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Comparison of Three Sacral Screw Internal Fixation Techniques in the Treatment of L4-S1 Lumbar Degenerative Disease with Osteoporosis: A Retrospective Observational Study

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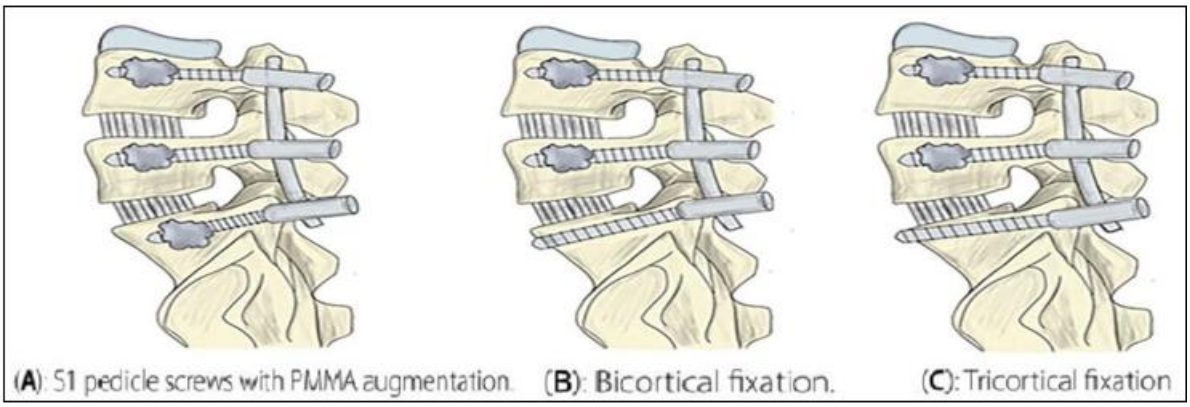
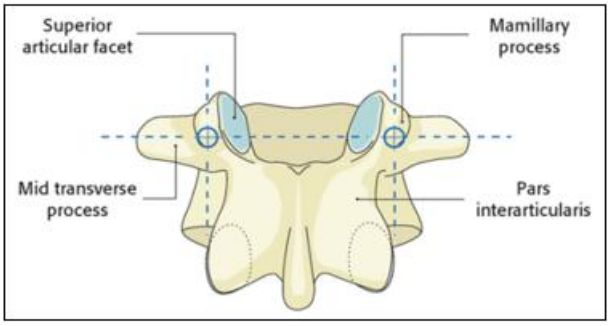
Abstract: ***Background: Patients with L4–S1 lumbar degenerative disease (LDD) with osteoporosis are prone to sacral-screw loosening during spinal internal fixation. We aimed to compare the clinical efficacy and imaging results of sacral bicortical, tricortical, and polymethylmethacrylate (PMMA)-augmented pedicle-screw fixation in the treatment of L4– S1 LDD with osteoporosis. Methods: This is a retrospective study, 36 patients were enrolled and divided into three groups according to the S1-screw fixation method: PMMA-augmented pedicle-screw fixation (Group A, n=12), bicortical fixation (Group B, n=12), and tricortical fixation (Group C, n=12). The visual analog scale (VAS) and Oswestry disability index (ODI) were recorded preoperatively and at the last follow-up, and the postoperative complications, screw-loosening rate, and fusion rate were compared between the three groups. Results: Upon the last follow-up, the VAS and ODI scores of the three groups were significantly improved compared with those recorded preoperatively. The VAS and ODI scores of Group A were significantly smaller than those of Groups B and C (P<0.005), with no significant difference between Groups B and C. Furthermore, we found that osteoporosis and change of lumbar lordosis (LL) value were independent risk factors for sacral-screw loosening in patients with L4–S1 LDD with osteoporosis. Conclusions: When patients with L4–S1 LDD with osteoporosis undergo lumbosacral fusion and fixation, the use of S1 pedicle screws with PMMA augmentation has better stability and less screw loosening.***

Keywords: Lumbar degenerative disease, Osteoporosis, Sacral screw, Polymethylmethacrylate -augmented

