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Injectable bone cement cannulated pedicle screw for lumbar degenerative disease in osteoporosis - clinical follow-up of over 5 years

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Abstract

Objective The aim of this study is to evaluate the clinical efficacy of injectable cemented hollow pedicle screw (CICPS) in the treatment of osteoporotic lumbar degenerative diseases through a large sample long-term follow-up study. Additionally, we aim to explore the risk factors affecting interbody fusion.

Methods A total of 98 patients who underwent CICPS for transforaminal lumbar interbody fusion (TLIF) for osteoporotic lumbar degenerative disease from March 2011 to September 2017 were analyzed. X-ray and electronic computed tomography (CT) imaging data were collected during preoperative, postoperative, and follow-up periods. The data included changes in intervertebral space height (ΔH), screw failure, cement leakage (CL), and intervertebral fusion. The patients were divided into two groups based on their fusion status one year after surgery: satisfied group A and dissatisfied group B. Surgical data such as operation time, intraoperative bleeding volume and surgical complications were recorded, and visual analog scale (VAS) and Oswestry disability index (ODI) were used to evaluate the improvement of lumbar and leg pain.

Results The mean follow-up time was 101.29 months (ranging from 70 to 128 months). A total of 320 CICPS were used, with 26 screws (8.13%) leaking, 3 screws (0.94%) experiencing cement augmentation failure, and 1 screw (0.31%) becoming loose and breaking. The remaining screws were not loose or pulled out. Female gender, decreased bone density, and CL were identified as risk factors affecting interbody fusion ($P < 0.05$). Early realization of interbody fusion can effectively prevent the loss of intervertebral space height ($P < 0.05$) and maintain the surgical treatment effect. Both VAS and ODI scores showed significant improvement during the follow-up period ($P < 0.05$). Binary logistic regression analysis revealed that decreased bone density and cement leakage were risk factors for prolonged interbody fusion.

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Conclusions The results of long-term follow-up indicate that PMMA enhanced CICPS has unique advantages in achieving good clinical efficacy in the treatment of osteoporosis lumbar degenerative diseases. Attention should be paid to identify female gender, severe osteoporosis, and CL as risk factors affecting interbody fusion.

Keywords Pedicle screw, Osteoporosis, Bone cement, Interbody fusion, Clinical efficacy

Introduction

With the advancement of science and technology and the enhancement of living standards, people's life expectancy is extended. The aging population has inevitably become a focal point of the world. The incidence of lumbar degenerative diseases in the elderly, including lumbar slip, lumbar disc herniation, and lumbar spinal stenosis, has increased year by year. The segment instability and corresponding nerve root compression of the back can lead to lower limb pain, affecting patients' health and daily life. If conservative treatment is ineffective, surgery is often necessary to relieve pressure and alleviate symptoms.

Although the research of some scholars has provided a valuable tool for the treatment of emerging non-fusion techniques in recent years [1], the posterior internal fixed fusion is still the gold standard of treatment. Decompressive fusion surgery combined with pedicle screw fixation is a viable solution for spinal problems and can enhance stability and fusion rates [2]. However, osteoporosis (OP) can impact the trabecular bone in the vertebral body, leading to a decrease in bone density and thinning of the bone cortex. This can result in reduced screw holding force and fixation failure [3, 4]. To improve the strength of screws in osteoporotic vertebrae, many new methods have been reported, including extending the length and increasing the diameter of the screw, modifying the trajectory of the screw, using expandable pedicle screw and using cement to enhance the pedicle screw [5–9]. Biomechanical experiments show that the cement-bone interface is formed, which improves the holding force and stable line of the screw.

Polymethylmethacrylate (PMMA) possesses high stability, high curing strength, and rapid curing [10, 11], making it the most effective choice for enhancing pedicle screws to achieve stable fixation [12–16]. However, the disadvantages of high heat polymerization temperature, monomer toxicity, and lack of bone conductivity cannot be ignored during use [17]. In order to utilize this technique, we developed and designed CICPS, outlined the screw design characteristics in the literature [18], and implemented clinical treatment for osteoporotic degenerative spinal diseases in 2011.

The purpose of this study is to evaluate the clinical efficacy of CICPS and explore the risk factors affecting interbody fusion in a long-term clinical follow-up study of patients with osteoporotic lumbar degenerative disease treated with transforaminal lumbar interbody fusion (TLIF).

Materials and methods

Research design

Our study retrospectively analyzed 98 patients with osteoporotic spinal degeneration who received CICPS from March 2011 to September 2017. The inclusion criteria for the study were: 1. Preoperative diagnosis of osteoporosis (two-photon bone mineral density test: T-2.5 SD) is confirmed. The patient also presents with a clear TLIF surgical indication after conservative treatment.<3 surgical segments; 4. Follow-up over 5 years. Exclusion criteria: 1. preoperative coagulation abnormalities or severe cardiopulmonary disease; 2.preoperative local or systemic infection; 3. allergic to any endoplant; 4. Incomplete data during follow-up was a limitation of this study. This study was approved by the Ethics Committee of Southwest Hospital (KY2024037) and conducted in accordance with the ethical guidelines of the Army Military Medical University. All the patients participating in this study signed the informed consent form.

