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Comparison of the fenestrated pedicle screw and conventional pedicle screw in minimally percutaneous fixation for the treatment of spondylolisthesis with osteoporotic spine

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ABSTRACT

Objectives: To assess the feasibility of cement-augmented fenestrated pedicle screw for patients with spondylolisthesis with osteoporotic spine.

Patients and methods: From January 2014 to March 2018, a retrospective study of 88 patients with spondylolisthesis and osteoporosis treated with minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF) using the conventional pedicle screw (CPS group, n = 52) and the fenestrated pedicle screw (FPS group, n = 36) was performed with a follow-up of 30 months (range, 10–58 months). Clinical outcomes, overall changes in slip degree, and interbody fusion rates were evaluated via questionnaires and radiographic parameters.

Results: The VAS, ODI and JOA scores at 3 months were significantly improved in both groups compared with the preoperative assessment ($p < 0.001$). No significant differences in scores were found between the two groups at any time. Imaging results at different time points revealed greater postoperative improvement in the Taillard index in the FPS group compared with the CPS group. No significant differences in the interbody fusion speed or rates were found between the two groups. In the FPS group, cement leakage occurred in 22 of 97 screws (22.7%), and symptomatic cement leakage was not found.

Conclusion: MIS-TLIF combined with fenestrated pedicle screws provided greater reduction than did MIS-TLIF combined with conventional pedicle screws in terms of postoperative slip degree. And the application of fenestrated pedicle screw did not obstruct the interbody fusion. Overall, MIS-TLIF combined with the fenestrated pedicle screws is an effective and safe technique for the treatment of spondylolisthesis with osteoporotic spine.

1. Introduction

Osteoporosis, a metabolic bone disease characterized by low bone mass, can lead to a decrease in pedicle screw fixation strength [1] and loosening and pullout [2], which consistently give rise to operation failure [3]. To increase the stability of the pedicle screw, several methods for modifying screw placement have been advocated [4], such as enlarging the screw diameter [5], altering the screw thread [6,7], injecting cement into the pilot hole [8–10] and using the injectable pedicle screw [11]. Among these approaches, the cement-augmented fenestrated pedicle screw, which is studied worldwide [12–14] because of its associated effective clinical outcomes and lower complication rates, has been gradually applied in the clinic [15,16]. Many biomechanical tests have demonstrated that the cement-augmented fenestrated pedicle screw shows a remarkable improvement of fixation strength [11,13,17].

However, the previously reported cement-augmented pedicle screws were mostly introduced for open surgery. Over the prior two decades, minimally invasive spine surgery has rapidly evolved, creating a new technique of percutaneous pedicle screw fixation. Originally aimed to decrease blood loss and lower complication rates, percutaneous pedicle screw fixation has been progressively used for the treatment of thoracolumbar fractures, spinal stenosis, and spondylolisthesis. To achieve both effective fixation and a minimally invasive surgery, Alphonse Lubansu et al. applied fenestrated pedicle screws in a percutaneous invasive approach and achieved safe and effective evidence in osteoporotic patients [18]. Thereafter, clinical research investigating minimally invasive surgery combined with cement-augmented pedicle screws for the treatment of spinal degenerative disease has been reported [19,20]. However, few articles have compared the

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long-term clinical effects of conventional and fenestrated pedicle screws in the treatment of spondylolisthesis with osteoporotic spine, either in open surgery or minimally invasive surgery.

Based on the pioneering research results, a novel percutaneous cement-augmented fenestrated pedicle screw (FPS) was designed herein. The purpose of this study was to introduce a new technique using FPS and to compare clinical outcomes using the conventional pedicle screw (CPS) and FPS in minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF) for the treatment of spondylolisthesis with osteoporotic spine in a retrospective patient series.

2. Material and methods

2.1. Screw design

Based on percutaneous fixation, FPS is designed to obtain a stable, safe and minimally invasive interbody fusion. Our original percutaneous fixation system has a special soft long tail, simplifying the procedure for fitting rods and shortening the operating time. The FPS is a polyaxial, dual-lead threaded and fully cannulated screw with three fenestrations in the distal tip. The polyaxial screw head is designed to simplify the procedure for fitting rods. The dual-lead thread can provide different fixation requirements for the cortical and cancellous bone [6]. The small thread proximity near the screw head can supply a higher holding strength aimed at the cortical zone of the lumbar vertebrae. Four fenestrations (round, diameter: 2 mm) are arranged surrounding the distal tip, which can partly limit the injected cement distribution to decrease the risk of leakage. After FPS insertion and for observations of intraoperative imaging, the cement in the period of wire drawing is injected using a special syringe. All instruments used in the percutaneous fixation system are shown in Fig. 1.