1. Background

Lumbar degenerative disease (LDD) is a common condition among middle-aged and older people, particularly middle-aged and older women, causing lower back pain and discomfort in the lower limbs.[1] Surgical treatment for Lumbar Degenerative Disease (LDD) is frequently necessary for patients experiencing neurological damage due to severe conditions like spinal stenosis, spondylolisthesis, or instability, especially when conservative treatments have failed.[2] The most common surgical approach for LDD involves pedicle screw fixation. However, older patients, who are a common demographic for this condition, often have osteoporosis, leading to weaker bones. This increases the risk of complications like screw loosening, breakage, and pseudoarthrosis (failed fusion) after surgery. [3, 4] Therefore, the surgical treatment of LDD with osteoporo sis has become an interesting topic. Due to the special anatomical structure and biome chanical characteristics of the sacrum, screw loosening is most common at the sacrum [5]. In recent years, various advanced technologies have been developed to enhance the pull-out resistance of sacral screws in patients with osteoporosis [6, 7]. Currently, bicortical, tricortical, and polymethylmethacrylate (PMMA)-augmented pedicle screw fixation are commonly used clinically. Although bicortical and tricortical fixation improve the strength of the sacrum-screw interface to a certain extent, there is still a certain rate of screw loosening with the extension of the fixed segment and the occurrence of osteo porosis [5]. In contrast, S1 pedicle screws with PMMA augmentation can increase the screw's pull-out resistance by approximately 81–252% by increasing the contact area between the screw and surrounding bone trabeculae through the bone cement medium [8]. Therefore, due to its simple operation and high fixation strength, the use of S1 pedicle screws with PMMA augmentation is gradually becoming one of the most commonly used methods to enhance the pull-out resistance of screws in osteoporotic vertebrae [9, 10]. Clinically, most cases of LDD are single-segmented, often occurring at the L4/5, while continuous double segment LDD is rare [11]. Previous studies found no significant difference in clinical effects when the PMMA-augmented pedicle-screw method was used in single-segment LDD with osteoporosis. Therefore, the use of PMMA-augmented technology is not recommended in single-segment LDD [5]. However, there is currently limited literature on whether the application of S1 pedicle screws with PMMA augmentation can reduce the screw-loosening rate and improve the fusion rate in patients with double-segment LDD with osteoporosis. Therefore, we aimed to conduct a clinical controlled study comparing the use of bicortical fixation, tricortical fixation, and S1 pedicle screws with PMMA augmentation when performing lumbosacral fusion fixation in patients with L4–S1 LDD combined with osteoporosis to explore the clinical efficacy of different sacral fixation methods and their ability to resist screw loosening.





2. Methods

Patient characteristics-This study included 36patients with L4–S1 LDD with osteoporosis (5 males and 31 females) aged 53–87 years (mean age, 69 years) who underwent transforaminal lumbar interbody fusion (TLIF) between January 2023 and May 2024. The patients were grouped as follows according to the sacrum fixation method used: Group A, S1 pedicle screws with PMMA augmentation group (n=12); Group B, S1 bicortical fixation group (n=12); and Group C, S1 tricortical fixation group (n=12).

All consecutive patients signed a written approval of the operation and were operated on by the same surgeon.

Inclusion and exclusion criteria-

The inclusion criteria were as follows: (i) diagnosed with L4–S1 LDD, and both degenerative levels were involved in the patient's symptoms (ii) all had severe lower back pain and/or lower limb pain before surgery, with regular conservative treatment for more than 3 months deemed as ineffective or having poor efficacy; and (iii) dual energy X-ray absorptiometry determining bone mineral density (BMD) as T≤-2.5 SD. The exclusion criteria were as follows: (i) the presence of coexisting fresh vertebral fractures, spinal tumors, or spinal infectious diseases; (ii) previous lumbar internal fixation of the operative segment; (iii) intolerance to surgery; and (iv) loss to follow-up

Anti-osteoporosis treatment-

All patients received calcium and vitamin D supplements and systemic anti-osteoporosis treatment throughout the treatment period: Vitamin D 60k once weekly, Calcium Carbonate 500mg once daily and subcutaneous injection of Denosumab Injection (60 mg / every six months).