Surgical methods

The surgical area was exposed along the posterior median incision in the prone position of the patient under general anesthesia. CICPS with appropriate specifications - diameter 6.5–7.0 mm, length 40–45 mm, slightly larger than the traditional pedicle screw - was selected according to the preoperative plan.1.5 mL of cement was injected with each screw in the C-arm. If bone cement leakage was found during the injection, the injection was stopped immediately. After the cement injection, TLIF was performed using lever locking screws. According to our previous treatment strategy [19], unilateral cement augmentation is recommended for lumbar spondylolisthesis below II degrees, lumbar disc herniation, and lumbar spinal stenosis, while bilateral cement augmentation is recommended for lumbar spondylolisthesis above III degrees. Due to the need for opening and pressurizing the decompression side, it is preferred to strengthen the decompression side of bone cement.

Post-operative management

Postoperative drainage was placed and the drainage was monitored to be less than 50 ml per 24 h; intravenous antibiotics were administered to prevent infection within 3 days. It was recommended to start walking on the

ground on the second day and continue until 3 months after surgery. Routine anti-osteoporosis therapy, including calcium, vitamin D, and phosphate supplementation, was also prescribed.

Observational parameters

Record the operation time, intraoperative bleeding volume, surgical complications, and other surgical data. The vertebral space height (H) was recorded by Choi JY [20] through the standing neutral lateral X-ray (Fig. 1a). The grade of graft fusion was determined by CT scan using the Christoph J. Siepe [21] evaluation system. Only grades I and II levels were defined as satisfactory fusion (Fig. 1b). A translucent shadow around the screw indicates that the screw is loose. Bone cement leakage (CL) is divided into 3 types according to the standards of Yeom [22], including type S (segmental vein leakage), type B (vertebral vein leakage), and type C (cortical defect leakage) (Fig. 2). Symptoms improvement was assessed using the Visual.

Statistical analysis

Data analysis was conducted using SPSS 25.0 software (IBM, USA). Continuous values are presented as mean ± standard deviation. The T-test is used when the data conforms to a normal distribution, while the rank sum test is used if the data do not meet normality. Pearson's $\chi 2$ test, continuity correction, or Fisher's exact test is used for counting data. Binary logistic regression was used to analyze the risk factors affecting interbody fusion. A p-value of <0.05 was considered to indicate statistically significant differences.

Results

General results

This study included a total of 98 patients, with a mean age of 61.29 ± 7.30, consisting of 14 males and 84 females. The patients had a bone mineral density of -3.21 ± 0.61. Diagnoses among the patients included lumbar spondylolisthesis (64), lumbar disc herniation (26), and lumbar spinal stenosis (8) (Table 1).

According to the study protocol, 78 people were in Group A (satisfied) and 20 people were in Group B

