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Efficacy of minimally invasive transforaminal lumbar interbody fusion plus cement-augmented pedicle screw fixation in the treatment of degenerative lumbar spine disease with osteoporosis in the elderly

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Abstract. – OBJECTIVE: The aim of this study was to evaluate the efficacy of minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF) plus cement-augmented pedicle screw fixation in the treatment of degenerative lumbar spine disease with osteoporosis in the elderly.

PATIENTS AND METHODS: From February 2020 to January 2021, 40 elderly patients with degenerative lumbar spine disease with osteoporosis admitted to our hospital were randomly assigned (1:1) to receive either MIS-TLIF plus cement-augmented pedicle screw fixation (group A) or TLIF plus cement augmentation (group B), with 19 cases in group A and 21 cases in group B. Outcome measures included visual analogue scale (VAS), Oswestry Dysfunction Index (ODI) and Japanese Orthopedic Association Scores (JOA), operative duration, intraoperative bleeding, postoperative drainage volume, and the incidence of complications. Frontal and lateral radiographs of the lumbar spine and computed tomography (CT) were performed 3 days after surgery to observe the distribution of bone cement. At 12 months postoperatively, the fusion of the bone graft was evaluated according to the Bridwell intervertebral fusion criteria based on the lumbar frontal and lateral radiographs.

RESULTS: All 40 cases completed the surgery successfully and were followed up for 12 months. The two groups did not differ significantly in terms of operative duration ($p>0.05$). MIS-TLIF plus cement-augmented pedicle screw fixation was associated with significantly less intraoperative bleeding volume (142.25±40.93 mL) and (76.25±17.54 mL) *vs*. TLIF plus cement augmentation (322.00±93.45 mL, 159.75±54.74 mL) ($p<0.05$). The difference in the VAS scores, ODI, and JOA scores between the two groups preoperatively and at the final follow-up showed no statistical significance ($p>0.05$). Patients receiving MIS-TLIF plus cement-augmented pedicle screw fixation had significantly lower VAS scores and ODI and higher JOA scores *vs*. TLIF plus cement augmentation ($p<0.05$). The lumbar frontal and lateral radiographs and CT of the two groups 3 days after surgery showed good cement distribution and no cement leakage. At the final follow-up, no complications were seen in group A, and there was one case of intervertebral cement leakage in group B. The intervertebral graft fusion was grade I in both groups.

CONCLUSIONS: MIS-TLIF plus cement-augmented pedicle screw fixation shortens the operative time, alleviates postoperative pain, facilitates operative lumbar spine function restoration, and provides favorable intervertebral implant fusion.

Key Words:
Osteoporosis, Lumbar degeneration, Interbody fusion, Minimally invasive, Cement-augmented pedicle screw fixation.

Introduction

Degenerative lumbar spine disease is a common spinal disorder that manifests as low back pain and seriously compromises the quality of life of patients[1]. In recent years, transforaminal lumbar interbody fusion (TLIF) has been commonly used for the management of degenerative lumbar spine diseases. Minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF) has also gradually gained clinical attention due to its characteristics of minimal soft tissue trauma, minimal intraoperative bleeding, and rapid postoperative recovery[2]. Osteoporosis can lead to weakened fix-

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ation of the pedicle screw in the vertebral body, resulting in screw loosening and extraction and even surgical failure. To address this issue, the present study adopted cement-augmented pedicle screw fixation to treat osteoporosis with degenerative lumbar spine disease in the elderly to evaluate and compare its clinical efficacy *vs.* traditional screw fixation.

Patients and Methods

Patient Characteristics

From February 2020 to January 2021, 40 elderly patients with degenerative lumbar spine disease with osteoporosis admitted to our hospital were randomly assigned (1:1) to receive either MIS-TLIF plus cement-augmented pedicle screw fixation (group A) or TLIF plus cement augmentation (group B), with 19 cases in group A and 21 cases in group B. In group A, there were 3 males and 16 females, aged 61-79 (70.95±5.35) years, with a bone mineral density of -3.08±0.19 SD; there were 13 cases with a lesioned segment at L4/5 and 6 cases at L5/S1. In group B, there were 6 males and 15 females, aged 63-81 (71.20±5.15) years, with a bone mineral density of -2.97±0.19 SD; there were 14 cases with a lesioned segment at L4/5 and 7 cases at L5/S1. The patient characteristics between the two groups were comparable (p>0.05) (Table I).