2.2. Patients

This study was approved by the medical ethics committee of the Second Affiliated Hospital of Army Medical University. From January 2014 to March 2018, 88 consecutive patients with spondylolisthesis and osteoporosis, who were treated with the conventional pedicle screw and FPS in our hospital, were retrospectively analyzed (Table 1). We introduced the novel percutaneous fixation system combined with FPS in April 2016 (FPS group, n = 36). Before this period, a portion of the patients with spondylolisthesis and osteoporosis in our department were treated using the same percutaneous fixation system with the conventional pedicle screw (CPS group, n = 52).

The mean follow-up period of the patients was 30 months (range, 10–58 months). There were 74 females and 14 males with a mean age of 66.8 years (range 43–83 years). The inclusion criteria were (1) suffering from osteoporosis: DEXA bone mineral density test demonstrating a mean T score for the femur less than -2.50 (-2.51 —-4.05, mean: -3.26 ± 0.46); (2) symptoms of spondylolisthesis: lower back pain, radicular pain, neurogenic claudication, *etc*.; (3) grade I or II isthmic or degenerative spondylolisthesis illustrated by the preoperative radiological assessment; (4) persistence of symptoms not relieved by conservative treatment for ≥6 months; (5) treatment by one-level MIS-TLIF. The exclusion criteria were (1) a mean T score for the femur greater than -2.5; (2) lumbar disc herniation or lumbar spinal stenosis without spondylolisthesis; (3) treatment by two-level or more MIS-TLIF; (4) treatment by surgical procedures other than MIS-TLIF.

Table 1
Demographic and clinical characteristics of patients in CPS and FPS groups.

Variable	CPS group	FPS group	p
No. of patients	52	36	
Mean age (years), SD	67.3 ± 6.55	65.9 ± 9.38	0.581
Mean follow-up time (months), SD	36.6 ± 5.92	15.4 ± 6.56	< 0.001
Sex, no. of patients			
Male	12	2	0.056
Female	40	34	
Fixation segment, no. of patients			
L3-4	1	1	
L4-5	22	15	
L5-1	13	12	
T score, mean (SD)	−3.23 ± 0.45	−3.31 ± 0.47	0.729
Preoperation			
back pain VAS	6.12 ± 1.44	6.31 ± 1.12	0.530
leg pain VAS	5.87 ± 1.03	6.03 ± 1.18	0.380
ODI	66.11% ± 8.07%	68.3% ± 6.19%	0.155
JOA	13.65 ± 4.22	13.25 ± 3.63	0.565
Radiographic parameters at preoperation			
Intervertebral space height (mm)	9.47 ± 2.01	9.39 ± 1.93	0.847
Taillard index (%)	18.71 ± 5.06	20.77 ± 6.53	0.100
Slip angle(°)	5.60 ± 5.57	7.18 ± 7.73	0.289
Lumbar lordosis angle(°)	47.02 ± 10.37	53.57 ± 8.01	0.002

2.3. Surgical techniques

2.3.1. FPS group

Under general anesthesia, the patients were placed in the prone position. Fluoroscopic guidance was used to confirm the diseased segments and to mark the incision line. A 3-cm incision was generated 2.5–3.5 cm from the midline. The posterior lumbar fascia was dissected up to the facet joint. After inserting the expansion tube, the METRx

