and local hematoma caused by extensive subcutaneous peeling, etc.[16,17]. At the same time, in order to further increase the convenience of operation and reduce the radiation exposure during operation, we designed the special retractor and fixation guide device based on the characteristics of new approach, making the operation simpler and more convenient and reducing the radiation exposure[17,18].

This study prospectively compared the data of patients in the two groups receiving TLIF *via* the modified paraspinal muscle space approach and the conventional open approach assisted by the self-designed surgical instrument, so as to compare the differences in curative effects, operation time and intraoperative radiation exposure doses between the two surgical methods in the lower lumbar spinal fusion.

Patients and Methods

General Data of Patients

Patients who needed TLIF were enrolled, and those admitted into hospital on odd days were enrolled into the intermuscular space group and received mini-open TLIF *via* modified intermuscular space (Mini-TLIF), while those admitted into hospital on even days were enrolled into the open group and received open TLIF (Open-TLIF). Inclusion criteria: 1) patients with lower lumbar pain accompanied with radiating pain in lower limbs and intermittent claudication; 2) patients who were not improved after conservative treatment; 3) patients diagnosed as single-segment lesion, including lumbar instability, pure protrusion of intervertebral disc, degenerative lumbar stenosis, fibrous ring prolapse and lumbar spondylolisthesis, according to preoperative physical examination, combined with lumbar dynamic radiographs, lumbar MRI and lumbar CT scan. Exclusion criteria: patients with more than one-segment lesion who needed operation; patients with a history of mental illness; patients with a history of lumbar surgery; patients with definite surgical contraindications, such as severe

Table I. Demographic data for the patients in the two groups.

		MOTLIF	COTLIF	*p*
	Cases	42	35	—
	Gender (female/male)	17/25	14/21	0.966
	Age (years)	54.4±7.8	56.29±5.4	0.2
	BMI	22.59±2.68	22.96±3.00	0.57
Etiology	Single-level lumbar instability	3	5	0.722
	Disc herniation	4	2	
	Lumbar spinal stenosis	17	10	
	Annulus fibrosusprolapse	9	11	
	lumbar spondylolisthesis (grade I-II)	6	5	
	lumbar spondylolisthesis (grade III-IV)	3	2	
Fusion levels	L3/4	6	2	0.391
	L4/5	17	18	
	L5/S1	19	15	

heart disease, diabetes, renal failure, respiratory failure, coagulation disorders and other serious medical diseases; patients with severe osteoporosis (T-value ≤-2.5 measured by dual-energy X-ray absorptiometry); patients who refused to sign the informed consent.

According to the above criteria, a total of 77 out of 104 patients with lumbar degeneration met the inclusion criteria from November 2012 to July 2014, including 42 patients in MOTLIF group and 35 patients in COTLIF group (Table I). This study was approved by the Ethics Committee of Taizhou People's Hospital affiliated to Nantong University. Signed written informed consents were obtained from all participants before the study.

Preoperative data were collected from the thoracolumbar anterioposterior and lateral radiographs, and lateral flexion and extension radiographs, lumbar MRI and lumbar CT scan. The physical examination of all patients must be consistent with the results of imaging examination. After operation, the placement of pedicle screw and interbody fusion cage was detected *via* conventional X-ray and CT scan for operative segment.