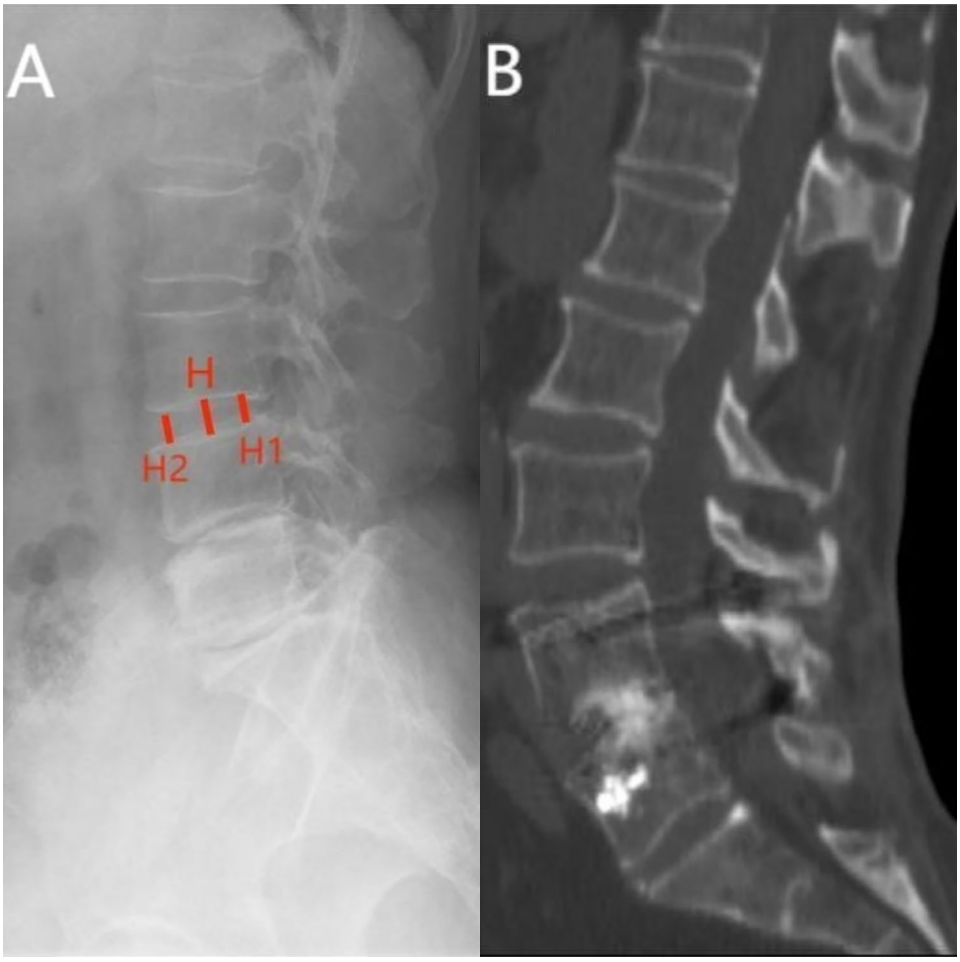

Fig. 1 The figure shows the vertebral space height H= (H1 + H2) / 2 (**A**) and the satisfactory fusion achieved in the vertebral space (**B**)

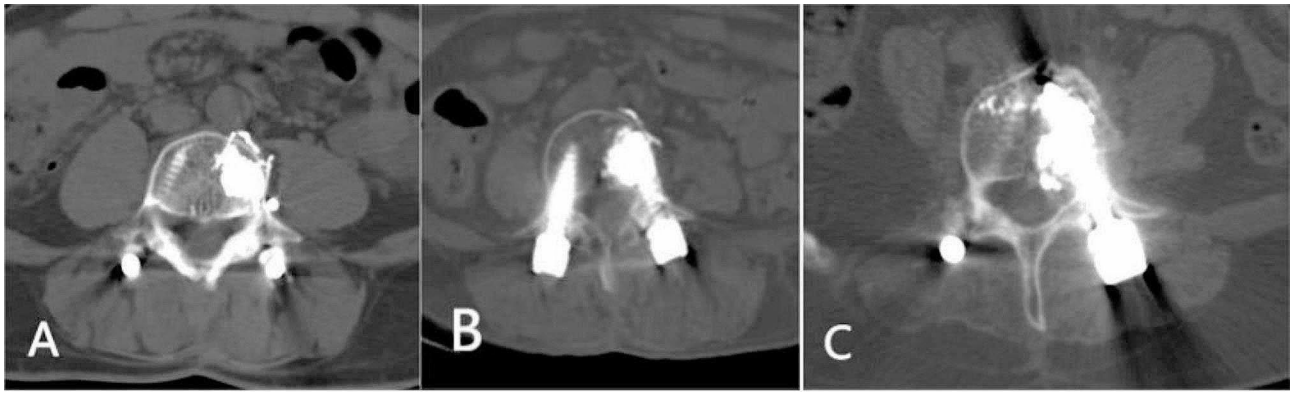

Fig. 2 Type S: segment vein leakage (**A**); Type C: Cortical defect leakage (**B**); Type B: vertebral vein leakage (**C**)

Table 1 Basic patient information and surgery

Variables	Value
Total cases	98
Male/female	14/84
Age (years)	61.29 ± 7.30
BMD (SD)	-3.21 ± 0.61
Disease type	
Lumbar spondylolisthesis	
Grades I	36
Grades II	20
Grades III	8
Lumbar disc herniation	26
Lumbar spinal stenosis	8
Operation time (min)	227.67 ± 55.08
Blood loss (mL)	429.59 ± 336.23
Follow-up time (month)	101.29 ± 15.91
Adverse event	
Bone cement leakage (number / screw)	22/26
Injection failed	3
The screw fracture	1
Shallow surface infection	2
Revision surgery	
percutaneous vertebroplasty (PVP)	4
Abnormal orthopaedic surgery	1
Cleanage surgery	2
Endofixation was taken	1

Table 2 Basic information of the two groups

Variables	Group A	Group B	*P*values
Age (years)	60.49 ± 7.51	62.60 ± 5.81	0.245
Male	14	0	
female	64	20	0.041*
BMD (SD)	-3.08 ± 0.47	-3.73 ± 0.81	0.002*
Operation time (min)	227.51 ± 57.75	228.3 ± 46.19	0.955
Blood loss (mL)	398.72 ± 361.54	550 ± 184.96	0.074

Note: *: $P<0.05$

Table 3 Vertebral space height (mm)