Inclusion criteria: ① patients aged ≥60 years; ② with low back pain or/and unilateral neurological symptoms with ineffective regular conservative treatment for 3-6 months; ③ imaging: radiographs suggest intervertebral foraminal stenosis, lumbar instability, lumbar slippage (I°, II°), CT and MRI suggest changes such as nerve root and spinal cord compression; ④ BMD ≤-2.5 SD; ⑤ with imaging and physical examination suggesting single-segment lesions; ⑥ who signed the medical ethics agreement.

Exclusion criteria: ① patients aged <60 years; ② with imaging findings incompatible with physical examinations; ③ with signs or imaging suggestive of ≥2 segmental lumbar spine lesions, severe scoliosis, or slippage above II°; ④ with bilateral neurological symptoms; ⑤ who were unable to receive surgical treatment; ⑥ with severe osteoporosis (BMD ≤-2.5 SD, with fracture); ⑦ with other spinal diseases.

Surgical Method

Group A: with the patient in the prone position, the upper and lower pedicle projections of the lesioned segment were identified and marked with the assistance of a C-arm machine after general anesthesia. After disinfection and draping, a 4-cm-long incision was made 1 to 2 cm lateral to the symptomatic side along the marked line. After bluntly peeling the soft tissue layer by layer through the longest muscle and multifidus muscle gap, the intervertebral foramen was exposed by inserting a surgical expansion tube system. Decompression of the intervertebral foramina was performed using a bone knife and laminar forceps, and the hyperplastic synovium and hypertrophic ligamentum flavum were removed. The nerve roots and dural sac were medially retracted, and the nucleus pulposus was removed with a nucleus pulposus forceps. After physiological saline irrigation and confirmation of the size of the intervertebral fusion device by trial molding, the occluded bony tissue was reshaped into bony particles, filled with polyetheretherketone (PEEK) Cage and placed in the appropriate position in the intervertebral space. An injectable cemented pedicle screw was placed under C-arm fluoroscopic guidance, and then the cement was slowly injected under fluoroscopic pressure from the tail of the screw (usually 1.5-2.0 ml per screw push) to diffuse around the lateral foramen at the head end of the screw and into the vertebral body. After solidification of the bone cement, the prebent connecting rods on both sides were installed

Table I. Patient characteristics.

Group	n	Sex		Age (year)	Lesioned segment		T
		Male	Female		L4/5	L5/S1	
A	19	3	16	70.95±5.35	13	6	-3.08±0.19
B	21	6	15	71.20±5.15	14	7	-2.97±0.19
t/χ^2				-0.100	0.014		-2.010
p		0.457*		0.921	0.906		0.059

and bilaterally held moderately tight. After determining that there was no nerve root compression, irrigation was performed, the decompression wound was covered with a gelatin sponge, a tube was placed on the decompression side to drain the wound, sutured layer by layer, and dressed externally with a sterile dressing.

Group B: with the patient in a prone position, the lesioned segment was identified after general anesthesia. After disinfection and draping, the skin, subcutaneous and lumbar dorsal fascia were incised in the posterior midline of the lumbar spine, and the sacrospinous muscle next to the lumbar spine was bluntly separated to reveal the articular eminence of the corresponding segment, which was retracted and fixed with a vertebral plate puller, followed by the placement of a short-arm pedicle screw. The screw placement was clarified under C-arm fluoroscopy, and then the bone cement (usually 1.5-2.0 ml) was pushed into the screw channel, followed by the placement of the pedicle screw and the observation of the distribution of the bone cement under C-arm fluoroscopy. The upper and lower portions of the symptomatic side of the articular eminence were removed with a bone knife and gun forceps and cut into bony granules for backup, and the thickened ligamentum flavum was excised to expose and protect the spinal nerve roots and dural sac. The nucleus pulposus and endplate cartilage were removed with a spatula and reamer. A fusion device filled with bone particles was implanted in the appropriate position in the corresponding vertebral space. The prebent connecting rods were placed bilaterally and held moderately tight. After determining that there was no nerve root compression, irrigation was performed, the decompression wound was covered with a gelatin sponge, a tube was placed on the decompression side to drain the wound, sutured layer by layer, and dressed externally with a sterile dressing.

Once all pedicle screws were placed, screw augmentation was performed. Augmentation with polymethyl methacrylate (PMMA) was used in all patients in whom we observed bone fragility during screw placement, even when bone density as measured on dual-energy X-ray absorptiometry was not lower than -2.0 ($t \geq -2.0$)[3]. A ready-to-use cement was used for augmentation. After the cement was transferred into syringes, the injection began with the fluoroscope's C-arm in the lateral projection. A stepwise injection technique was used, closely monitoring cement flow in real-time. If we observed cement leakage or uncontrolled cement flow, we stopped the injection immediately[3].

