

Clinical Study

Minimally Invasive TLIF Using Unilateral Approach and Single Cage at Single Level in Patients over 65

Hyeong-Jin Lee, Jin-Sung Kim, and Kyeong-Sik Ryu

Department of Neurosurgery, Seoul St Mary's Hospital, College of Medicine, The Catholic University of Korea, 222 Banpo-daero Seocho-gu, Seoul 137-701, Republic of Korea

Correspondence should be addressed to Jin-Sung Kim; mddavidk@gmail.com

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Background. Minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF) is a widely accepted surgical procedure. But there are only a few reports of MIS-TLIF using the unilateral approach and single cage in elderly patients. **Objective.** The study investigated the clinical and radiological outcomes of MIS-TLIF using the unilateral approach and single cage in the patients over 65 years of age. **Methods.** Thirty-eight patients were followed for a mean of 15.5 ± 11.61 months. Radiological data include fusion rate, change of disc height, and central canal area. The numeric rating scale (NRS) and Oswestry disability index (ODI) were used to assess clinical outcomes. **Results.** The mean age of these patients at operation was 71.82 ± 4.71 years (range, 65–82 years). Evidence of fusion was observed radiologically in 64.71% at 6 months and 87.5% at 12 months after surgery, giving a final fusion rate of 100%. The mean NRS scores for back and leg pain and ODI scores improved significantly at the final follow-up. **Conclusions.** Clinical and radiologic outcomes of MIS-TLIF using unilateral approach and single cage in elderly patients indicate an acceptable method for the treatment of various kinds of lumbar spinal diseases.

1. Introduction

As the global population proportionally becomes more aged, the number of elderly patients with spine disease who need surgery is increasing [1]. However, high rates of comorbidities and decreased bone density influence negative results in older patients [2]. Increased patient age, longer surgical time, and comorbidities influence the risks of postoperative morbidity and mortality in posterior spine surgery [3–6]. Several studies reported that patients aged 80 years or older who undergo lumbar spine surgery have greater chances of increased hospital stay and mortality [7]. Rates of morbidity and mortality increase with age [5].

Since Foley first introduced minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF) in 2002, this technique has been used to treat various kinds of lumbar spinal disease that require fusion [8]. The advantages of MIS-TLIF include reduced blood loss, length of stay, complications, less postoperative pain, and earlier ambulation [9–13].

Although clinical outcomes and complications with MIS-TLIF have been assessed in many studies, little is published

that is specific to elderly patients, especially the unilateral approach. To our knowledge, only two previous studies reported the results of MIS-TLIF in older patients [2, 14]. Older patients can gain the most benefit from the low morbidity and mortality of MIS-TLIF. The purpose of this study is to investigate the clinical and radiological results of MIS-TLIF with unilateral approach with single cage in patients older than 65 years of age.

2. Materials and Methods

2.1. Study Design. This is a single center, retrospective study investigating the clinical and radiological outcomes of MIS-TLIF in patients over 65 years of age using unilateral approach and single cage at single level. Between June 2012 and December 2015, 87 MIS-TLIF procedures were performed in our institute. The patients included in this study were more than 65 years old, who satisfied the clinical and radiological criteria. Forty-one patients were excluded because they were younger than 65 years at the time of surgery. All patients were evaluated for operation risk by cardiologist

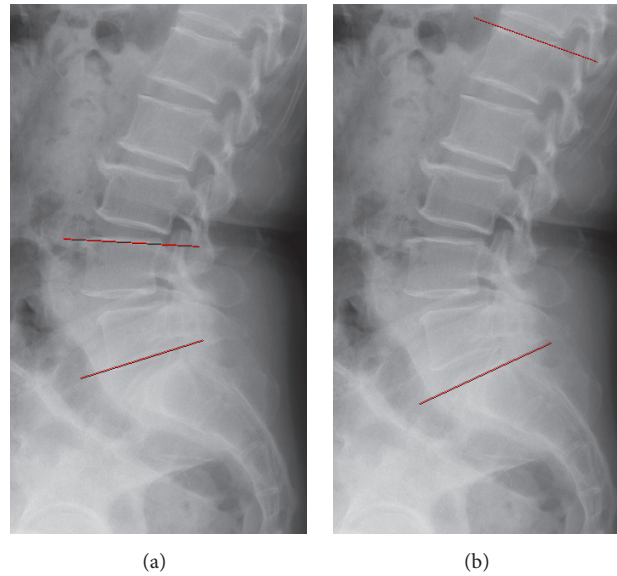


FIGURE 1: Segmental lordotic angle (a) and lumbar lordotic angle (b).

and pulmonologist preoperatively, and they were classified to high, intermediate, low risk group. And we excluded patients within the high risk group.

Inclusion criteria are as follows:

Clinical Requirements

Age: over 65 years at the time of surgery.

At least one of:

- (i) NRS score over 6 at back or leg
- (ii) Neurogenic intermittent claudication
- (iii) Progressive neurologic deficit

Radiological Requirements

Single-level lumbar spine disease.