Variables	Group A	Group B	*P*values
Preoperative	8.10 ± 2.41	8.79 ± 1.28	0.087
Postoperative	12.36 ± 1.06	12.44 ± 0.98	0.779
1-y after surgery	11.91 ± 0.13	12.18 ± 1.01	0.297
3-y after surgery	11.59 ± 1.09	11.08 ± 0.87	0.054
5-y after surgery	11.52 ± 1.05	11.04 ± 0.87	0.061
Final follow-up	11.51 ± 1.06	11.00 ± 0.86	0.051

Table 4 Δ H change in two groups (mm)

Variables	Group A	Group B	*P*values
ΔH1	0.46 ± 0.28	0.26 ± 0.18	0.003*
ΔH2	0.31 ± 0.34	1.10 ± 0.42	< 0.001*
ΔH3	3.41 ± 2.11	2.21 ± 1.19	0.002*

Note: ΔH1 represents the difference between postoperative and 1 year after surgery; ΔH2 represents the difference between 3 years after surgery and 1 year after surgery; ΔH3 represents the difference between postoperative and final follow-up. * indicates statistical significance at $P<0.05$

(dissatisfied). There were significant differences in gender and bone density between the two groups ($P<0.05$), and no significant difference in age, operation time, and blood loss ($P>0.05$) (Table 2).

Radiographic evaluation

There was no significant difference in vertebral space height between the two groups during the study ($P>0.05$, Table 3). The increase in vertebral space height until the last follow-up in group A (3.41 ± 2.11 mm) was more significant than the increase in group B (2.21 ± 1.19 mm) ($P<0.05$, Table 4).

Clinical efficacy

Preoperative VAS and ODI scores in group A of 4.33 ± 1.35 and 36.61 ± 2.17 were higher than the last follow-up score. In group B, preoperative VAS and ODI scores of 3.6 ± 1.05 and 37.14 ± 2.17 were also higher than the last follow-up score, indicating a statistically significant improvement in pain symptoms ($P<0.05$, Table 5).

Table 5 VAS, ODI (%) scores of two groups

Variables	Preoperative	Final follow-up	Improve the score	P12 values	P34 values
VAS					
Group A	4.33 ± 1.35	1.03 ± 0.16	3.31 ± 1.34	< 0.001*	< 0.001*
Group B	3.60 ± 1.05	1.10 ± 0.37	2.50 ± 0.92	< 0.001*	
ODI					
Group A	49.80 ± 17.81	6.73 ± 2.43	43.07 ± 17.61	< 0.001*	< 0.001*
Group B	40.22 ± 10.96	7.47 ± 2.83	32.75 ± 10.12	< 0.001*	

Note: P12 for comparison of preoperative and final follow-up, P34 for comparison of improvement scores between groups; * indicates significance at $P < 0.05$

Table 6 χ2 test for surgical factors

Variables	Group A	Group B	*P*values
Pressure reduction			
Unilateral	50	12	0.335
Bilateral	26	10	
Surgical section			
Single segment	52	18	0.339
Multiple segments	12	4	
Disease type			
Spondylolisthesis	46	18	0.448
Disc herniation	22	4	
Spinal stenosis	6	2	
Bone cement			
Leakage	14	8	0.035*
No leakage	64	12	

Note: *: $P < 0.05$

Table 7 Presents the results of the logistic regression analysis on the fusion factors influencing the outcome

Variables	OR	95%CI	P值
BMD (SD)	0.167	0.060–0.470	0.001*
Bone cement leakage	0.111	0.028–0.440	0.002*

Note: *: $P < 0.05$

Correlation study

There were no significant differences in decompression methods, surgical segment, or disease type ($P > 0.05$). However, there was a significant effect of cement leakage on fusion ($P < 0.05$) as shown in Table 6.

Further analysis of bone mineral density and cement leakage revealed a significant difference in their impact on interbody fusion ($P < 0.05$) (Table 7).

Complication

A total of 150 CISPS experienced CL in 98 patients: 22 patients (22.45%), 26 screws (8.13%), including 10 S (3.13%), 10 type C (3.13%), and 6 type B (1.87%). Three screws (0.94%) had bone cement reinforcement failure, and 1 screw (0.31%) was loose and fractured at 2 years of follow-up (Fig. 3). The remaining screws were not loose, pulled out, or broken. Four patients developed osteoporotic compression fractures about 5 years after surgery, and one patient gradually developed scoliosis deformity. Orthopcorrection was performed 10 years after surgery (Fig. 4). Two patients underwent debridement and suturing for superficial infections, while another patient was instructed to consciously take screws and perform internal fixation and removal (Fig. 5).

