



Pedicle Screw Fixation in Single-Level, Double-Level, or Multilevel Posterior Lumbar Fusion for Osteoporotic Spine: A Retrospective Study with a Minimum 2-Year Follow-Up

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■ **BACKGROUND:** Pedicle screw loosening is a common postoperative complication for osteoporotic patients, and several studies have identified the important role of fusion length in internal fixation failure, but the relationship between the number of fusion segments and the potential risks remains unclear. This study aimed to investigate the rate and risk factors of screw loosening in osteoporotic patients with different levels of degenerative lumbar disease.

■ **METHODS:** The total cohort of 217 patients was divided into 3 groups according to the different fusion levels: single-level (group A; 100 cases), double-level (group B; 73 cases), and multilevel group (group C; 44 cases). Patient baseline demographic characteristics and assessments with a visual analog scale (VAS) and the Oswestry Disability Index (ODI) before operation and at the last follow-up were compared among the 3 groups.

■ **RESULTS:** Compared with preoperative values, VAS and ODI scores at the last follow-up were significantly improved in all 3 groups. Operative time, blood loss, length of hospital stay, screw loosening rate, fusion rate, and VAS and ODI scores at the last follow-up obviously increased with the increasing number of fusion segments (group C > group B > group A). Of note, **all the screw loosening was**

observed in cranial and caudal vertebra. Furthermore, multivariate logistic regression analysis identified **lumbosacral fixation, larger pelvic incidence (PI)—lumbar lordosis (LL) difference (PT-LL), and greater postoperative pelvic tilt (PT) as independent predictors of screw loosening.** However, sex, bone mineral density, body mass index, LL, sacral slope, PI, the change in LL, and preoperative PT were not relevant to screw loosening ($P > 0.05$).

■ **CONCLUSIONS:** Owing to the high rate of screw loosening in cranial and caudal vertebra, osteoporotic patients with double-level or multilevel pedicle screw fixation benefited less than those with single-level pedicle screw fixation. Larger PI-LL, larger PT, and lumbosacral fixation are other risk factors for screw loosening. **An instrument with stronger holding strength at cranial and caudal pedicle screws is recommended for those high-risk patients.**

INTRODUCTION

With the aging of society, an increasing number of elderly patients with lumbar degenerative diseases are requiring surgical treatment. Posterior pedicle screw

Key words

- Lumbar degenerative diseases
- Osteoporosis
- Posterior interbody fusion
- Screw loosening

Abbreviations and Acronyms

- BMD:** Bone mineral density
- BMI:** Body mass index
- CT:** Computed tomography
- LL:** Lumbar lordosis
- ODI:** Oswestry Disability Index
- PI:** Pelvic incidence
- PLIF:** Posterior lumbar interbody fusion
- PMMA:** Polymethylmethacrylate
- PT:** Pelvic tilt
- SS:** Sacral slope

TLIF: Transforaminal lumbar interbody fusion

VAS: Visual analog scale

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fixation has been considered the gold standard for spine internal fixation in patients with lumbar degenerative diseases, metastatic spinal tumors, thoracolumbar vertebral fractures, and pyogenic spondylitis.^{1,2} However, the inevitable emergence of senile low bone quality in the spine increases the risk of screw loosening and thus limits postoperative efficacy.²⁻⁵

Numerous risk factors have been identified as responsible for screw loosening after pedicle screw fixation, including increasing age, lower bone mineral density (BMD), long segment fixation, screw misplacement, unbalanced lumbar lordosis, and degeneration of paraspinal muscles⁶⁻⁸; BMD and long-segment fixation are especially important.^{1,3,8} However, all of those studies enrolled both osteoporotic and nonosteoporotic patients indiscriminately, and only a few reports to date have focused on spinal degenerative disease. In the present study, we aimed to investigate the rate and the risk factors of screw loosening in osteoporotic patients with different levels of segment fixation.