Outcome assessment

Clinical assessment-

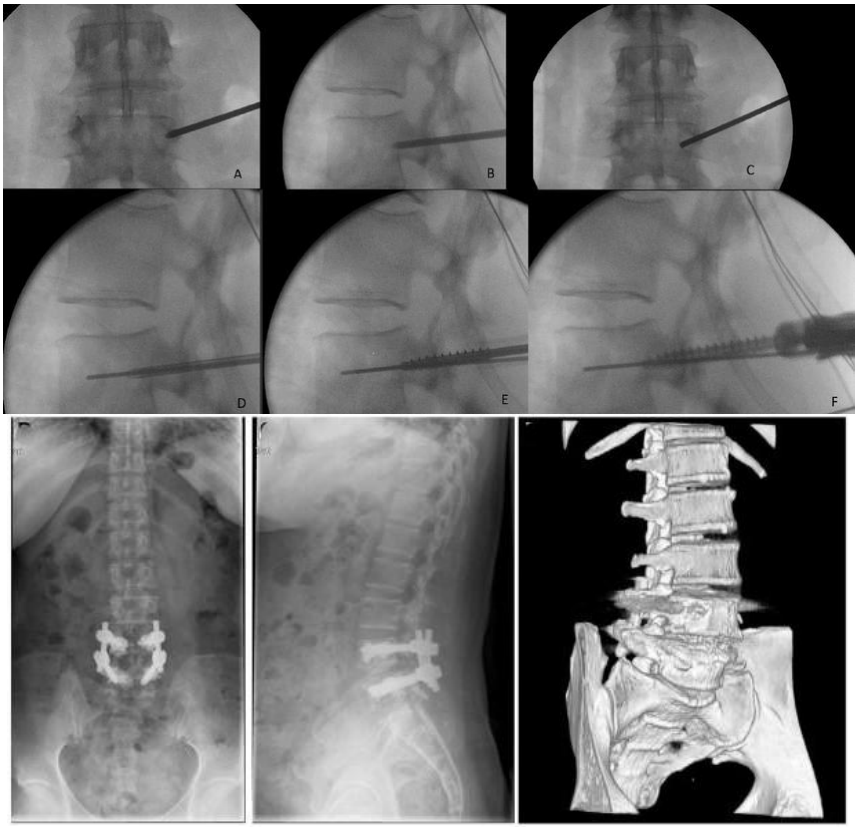
To assess the clinical outcomes, we recorded the visual analog scale (VAS) and Oswestry disability index (ODI) scores of the patients before surgery and at the last follow-up. VAS and ODI scores were recorded by ward physicians during outpatient visits or telephone follow-up. The intraoperative time, intraoperative blood loss, and hospitalization time of the three groups of patients were analyzed. Additionally, the incidence rates of complications such as surgical site infection, nerve root injury, and dural sac tear were compared between each group

Radiographic assessment-

Lumbar spine X-ray or computed tomography (CT) examination was performed at the last follow-up to record the incidence of screw loosening, intervertebral fusion, and bone cement leakage. Spinopelvic parameters such as lumbar lordosis (LL), pelvic inclination (PI), pelvic tilt (PT), sacral slope (SS), and PI-LL were measured before surgery and at the last follow-up. Screw loosening was defined as a halo sign of >1 mm around the screw visible upon postoperative X-ray or CT. Moreover, intervertebral fusion was defined as visible bone tissue growth in or around the fusion cage upon postoperative X-ray or CT and the formation of a continuous cancellous bone bridge between the vertebral bodies of the fused segments. Furthermore, the bone leakage rate was calculated as follows: bone cement leakage rate = (number of leaking screws/total number of reinforced screws) × 100