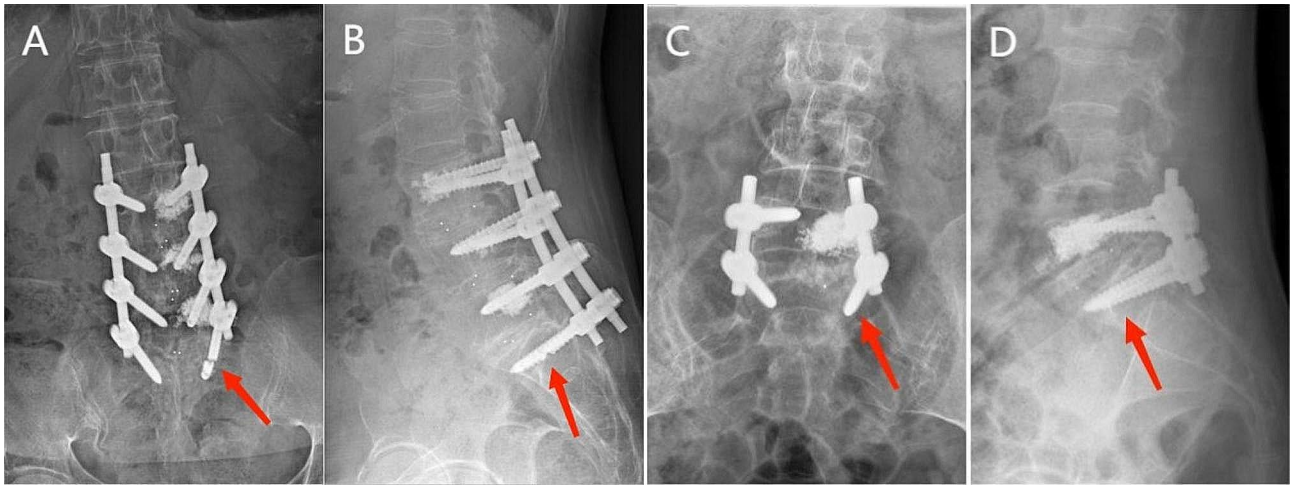

Fig. 3 **A-B**: A 57-year-old female with L4/5-L5/S1 postoperative X-ray showed failure of left S1 screw cement augmentation and a 2-year screw fracture (red arrow). During the follow-up period, a 54-year-old woman with L5 spondylolisthesis postoperative underwent a lateral X-ray which showed failure of left S1 screw cement augmentation, with no screw loosening, extraction, or fracture (red arrow) present