MATERIALS AND METHODS

Study Population

Between May 2011 and August 2015, patients visiting our hospital for the degenerative lumbosacral disease were recruited. The inclusion criteria included (1) patients diagnosed with degenerative lumbosacral disease based on medical history, symptoms, and imaging findings; (2) patients who received regular, conservative treatment for at least 3 months before surgery; (3) patients whose lumbar vertebral BMD measured by dual-energy X-ray absorptiometry was ≤ -2.5 SD; and (4) patients who underwent posterior lumbar fusion (posterior lumbar interbody fusion [PLIF] or transforaminal lumbar interbody fusion [TLIF]) combined with pedicle screw fixation. Exclusion criteria included (1) patients with vertebral fracture, tumors or infection; (2) patients who had undergone polymethylmethacrylate (PMMA) augmentation or previous spine surgery; (3) patients with serious medical diseases or intolerance of the operation; and (4) patients with insufficient follow-up time (< 2 years) or incomplete imaging data.

A total of 329 patients were identified who had undergone posterior lumbar fusion and pedicle screw fixation. According to the foregoing criteria, 112 patients were excluded because of insufficient follow-up ($n = 55$), previous spinal surgery or PMMA augmentation ($n = 33$), or other diseases ($n = 24$). Thus, the study cohort comprised 217 patients, including 43 males and 174 females, ranging in age from 44 to 86 years (mean age, 65.0 ± 9.3 years), with T scores ranging from -2.5 to -5.2 SD (mean, -3.1 ± 0.6 SD) and follow-up ranging from 24 to 60 months (mean, 31.8 ± 9.3 months). More narrowly, 137 patients had lumbar spinal stenosis, 77 had lumbar spondylolisthesis, and 3 had degenerative scoliosis. The patient cohort was divided into 3 groups based on level of fixation: single-level fixation group (group A; 100 cases), double-level fixation group (group B; 73 cases), and multilevel fixation group (group C; 44 cases). All patients received anti-osteoporosis drugs through the entire treatment period, including calcium carbonate tablets (600 mg twice daily), vitamin D3 drops (400 IU twice daily), and zoledronic acid injection (5 mg once yearly). This study was approved by the Ethics Committee of The First Affiliated Hospital of Guangzhou University of Chinese Medicine.

Surgical Technique

All operations were performed under general anesthesia. Patients were placed on a carbon plate in a prone position owing to the need for intraoperative fluoroscopy. All patients underwent standard PLIF and TLIF.^{4,9} The pedicle screws were inserted using a standard technique as described previously.¹⁰ In general, pedicle screws with a diameter of 6.5 mm and length of 45 mm were used in lumbar vertebrae, and screws with a diameter of 6.5 mm and length of 40 mm were used in the sacrum. In addition, a polyetheretherketone interbody cage (Guona Science and Technology, Sichuan, China) and bone grafting (mixture of local bone harvested from the lamina and allograft bone) were used for lumbar interbody fusion. The same surgical team performed all surgeries.

Evaluation Indicators

The visual analog scale (VAS) and Oswestry Disability Index (ODI) scores were recorded by ward clinicians, during outpatient visits, or by telephone follow-up. Data on operative time, blood loss, and length of hospital stay were abstracted from medical records. The incidence of complications, such as nerve injury and dura matter laceration, were compared among the 3 groups.

X-rays and computed tomography (CT) scans obtained at the last follow-up were reviewed to evaluate the level of interbody fusion and fixation reliability. Screw loosening was defined as a halo sign showing a radiolucent line of ≥ 1 mm around the screw on simple radiographic films or CT images on 1 or both sides after the surgery.^{8,11} Fusion status was evaluated using the final follow-up films and the following criteria: (1) bridging interbody bone, (2) no motion on dynamic X-ray images, and (3) absence of continuous interbody radiolucent lines. A solid fusion was determined by the presence of at least 2 criteria.¹²

All the spinopelvic parameters of total spine photography were measured twice by 2 orthopedists independently, and the mean values of these measurements were used for analysis. The measurement parameters included¹³ lumbar lordosis (LL), assessed from the inferior endplate of L1 to the superior endplate of S1; pelvic tilt (PT), defined as the angle subtended by a line drawn from the midpoint of the sacral endplate to the center of the bicoxofemoral axis and a vertical plumb line extended from the bicoxofemoral axis; sacral slope (SS), the angle between the endplate of S1 and the horizontal line; and pelvic incidence (PI), the angle between the line perpendicular to the sacral endplate at its midpoint and the line connecting this point to the midpoint of femoral heads axis. PI-LL is defined as the difference between PI and LL.