At least one of:

- (i) Degenerative disc disease with spinal instability
- (ii) Spondylolisthesis with spinal instability
- (iii) Spinal stenosis

Matching clinical symptoms and radiological findings

Failure of conservative treatments over 2 months

Exclusion criteria are as follows:

- Scoliosis (Cobb's angle > 15 degrees)
- Spinal infection
- Trauma
- Spine metastasis
- Life threatening medical disease (high risk group)
- Prior history of lumbar fusion surgery

2.2. Clinical Assessment. Data were collected for 87 patients who had undergone one level MIS-TLIF from June 2012 to December 2015. Diagnoses included degenerative disc disease, spondylolisthesis, and spinal stenosis. None of the patients had prior history of fusion surgery. Data were collected from the preoperative period to 4 years postoperatively. Clinical data were collected on preoperative period of less than 1 month and 3, 6, 12, 24, 36, and 48 months postoperatively to assess the clinical outcomes. The clinical data included comorbidities, numeric rating scale (NRS, 0–10), Oswestry disability index (ODI, 0–100%) score, and patient satisfaction rate (PSR). Perioperative data included the level of spine fused, type of decompression (unilateral laminectomy for bilateral decompression [ULBD] and non-ULBD), day of drain removal, length of operation, and length of anesthesia.

2.3. Radiological Assessment. Routine simple X-ray images were obtained before surgery and postoperatively at 6 months and 1, 2, 3, and 4 years. Disc height was measured at the midpoint of spinal column on plain standing lateral radiography. The segmental lordotic angle was measured between the upper endplate of the cranial side vertebral body and the lower endplate of the caudal side vertebral body for the operated level (Figure 1) [15]. The lumbar lordotic angle was measured between the upper endplate of the L1 vertebral body and the upper endplate of the S1 vertebral body (Figure 1) [15]. Computed tomography (CT) images were obtained before surgery and at the same times postoperatively. Fusion was defined by Modified Bridwell fusion criteria [16, 17]. The foramen and spinal canal area was measured using the Marotech PACS program (M-view 5.4; Marotech, Seocho-Dong, South Korea). Postoperative foraminal area was measured using an imaginary line between the upper and lower pedicles (Figure 2(a)). Postoperative spinal canal area was measured using an imaginary line between the facet and

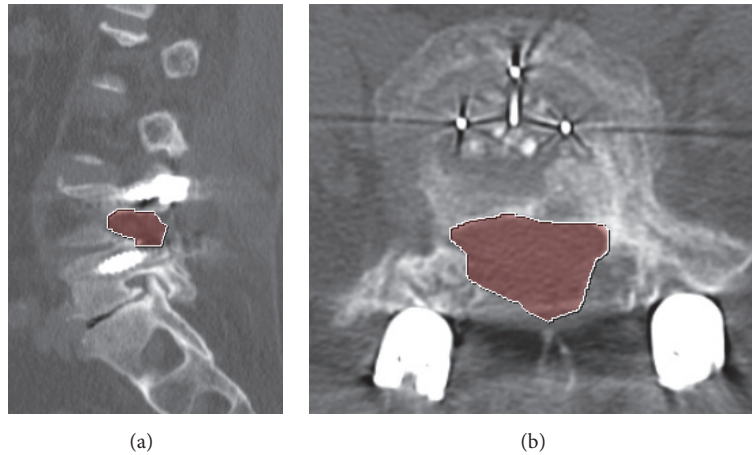


FIGURE 2: Foraminal area (a) and spinal canal area (b).

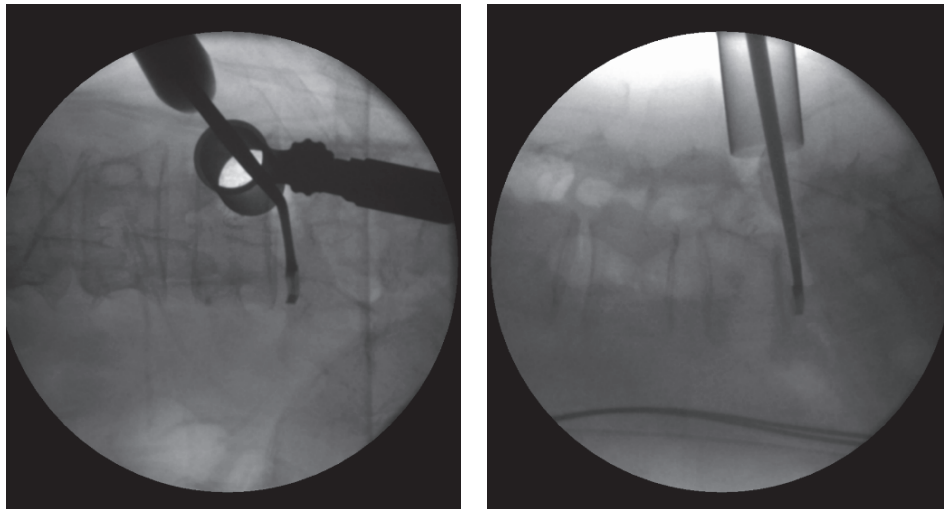


FIGURE 3: The location of the angled curette.

lamina (Figure 2(b)). Any cage subsidence, cage dislodgment, or hardware failure was recorded.