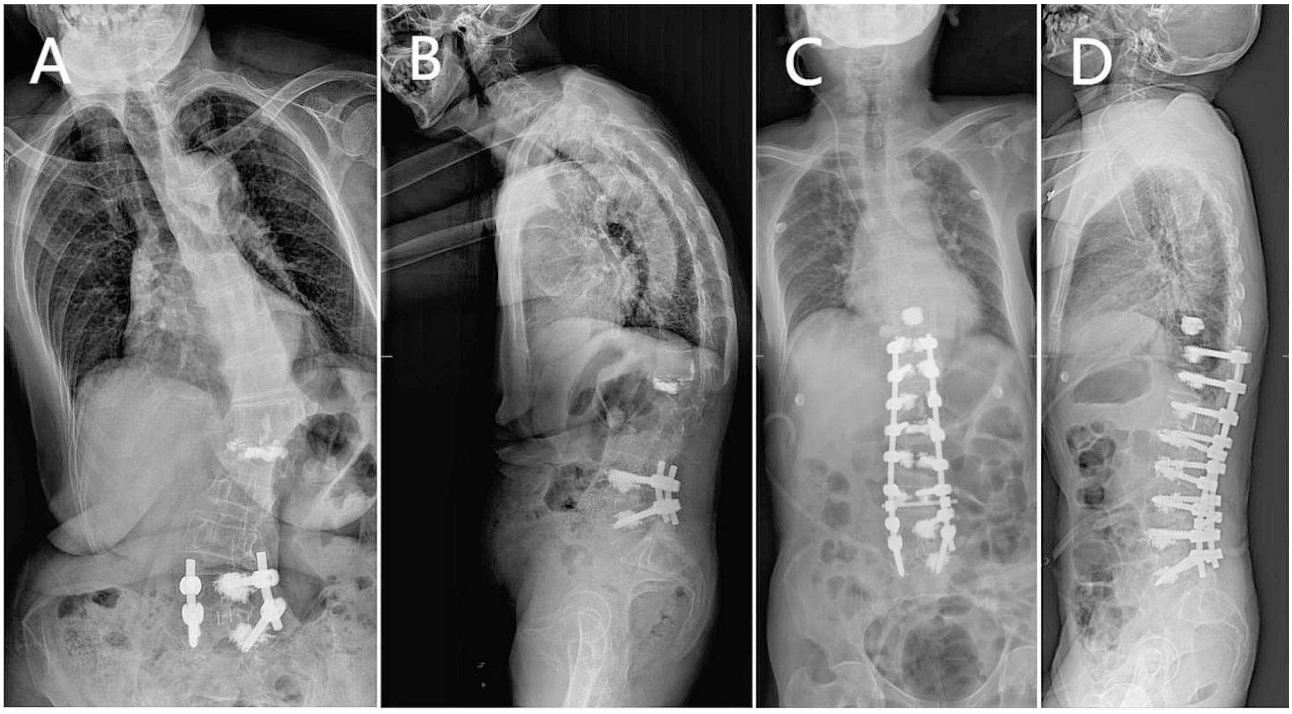

Fig. 4 Shows a 68-year-old woman with L4 anterior spondylolisthesis, Isthmus crack type, who underwent PVP for a T12 vertebral fracture. The postoperative X-ray showed T12 vertebral cement diffusion with no obvious leakage, complete fusion of the L4/5 vertebral space, and a highly satisfactory vertebral space. **C-D**: After 10 years, there was no loosening of the intraoperative L4 and L5 screws. The postoperative X-ray showed restored spine physiological curvature, no obvious cement leakage, and no significant changes in L4/5 vertebral space height

Discussion

The treatment of lumbar degenerative diseases aims to achieve stable fixation of the spinal column by providing adequate decompression to relieve symptoms of nerve root compression, promoting fusion with interbody bone grafting, and implanting pedicle screws [23]. In our study, all patients underwent TLIF surgery for spinal decompression, used a Polyether ether ester (PEEK) cage for graft fusion, and received PMMA-enhanced CICPS fixation. There were no significant differences in operation time, intraoperative bleeding, decompression method, surgical segment, or disease type among the patients (refer to Tables 2 and 4).

Realizing that good intervertebral fusion is based on the stability of the surgical segment, PMMA increased CICPS provides strong stability for three vertebrae in osteoporosis. However, the cytotoxicity of bone cement itself [24] has a certain impact on the surrounding local metabolism, and there is a risk of embolizing vertebral vessels, thus reducing the endplate blood supply and affecting intervertebral fusion [25]. In our study, we examined the amount of cement used and whether leakage occurred. The results showed no statistical difference in the amount of cement used on interbody fusion, but there was a significant negative correlation between CL and promoting intervertebral fusion (Table 6). The binary Logistic regression analysis also showed that CL is an independent risk factor affecting intervertebral fusion (Table 7). Although CL will not affect the final fusion in our study, as all patients achieved full level fusion in the surgical segment within 3 years postoperatively, it did increase the time required for satisfactory fusion in the surgical segment. A longer fusion time indicates less stability in the surgical section later on, which can have a negative impact on the treatment outcome. Therefore, we recommend avoiding the occurrence of CL as much as possible. This is not only to prevent potential local or systemic effects of leakage but also as a crucial step in improving the rate of interbody fusion and ensuring clinical efficacy.

Cage plays an important role in improving the intervertebral space height, promoting intervertebral body fusion, and restoring the stability of unstable segments [26]. However, the subsidence of cage is the most common postoperative complication, and its most direct effect is the decrease of vertebral space height, the weakening of the surgical effect, and the generation of new compression symptoms [27]. Choi et al. [20] conducted a study on the postoperative subsidence stage, evaluating the relationship between interbody fusion, symptom recurrence, and subsidence development through imaging data. They found no direct relationship between subsidence and symptom recurrence or imaging fusion. In contrast, Marchi et al. [27] demonstrated that cage subsidence could