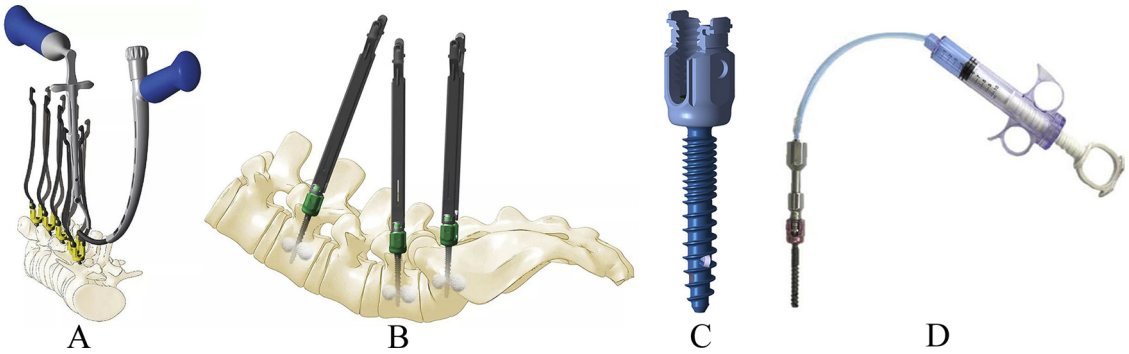

Fig. 1. Minimally percutaneous fixation system combined with fenestrated pedicle screws(FPS). (A) The novel percutaneous fixation system. Our original percutaneous fixation system has special soft long tails different from the metal extenders in the conventional percutaneous fixation system, which simplified the procedure for fitting rods and shortened the operating time. (B) Schematic diagram of cement-augmented pedicle screws in lumbar vertebra. Bone-screw interface strength was promoted by cement injection. (C) Fenestrated pedicle screw(FPS). The fenestrated pedicle screw is polyaxial, dual-lead threaded, and fully cannulated with three fenestrations at the distal tip. (D) Injection device of FPS. Cement can be injected via a special syringe.

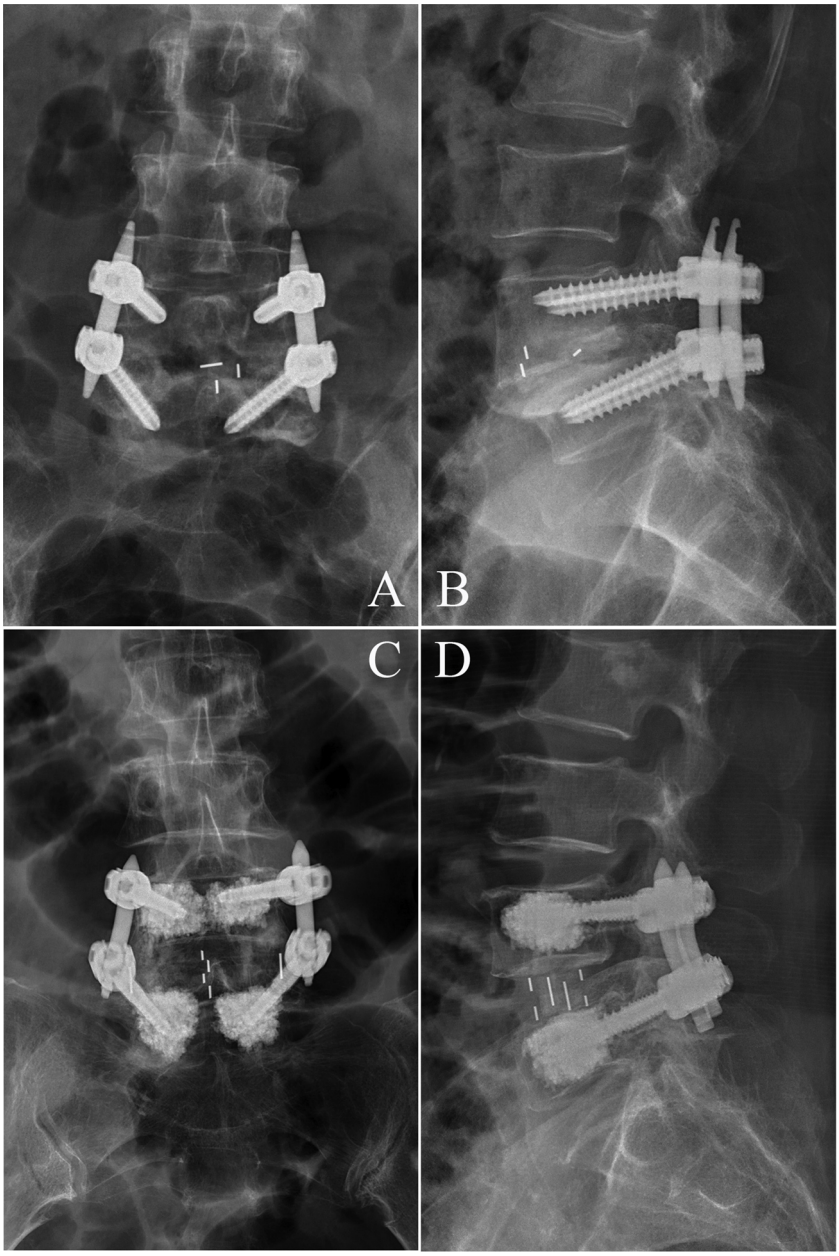

Fig. 2. Plain radiographs showing the minimally invasive interbody fusion in different pedicle screws. A, B: Radiographic images in the CPS group. C, D: Radiographic images in the FPS group.