2.4. Surgical Approach. Decompression and cage insertion were accomplished using a tubular retractor. A senior surgeon (JS Kim) performed MIS-TLIF using a single cage via the unilateral approach at index level. We selected the direction of approach based on the clinical symptoms. Using fluoroscopic image, a 2.5–3.5 cm paraspinous skin incision was made between the upper and lower pedicles on the anteroposterior image. The lumbodorsal fascia was excised between the multifidus and longissimus muscles, and sequential widening of the incision was done using tubular dilators (Insight Access Retractor System; DePuy-Synthes Spine, Raynham, MA, USA) and a 22 mm tubular retractor was docked. Under microscope guidance, total facetectomy and partial laminectomy were done. The ligamentum flavum was resected. Complete discectomy was done and grinding of the central and contralateral endplates was done with angled ring curettes (Figure 3). The patients who had undergone

unilateral approach and bilateral decompression (ULBD) were classified to group A and the other patients who had unilateral radiating pain or bilateral stenosis on MRI images were assigned to group B (Figure 4). The patients who had bilateral radiating pain and unilateral stenosis on MRI images were assigned to group A and the patients who had unilateral radiating pain and unilateral stenosis on MRI images were assigned to group B. Group A patients underwent bilateral decompression through the unilateral laminofacetectomy site. This was done by dissecting portions of the contralateral inferior articular process, lamina, and ligamentum flavum through the corridor created by ipsilateral laminofacetectomy site. To obtain better visual field of the contralateral side, the tubular retractor needed to be angled so that the distal end of the retractor was facing the base of the spinous process, away from the surgeon. After that, we tilted the table away from the surgeon to obtain a comfortable posture during the operation. After completion of discectomy and foraminal decompression, the cage was inserted. A banana-shaped cage and straight cage were used in this study. The cage was filled with mixed form of locally harvested autologous cancellous

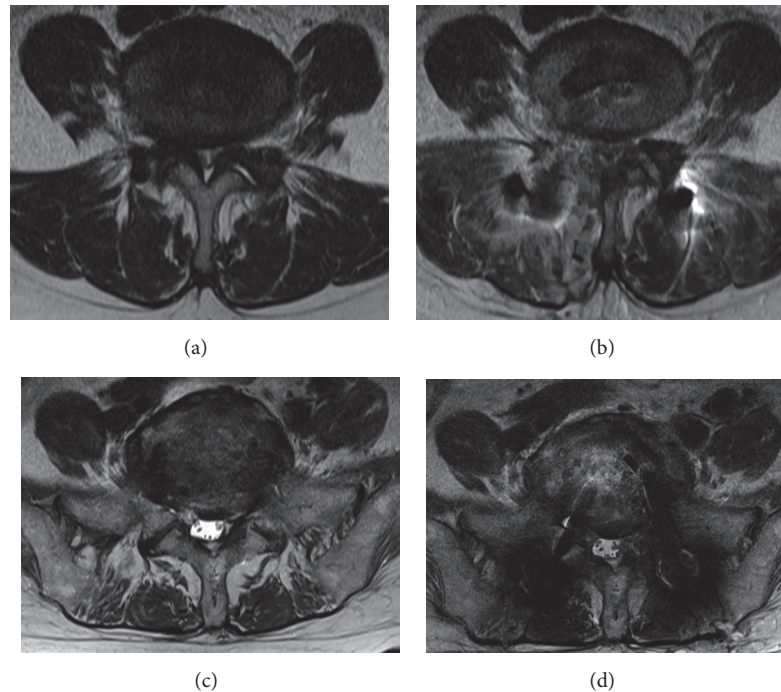


FIGURE 4: Preoperative and postoperative state of group A ((a) and (b), resp.) and group B ((c) and (d), resp.).

bone and allograft (Figure 5). The screws were inserted by percutaneously under C-arm fluoroscopic guidance. The wounds were irrigated; drainage catheters were inserted on the side of approach; and the wounds were closed layer by layer. Group B patients underwent unilateral decompression through the unilateral laminofacetectomy site. The rest of the procedure was the same as above.

2.5. Statistical Analysis. Statistical analysis was done by statisticians in our institute using the SAS system for windows Version 9.3. Descriptive statistics analysis, frequency analysis, Chi-square test, Fisher's exact test, unpaired *T*-test, repeated measures ANOVA were used. A *P* value < 0.05 was considered significant.

3. Results

All patients were followed up for at least 6 months, with a mean follow-up of 15.5 ± 11.61 months (range, 6–48 months). Eighty-seven patients were operated on using MIS-TLIF with the unilateral approach and single cage between June 2012 and December 2015. Forty-one patients under 65 years of age were excluded, leaving 46 patients. Of the 46 patients, two were excluded due to severe scoliosis (Cobb angle >15 degrees) and six were excluded due to fusion over level 2 (Figure 6). Thirteen patients were followed up for 6 months, 10 patients for 12 months, eight patients for 24 months, five patients for 36 months, and two patients for 48 months. Because the number of patients who were followed up for 48 months was too small, statistician included them to the group who were followed up for over 36 months. The mean age of patients at the time of operation was 71.82 ± 4.71 years (range,

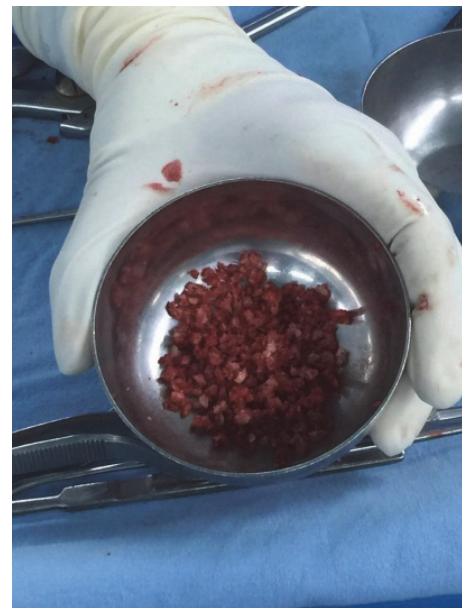


FIGURE 5: Locally harvested bone from facet joint and laminar in patient.