Postoperative Management

After the operation, the patient received dexamethasone through intramuscular injection and 20% mannitol through intravenous drip for 3 days. The drainage tube was removed after 24 hours of drainage <50 ml. After 3 days, the patient was allowed to perform off-bed activities with a back protector. The patient was instructed to receive anti-osteoporosis treatment with active calcium and alendronate sodium tablets. Three days after surgery, the lumbar frontal and lateral X-rays and CT were reviewed to determine the position of the internal fixation and to understand the distribution of bone cement. At 3, 6, and 12 months after surgery, frontal and lateral X-rays of the lumbar spine were performed to observe whether the pedicle screws were loose or retracted and to assess and record the recovery of the lumbar spine function of the patients.

In addition, at the early stage after the operation, the patients were required to perform lower limb exercises on the bed. The drainage tube was removed when the amount of drainage was <50 mL/d. All patients began to walk with protection on the waist 3 or 4 days after the operation. Patients were required to wear a waist protector for the first month after the operation. Routine postoperative thorax radiography was performed in augmented patients, and patients complaining of discomfort in the heart or lung received additional thoracic CT. All patients received anti-osteoporosis treatment – calcium carbonate, vitamin D3, and bisphosphonate –throughout the treatment period[4].

Outcome Measures

The visual analogue scale (VAS), Oswestry Dysfunction Index (ODI), and Japanese Orthopedic Association (JOA) scores before surgery, at 3 months, 6 months, and at the final follow-up visit, and the fusion of the intervertebral implants at 12 months after surgery were monitored and compared between the two groups. The operative duration, intraoperative bleeding, and postoperative drainage were observed and compared. Frontal and lateral radiographs of the lumbar spine were obtained at 3 months, 6 months, and the last follow-up after surgery to observe any changes in the position of the screw and fusion device or any sinking of the fusion device.

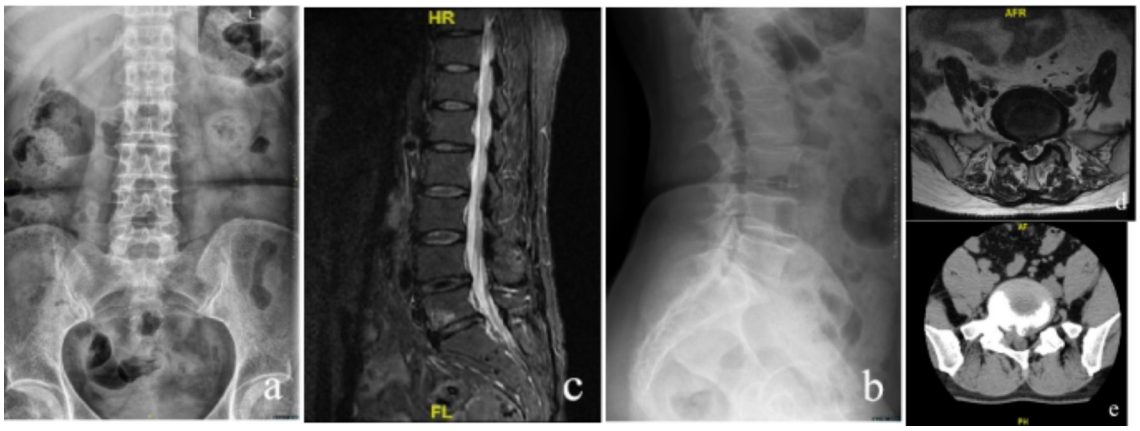

Figure 1. a-b, preoperative lumbar frontal and lateral radiographs showing degenerative changes in the lumbar spine; (**c-e**) MRI and CT of lumbar spine showed L5/S1 disc herniation and endplate inflammation, CT showed small joint hyperplasia, lateral saphenous fossa stenosis, posterior margin bone formation, and disc herniation compressing the dural sac.

Statistical Analysis

SPSS 26.0 (IBM Corp., Armonk, NY, USA) statistical software was used for the statistical analysis of the data. The measurement data were expressed as mean±standard deviation (±s) and analyzed by the independent sample *t*-test for intra-group comparisons and the LSD method for inter-group comparisons. The Chi-square test was applied to analyze the count data. $p<0.05$ suggests that the difference is statistically significant.

Results

At the final follow-up, no complications were seen in group A, and there was one case of intervertebral cement leakage in group B. The intervertebral graft fusion was grade I in both groups. MIS-TLIF plus cement-augmented pedicle screw fixation was associated with significantly less intraoperative bleeding volume (142.25±40.93 mL) and (76.25±17.54 mL) *vs.* TLIF plus cement augmentation (322.00±93.45 mL, 159.75±54.74 mL) ($p<0.05$). The difference in the VAS scores, ODI, and JOA scores between the two groups preoperatively and at the final follow-up showed no statistical significance ($p>0.05$). Patients receiving MIS-TLIF plus cement-augmented pedicle screw fixation had significantly lower VAS and ODI scores and higher JOA scores *vs.* TLIF plus cement augmentation ($p<0.05$) (Table II, III, IV, V).