Statistical Analysis

Data analyses were done using SPSS version 19.0 (IBM, Armonk, New York, USA). Measurement data (age, BMD, BMI, follow-up, VAS, ODI, operative time, blood loss, and hospital stay) among the 3 groups were analyzed using 1-way ANOVA, and count data (sex, fusion methods, complications, screw loosening, nonunion) were analyzed using the χ^2 test. Differences in the continuous variables between the loosening group and nonloosening group were compared using the independent-samples t test (age, BMD, BMI, preoperative and postoperative LL/SS/PT/PI, change in LL). The χ^2 test was used to compare the classification variables (sex,

Table 1. Baseline Patient Data

Characteristic	Group A	Group B	Group C	P Value
Sex, male/female, number	19/81	13/60	5/39	0.077
Age (years), mean \pm SD	64.2 \pm 9.6	64.9 \pm 9.8	67.0 \pm 7.6	0.259
BMD, mean \pm SD	-3.1 \pm 0.6	-3.1 \pm 0.7	-2.9 \pm 0.5	0.264
BMI, mean \pm SD	23.5 \pm 3.0	23.3 \pm 3.0	24.4 \pm 2.7	0.141
Fusion method, TLIF/PLIF, number	76/24	58/15	33/11	0.832
Follow-up (months), mean \pm SD	31.3 \pm 9.2	33.2 \pm 9.4	30.5 \pm 9.2	0.238
VAS score, mean \pm SD	7.2 \pm 1.0	7.0 \pm 0.9	7.4 \pm 0.8	0.140
ODI (%), mean \pm SD	52.2 \pm 8.9	51.7 \pm 8.1	53.3 \pm 7.5	0.612

BMD, bone mineral density; BMI, body mass index; TLIF, transforaminal lumbar interbody fusion; PLIF, posterior lumbar interbody fusion; VAS, visual analog scale; ODI, Oswestry Disability Index.

lumbosacral fixation). Multinomial logistic analysis was performed to identify independent predictors for screw loosening. $P < 0.05$ was considered to indicate statistical significance.

RESULTS

There were no statistically significant differences among the 3 groups in terms of sex, age, BMD, BMI, fusion method, preoperative VAS and ODI scores, and follow-up time (Table 1). Levels

of fixation in the 3 groups are shown in Figure 1. In terms of perioperative complications, in group A, 2 patients suffered from transient leg radiating pain, 1 patient had an incision infection and was discharged 1 month after wound debridement, 1 patient had a dural tear and was discharged after surgical suture repair, 1 patient had incorrect implantation of pedicle screws and underwent revision surgery, and 1 patient had congestive heart failure after surgery but recovered after treatment. CT was used to evaluate screw loosening in 68