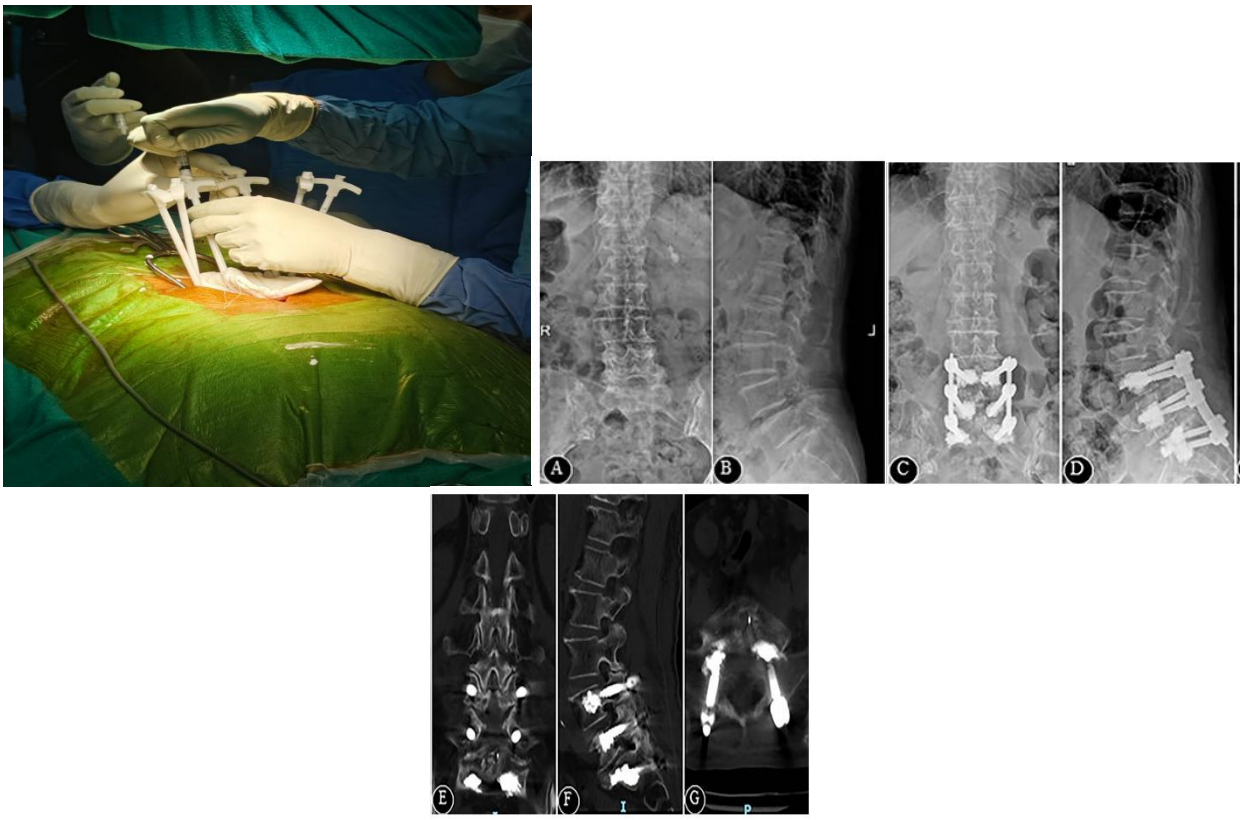
Surgical Methods

All patients underwent L4–S1 TLIF. The initial incision was made along the posterior median approach, after which the lateral part of the "herringbone ridge" was exposed in sequence for needle insertion into the pedicle.



S1 pedicle screws with PMMA augmentation group

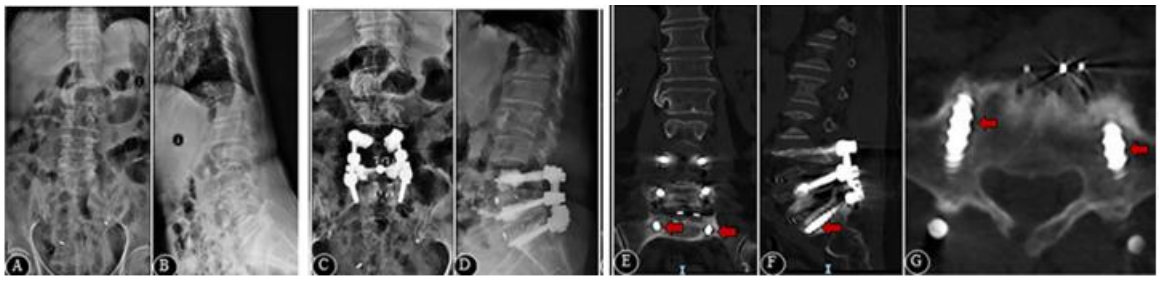
Under fluoroscopy, Fenestrated pedicle screws were inserted into the lumbar pedicle and bone cement was injected through these. The Cement pusher wasconnected to the sacral pedicle screw to inject bone cement. Bone cement injection was stopped when it was close to the posterior edge of the vertebral body. single-screw injection inserted approximately 2.0 mL of bone cement into the duct. Next, the transforaminal lumbar interbody fusion was completed. A polyether ether ketone interbody cageand autogenous and allogeneic bones were used.