Typical cases:

Group A: A female, 72 years old, was admitted due to "low back pain with numbness and weakness in the right lower limb for 5 years".

Diagnosis: degenerative lumbar 5/sacral 1 disc herniation, osteoporosis, with a bone mineral density (BMD) of -2.6 SD. The preoperative and postoperative imaging data are shown in Figures 1, 2, and 3.

Group B: A female, 71 years old, was admitted to the hospital due to "low back pain with numbness and discomfort in the left lower limb for 3 years, aggravated for 1 month".

Diagnosis: degenerative L4/5 disc herniation, lumbar spinal stenosis, osteoporosis, with a BMD of -2.7 SD. Imaging data are shown in Figures 4, 5, and 6.

Table II. Operative time, bleeding volume, and postoperative drainage.

	Operative time (min)	Bleeding volume (ml)	Postoperative drainage (ml)
A	113.30±4.37	142.25±40.93	76.25±17.54
B	113.55±3.93	322.00±93.45	159.75±54.74
t	-0.368	-8.402	-6.464
p	0.717	0.000	0.000

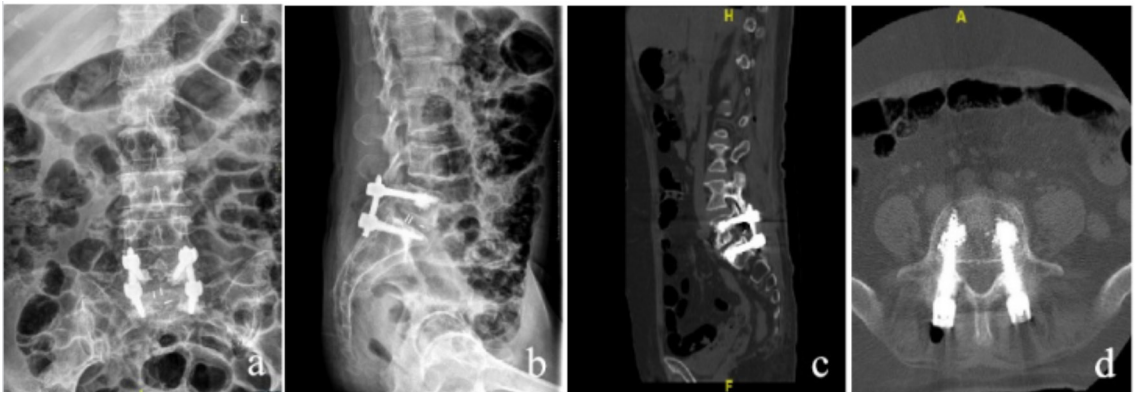

Figure 2. a-b, 3 days postoperative frontal and lateral radiographs of the lumbar spine, with the lumbar internal fixation in place and no leakage of bone cement. **c-d**, 3 days after surgery, CT of the lumbar spine showed good position of the pedicle screws and satisfactory diffusion of bone cement around the screws in the vertebral body with no leakage.

Table III. Oswestry Dysfunction Index (ODI).

Timepoints	A	B	*t*	*p*
Preoperatively	74.50±3.94	74.40±2.80	0.095	0.925
3 months postoperatively	9.20±2.38*	10.08±1.89*	-2.557	0.019
6 months postoperatively	9.00±2.29*	10.40±1.39*	-2.152	0.044
Final follow-up	8.90±2.38*	9.40±1.31*	-0.839	0.412

*indicates $p<0.05$ when compared pre-treatment.

Table IV. Visual Analogue Scale (VAS) scores.

Timepoints	A	B	*t*	*p*
Preoperatively	8.05±0.76	8.00±0.73	0.271	0.789
3 months postoperatively	0.90±0.45*	1.50±0.69*	-3.269	0.004
6 months postoperatively	0.75±0.55*	1.05±0.51*	-2.349	0.030
Final follow-up	1.00±0.56*	1.10±0.55*	-0.490	0.629

*indicates $p<0.05$ when compared pre-treatment.

Table V. Japanese Orthopedic Association Scores (JOA) scores.

Timepoints	A	B	*t*	*p*
Preoperatively	10.05±1.40	9.90±1.68	0.334	0.742
3 months postoperatively	24.70±0.80*	23.20±1.06*	4..943	0.000
6 months postoperatively	25.10±1.07*	24.15±0.81*	3.226	0.004
Final follow-up	25.40±1.05*	25.00±0.65*	1.453	0.163

*indicates $p<0.05$ when compared pre-treatment.