Surgical Procedure
MOTLIF Group

Under conventional general anesthesia, "eyeglass frame"-like locator was used to position the intervertebral space and pedicle *via* modified intermuscular space approach, and the median incision between upper and lower vertebral pedicles was made with the length of about 5 cm-6 cm (Figure 1). Generally the incision was extended towards the head side, so as to place the screw and fusion cage easily (the placement of lower lumbar screw and interbody fusion cage generally needs a certain tail angle). The skin was cut along the supraspinous ligament subcutaneously until the supraspinous ligament, and then the deep fascia and adherent section of supraspinous ligament were cut along both sides of supraspinous ligament (the thyroid retractor was used to pull the skin up and down to further expose the upper and lower deep fascia of incision, so that the deep fascia incision was 0.5-1.0 cm longer than the upper and lower skin incision), and the skin was separated along the bilateral multifidus muscle and deep fascia to the space between multifidus and longissimus muscles until the lateral border of facet joint. Pedicle site was exposed along the intermuscular space, and the inside and outside retractors were placed. The local fixation marks were identified repeatedly during operation, including mastoid, sub-mastoid, lateral border of upper joint and transverse process. For patients with obvious facet hypertrophy, the osteophyte should be removed properly to expose the articular surface and further clarify the lateral border of upper joint. After the entry site was determined, the guide pin was inserted using guider according to the entry direction measured before operation and the relationship between screw vertebra and supraspinous ligament of the last vertebra. The conventional fluoroscopic examination was generally performed after the first guide pin was inserted to determine if the surgical segment was correct, and then fluoroscopic examination was not needed in the subsequent operation (Figure 2). Decompression and interbody fusion treatment: According to the patients' symptoms and signs, those with severe symptoms in both lower limbs were treated with interbody fusion cage for bilateral decompression, but the

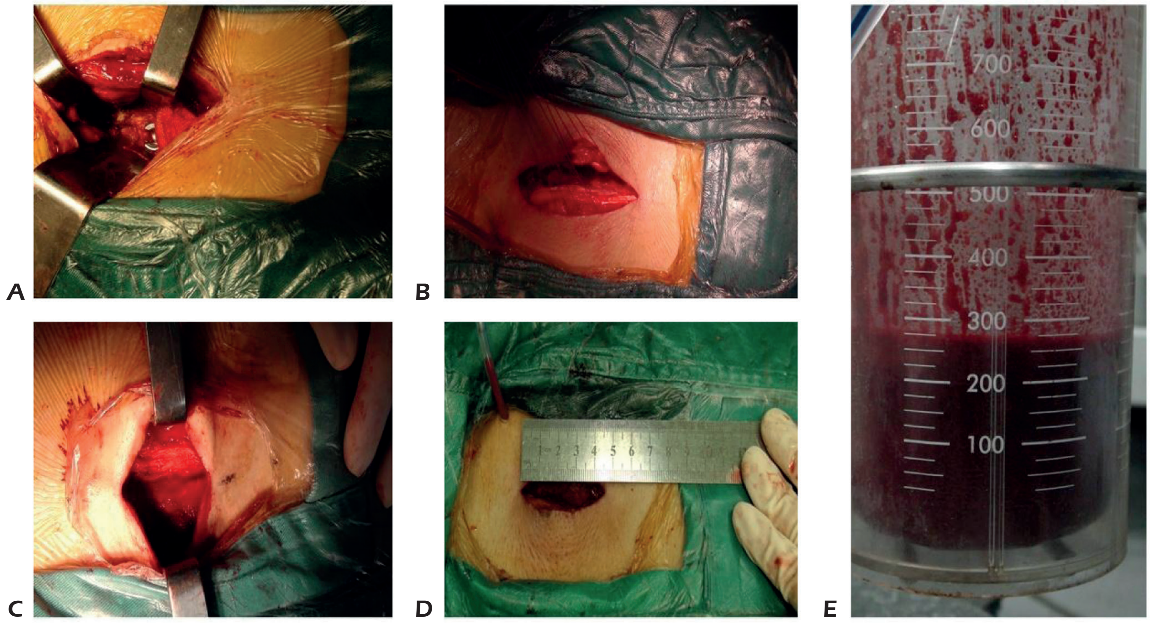

Figure 1. Procedures for TLIF via Mini-open Wiltse's Approach. ***A***, Screw fixation via the unilateral intermuscular space assisted by the retractor; **B**, Bilateral deep fascia and spinous process were sutured together to close the incision; **C**, Well-preserved multifidus muscles on both sides; ***D***, Length of surgical incision; **E**, Single-segment patients receiving bilateral decompression, intraoperative blood loss of 280 mL.

opposite decompression is generally not needed for unilateral symptoms. Before the placement of interbody fusion cage, the autogenous bone (from the laminectomy and the removal of facet joint) was routinely implanted into the intervertebral space. Deep fascia on both sides and supraspinous ligament in the middle were sutured together to close the surgical incision (Figure 3), and the drainage tube and vacuum bottle were connected on the decompression side, but drainage tube was generally not needed on the simple screw side.