S1 pedicle screws with PMMA augmentation
(a)-(b): Pre OP (C)- (D): Post OP X- ray (E)-(G): Post OP CT

Bicortical and tricortical fixation groups

The surgical procedures for bicortical and tricortical fixations were are principally the same as that for S1 pedicle screws with PMMA augmentation; however, these two procedures only used pedicle screws with PMMA augmentation on the lumbar spine, while simple solid pedicle screw fixation was used on the sacrum. The bicortical screw was placed parallel upper endplate of S1, penetrating the vertebral body, with the tip of the screw penetrating the anterior bone cortex. In contrast, the tricortical screw was placed at a 25°-angle between the sacral promontory and the sagittal plane, with the tip of the screw penetrating the cortex of the sacral promontory.



(A)- (B): Preoperative X-ray (C)- (D): Postoperative X-ray (E)- (G): Postoperative CT showed halo sign has appeared around the S1 screws (red arrows), and the S1 pedicle screw has loosened

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Statistical analysis

All data were analyzed. Continuous data are expressed as means ± standard deviations, while categorical variables are expressed as numbers and percentages. The data that met the normal distribution and variance homogeneity between the two groups were compared by t-test, and the data that did not meet the normal distribution or variance heterogeneity were compared by nonparametric rank sum test. The data that met the normal distribution among multiple groups were compared by 1-way ANOVA, and the data that did not meet the normal distribution were compared by Kruskal-Wallis test.

The chi-square test was used to compare categorical variables

Risk factor analysis

After univariate analysis, the variables with statistically significant differences were included in the binary logistic regression analysis. Multi variate logistic regression analysis was used to determine the independent risk factors for screw loosening after double-segment fixation. $P < 0.05$ was considered statistically significant.

Partial correlation analysis: After controlling for BMD, partial correlation analysis was used to analyze the correlation between S1 fixation method and screw loosening.

3. Result

Baseline data Notably, no statistical difference was observed between the three groups of patients in terms of age, sex, BMD, body mass index (BMI), follow-up time, preoperative VAS, and ODI ($P > 0.05$). These variables were comparable between the three groups.

Table 1: Comparison of base data in three groups Characteristic

	Group A (n = 12)	Group B (n = 12)	Group C (n = 12)	p-value
Age(year)	68.73 ± 6.99	71.41 ± 9.47	68.67 ± 7.44	0.42
Sex (male/female)	02:10	02:10	01:11	0.73
BMD	-3.48 ± 0.41	71.41 ± 9.47	-3.26 ± 0.47	0.09
BMI	22.35 ± 3.52	-3.23 ± 0.41	22.40 ± 2.73	0.75
Follow-up(months)	36.31 ± 9.12	34.73 ± 12.72	39.46 ± 15.97	0.44
Pre-op VAS score	7.27 ± 1.00	7.05 ± 1.05	7.17 ± 1.09	0.76
Pre-op ODI score	51.90 ± 9.64	53.96 ± 5.83	51.08 ± 8.44	0.48

Clinical outcomes

Postoperative follow-up was done at 6 and 12 months. At the last follow-up, the VAS and ODI scores of Group A were significantly smaller than those of Groups B and C (all $P < 0.05$); however, no significant difference was observed in the VAS and ODI scores of Groups B and C ($P > 0.05$). Additionally, no statistical difference was noted in the

operation time, intraoperative blood loss, and hospitalization time between the three groups (all P > 0.05). (Table 2)

Radiological outcomes

Comparison of the bone-cement leakage rates In Group A, the average bone-cement injection volume per screw was 2.04 ± 0.63 ml and the lumbar bone cement leakage rate was 18.27% . Moreover, the average bone-cement injection volume per screw in S1 was 1.76±0.59 mL, with a bone-cement leakage rate of 19.23% . The total bone-cement leakage rate was 18.59%. In Group B, the average bone-cement injection volume per screw was 1.50±0.46 ml, and the lumbar bone-cement leakage rate was 18.19%. Similarly, the average bone-cement injection volume per screw in Group C was 1.77±0.47 mL, with a lumbar spine bone-cement leakage rate of 17.71%.