Quadrant System (Medtronic, USA) was placed above the facet joint, which was confirmed by fluoroscopy. A complete facetectomy was accomplished by using the osteotome and rongeur. After removal of the ligamentum flavum, the border of the dura and nerve roots was identified. A complete discectomy was performed inside Kambin's triangle. After verifying the extensive decompression of the dura and nerve roots, a single PEEK interbody cage (SANYOU, China) was inserted. The FPS was then inserted through the same incision and fitted to the cement delivery system. The PMMA bone cement (HERAEUS, Germany) was injected through the delivery system. To decrease the risk of cement leakage, the PMMA distribution was observed under fluoroscopy following injection of 1.5–2 ml of PMMA into the FPS. The surgeon could stop the injection if any PMMA leakage occurred (Fig. 2C and D).

2.3.2. CPS group

The operative procedure for CPS was the same as in the FPS group before pedicle screw insertion. The CPS was inserted without cement injection (Fig. 2A and B).

2.4. Clinical outcomes

Clinical evaluations were performed through a review of inpatient records and a questionnaire, and data included the operation time, blood loss, X-ray exposure time and complications. The primary measures of this study were the visual analog scale (VAS), Oswestry Disability Index (ODI) and Japanese Orthopedic scale (JOA) scores.

2.5. Radiologic assessment

Radiologic images were obtained during the preoperation, postoperation (3 days after the operation), 6 and 12 months after surgery, and at the final follow-up. The radiological evaluation included X-rays, CT scans and magnetic resonance imaging (MRI). Static and dynamic plain X-rays were used to assess the stability of the pedicle screws and

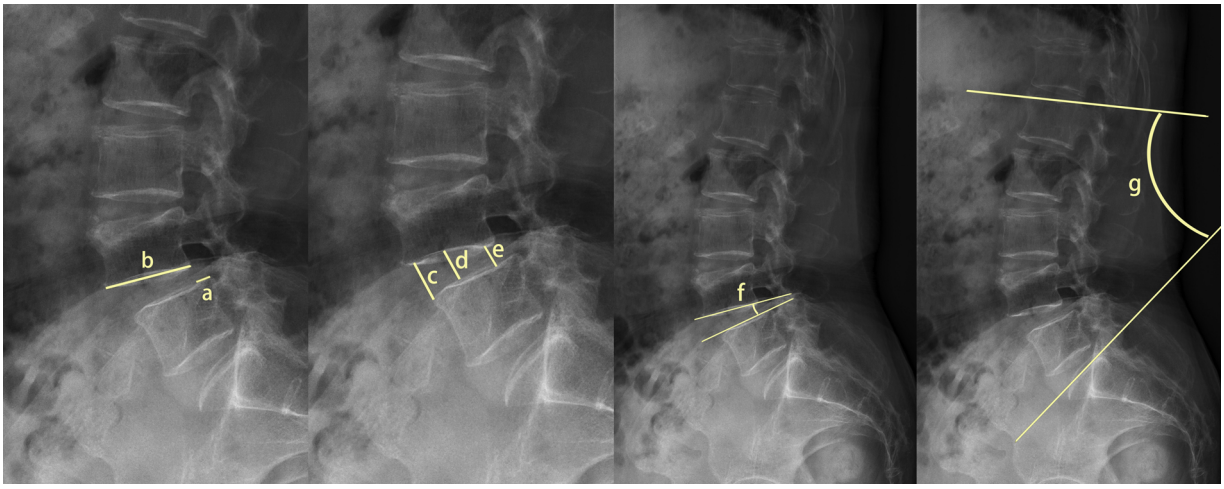

Fig. 3. Radiologic assessment parameters of lumbar lordosis. a/b: Taillard index, (c + d + e)/3: intervertebral space height, f: slip angle, g: lumbar lordosis angle. The evaluation was achieved by Centricity Radiology RA 600 v8.0 (GE Healthcare, USA).

changes in lumbar lordosis with specific parameters, including the Taillard index [21], intervertebral space height, slip angle and lumbar lordosis angle [22](Fig. 3).

The level of interbody fusion was evaluated by CT scans. The evaluation methods were performed according to Christoph J. Siepe [23]. Effective fusion could be identified by the establishment of trabecular bony bridges between fusion vertebral bodies. By applying the CT reconstruction images, the interbody fusion characteristics were classified into 4 grades, respectively: solid fusion (Grade I), complete signs of fusion (Grade II), incomplete signs of fusion (Grade III) and nonunion (Grade IV). The CT images were accessed by two independent radiologists with experience in spinal radiology.