COTLIF Group

In the COTLIF group, 8-10 cm-long skin incision was made *via* the posterior median approach to the supraspinous ligament, deep fascia was cut along the bilateral supraspinous ligaments, and multifidus muscle was peeled off along the spinous process and vertebral plate and pulled using automatic retractor, followed by screw fixation and decompression fusion under direct vision. During operation, Kirschner wire was used for positioning first, followed by fluoroscopic examination *via* C-arm X-ray machine and adjustment of screw path according to fluoroscopic examination. The side with severer protrusion of intervertebral disc or spinal canal stenosis or symptoms was selected as the approach side of TLIF. If there were symptoms on both sides, the side with severe symptoms generally received TLIF, while the side with mild symptoms received laminectomy and detection of dura mater and nerve root. Even in the bilateral decompression, the spinous process and supraspinous ligament were retained generally, and drainage tube and vacuum bottle were placed after operation.

The two groups received no allogeneic bone graft, pedicle screw-rod system and interbody fusion cage are designed in the same type, and the installation steps are the same. After anesthetic awareness, the muscle strength and sensory condition of both lower limbs were observed. At 6 h after operation, patients were encouraged to receive the straight-leg raising exercise. According to drainage volume, drainage was removed at 48-72 h after operation, followed by routine dressing. All patients were treated with antibiotics (one-generation cephalosporins) once at 30 min before operation. After operation, in addition to analgesic pump and patient-controlled analgesia, patients received the appropriate dehydrating agents, hormones and neurotrophic drugs to reduce the postoperative nerve edema and accelerate the recovery of nerve function. After operation, patients were required to exercise out of bed, and the waist activity was limited *via* lumbar brace within 3 months.