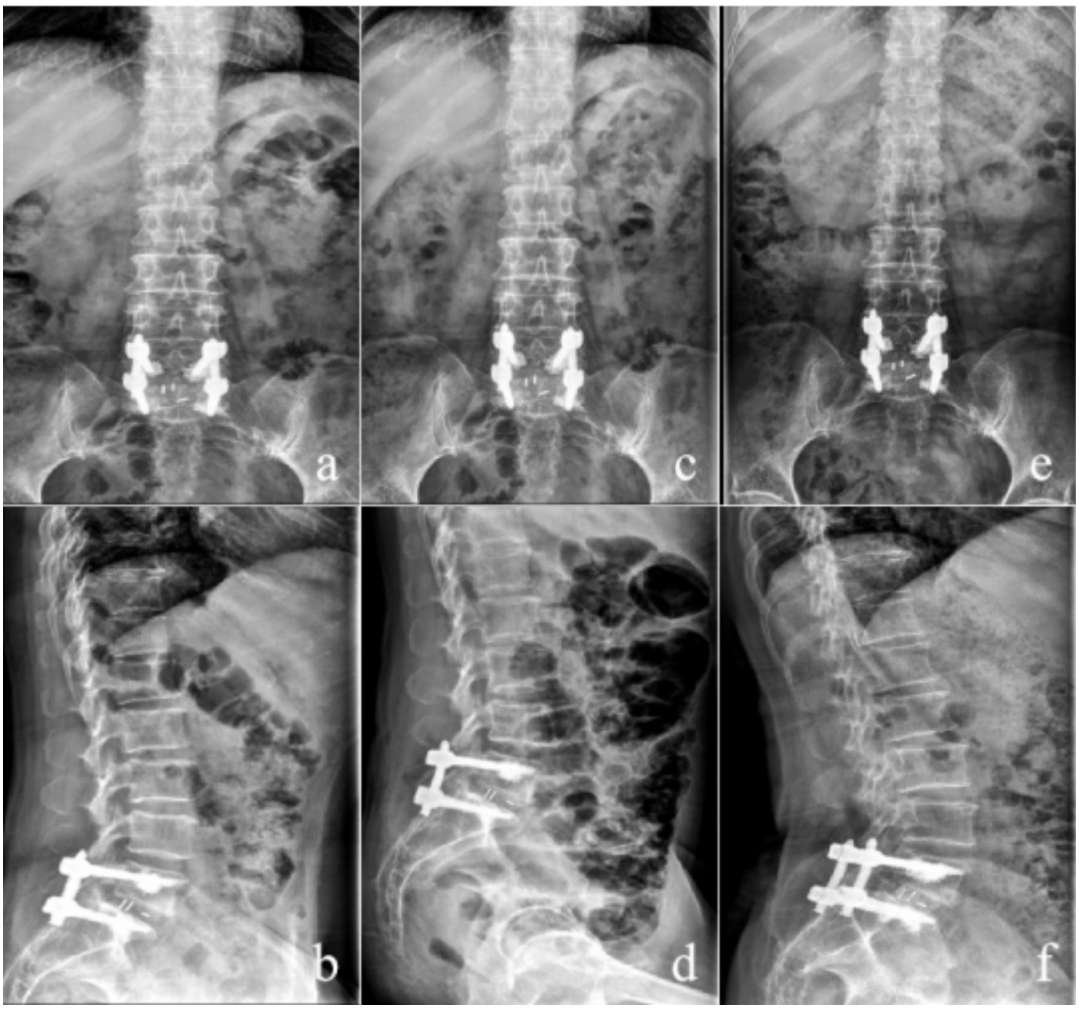

Figure 3. a-b, 3 months postoperatively, frontal and lateral radiographs of the lumbar spine showed good internal fixation, no loosening or retraction of the screw, and no collapse of the intervertebral fusion device. **c-d**, 6 months postoperatively, frontal and lateral radiographs of the lumbar spine showed bone trabeculae formation with good position of screw and intervertebral fusion. **e-f**, The final follow-up lumbar frontal and lateral radiographs showed continuous trabecular bone formation in the intervertebral space and Bridwell intervertebral bony fusion grade I.