The cement distribution in the vertebra and leakage were recorded and evaluated using dual energy CT scans postoperatively (3 days after the operation). Evaluation methods for cement distribution were conducted according to Ming-Hsien Hu's cement evaluation model [24]. Using computer software (Centricity Radiology RA 600 v8.0, USA), the axial view of the vertebra was partitioned by grids and divided into four zones (Fig. 4). The extension of PMMA within the vertebra was then classified into four zones: the anterior third of the vertebral (Zone 1), the middle third of the vertebral (Zone 2), the posterior third of the vertebral (Zone 3), and the pedicle and spinal canal area (Zone 4).

Cement leakage was evaluated according to J. S. Yeom's classification of patterns of cement leakage in percutaneous transpedicular vertebroplasty [25]. Based on the leakage paths, all instances of cement leakage were classified into three types (B, S and C) as follows: Type B, leaking into the posterior margin of the vertebra via the basivertebral vein; Type S, leaking via the segmental vein; and Type C, leaking through a cortical defect.

2.6. Statistical analysis

Statistical calculations were performed using SPSS 23.0 for Mac OS. Data were calculated and expressed as the mean ± standard deviation. A paired t-test*t*-test was used to compare preoperative and postoperative data. An independent samples *t*-test was used to compare clinical outcomes between the CPS and FPS group. The Mann-Whitney Test was used to analyze abnormal and heteroscedastic data. Interbody fusion rates were compared using the Chi-square test. The statistical significance was set at $p < 0.05$.

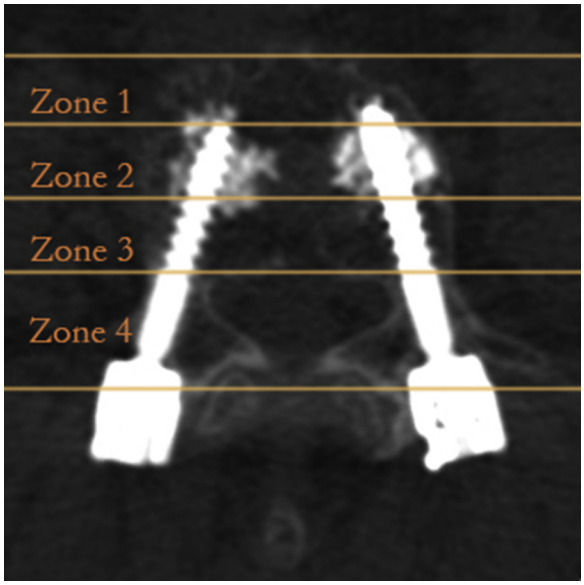

Fig. 4. CT axial view of PMMA distribution zones: Zone 1, anterior third of the vertebral body; Zone 2, middle third of the vertebral body; Zone 3, posterior third of the vertebral body; and Zone 4, pedicle and spinal canal area. A concentrated type with 3 zones distribution.

3. Results

3.1. Clinical outcomes

There were no significant differences in operative time, blood loss, or X-ray time between the two groups (Table 2). All the scores were significantly improved at 3 months after the operation compared with the preoperative readings ($p < 0.001$); however, there were no significant differences at different time points during the follow-up period. Furthermore, there were no significant differences in scores between these two groups at any time (preoperation, 3, 6, and 12 months after the operation and the final follow-up). There were no serious intraoperative complications such as pulmonary embolism or spinal cord compression. 12 months after the operation, all the patients in our study achieved satisfactory outcomes.

Table 2
Comparison of peri- and postoperative parameters data between FPS and CPS.

Variable		CPS group	FPS group	p
Perioperative parameters data				
Mean operative time (min)		166 ± 29	176 ± 37	0.151
Intraoperative blood loss (ml)		146 ± 52	161 ± 55	0.183
Postoperative blood loss (ml)		120 ± 50	123 ± 61	0.129
X-ray time (s)		71 ± 23	63 ± 18	0.541
The average size of screws				
Diameter (mm)		6.5	6.5	–
Length (mm)		41.15 ± 2.96	41.11 ± 2.67	0.890
Interbody fusion rates				
Time points	Fusion grade			
6 months	I	27(51.9%)	17(47.2%)	0.665
	II	19(36.5%)	14(38.9%)	0.823
	III	6(11.6%)	5(13.9%)	
12 months	I	42(80.8%)	30(83.3%)	0.759
	II	10(19.2%)	6(16.7%)	
	III	0	0	
Final follow-up	I	47(90.4%)	24(96%)	0.684
	II	5	1	
	III	0	0	
Clinical outcome scores postoperatively				
back pain VAS		2.31 ± 0.61[a]	2.19 ± 0.75[a]	0.447
leg pain VAS		1.06 ± 0.89[a]	1.19 ± 0.95[a]	0.202
ODI		0.22 ± 0.05[a]	0.22 ± 0.05[a]	0.951
JOA		23.67 ± 1.32[a]	23.36 ± 1.40[a]	0.567
Radiographic parameters postoperatively				
Intervertebral space height (mm)		13.33 ± 1.71[a]	13.84 ± 1.84[a]	0.186
Taillard index (%)		13.12 ± 3.81[a]	7.04 ± 3.11[a]	< 0.001
Slip angle(°)		8.02 ± 3.99	8.10 ± 6.13	0.734
Lumbar lordosis angle(°)		47.08 ± 8.81	52.39 ± 9.82	0.01

[a] Compared with the preoperative period, $p < 0.01$.