65–82 years). Ultimately, 38 patients were included. Twenty-four patients received ULBD.

The sociodemographic and clinical characteristics of the patients are presented in Table 1, and patient comorbidities are shown in Table 2. Of the 38 patients, 31 (82%) had comorbidities, most commonly hypertension (51.02%, 25/38). 10 Patients (26.32%) had more than one comorbidity. And 1

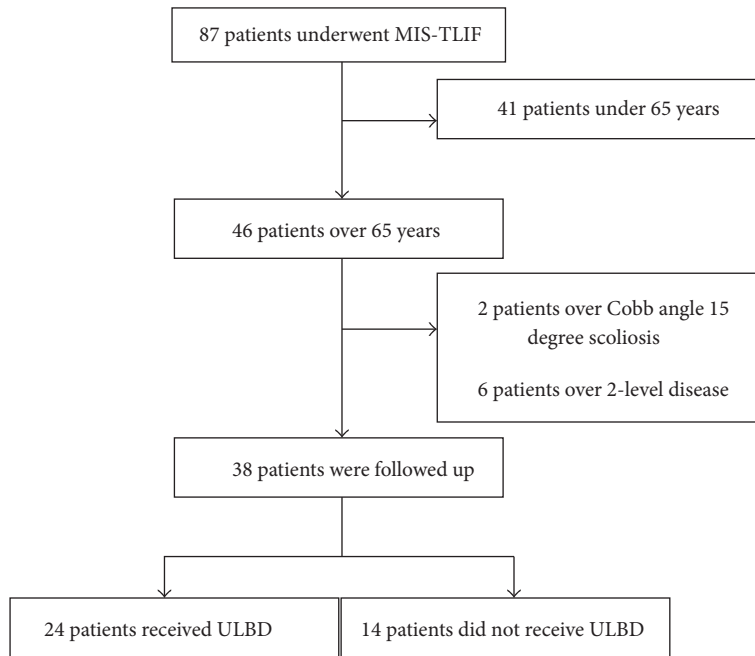


FIGURE 6: Flow diagram of patient selection.

TABLE 1: Demographic data of the 38 patients.

Mean age, years	71.82 ± 4.71
Gender F : M	25 : 13
Mean follow-up, months	15.5 ± 11.61
Diagnosis	
(i) Herniated nucleus pulposus	3 (7.89%)
(ii) Spondylolisthesis	17 (44.74%)
(iii) Spinal stenosis	18 (47.37%)
Level	
(i) L4/5	29 (76.32%)
(ii) L5/S1	9 (23.68%)
Side	
(i) Right	12 (31.58%)
(ii) Left	26 (68.42%)
Bone mineral density change	-2.01 ± 1.28

TABLE 2: Comorbidities.

(i) Hypertension	25 (51.02%)
(ii) Diabetes mellitus	9 (18.37%)
(iii) Past history of myocardial infarction	2 (4.08%)
(iv) Chronic obstructive pulmonary disorder	1 (2.04%)
(v) Hypothyroidism	1 (2.04%)
(vi) Prostate cancer	1 (2.04%)
(vii) Past history of prostate cancer	2 (4.08%)
(viii) Past history of colon cancer	1 (2.04%)
(ix) Past history of thyroid cancer	1 (2.04%)
(x) Past history of gastric cancer	1 (2.04%)
(xi) Rheumatoid arthritis	1 (2.04%)
(xii) Osteoarthritis	1 (2.04%)
(xiii) Past history of cerebral infarction	1 (2.04%)
(xiv) Bronchiectasis	1 (2.04%)

patient with prostate cancer was TNM stage I on image study and was scheduled to surgery after TLIF.

A banana-shaped cage and straight cage were used for nine and 29 patients, respectively.

3.1. Clinical Outcomes. The clinical outcomes are summarized in Table 3. ODI was significantly improved at the final follow-up, from 44.59 ± 11.9% to 21.5 ± 15.18% ($P < 0.05$; Figure 7). NRS scores for back and leg pain were significantly improved at the final follow-up, from 4.24 ± 1.85 to 0.71 ± 0.76, and from 6.79 ± 1.28 to 0.86 ± 1.21, respectively (both $P < 0.05$; Figure 8). Patient's satisfaction rate was 86.9 ± 11.56%. The claudication rate was significantly improved from 63.16% (24/38) to 5.26% (2/38) ($P < 0.05$; Table 4). The mean

TABLE 3: Clinical outcomes.