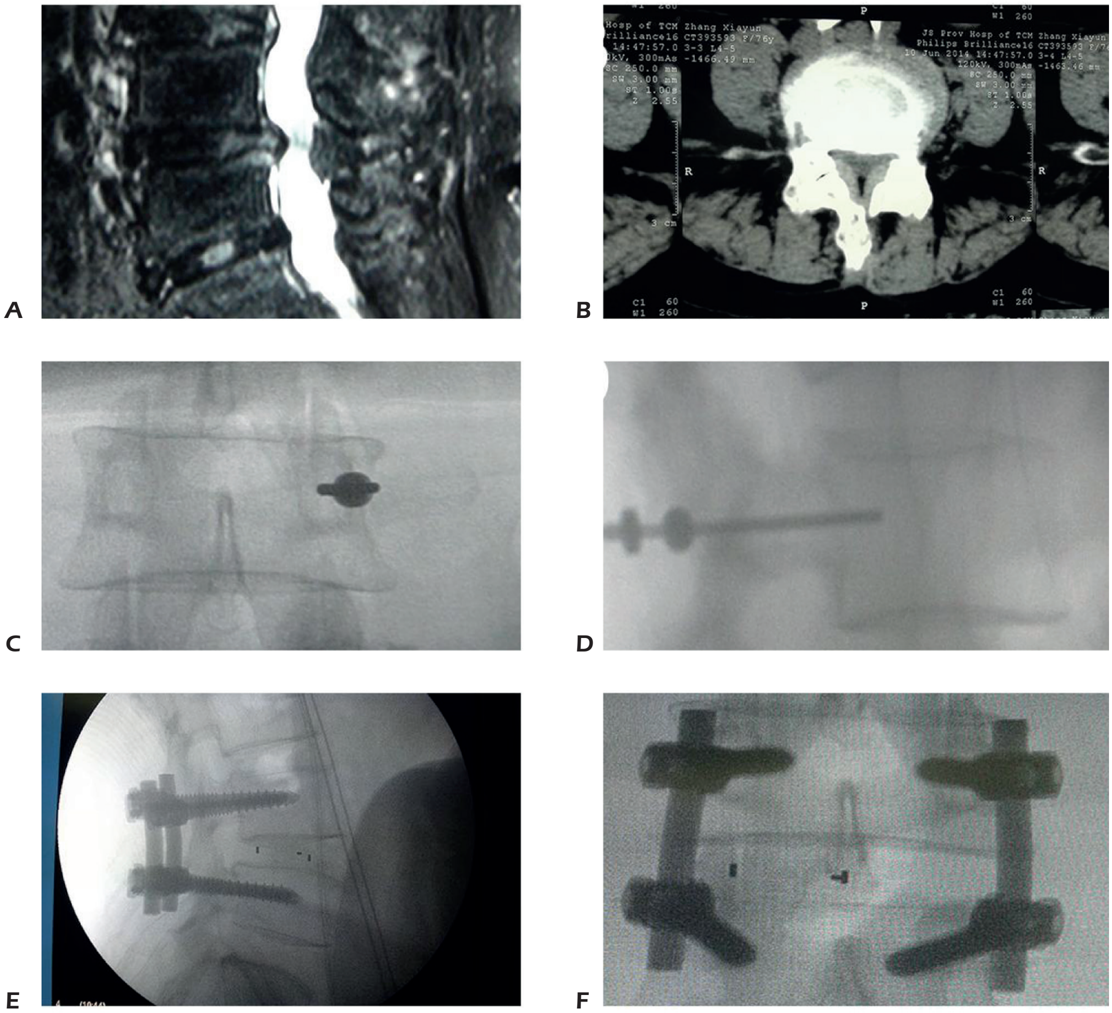

Figure 2. Radiological images for a case with lumbar degenerative disease aged 53 years old: **A**, Sagittal and **B**, cross-sectional view suggested the severe degenerative spinal canal stenosis in L4/5; **C-D**, The guide pin was inserted using guider during operation, followed by fluoroscopic examination once, to confirm the vertebral segment and the direction of guide pin; the direction of guide pin could be basically parallel to the superior endplate guided by the guider; **E-F**, Secondary fluoroscopic examination after operation suggested that the positions of internal fixation and fusion cage are satisfactory.

Observation Indicators

Perioperative observation indicators were as follows: (1) ODI (Oswestry disability index) and VAS scores (visual analogue scale/score) before operation, operation time, intraoperative blood loss, postoperative drainage volume, blood transfusion rates, postoperative bedridden time, postoperative hospital stays, intraoperative fluoroscopic time, levels of serum CPK before operation, 3 days and 1 week after operation, VAS scores at 3 days and 1 week after operation. The follow-up observation indicators included ODI score and VAS score. When drainage volume was less than 50ml/24h after operation, drainage tube was removed. Under the protection of waist support, patients were encouraged to exercise out of bed early. The observation indicators are defined specifically as follows. Operation time: the total time from skin incision to skin suture; intraoperative blood loss: the total blood loss collected in the aspirator during operation and blood loss in gauzes estimated by weighing; postoperative drainage volume: total drainage volume after operation; blood transfusion rate: the proportion of patients who need blood transfusion in all patients; postoperative bedridden time: the time from the second day after operation to the off-bed activity under the protection of waist support; postoperative hospital stays: the total days from the second day after operation to the