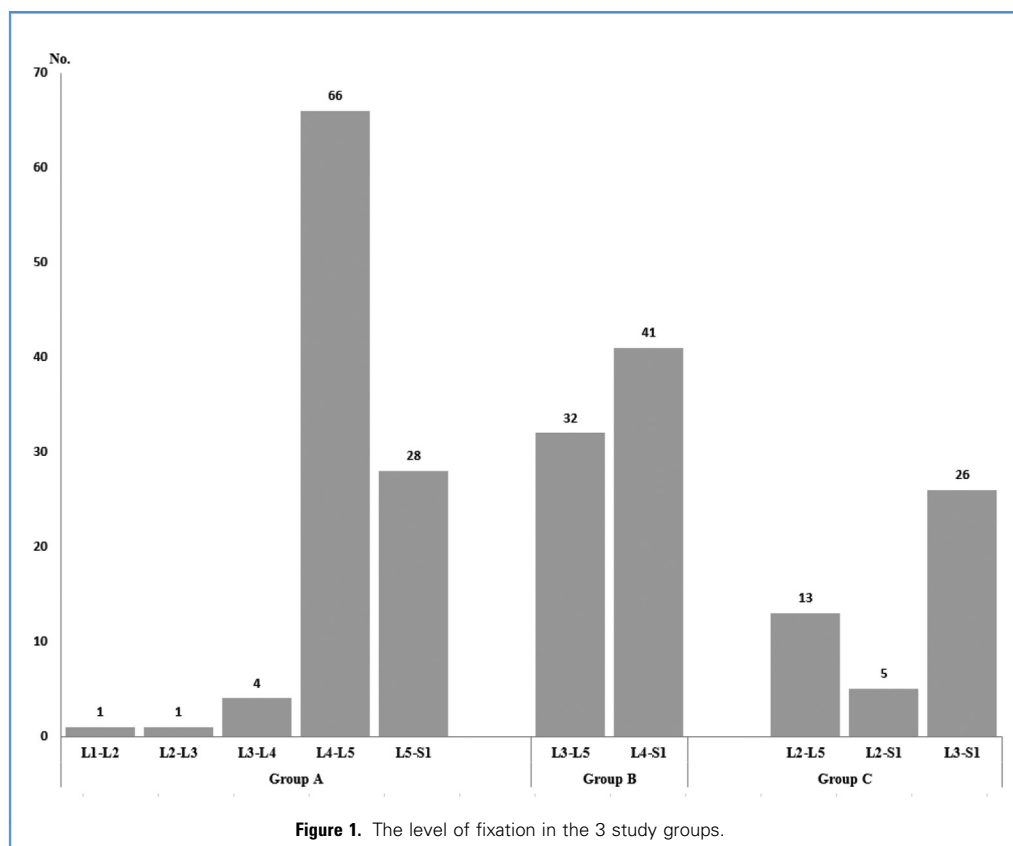


Figure 1. The level of fixation in the 3 study groups.

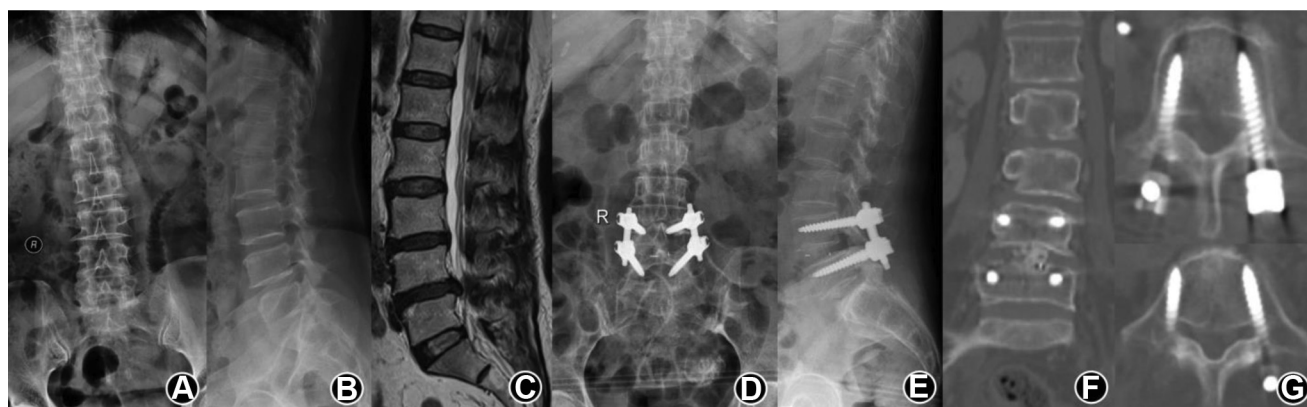


Figure 2. Female, 62-years-old, $T = -3.0$ SD (A, B). Preoperative x-ray image showed lumbar vertebral degeneration and the height of L4-5 vertebrae interval was decreased (C). Preoperative MRI: L4-5 level lumbar disk herniation with spinal canal stenosis (D, E). Postoperative x-ray showed the

internal fixation was in good position and satisfactory improvement of the intervertebral height (F, G). 2.5 years after the operation, the CT illustrated that L4-5 were interbody fusion and the pedicle screws were not loosened.

patients (68%). Four patients (4%) had 6 loosened screws in the caudal vertebrae, and 1 patient had pseudarthrosis at L4-5; thus, the fusion rate was 99.0%. No patient required revision surgery. A typical case is shown in [Figure 2](#).

In group B, 3 patients had transient leg pain; 2 patients had a superficial infection of the skin, and the wound healed by debridement; and 1 patient experienced a dural tear and was discharged after surgical suture repair. In 52 patients (71.23%), CT was used to evaluate the screw loosening rate. Fifteen patients (20.55%) had a total of 25 loosened screws in cranial and (or) caudal vertebrae, and 3 patients had pseudarthrosis at L5-S1 and 1 patient had pseudarthrosis at L4-5, for a fusion rate of 94.52%. One patient required revision surgery (1.37%). A typical case is shown in [Figure 3](#).