Clinical outcomes	
Mean postoperative hospitalization, days	8.89 ± 3.81
Mean time of drain removal, days	3.31 ± 1.04
Patient satisfaction rate (PSR), %	86.90 ± 11.56
Induction time, minutes	249.71 ± 45.73
Operation time, minutes	182 ± 53.21

operation time and induction time were 182 ± 53.21 minutes and 249.71 ± 45.73 minutes, respectively. Single-level MIS-TLIF plus adjacent-level discectomy or decompression was

TABLE 4: Claudication.

Claudication	Preoperative (%)	Postoperative (%)
Severe (0–20 min)	60.53 (23/38)	0 (0/38)
Moderate (20–40 min)	2.63 (1/38)	0 (0/38)
Mild (40–60 min)	0 (0/38)	5.26 (2/38)
None	36.84 (14/38)	94.74 (36/38)

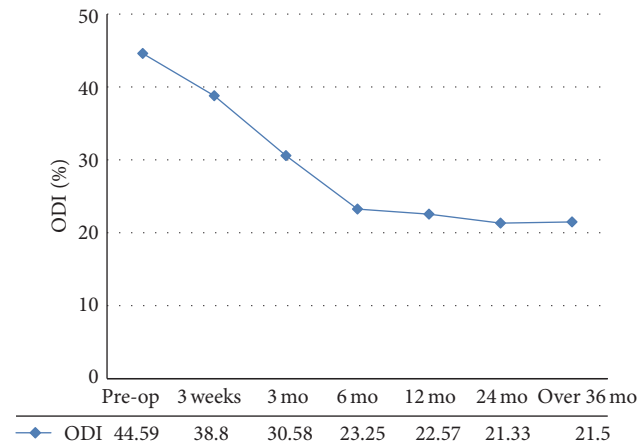


FIGURE 7: Perioperative change of ODI score.

performed in eight patients. Of these, seven underwent 1-level decompression and 1 patient underwent additional 2-level decompression. The decompression or discectomy in adjacent level increased the overall mean surgical time. The mean time to remove drain was 3.31 ± 1.04 days (range, 1–7 days). The mean postoperative stay was 8.89 ± 3.81 days (range, 4–24 days).

3.2. Radiological Outcomes. Six-month, one-year, two-year, and three-year Modified Bridwell fusion rate was 17.65%, 37.5%, 70%, and 80%, respectively, in fusion grade A and 47.06%, 50%, 30%, and 20%, respectively, in fusion grade B (Figure 9). The contralateral facet fusion rate was 25% (6/24) of patients in the ULBD group.

Disc height was significantly increased from 8.94 ± 2.46 mm to 11.88 ± 2.59 mm postoperatively ($P < 0.05$; Figure 10). After 3 years, disc height was decreased to 9.19 ± 1.63 mm ($P < 0.05$). Disc height was significantly decreased with time. The segmental lordotic angle of the operated level was significantly increased from 12.9 ± 5.19 degrees to 15.89 ± 5.86 degrees ($P < 0.05$). After 3 years, the angle was decreased to 10.6 ± 3.86 degrees ($P < 0.05$; Figure 11). The segmental lordotic angle was significantly decreased with time. The lumbar lordotic angle did not change significantly postoperatively (36.0 ± 10.91 degrees to 35.62 ± 11.05 degrees, $P = 1.00$). After 3 years, the angle was significantly increased to 42.97 ± 16.88 degrees ($P < 0.05$). The lumbar lordotic angle was significantly increased with time. These changes of lumbar lordotic angle may be due to small number of patients followed up for 2 or 3 years.

The ipsilateral foramen area, which was the direction of approach, was significantly increased from $127.52 \pm$

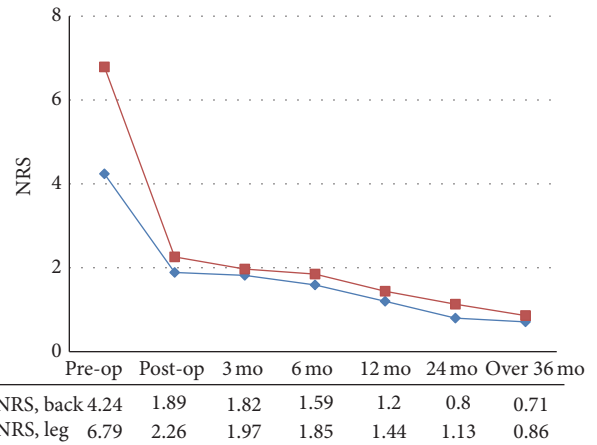


FIGURE 8: NRS score of back and leg.

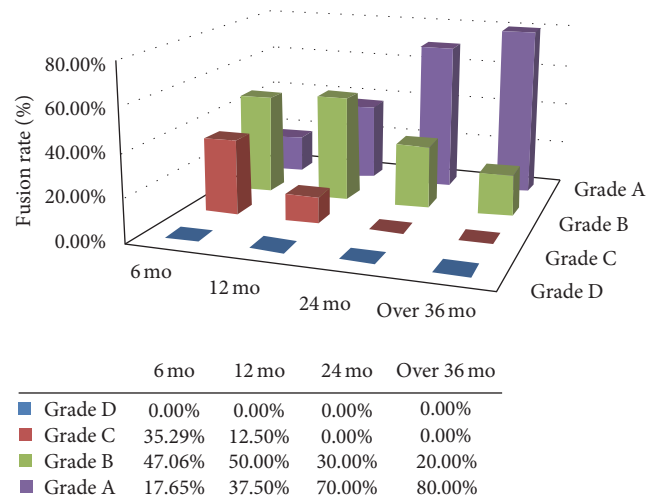


FIGURE 9: Fusion grade changes.