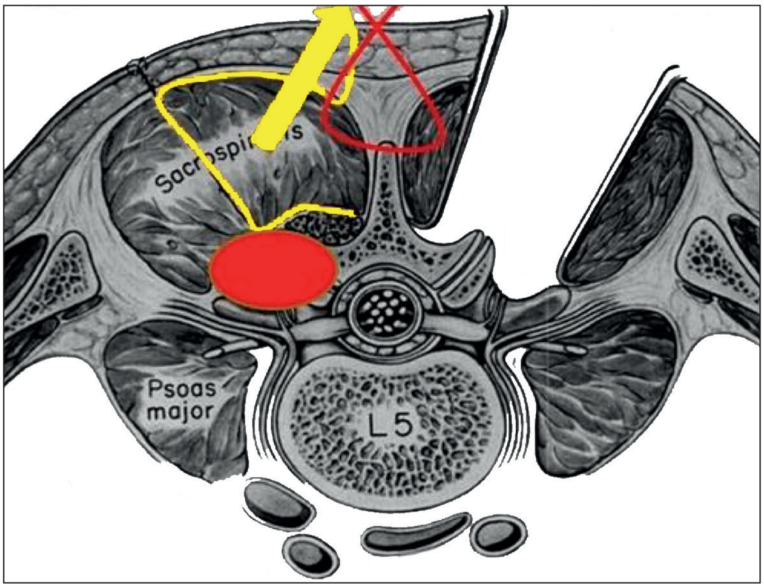

Figure 3. Schematic map for modified Wiltse's approach. Yellow line indicates the modified approach, red elliptic region indicates the operating range of spinal operation, and arrow indicates the direction of muscle movement after the muscles were pulled during operation. Red line indicates that the bilateral deep fascia can be sutured directly to the supraspinous ligament after completion of operation.

discharge; intraoperative fluoroscopic time: automatic accumulation of exposure time of C-arm X-ray machine during operation. ODI score and VAS score: evaluated *via* questionnaire survey in the corresponding time points; level of serum CPK: measured by drawing blood in the morning before breakfast according to the corresponding time points.

Statistical Analysis

All continuous data were presented as mean ± standard deviation (SD), and categorical data were presented as percentage or number ratio. Unpaired *t*-test or nonparametric Kruskal-Wallis test was used for the comparison of continuous data between groups, and chi-square test was used for comparison of ratios between groups. $p<0.05$ suggested that the difference was statistically significant, and all data were analyzed using Statistical Product and Service Solutions (SPSS 20.0, IBM, Armonk, NY, USA).

Results

General Data of the Patients for the Two Groups

There were no significant differences in the general data, complication, gender, age and BMI between the two groups ($p>0.05$). There was no significant difference in the diagnosis constituent ratio between the two groups ($p=0.722$); there was no significant difference in fused segment between the two groups (p=0.0.391) (Table I). Postoperative CT scan showed that there were 3 pedicle screws breaking through the cortical bone on the medial wall of pedicle and 3 pedicle screws breaking through the cortical bone on the lateral wall of pedicle in the open group; and there were 4 pedicle screws breaking through the lateral cortex of pedicle and 1 pedicle screw breaking through the medial cortex of pedicle in the MOTLIF group. There were no nerve root, spinal cord, vascular injury or other complications in patients of the two groups, and the fusion cages were placed in the intervertebral space without entering spinal canal or forward and lateral protrusion. There was 1 case of local skin necrosis in MOTLIF group, so it received the local dressing and delayed healing. There was 1 case of infection in open group, so it received the debridement, irrigation-drainage and healing; and there was 1 case of fat liquefaction in incision, so it received the local dressing and delayed healing.

Comparison of Clinical Effects Between the Two Groups In Perioperative Period

There were significant differences in the operation time (MOTLIF: 115.2±18.8 min *vs.* COTLIF: 125.1±20.0 min; $p=0.028$), intraoperative blood loss (MOTLIF: 242.02±90.20 mL *vs.* COTLIF: 425.43±168.58 mL; $p<0.01$), postoperative drainage volume (MOTLIF: 121.67±85.30 mL *vs.* COTLIF: 267.14±99.09 mL; $p<0.01$), blood transfusion rate ($p=0.03$), postoperative bedridden time (MOTLIF: 7.0±4.4d *vs.* COTLIF: 16.6±6.0

Table II. Comparison of clinical outcomes between the two groups in perioperative period.