There was no statistically significant difference in the bonecement leakage rates between the three groups (P>0.05). S1 bone-cement leakage was caused by the screw penetrating the anterior bone cortex. Notably, we observed no serious complications such as nerve damage or pulmonary embolism caused by bone-cement leakage

Comparison of the screw-loosening and interbody fusion rates

No screw loosening or breakage occurred in any of the 26 patients in Group A, and all surgical segments achieved bony fusion at the last follow-up (Fig. 2). In contrast, four patients in Group B showed S1 screw loosening (25.93%), of which one patient had L5–S1 non-fusion (Underwent revision surgery at an external hospital) and three patients had L5/S1 fusion (three patients did not undergo revision surgery) (Fig. 3). Similarly, four patients in Group C had S1 screw loosening (25.81%), of which one patient had L5–S1 non-fusion, one patient underwent revision surgery in our hospital 1 year later due to adjacent segment degeneration, and two patients had L5/S1 fusion (three patients did not undergo revision surgery) (Fig. 4). Group A had the lowest screw loosening rate and the highest intervertebral fusion rate, but there was no statistically significant difference between groups (P>0.05)

Table 2: Comparison of clinical effects and complications among three group

Characteristic	Group A (n=12)	Group B (n=12)	Group C (n=12)	P value		
				A vs. B	A vs. C	B vs. C
Operation time (min)	267.88±62.42	241.50± 47.75	277.29 ± 73.43	0.11	0.85	0.19
Intraop blood loss(ml)	409.23±189.14	513.64±364.66	455.00 ± 340.83	0.73	0.87	0.67
Hospital stay(day)	13.58±7.13	15.82± 6.43	15.66± 4.76	0.12	0.06	0.72
Screw loosening(n)	0	2	2	0.08		
Complication(n)	0	1	1	0.85		
Fusion rate (n)	12	10	10	0.54		
Cement leakage(n)	9/72	5/48	5/48	0.99		
vas at last follow up	2.23± 0.76	2.95± 1.05	2.96±1.00	**0.01**	**0.01**	0.95
ODI at last follow up	17.77±7.99	22.55±5.76	22.00±5.36	**0.02**	**0.02**	0.74

Univariate analysis of risk factor for screw loosening

Variable	Loosening Group	Non looseing group	Statistical Value	P value
Age	72.38±8.48	69.47±8.52	t=0.876	0.39
Sex(male/female)	1:1	2:12		1.00
BMD	-3.53±0.44	-3.19±0.42	z=-2.085	0.03
BMI	27.58±3.38	25.76±3.15	t=1.463	0.15
LL (°) Pre operation	35.62±4.87	35.73±15.03	t=-0.20	0.98
Post operation	38.30±4.49	39.94±14.91	t=-0.569	0.57
Change of LL (°)	2.68±0.63	4.21±0.93	t=-4.463	<0.001
SS(°) Pre operation	37.60±13.84	33.36±3.79	t=0.880	0.38
Post operation	36.11±8.89	36.06±10.96	t=0.015	0.99
PT(°) Pre operation	16.32±6.52	20.60±3.79	t=-1.791	0.11
Post operation	20.20±8.65	17.45±4.46	z=-0.493	0.62
PI(°) Pre operation	59.33±3.69	56.58±9.85	t=1.331	0.19
Post operatior	60.80±3.81	55.90±9.59	t=1.411	0.17
PI-LL(°) Pre operation	23.71±6.05	20.86±13.76	t=0.570	0.57
Post operation	22.50±5.72	15.96±13.29	t=2.214	0.04