In group C, 7 patients had perioperative complications. One patient had an incisional infection, 1 patient developed deep venous thrombosis of the lower extremities, and 5 patients had worsening radiating pain in the lower extremities. Three of these patients recovered after 1 month, but 2 patients still complained of numbness at the last follow-up. In 33 patients (75%), CT was used to evaluate screw loosening. Eighteen patients (40.91%) had 39 screws loosened in cranial and/or caudal vertebrae. Five patients had pseudarthrosis at L5-S1, and 1 patient had pseudarthrosis at L3-5, for a fusion rate of 86.36%. Three patients required revision surgery (6.82%). A typical case is shown in [Figure 4](#).

Overall, the VAS and ODI scores were significantly improved at the last follow-up compared with preoperative values in all 3 groups. At the last follow-up, scores were significantly increased

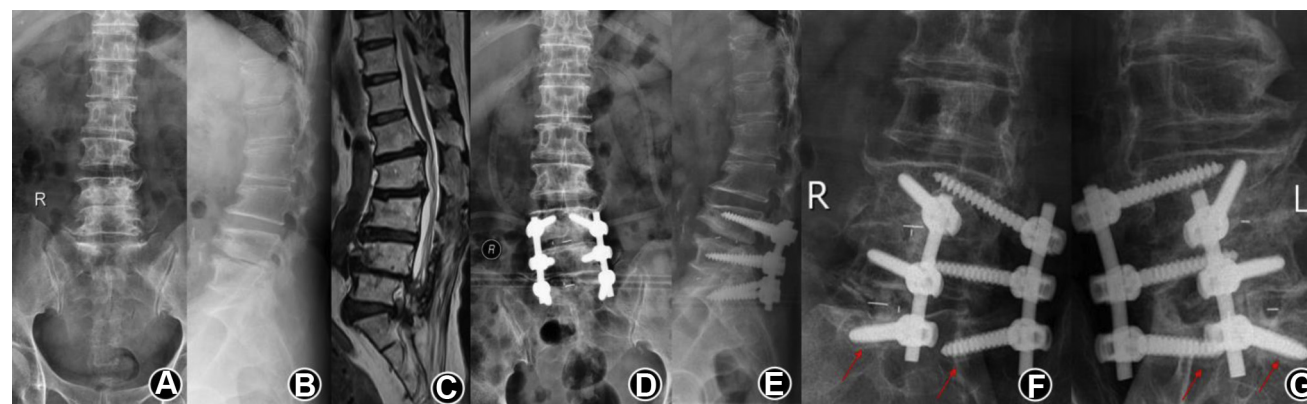


Figure 3. Female, 70-years-old, $T = -2.8$ SD (A, B). Preoperative X-rays showed degenerative changes of lumbar spine and kyphotic deformity in thoracolumbar spine (C). Preoperative MRI showed stenosis in L4-S1 (D, E). The lumbar anterior-posterior radiographs after surgery showed well

position of the internal fixation and good recovery of the intervertebral height (F, G). Three years after the operation, the X-ray illustrated the S1 pedicle screws has loosened in bilateral.