Discussion

Degeneration of the intervertebral discs and synovial joints, resulted in ligament and joint capsule laxity. The lumbar muscles increase their load to maintain stability, leading to chronic strain, decreased muscle strength, and decreased spine stability, eventually contributing to lumbar spine disease. Osteoporosis is a compensatory bone disease characterized by low bone mass, which causes reduced fixation of pedicle screws and screw loosening, thus failing to ensure screw stability and compromising treatment efficacy[5,6]. Enhancing the extraction resistance and stability of pedicle screws in osteoporotic vertebral bodies constitutes a current clinical challenge[7,8]. Scholars[9] attempted to increase the screw diameter of pedicle screws to enhance their holding force in the vertebral body, but the results showed that the risk of pedicle fracture increased with increasing screw diameter. Previous studies[10-12] strengthened the screw fixation by changing the thread of the pedicle screw, injecting bone cement into the pedicle tract to strengthen the screw fixation, and inventing cement-augmented pedicle screw fixation. Biomechanical studies[13,14] have shown that screws showed weaker resistance to extraction in cement-reinforced nail channels than in ce-

ment-augmented pedicle screw fixation, and that cement-augmented pedicle screw fixation had significantly fewer postoperative complications than screw channel reinforcement, with less damage to nerve function.

A firm internal fixation is significant for the long-term postoperative outcome of the patient[15]. It has been shown[2] that after the bone density of patients with moderate to severe osteoporosis decreases to 80-90 mg/cm, the vertebral body fails to provide the required holding force for pedicle screws[16]. A more common method of increasing the holding power of the vertebral body is to strengthen the pedicle screw tract with bone cement, but this method has high requirements for operations. In this study, cement-augmented pedicle screw fixation was used to increase the stability of the vertebral body by slowly pressurizing the bone cement in the dough time from the upper end of the screw after screw insertion, so that the bone cement is evenly distributed in the vertebral body to increase the contact area between the screw and the vertebral body. In the present study, PMMA bone cement was used, and the bone cement was injected during dough time because the bone cement had the strongest reinforcement effect and low risk of leakage at dough time[17]. Research[18] has shown that cement-augmented pedicle screw fixation provides a stronger screw-bone interface grip and reduces the risk of loose screws. In the present study, no internal fixation failure was found in group A at the last follow-up, while one patient in group B had cemented intervertebral leakage, and patients receiving MIS-TLIF plus cement-augmented pedicle screw fixation showed significantly lower JOA and VAS scores and lower ODI *vs.* TLIF plus cement augmentation, which suggested that strong internal fixation ensures the postoperative outcome of the patient, thus ensuring the stability and safety of correction. MIS-