Comparison of the screw-loosening and non-loosening groups

Patients in Groups B and C were further divided into a loosened screw group and a non-loosened screw group based on S1 screw loosening. Upon comparison of age, sex, BMI, BMD, and spine-pelvic sagittal parameters between these groups, we found that the two groups had statistically significant differences in BMD, postoperative PI–LL and Change of LL. However, no significant differences were noted in age; sex; BMI; preoperative and postoperative LL, SS, PT, and PI; and preoperative PI–LL (P>0.05, Table 3). BMD, postoperative PI-LL and Change of LL were included

in binary logistic regression analysis. The results showed that BMD and Change of LL were independent risk factors for screw loosening after L4-S1 internal fixation (P<0.05 Table 4)

Correlation analysis between sacral 1 fixation methods and screw loosening

In order to more scientifically reflect the correlation between S1 fixation method and screw loosening, partial correlation analysis was used to analyze the correlation between S1 fixation method and screw loosening after controlling BMD factors. The results showed that S1 fixation method was correlated with screw loosening (r=- 0.281, P=0.018)

Complications

The following complications were observed in *Group A*: one patient developed numbness of the contralateral lower limb after surgery, which improved after 2 weeks of symptomatic treatment such as neurotrophic treatment, and the patient did not complain of discomfort at the last follow-up; and The following complications were observed in *Group B*: (i) two patients experienced worsening numbness in the lower limbs on the affected side, of which one patient improved after 10 days of symptomatic treatment and one patient still complained of numbness in the lower limbs at the 1-year follow-up; however, the symptoms were mild. The following complications were observed in *Group C*: (i) one patient suffered a dural sac tear, which was repaired during the operation and improved after postoperative symptomatic treatment; (ii) one patient had decreased muscle strength in both lower limbs after surgery, which improved after 1 week, and the patient did not complain of discomfort at the last follow-up; (iii) one patient developed numbness of the contralateral lower limb after surgery, which improved after 2 weeks of symptomatic treatment such as neurotrophic treatment, and the patient did not complain of discomfort at the last follow-up.

4. Discussion

Biomechanical studies have shown that the local stress at the lumbar-sacral transition is relatively concentrated, the sacral pedicle is wide in diameter and short in length, and the sacral cortical bone is weak [14]. After surgical fixation for LDD, the reduction of movable vertebral bodies causes the head and tail screws to bear the increased load. Additionally, when in combination with osteoporosis, the risk of screw loosening in the sacrum is higher, with an incidence rate of 15.6–46.5% [15]. Therefore, obtaining adequate sacral fixation is an important and challenging clinical issue when patients with LDD combined with osteoporosis require sacral fixation. Currently, sacral bicortical and tricortical pedicle screws are widely used to improve the fixation strength of sacral screws. Bicortical screws increase the holding power of the anterior cortex of the sacrum, while tricortical screws increase the anchoring of the bony dense area of the upper endplate on the basis of bicortical screws. However, some studies have shown that with the extension of the fixed segment and the occurrence of osteoporosis, a certain rate of bicortical and tricortical pedicle screw-loosening remains [14]. Additionally, because the anterior of the sacrum is close to the main neurovascular structures, bicortical and tricortical pedicle screws have the potential risk of damaging the nerves and blood vessels anterior to the sacral spine [16]. Currently, S1 pedicle screws use PMMA augmentation to increase the contact area between the screw and surrounding bone trabeculae, increasing the screw's pull-out resistance. In fact, biomechanics shows that its pull-out resistance is nearly five times higher than that of ordinary pedicle screws. Furthermore, these screws can provide an immediate stabilizing effect; therefore, this has become one of the most commonly used surgical methods [9, 10]. Previously, Ngu et al. [17] compared the pull-out resistance of S1 expansion screws and bone cement-reinforced screws and found that the pull-out resistance of bone cement-reinforced screws was better than that of expansion screws. Moreover, Zhuang et al. [18] compared the biomechanical strength of bicortical fixation and monocortical bone cement-enhanced fixation using cadaveric sacrum specimens. They found that bone cement-enhanced fixation provided better fixation strength. Furthermore, the use of pedicle screws with PMMA augmentation has been shown to effectively reduce the occurrence of internal fixation complications in clinical practice. However, the research subjects of existing studies are often single-segment or mixed single-segment and multi-segment patients [5, 19], and few clinical reports on the application of sacral pedicle screws with PMMA augmentation in double-LDD with osteoporosis exist. The present study compared the clinical efficacy of bicortical fixation, tricortical fixation, and S1 pedicle screws with PMMA augmentation in the treatment of L4–S1 LDD with osteoporosis. The results showed that none of the 26 patients who underwent fixation using S1 pedicle screws with PMMA augmentation had sacral screw loosening, and all achieved good intervertebral fusion. In contrast, four patients in each of the bicortical and tricortical fixation groups showed S1 screw loosening and decreased intervertebral fusion. Moreover, at the last follow-up, the VAS and ODI scores were significantly higher in the bicortical and tricortical fixation groups than those in the S1 pedicle screws with PMMA augmentation group (P<0.05) By evaluating the cases of intervertebral fusion failure, we propose that the loosening of the S1 screw partially contributed to the decreased intervertebral fusion rate, with other causes being that the upper and lower endplates of the bone grafting site were not cleaned and the bone grafting was insufficient.