34.46 mm^2 to $189.94 \pm 38.31 \text{ mm}^2$ after 6 months postoperatively ($P < 0.05$) (Figure 12). The area significantly changed after 3 years (from $189.94 \pm 38.31 \text{ mm}^2$ to $181.36 \pm 34.93 \text{ mm}^2$, $P < 0.05$). The ipsilateral foramen area was significantly decreased with time. Contralateral foramen area was significantly increased from $126.98 \pm 36.78 \text{ mm}^2$ to $152.97 \pm 33.88 \text{ mm}^2$ after 6 months postoperatively ($P < 0.05$). The area significantly changed after 3 years (from $152.97 \pm 33.88 \text{ mm}^2$ to $151.01 \pm 27.14 \text{ mm}^2$, $P < 0.05$). Spinal canal area was significantly increased from $226.07 \pm 76.61 \text{ mm}^2$ to $397.58 \pm 94.91 \text{ mm}^2$ after 6 months postoperatively ($P < 0.05$; Figure 13). The area significantly changed after 3 years (from 397.58 mm^2 to $400.47 \pm 60.06 \text{ mm}^2$, $P < 0.05$). There was no significant change between 12 months and 24 months and 24 months and 36 months in statistical analysis (repeated measures ANOVA, $P = 1.00$ and $P = 0.72$, each) There were 13 cases of subsidence (mean 3.3 mm; range, 0.8–6.5 mm) and no cases of cage migration.

3.3. ULBD versus Non-ULBD. Twenty-four patients received ULBD and were assigned to group A. The remaining

TABLE 5: ULBD versus Non-ULBD.

	Group A (N = 24)	Group B (N = 14)	P-value
Mean age, years	73.17 ± 4.57	69.5 ± 4.15	—
Gender, female : male	16 : 8	9 : 5	—
Mean postoperative hospitalization, days	8.2	10.07	0.21
Mean time of drain removal, days	3.92	4.08	0.52
Induction time, minutes	258.54	234.57	0.12
Operation time, minutes	188.71	176.21	0.49

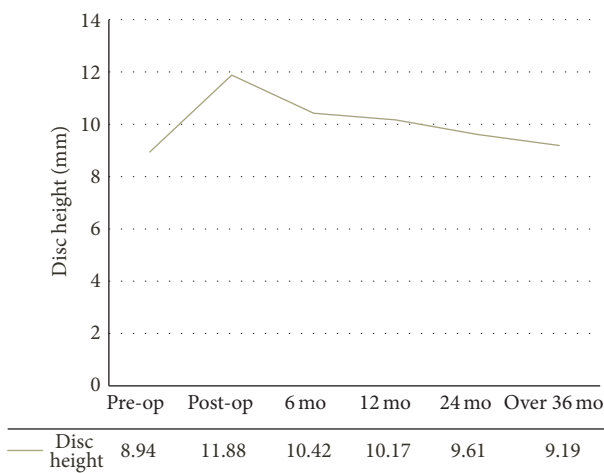


FIGURE 10: Disc height.

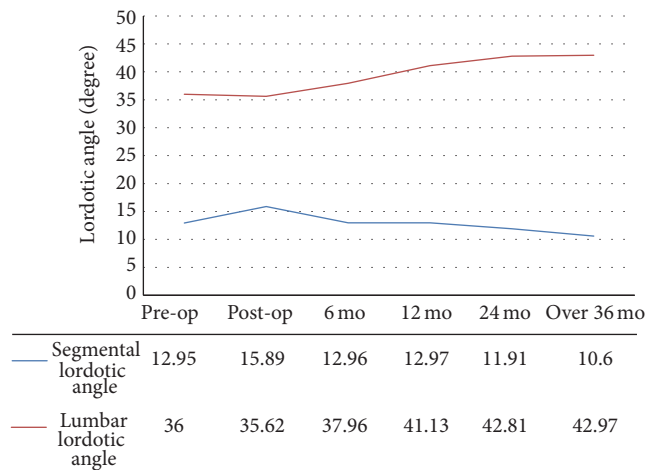


FIGURE 11: Segmental and lumbar lordotic angles.

14 patients were assigned to group B. The outcomes are summarized in Table 5. There were no significant changes in gender, postoperative hospitalization, time to drain removal, induction time, and operation time ($P > 0.05$), except ages ($P < 0.05$). There were no significant differences in NRS of back and leg between groups A and B (Figures 14 and 15, $P > 0.05$). Postoperative back NRS was significantly decreased

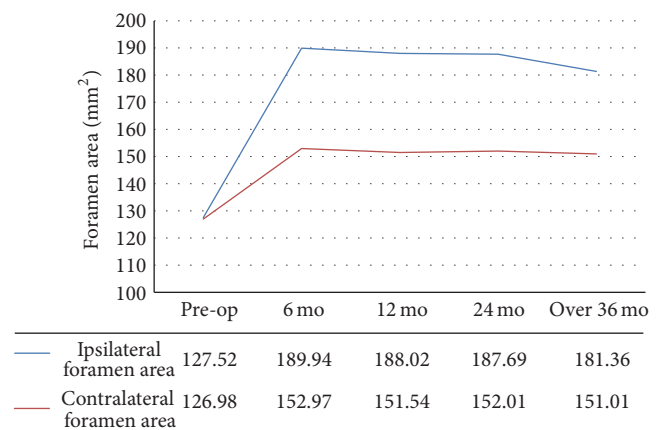


FIGURE 12: Ipsilateral and contralateral foramen areas.