3.2. Radiographic evaluation

3.2.1. Analysis of interbody fusion

CT scans were performed at 6 months, 12 months and the final follow-up postoperatively, and all the patients in the experimental group showed radiological evidence of solid fusion at 12 months after the operation. The degree of interbody fusion in both groups at different time points is shown in Table 2. There was no significant difference in interbody fusion rates and speeds between the two groups.

3.2.2. Improvement in slip degree

In both the CPS and FPS group, surgery was associated with a significant increase in intervertebral space height (mm) ($p < 0.001$) and a significant decrease in the Taillard index ($p < 0.001$). Patients in the FPS group experienced a significant improvement in the Taillard index compared with the CPS group ($p < 0.01$). There were no significant differences in the slip angle or lumbar lordosis angle between the preoperation and postoperation periods ($p > 0.05$). The results obtained for the radiographic parameters are shown in Table 2.

The statistical evaluation of intervertebral space height and the Taillard index at different time points is shown in Fig. 5. There was a significant decrease in intervertebral space height at 6 months after the operation compared with the postoperative assessment ($p < 0.001$). No significant differences were found with respect to the Taillard index at different follow-up time points ($p > 0.05$).

An illustrative case in the FPS group is shown in Fig. 6. CT scans at 12 months after the operation showed complete signs of fusion.

3.2.3. Analysis of the cement distribution

There were 97 cement-augmented pedicle screws in the FPS group. There were 7 pedicle screws with cement distributed in zone 2 (7.2%); 5 screws (5.2%) in zones 1 and 2; 18 screws (18.6%) in zones 2 and 3; 54 screws (55.7%) in zones 1, 2, and 3; 3 screws (3.1%) in zones 2, 3, and 4; and 10 screws (10.3%) in all 4 zones. In general, most of the cement distribution covered three of the four zones (zones 1, 2, and 3, and zones 2, 3, and 4), making up 58.8% of the entire FPS.

Cement leakage occurred in 22 of 97 screws (22.7%), and none of the 13 of 36 patients (36.1%) suffering from cement leakage were symptomatic. Among these 22 screws, pre- or paravertebral leakage occurred in 81.8% (18 screws) through cortical defects (Type C). Only four of the 22 leakages (18.2%) were Type S. Of the Type C leaks, one of the leakage screws broke the lateral cortical shell of the vertebral body and caused leaks; however, no symptomatic complications were found in that patient. The BMD of the cement leakage-related patients (13 patients) and others in the FPS group (& patients) was compared, and no significant differences were identified ($p = 0.885$).

4. Discussion

Osteoporosis can compromise the screw-bone interface strength and give rise to screw loosening or pullout, which will always result in fixation failure [3]. To improve the holding capacity of the pedicle screws, several attempts have been applied to increase the fixation strength in the osteoporotic spine [4].

Santoni et al. used the cortical bone trajectory (CBT) to fit the pedicle screw, and they found that CBT screws could provide comparable stability compared with the standard trajectory (ST) [26]. Akpolat YT. et al. compared CBT and ST in terms of fatigue experience, and the results demonstrated that CBT provided worse fatigue performance and applicability [27]. Polly DW. et al. added the diameter and length of the pedicle screw to improve the strength [5]. However, as the pedicle screw diameter was increased, a greater risk of vertebral pedicle fracture was noted. Leonardo B.C. et al. explored the characteristics of a dual-threaded pedicle screw in cadaveric spines, and they found that, compared with single-threaded screws, the dual-threaded screws required an increased insertion torque but resulted in greater holding power in the osteoporotic bone [6].

Many researchers have explored the cement-augmented pedicle screw to enhance the fixation strength [9,11,28]. Compared with the injection of cement into the screw hole before pedicle screw insertion, the cement-augmented fenestrated pedicle screw is safer in terms of cement leakage [28]. Various biomechanical tests have indicated that the cement-augmented fenestrated pedicle screw provides remarkable improvement of the fixation strength and a reduced risk of cement leakage [11]. In our study, FPS provided the advantages of both dual-thread and fenestrated pedicle screws.