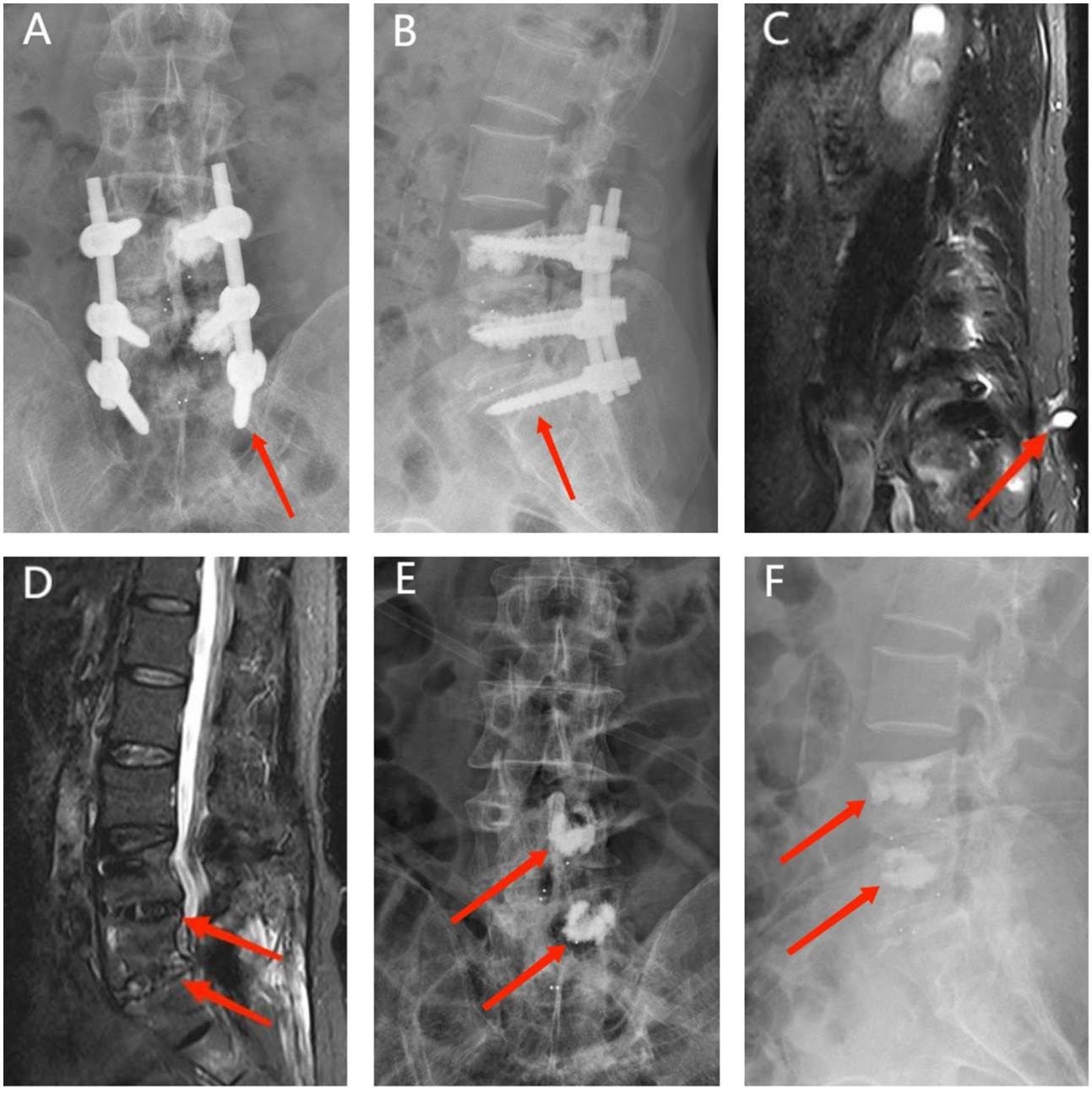

Fig. 5 **A-B**: A 55-year-old male with L4/5-L5/S1 level intervertebral disc herniation. The posterior anterior-lateral X-ray revealed that the bone cement augmentation with the left S1 screw had failed. There were no signs of loosening, pulling out, or breakage of the screws during the follow-up (red arrows). **C-D**: Sinus tract present for 10 years, but the MRI examination showed no obvious signs of infection in the surgical area. There was no significant degeneration of the superior disc, only a local superficial soft tissue infection (red arrow). **E-F**: Debridement and suture + removal of internal fixation. No screw fracture occurred during the surgery. The lateral X-ray indicated intact removal of bilateral screws with no damage to the bone cement and good vertebral integrity (red arrow)

lead to early pain symptoms, which gradually improved with the stabilization of interbody fusion. This is similar to our study. While the height of the two groups was not different during follow-up (Table 3), the changes between the last follow-up and the postoperative vertebral space height were significantly different (Table 4). Additionally, the pain symptoms in Group A with less vertebral height loss showed more relief, and the decrease in VAS and ODI scores was also statistically significant (Table 5). Therefore, we believe that effectively preventing the subsidence of Cage should be the focus of attention. In future research development, the direction may be to find a rate that can effectively improve interbody fusion and avoid stress occlusion, similar to PEEK Cage.

Many studies have shown that decreased bone mass or osteoporosis, measured by DEXA or CT methods, may increase the risk of Cage subsidence [28–33]. The study by Chen et al. [34] noted that women and body mass index (BMI) are also risk factors for Cage subsidence. We also analyzed age and showed no significant difference in the age composition between the two groups (Table 2). Therefore, great attention should be paid to the treatment of women and patients with severe osteoporosis. Patients should be informed of the possible risks to prevent the occurrence of postoperative adverse events related to surgery.

A follow-up study of 79 patients who underwent spinal fusion surgery showed that settlement was no longer observed when intervertebral fusion occurred and new bone was able to withstand the load at the Cage-endplate interface [35]. In our study, the loss of vertebral space height at 1 year after surgery in group A was slightly higher than in group B, and the loss of vertebral space height at 3 years after surgery in group B was much higher than in group A (Table 4), with both comparisons being statistically significant. The reason for the analysis may be that good fusion closely connects the Cage surface to the endplate. The faster the early osteogenesis rate, the faster the decline of the intervertebral space. Prolonged vertebral fusion can lead to dissolution and absorption of the implanted bone. After osteolysis absorption, the stress between Cage and end plate increases. When the stress is too large, Cage subsidence occurs, causing excessive loss of intervertebral space height. The instability of the intervertebral space will further affect the time of intervertebral fusion. Therefore, it is important to improve the early fusion of the intervertebral space, prevent the loss of intervertebral space height, and maintain the clinical effect of surgery.