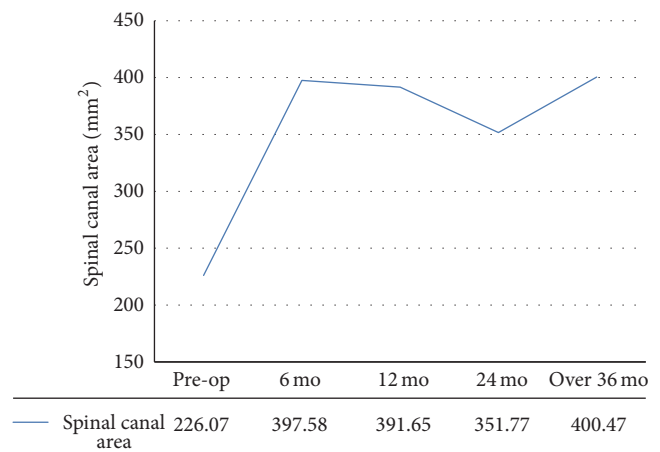


FIGURE 13: Spinal canal areas.

from 4.25 ± 1.87 to 1.83 ± 0.92 in group A ($P < 0.05$) and from 4.21 ± 1.89 to 2 ± 0.88 in group B ($P < 0.05$). Postoperative leg NRS was significantly decreased from 6.83 ± 1.37 to 2.08 ± 1.14 in group A ($P < 0.05$) and from 6.71 ± 1.14 to 2.57 ± 1.28 in group B ($P < 0.05$). After 3 years, the back NRS was significantly decreased from 4.25 ± 1.87 to 0.6 ± 0.89 in group A ($P < 0.05$) and from 4.21 ± 1.89 to 1 ± 0.00 in group B ($P < 0.05$). After 3 years, the leg NRS was significantly

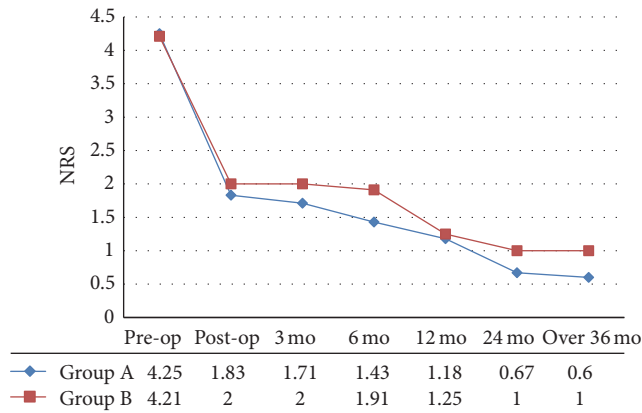


FIGURE 14: Back NRS of groups A and B.

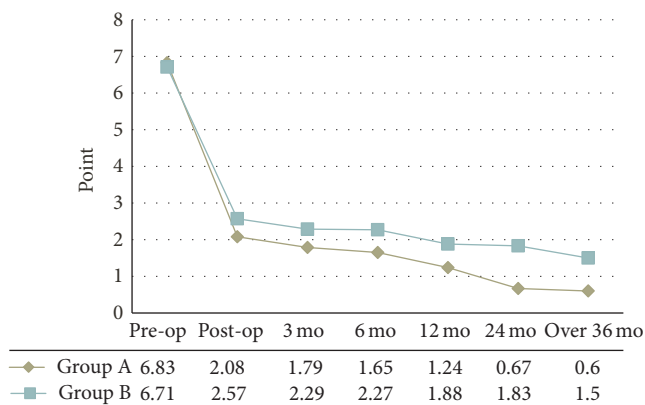


FIGURE 15: Leg NRS of groups A and B.

decreased from 6.83 ± 1.37 to 0.67 ± 0.71 in group A ($P < 0.05$) and from 6.71 ± 1.14 to 1.5 ± 2.12 in group B ($P < 0.05$).

3.4. Complications. Six perioperative complications were recorded, representing a complication rate of 15.8% (6/38). Approach-related complications (screw malposition and dura tear, one each) were evident in two of 38 patients (5.3%). Pulmonary thromboembolism ($n = 1$) was treated in the cardiology department and the patient stayed in hospital 24 days. Other minor complications included thrombocytopenia, prerenal azotemia, and urinary difficulty (one each) and were transient (less than 1 week).