In our experience, two clinical findings were broadly shown. First, the FPS group achieved greater improvement reduction than the CPS group did in the postoperative slip degree. This finding could be concluded based on the postoperative differences in the Taillard index between the two groups. Second, the interbody fusion speed and rates were comparable between the FPS and CPS group. Comparison of the interbody fusion speed and rates indicated that the FPS would not obstruct the interbody fusion. Previous studies showed that reduction can restore physiologic alignment and balance, especially for high-grade spondylolisthesis [29,30]. In the CPS group, because of the low bone-screw interface strength, surgeons suffered from fixation failure after trying to correct the slippage defects. In addition, with the evaluation of low insertion torque when placing screws, surgeons would perform spinal arthrodesis in situ for fear of screw loosening and pullout. Furthermore, some surgeons had placed a revised pedicle screw after a

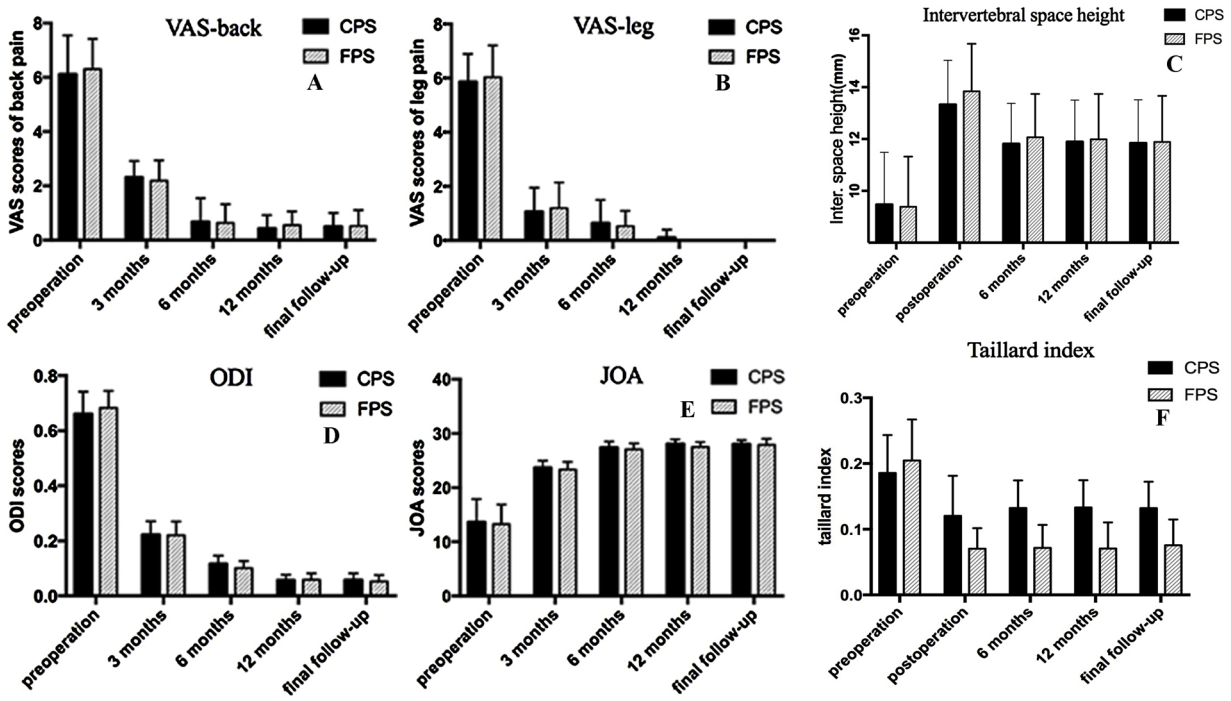

Fig. 5. Clinical outcomes and radiographic parameter values for patients at different time points. A, B, D, E: Compared with the preoperative time point, VAS, ODI and JOA scores were significantly improved at 3 months ($p < 0.001$). No significant differences in scores were found between the two groups at any time point (preoperation, 3, 6, and 12 months after the operation and the final follow-up). C: The intervertebral space height decreased significantly at 6 months after the operation compared with the postoperative period ($p < 0.001$). F: The FPS group achieved greater decrease in the Taillard index than the CPS group did. Time points: preoperation, postoperation, 6 months after the operation, 12 months after the operation, and final follow-up.