Furthermore, through the comparison of age, sex, BMD, and spinopelvic parameters between the screw loosening and non-screw-loosening groups, we found that the two groups had statistically significant differences in BMD, postoperative PI–LL and Change of LL. Binary logistic regression analysis showed that BMD and Change of LL were independent risk factors for screw loosening after L4-S1 internal fixation. Therefore, we recommend that: (i) it is critical to complete a preoperative BMD examination. Since our study found that patients with BMD T value ≤-3.5 SD have an increased probability of screw loosening. we propose that using S1 pedicle screws with PMMA augmentation is a better surgical option for patients with low BMD; (ii) the spinopelvic parameters should be fully considered preoperatively. It is necessary to increase the LL to the greatest possible extent intraoperatively to restore the matching of the lumbar spine and pelvic parameters. Simultaneously, the characteristics of osteoporosis in older patients should be taken into account, and it is not recommended to force or overcorrect in these

patients; (iii) Since PMMA augmented pedicle-screws are used in both L4 and L5, the local stress of S1 pedicle-screw is enhanced, which increases the risk of screw loosening. The use of PMMA augmented S1 screw can balance the strength of anchors and is therefore a better choice. (iv) Furthermore, close attention should be paid to controlling the patient's activity level, active antiosteoporosis treatment, and follow-up conditions.

Previous studies have reported the incidence of cement leakage with PMMA augmentation pedicle screws to be approximately 38.3–93.6%. Therefore, the bone-cement leakage rate found in this study was lower than that reported in previous studies. In our previous research, we found that the use of small doses (1.5–2.5 ml) of bone cement slowly injected into a single nail channel under fluoroscopy can reduce the bone-cement leakage rate. therefore, we recommend that less experienced surgeons be guided by a senior physician during the operation to avoid the leakage of bone cement into the spinal canal, which may cause severe complication.

5. Limitations

The present study had some limitations. First, this was a single-center retrospective study with a small number of included cases and a short follow-up period. Further prospective randomized controlled studies are needed to confirm the clinical efficacy of this technology. Second, although all operations were performed by the same surgeon, due to the long time span, experience at different stages might have had different effects on the results, which may lead to bias in the clinical results. Finally, due to limited conditions, no biomechanical studies have been conducted to compare the mechanical strength of bicortical, tricortical, and PMMA-augmented pedicle-screw fixation, which will be our future research direction

6. Conclusions

The present study showed that when patients with L4–S1 LDD combined with osteoporosis undergo lumbosacral fusion and fixation, S1 pedicle screws with PMMA augmentation has better stability and less screw loosening. This surgery is recommended for patients with osteoporosis, and the LL should be increased as much as possible during the operation to restore the matching of lumbar and pelvic parameters. Additionally, these patients should actively prevent the occurrence of screw loosening after surgery and receive systematic antiosteoporosis treatment.

Abbreviations
BMD Bone mineral density
BMI Body mass index
CT Computed tomography
LL Lumbar lordosis
LDD Lumbar degenerative disease
ODI Oswestry Disability Index
PMMA Polymethylmethacrylate
PT Pelvic tilt
PI Pelvic inclination
SS Sacral slope
TLIF Transforaminal lumbar interbody fusion
VAS Visual Analog Scale

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