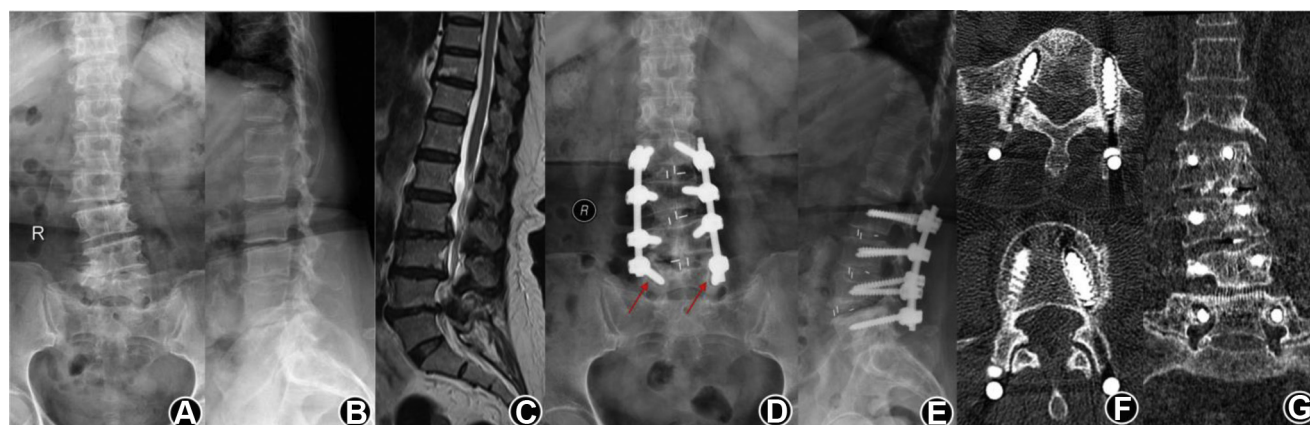


Figure 4. Female, 73-years-old, T= -2.6 SD (A, B). Preoperative X-rays showed degenerative changes and scoliosis in lumbar spine (C). Preoperative MRI showed L2-5 level lumbar disk herniation with spinal canal stenosis (D, E). The lumbar radiographs of 6 months after surgery showed

screws loosening occurred in L5 (F, G). Three years after the operation, CT illustrated L2 pedicle screw has loosened in left and L5 pedicle screw has loosened in bilateral. Meanwhile, L2-3 was interbody fusion, but there was no continuous callus across L3-5.

with the increasing number of fusion segments (group C > group B > group A), including the operative time, blood loss, hospital stay, screw loosening rate, fusion rate, and VAS and ODI scores. The results are presented in **Table 2**.

Moreover, groups B and C were divided into a loosening subgroup and a nonloosening subgroup for further comparisons. Only 23 patients in the loosening subgroup and 48 cases in nonloosening subgroup were enrolled for comparing the spinal-pelvic parameters, because the remaining patients had only lumbar X-rays. **Some parameters, including lumbosacral fixation, larger PI-LL, and greater postoperative PT were found to be independent predictors for screw loosening;** however, sex, BMD, BMI, LL, SS, PI, change in LL, and preoperative PT were not associated with

screw loosening ($P > 0.05$). The results are presented in **Tables 3–5**.

DISCUSSION

Osteoporosis leads to decreased bone trabecula and increased bone fragility, which severely reduce the binding strength of the interface between screws and bone and decrease the pullout strength of pedicle screws.^{6,14-16} Therefore, instrumentation failure, including pseudarthrosis formation and screw loosening or pullout, often occurs in these patients, resulting in an unsatisfactory therapeutic effect and the need for revision surgery in some cases.^{17,18} **The reported rate of pedicle screw loosening**

Table 2. Operation and Clinical Effects

Variable	Group A (N = 100)	Group B (N = 73)	Group C (N = 44)	P Value		
				A versus B	A versus C	B versus C
Operative time (minutes), mean ± SD	184 ± 48.6	222 ± 67.8	287 ± 76.2	0.000	0.000	0.000
Blood loss (mL), mean ± SD	297 ± 96.6	489 ± 99.8	986 ± 137.2	0.000	0.004	0.046
Hospital stay (days), mean ± SD	13.6 ± 6.2	16.4 ± 5.5	20.1 ± 7.9	0.008	0.000	0.025
Complications (number)	6	6	7	0.763	0.066	0.233
Screw loosening (number)	4	15	18	0.001	0.000	0.021
Nonunion patients (number)	1	4	6	0.163	0.003	0.174
VAS at last follow-up, mean ± SD	1.8 ± 0.7*	2.5 ± 1.1*	3.1 ± 0.9*	0.000	0.000	0.004
ODI at last follow-up, mean ± SD	14.8 ± 4.6*	19.8 ± 7.4*	24.5 ± 6.0*	0.000	0.000	0.001

VAS, visual analog scale; ODI, Oswestry Disability Index.

* $P < 0.05$ compared with preoperation.

Table 3. Patient Data in the Loosening and Nonloosening Groups

Variable	Loosening Group (N = 37)	Nonloosening Group (N = 180)		P Value
Sex, male/female, number	4/33	33/147	$\chi^2 = 1.347$	0.342
Age (years), mean \pm SD	69.1 \pm 5.6	71.9 \pm 8.1	$t = 1.601$	0.118
BMD, mean \pm SD	-3.1 \pm 0.6	-2.9 \pm 0.6	$t = 2.042$	0.433
BMI, mean \pm SD	23.5 \pm 3.0	24.0 \pm 2.7	$t = 0.828$	0.654
Lumbosacral fixation, yes/no, number	23/14	77/103	$\chi^2 = 4.647$	0.045
Fusion method, TLIF/PLIF, number	25/12	142/38	$\chi^2 = 2.084$	0.197

BMD, bone mineral density; BMI, body mass index; TLIF, transforaminal lumbar interbody fusion; PLIF, posterior lumbar interbody fusion.

is 0.6%–19.5% in patients without osteoporosis¹ but up to ~60% in patients with osteoporosis.¹⁴ However, few studies have

reported the effect of different fusion levels on the rate of pedicle screw loosening in patients with osteoporosis.