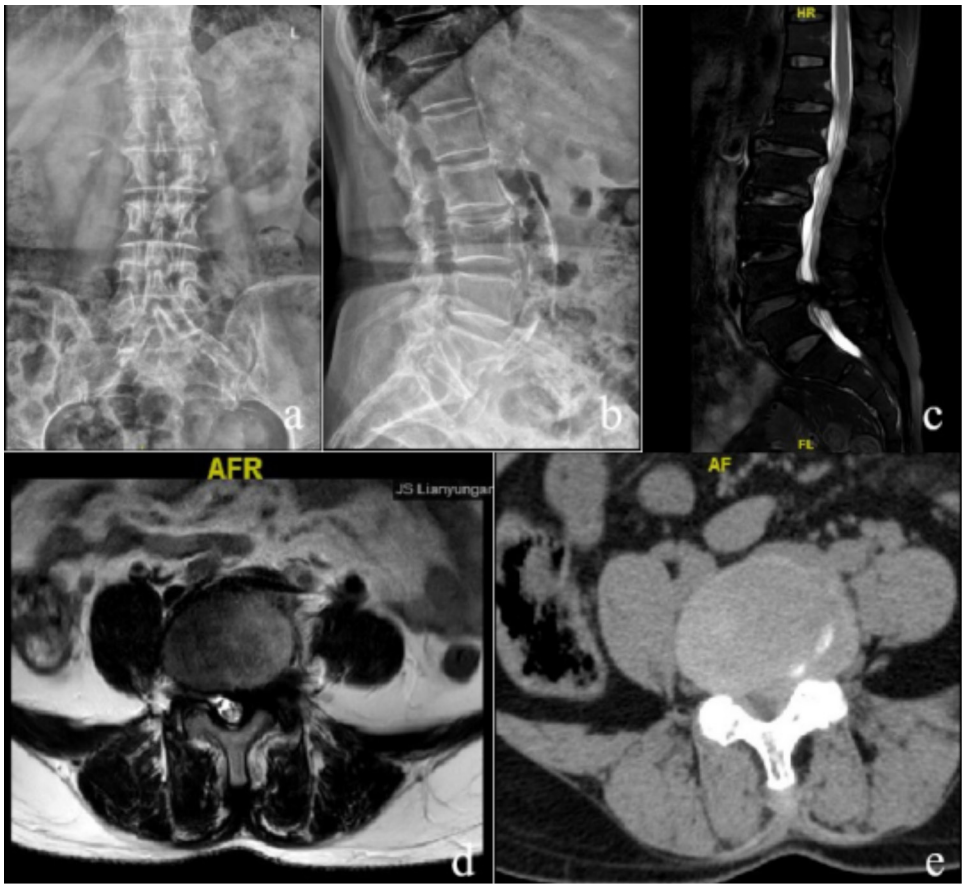

Figure 4. **a-b**, preoperative frontal and lateral radiographs of the lumbar spine showed degenerative changes in the lumbar spine. **c-e**, MRI and CT of the lumbar spine showed herniated and bulging L4/5 disc with lumbar spinal stenosis and compression of the dural sac by the herniated disc.

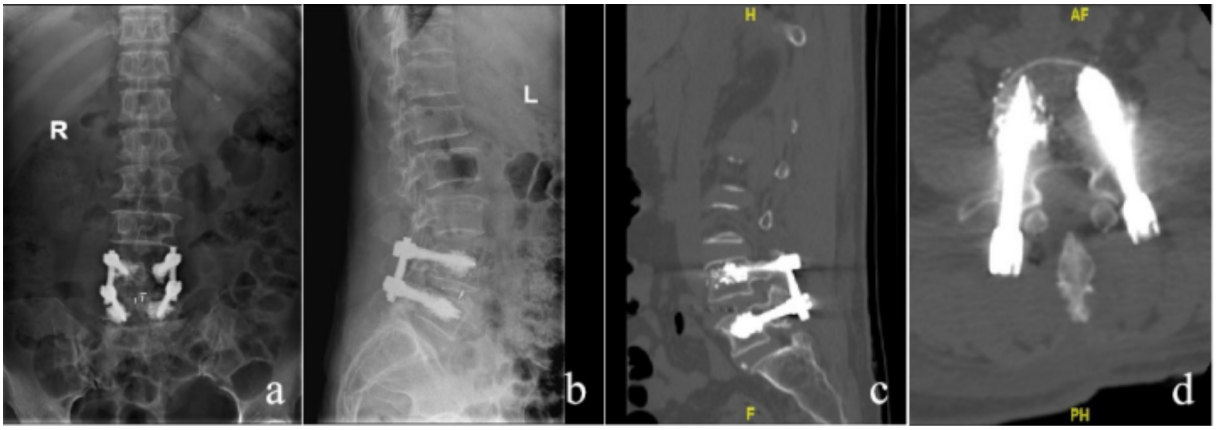

Figure 5. **a-b**, 3 days postoperatively, frontal and lateral radiographs of the lumbar spine showed the lumbar internal fixation in place and no cement leakage. Figure **c-d**, 3 days after surgery, CT of the lumbar spine showed good position of pedicle screws and satisfactory distribution of bone cement.