	MOTLIF (42)	COTLIF (35)	*p*
Duration of operation (min)	115.2±18.8	125.1±20.0	0.028
Blood loss (mL)	242.02±90.20	425.43±168.58	<0.01
Volume of drainage (mL)	121.67±85.30	267.14±99.09	<0.01
Cases required blood transfusion	1	7	0.03
Time in bed (day)	7.0±4.4	16.6±6.0	<0.01
Hospital stay (day)	10.2±2.6	11.8±2.6	0.009
Fluoroscopy time (s)	10.1±3.9	18.1±7.0	<0.01

d; $p<0.01$), postoperative hospital stays (MOTLIF: 10.2±2.6 d *vs*. COTLIF: 11.8±2.6 d; $p<0.01$) and intraoperative fluoroscopic time (MOTLIF: 10.1±3.9 s *vs*. COTLIF: 18.1±7.0 s; $p<0.01$) between the two groups, and all indicators of MOTLIF group were superior to those of open group (Table II).

Levels of CPK Before and After Surgery

There was no significant difference between the two groups in level of CPK before operation; but there was statistically significant difference between the two groups in that at 3 days after operation ($p<0.01$). The level of CPK in open group was increased more significantly than that in MOTLIF group; there was no significant difference between the two groups at 1 week after operation ($p=0.38$) (Table III).

Comparisons of ODI and VAS Scores

There were no differences between the two groups in ODI and VAS scores before operation ($p>0.05$); there was significant difference between the two groups in ODI score in the last follow-up ($p=0.01$), and ODI score in MOTLIF group was superior to that in open group. There was significant difference between the two groups in VAS score at 3 days and 1 week after operation and the last follow-up ($p<0.01$), and VAS score in MOTLIF group was superior to that in open group. Intra-group comparison: there was significant difference in ODI score before operation and in the last follow-up within the two groups ($p<0.01$), and there was significant difference in VAS score before operation and in the last follow-up within the two groups ($p<0.01$) (Table IV).

Table III. Level of creatine phosphokinase in serum (U/L) before and after operation.

CPK (U/L)	MOTLIF	COTLIF	p value
Before operation	56.5±18.8	63.3±19.1	0.12
3 day after operation	467.4±189.4	647.4±178.6	<0.01
1 week after operation	63.4±15.2	67.0±20.2	0.38

Table IV. Comparison of ODI and VAS scores in the follow-up.

		MOTLIF	COTLIF	*p*-value
Time of the last follow-up (month)		20.2±5.0	22.1±4.9	0.11
ODI	Before operation	56.0±11.1	58.5±10.4	0.31
	The last follow-up	16.1±7.8a,b	20.9±8.5a	0.01
VAS	Before operation	5.3±1.6	5.4±1.6	0.82
	3 day after operation	2.9±1.1a,b	4.0±1.2a	<0.01
	1 week after operation	1.3±0.8a,b	2.5±1.3a	<0.01
	The last follow-up	0.7±0.9a,b	1.7±1.1a	<0.01

Discussion

In COTLIF, median incision is generally made, and paraspinal muscles are peeled off from the spinous process during operation, and then pulled to both sides to obtain the clear operative filed and ensure the space required for abduction angle of pedicle screw. But the peeling of soft tissue and long-time pulling will lead to muscle ischemia, denervation of paraspinal muscles and postoperative persistent waist pain. At the same time, the peeling of paraspinal muscle will prolong the operation time, increase the intraoperative blood loss, cause the postoperative refractory waist pain and posterior ligament complex injury, and delay the recovery time[19]. In 1968, Wiltse first described the lumbar surgery *via* the paraspinal muscle space, namely the approach between multifidus and longissimus muscles, effectively solving the above problem[20]. Then he modified the approach in 1988: The median incision was made, peeled outward subcutaneously till the starting point of fascia of intermuscular space approach, and then longitudinal incision was made on the bilateral fascia till the intermuscular space.