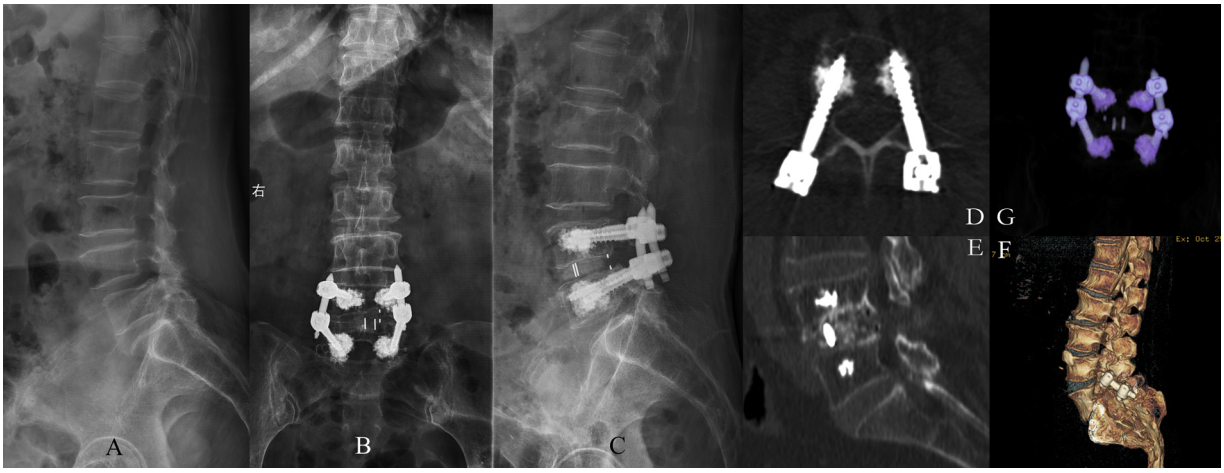

Fig. 6. A 75-year-old female patient suffering from spondylolisthesis and osteoporosis. A: Preoperative X-ray; B, C: Postoperative X ray; D-G: CT scans at 12 months after the operation.

failure reduction, which encouraged them to perform arthrodesis in situ. In contrast, for the PBS group, the enhanced fixation strength after cement-augmentation ensured the stability and safety of the correction. Surgeons can perform complete reduction without considering the risk of fixation failure. Consequently, FPS can improve reduction of spondylolisthesis.

Like all usual cement-augmented pedicle screws, FPS also presents risks [15,31–33]. The most common risk is cement leakage [15]. Jan U. Mueller et al. [33] performed a prospective analysis of 98 patients and 474 augmented pedicle screws. He found that perivertebral cement leakage often occurs in cement-augmented pedicle screws (73.3%) and that the patients are always asymptomatic. In the present study, 22 of 97 screws (22.7%) demonstrated varying degrees of cement leakage, but none of the patients experienced any discomfort. Another rare but severe complication is pulmonary cement embolism (PCE). Insa Janssen et al. [32] performed a retrospective cohort study of 165 patients and found that 13 patients had a PCE (7.9%), of whom 7 had emboli localized in central pulmonary arteries. In our study, there were no symptomatic complications of PCE. In addition, cement-augmentation may affect the biomechanics of the vertebral body, which may increase the fracture risk of the vertebral body or adjacent vertebral body [34]. However, this new viewpoint requires confirmation based on detailed experiments and long-term clinical outcomes.

There are several limitations of this study. First, there is no absolute indication for the use of the FPS in osteoporosis. In our study, we considered a T score < -2.5 as a proper indication. However, we still lack support from evidence-based medicine. Additionally, the proper cement volume for pedicle screw augmentation remains controversial.

In our study, we injected 1.5–2 ml cement approximately into the FPS. Several studies have compared the effect of different volumes on the fixation strength. Different levels of osteoporosis may require different volumes of cement to accomplish an absolute stable fixation. Of course, this postulate should be verified in future research. In addition, FPS removal may be somewhat difficult. Although some experiments have shown that removal does not lead to vertebral fracture, pedicle removal is still more challenging after cement augmentation.

5. Conclusions

Our results indicated that MIS-TLIF combined with the FPS provided greater improvement in slip reduction than did MIS-TLIF combined with the CPS. Moreover, this technique did not influence interbody fusion rates. Although several patients experienced asymptomatic PMMA leakage, the overall efficacy was definite and effective. In summary, MIS-TLIF combined with the FPS is an effective and safe technique for the treatment of spondylolisthesis with osteoporotic spine.

Conflict of interest

Wenkai Wang, Chao Liu, Jie Li, Haiyin Li, Junlong Wu, Huan Liu, Changqing Li, and Yue Zhou declare that they have no conflict of interest.

Acknowledgments

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