4. Discussion

As the population ages, the numbers of older patients who need fusion surgery increases. Higher rates of postoperative morbidity and mortality are typical in older patients [14, 18]. Carreon et al. reviewed 98 patients aged 75 years or older who underwent posterior lumbar decompression and fixation and found that increased age was associated with an increased rate of major complications [4]. Daubs et al. reported that patients older than 69 years were nine times more likely to have a major complication than younger patients [19]. The increased rates of morbidity and mortality in older patients

may reflect increased number of comorbidities, increased operative blood loss, and longer hospital stay [9].

MI-TLIF was introduced in 2002 [8]. The innovation laid the cornerstone of spinal fusion surgery. MIS-TLIF has gained popularity with the advantages of smaller incisions, preservation of paraspinal muscles, reduced soft tissue injury, decreased intraoperative blood loss, shorter hospital stay, and decreased rate of operative site infection, all of which contribute to decreased postoperative morbidity [10, 12, 20–24]. Karikari and Isaacs reported TLIF complication rates of 0–33.3% [10]. The low rates of complications and tissue injury are advantageous for older patients, and they are likely to benefit from MIS-TLIF [11]. Lee and Fessler reviewed 84 patients who underwent single-level MIS-TLIF and found that older patients were not at increased risk of intraoperative or postoperative complications compared to younger patients [14].

Two previous studies were reported about the results of MIS-TLIF in older patients [2, 14]. However, these studies comprised both the unilateral and bilateral approaches. In this study, only the unilateral approach was used, with or without bilateral decompression and with single cage. The unilateral approach in MIS-TLIF causes minimal tissue damage. Along with the unilateral approach, we used a single long cage to weigh the spinal column.

The elderly can experience difficulties with spine surgery. One difficulty is the higher frequency of comorbidities. In our study, 82% (31/38) of patients had comorbidities. The most common comorbidity was hypertension. Other medical comorbidities included diabetes, past history of myocardial infarction, chronic obstructive pulmonary disease, past history of cerebral infarction, hypothyroidism, and cancer. Also, many of the patients were taking medications that can increase the risk of operative bleeding, such as aspirin and clopidogrel. In our study, the complication rate of 15.8% (6/38) was lower than the 19.2–80% rate reported in several other series of older patients [4, 25]. Ringel et al. reported that of 488 percutaneous screws implanted in 104 patients, postoperative computed tomography scan showed that 87% of screws were in a good position, 10% were acceptable, and 3% were unacceptable [26]. Symptomatic screw malposition always needs reoperation. In our case series, there was one case of revision case because of screw malposition. After reoperation, the symptom was cleared and there were no neurologic sequelae. A dura tear rate of 1.6%–16.7% has been reported during MIS-TLIF [27–29]. We observed one case of dura tear, which healed spontaneously 1 week after surgery. The same patient developed deep vein thrombosis that required intensive medical treatment with several days of bedrest. The patient was transferred to our internal medical department and treated with heparin. Three other complications lasted less than 1 week. These results show that MIS-TLIF is an acceptable method for older patients.

Low bone mineral intensity can complicate fixation and fusion. Osteoporotic bone is believed to be at risk of subsidence, screw loosening and fusion failure [30–32]. In our study, the average bone mineral density change was -2.01 ± 1.28 . Thirteen of 38 (34.2%) patients developed radiological evidence of subsidence. The average length of subsidence

was 3.34 mm. And there was significant relationship between bone mineral density and subsidence in our study ($P < 0.05$). There were no cases of screw loosening.

A number of studies have reported lower fusion rates in older patients. In one the fusion rate in older patients was 88.4% and in younger patients it was 90.8% [2]. The over three-year fusion rate was 80% in grade A and 20% in grade B. In general, fusion was completed from 6 to 12 months after surgery. But in our study, the 6-month fusion rate was 17.65% in grade A and 12-month fusion rate was 37.5% in grade A. After 24 months, the fusion rate was 70% in grade A. The results indicate a delay in the time needed for fusion in older patients. Patients more than 65 years old in this group may have less potency of bone growth than younger patients, which will influence fusion. In our study, the segmental lordotic angle was increased immediately after surgery and decreased with time. The lumbar lordotic angle did not change immediately after surgery and increased with time. It is interesting that the direction of angle change was opposite. We think that this reflects compensation of the paraspinal muscle. Group A underwent bilateral decompression and intraoperative parameters did not significantly differ from group B. After a follow-up time of at least 6 months, there was significant clinical improvement in both group A and group B, and group A showed slightly more pain relief although there were no statistical significant differences.

Our study has a number of limitations. It is a retrospective study with a small number of patients and a relatively short follow-up period. So, there may be an observational bias. Second, all operations were done by a single experienced surgeon, and the results might have been different if a less experienced surgeon was involved. Third, there was no control group. It may be needed to compare the clinical and radiological results of MIS-TLIF in older patients to the results of conventional approach in older patients to choose a better approach in older patients. Comparison between the results of MIS-TLIF in older patients and the results of MIS-TLIF in younger patients would help establish the relative risk. Fourth, this study was limited to patients undergoing single-level TLIF; the results may be different from results of multilevel MIS-TLIF.

5. Conclusion

Despite the high rates of comorbidities, our results for MIS-TLIF in older patients with unilateral approach with single cage show satisfactory clinical and radiological outcomes. There is a delayed tendency of fusion process in MIS-TLIF with the unilateral approach with single cage in patients more than 65 years old.

Competing Interests

The authors declare that there is no conflict of interests.

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