In the comparison with the COTLIF group, the intraoperative blood loss and postoperative exudation caused by extensive peeling of paraspinal muscles were avoided, so the mean intraoperative blood loss was 242.02±90.20 mL, which was significantly decreased compared with that in open group (425.43±168.58 mL); the mean postoperative drainage volume was 121.67±85.30, which was also significantly decreased compared with that in open group (267.14±99.09); only 1 out of 42 patients required blood transfusion, while 7 out of 35 patients in open group required blood transfusion. The level of CPK after operation is generally thought to be correlated with the degree of intraoperative muscle damage[21]. The level of CPK in MOTLIF group at 3d after operation was significantly decreased compared with that in open group, which also proves the protective effect of the approach on muscle. Other benefits of complete protection of soft tissue are the early pain relief, functional recovery and significantly shorter recovery time of patients after operation. The mean postoperative bedridden time in MOTLIF group was (7.0±4.4) d, while that in open group was (16.6±6.0) d. In MOTLIF group, patients could usually exercise out of bed under the protection of brace before the discharge and after drainage tube was removed; but the bedridden time in open group was longer, and patients still needed to stay in bed at discharge, leading to the difference in postoperative hospital stays between the two groups, and the mean hospital stay of MOTLIF group was 1.6d fewer than that of open group. Small soft tissue injury was also reflected in the postoperative VAS score, and the results in MOTLIF group at 3 d and 1 week after operation and even the last follow-up were superior to those in open group. Early pain relief is closely related to the tissue injury during operation, and if the muscle injury is severe, the local trauma response will be great, and the pain will be aggravated. So results in MOTLIF group at 3d and 1 week after operation were superior. The long-term waist pain is generally related to the muscle atrophy and denervation, etc. In the last follow-up, MOTLIF group was still superior to open group, indicating that open surgery can cause the long-term muscle injury, which is irreversible for some patients.

In the spine surgery, the purpose of fluoroscopic examination is to guide the pedicle screw fixation and verify whether the positions of pedicle screw and interbody fusion cage are correct. Our preliminary study[22] found that the head-tail tilt angles of pedicle from T1 to L4 was basically vertical to the supraspinous ligament, nearly 90°, while it changed a lot in L5 and S1, about 80°-85°, so the fixation angle of screw is sometimes more difficult in the lower lumbar spine. In MOTLIF group, according to the positioning of supraspinous ligament, the accurate head-tail tilt angles of pedicle screw could be obtained. Fluoroscopic examination after implantation of guide pin can help further adjust the direction of screw, and as confirmed in our previous experiment, pedicle screw can be inserted without adjustment in most cases. This is also the reason why less radiation exposure was needed in MOTLIF group. In both COTLIF group and MOTLIF group, local anatomical structure was used to determine the position of screw; although the fluoroscopic time in open group was slightly longer, the time of radiation exposure was shorter in both groups. Mini-TLIF technique is generally combined with percutaneous fixation technique. The standard percutaneous puncture technique generally requires more radiation exposure[23]. In the report of Schmidt, the average fluoroscopic time of four-screw two-rod percutaneous fixation was (5.99±3.5) min[24]. In Rampersaud's study[25], the radiation exposure dose was 10-12 times higher than that of open surgery. The above data confirm that the radiation exposure time using percutaneous fixation technique is significantly increased compared to that of open surgery. In Mini-TLIF, channel and percutaneous fixation technique often require to be combined, so the frequent fluoroscopy not only exposes the patients to unprotected radiation, but also exposes doctors to low-dose radiation. Although the risk of long-term low-dose radiation exposure is unknown, spine surgeons should pay attention to it. The risk of excessive radiation exposure for young patients with complex spinal diseases during operation should also be attached great importance[26].

Conclusions

Compared with the conventional open TLIF, mini-open TLIF *via* Wiltse's approach using the self-designed operating apparatus is characterized by the convenient operation, small trauma and quick recovery after operation. At the same time, the radiation exposure is lower and long-term follow-up effect is superior. Its short-term and long-term effects in the treatment of lower lumbar degenerative disease are also superior.

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Conflict of Interests:
The authors declared no conflict of interest.

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