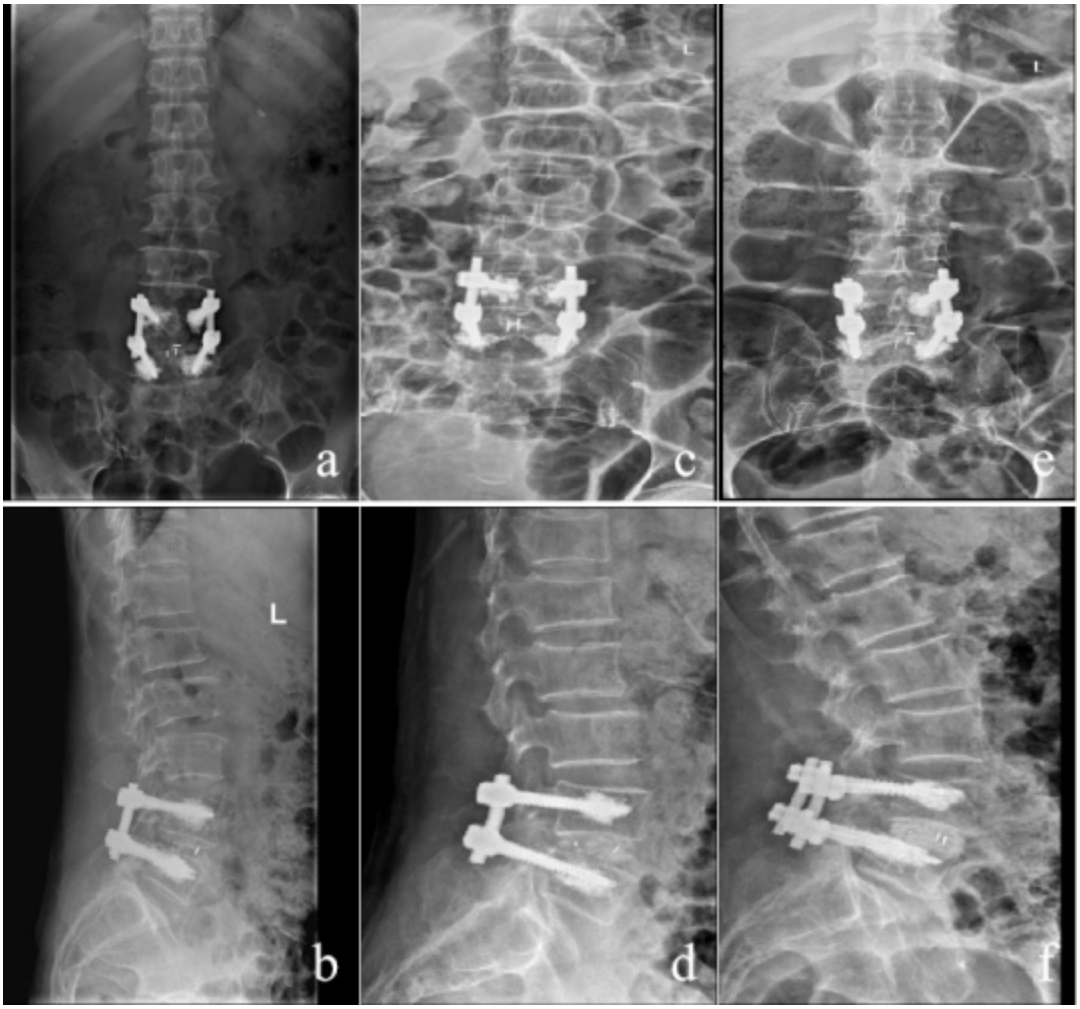

Figure 6. **a-b**, Frontal and lateral radiographs of the lumbar spine at 3 months postoperatively showed a well-positioned pedicle screw with no retraction of the nail. No collapse of the intervertebral fusion was observed. **c-d**, 6 months postoperatively, frontal and lateral radiographs of the lumbar spine showed well positioned pedicle screws with no retraction of the screws. The intervertebral fusion did not collapse, and intervertebral trabeculae formation was visible. **e-f**, At the last follow-up, the frontal and lateral lumbar spine radiographs showed an increase in intervertebral space bone trabeculae compared to 6 months postoperatively and intervertebral bony fusion, which was classified as grade I according to Bridwell's fusion criteria.

TLIF causes less damage to paravertebral tissues and fewer postoperative back pain complications, but it has limited operating space and a narrow operative field[19]. To avoid these complications, the operator is required to master the MIS-TLIF technique, be familiar with the anatomy around the vertebral body, and be exceptionally careful during the operation. In the present study, no complications related to cerebrospinal fluid leakage were documented. Bone cement leakage is the most common complication of cement-augmented pedicle screw fixation, and different doses of bone cement provide different stabilizing effects on pedicle screws. It has been shown[2] that in severe osteoporosis, injection of 3 ml of bone cement is most effective in stabilizing the pedicle screw without leakage of bone cement. A relevant study[20] has shown that the pedicle screw has the strongest resistance to extraction at a dose of 2 ml of injected bone cement. Therefore, the amount of bone cement injected is commonly maintained at 2.0 ml-3.0 ml. The risk of bone cement leakage can be reduced by controlling the depth of pedicle screw placement and the time of bone cement placement during screw placement[21]. During the follow-up, there was no bone cement leakage in groups A and B.

There are several shortcomings in this study. (1) The sample size of randomized controlled studies was small; (2) the follow-up period was short; and (3) there was a lack of a gold standard for the use of cement-augmented pedicle screw fixation in the treatment of patients with osteoporosis. Future studies with increased sample size and longer follow-ups will be conducted to provide more reliable data.

Conclusions

MIS-TLIF plus cement-augmented pedicle screw fixation shortens the operative time, alleviates postoperative pain, facilitates operative lumbar spine function restoration, and provides favorable intervertebral implant fusion.

Conflict of Interest

The Authors declare that they have no conflict of interests.

Ethics Approval

The trial protocol and all amendments were approved by the Ethics Committee of The First People's Hospital of Lianyungang (KY-201712270001/LW-20230529002-01). Clinical Trial Registration Number: ChiCTR2300072723.

Informed Consent

Written Informed consent was obtained from patients involved in the study.

Authors' Contributions

All authors made equal contributions to this article.

Availability of Data and Materials

All data generated or analyzed during this study are included in this published article.

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