0.6–11% of the fusion failures are due to loosening [36–39] of pedicle screws. The study by Frankel BM et al. [40] showed a pedicle screw loosening rate of 4.1–12.9% in osteoporotic spinal degenerative disease. In our study, three S1 screws failed to provide reinforcement in 320 PMMA-enhanced CICPS. This failure may have been caused by the improper insertion of the screws into the S1 vertebral cortical bone during the operation and the blockage of cement from exiting the side hole. One screw loosened during the follow-up period, with a loosening rate of 0.31%, and ultimately broke in the second year of follow-up. This breakage may be attributed to the significant shear force generated by the anatomical structure of the S1 vertebral body (Fig. 3).

It has been reported in the literature that reinforced pedicle screws can improve the stability of internal fixation and achieve satisfactory fusion in spinal bones with poor bone mass. Fusion rates have been reported to range from 92.50 to 100% [36, 41–43]. In our study, the vertebral fusion rate at 1 year after surgery was 79.59%, mainly occurring in the Cage, indicating the importance of stability at the local fusion interface. By 3 years after surgery, the fusion rate reached 100%, with most of the bone graft around the Cage being dissolved and absorbed. This resulted in true full-level fusion over the three years, with no significant changes in the height of the intervertebral space once full-level fusion was achieved.

The results of Martin-Fernandez M et al. [44] showed that most postoperative infections were found in revision surgery or diabetes patients. Additionally, most infected patients could achieve satisfactory clinical results after conservative treatment. Early surgical intervention should be performed in patients with deep tissue infection. The results also showed that there was no significant correlation between the use of PMMA and the postoperative infection, and it did not need to be cleared during the operation. In our study, two patients developed superficial lumbar soft tissue infection and sinus tract formation during the seventh and tenth years of follow-up. There were no instances of screw area or deep soft tissue infection, and satisfactory results were achieved after debridement (Fig. 5).

Many studies have shown that pedicle screws augmented with PMMA can be safely and completely removed during surgery, but more torque is required to unscrew the screw. Throughout the removal procedure, the vertebral cement will remain intact, and the vertebral body itself will not sustain any damage [15–47]. In our study, one patient wanted to obtain internal fixation for 10 years after surgery, during hospital treatment. No screw loosening was seen during the removal of the screw along the long axis of the screw, and the cement and vertebral body were not damaged. Despite fewer revision procedures, it is reasonable to believe that PMMA-enhanced CICPS are safe and feasible in revision surgery (Fig. 5).

Many researchers have suggested that the use of PMMA may contribute to the occurrence of new vertebral fractures in adjacent segments [48–50]. However, a study by Aquarius R et al. [51] showed that PMMA itself does not lead to new fractures in adjacent vertebrae. In our study, we observed four patients who experienced vertebral fractures 4–8 years postoperatively. The new vertebral fractures were mainly concentrated in the thoracic and lumbar areas, while our surgical focus was primarily on the lumbosacral area. Combined with our 3–5 years of anti-osteoporosis treatment, we believe that this phenomenon is caused by the worsening of osteoporosis. The thoracic and lumbar areas are known stress concentration areas, leading to the majority of new fractures occurring in this region. Therefore, we recommend the

continuous use of anti-osteoporosis drugs throughout the treatment process.

This study also has certain limitations. Firstly, it is a retrospective study with a long-term follow-up, spanning a wide time period, involving a large number of patients, and requiring difficult return visits. These factors may impact the accuracy of the study results. Secondly, it is a single-center study that lacks the credibility of further verification of the results of the control group. Thirdly, a prospective study is necessary to further confirm the observed differences.

Conclusions

Promoting vertebral fusion and preventing the loss of vertebral space height is a diverse and complex process. In women, severe osteoporosis is a risk factor that can affect vertebral fusion. It is important to identify this risk factor and try to avoid the occurrence of compression fractures to minimize the impact on vertebral fusion. Long-term follow-up results have shown that using PMMA enhanced CICPC in the treatment of osteoporosis-related lumbar degenerative disease can achieve good clinical outcomes and has unique advantages.

Abbreviations

CICPS bone cement	injectable cannulated pedicle screws
CL	cement leakage
CT	computed tomography
PMMA	polymethylmethacrylate
TLIF	transforaminal approach to lumbar interbody fusion

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Not applicable.

Author contributions

Conception and Design: F.D. Acquisition of Data: C.L., R.Z., X.Y. Analysis and Interpretation of Data: C.L., Y.J., J.X. Drafting the Article: C.L. Critically Revising the Article: L.S. Reviewed submitted version of manuscript: L.S. Approved the final version of the manuscript on behalf of all authors: F.D. Statistical analysis: W.W., Y.Z.

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Data availability

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

This study was approved by the Ethics Committee of Southwest Hospital (KY2024037) and conducted in accordance with the ethical guidelines of the Army Military Medical University. All patients participating in this study signed the informed consent form.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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