Fixation strength and load are 2 key factors affecting pedicle screw loosening. The fixation strength of pedicle screws depends mainly on the mechanical properties of bone trabeculae between bone and screw, as well as on the geometric properties of screws, including the length, diameter, and thread of implanted screws.^{7,19} The mechanical properties of bone trabeculae are affected mainly by bone quality and time of screw adjustment, which is closely related to sex, age, BMI, medical comorbidities, drug use, and surgeon's skill.¹⁹ On the other hand, the load on pedicle screws is closely related to surgical treatment, fusion levels, spinal and pelvic parameters, and BMI. Therefore, increasing loads usually contribute to the high prevalence of loosening.^{17,20,21}

Our results show that the fusion segment is an important factor in the loosening of pedicle screws. Compared with the single-level fusion group, the rate of pedicle screw loosening was significantly greater in the other 2 groups (4.00% in single-level group A, 20.55% in double-level group B, and 40.91% in multilevel group C), and screw loosening also leads to the formation of pseudarthrosis. Moreover, loosening occurred more often in the cranial vertebrae (15 cases) and caudal vertebrae (55 cases), and much more frequently with caudal screws (78.57%), in concordance with previous studies.^{15,21} The cause of this trend may be related to the mechanical overload on cranial and caudal pedicle screws, which may result in a concentration of stress on lumbosacral segments. Therefore, several pedicle screw fixation techniques, such as expansive pedicle screw, cement-augmented pedicle screw, and assistance of a lamina hook may be recommended for double-level or multilevel fixation in patients with an osteoporotic spine, which is aimed at improving the anchoring strength and limiting the risk of loosening.^{7,22}

Lumbosacral fixation is another independent risk factor for screw loosening. Pedicle screw fixation across the lumbosacral junction is widely used in patients without osteoporosis to facilitate fusion and postoperative rehabilitation; however, this technique is associated with a high rate of postoperative screw loosening and backout when used in patients with osteoporosis.^{23,24} This may be related to anatomic and biomechanical factors: first, the lumbosacral area is the region of stress concentration; second, S1 pedicles have a larger diameter and

Table 4. Spinopelvic Parameters in the Loosening and Nonloosening Groups

Parameter	Loosening Group (N = 23)	Nonloosening Group (N = 48)	t Value	P Value
LL (°)				
Preoperation	36.0 \pm 15.4	39.9 \pm 14.7	$t = -0.919$	0.362
Postoperation	38.8 \pm 12.8	41.1 \pm 11.6	$t = -0.647$	0.521
Change in LL	2.8 \pm 10.4	1.2 \pm 8.8	$t = 0.616$	0.541
SS (°)				
Preoperation	36.1 \pm 11.7	37.0 \pm 9.7	$t = -0.304$	0.763
Postoperation	36.0 \pm 11.0	37.1 \pm 9.6	$t = -0.377$	0.708
PT (°)				
Preoperation	20.9 \pm 9.9	16.1 \pm 10.8	$t = 1.653$	0.105
Postoperation	20.9 \pm 10.1	15.5 \pm 6.4	$t = 2.318$	0.025
PI (°)				
Preoperation	57.8 \pm 17.1	54.0 \pm 13.0	$t = 0.900$	0.372
Postoperation	58.5 \pm 17.2	54.2 \pm 13.0	$t = 0.991$	0.326
PI-LL (°)				
Preoperation	21.8 \pm 11.9	14.2 \pm 11.6	$t = 2.319$	0.025
Postoperation	19.6 \pm 9.7	13.2 \pm 7.3	$t = 2.665$	0.010

LL, lumbar lordosis; SS, sacral slope; PT, pelvic tilt; PI, pelvic incidence.

Table 5. Multivariate Logistic Analysis Results for the Loosening Group

Factor	OR (95% CI)	P Value
Lumbosacral fixation (yes/no)	2.20 (1.06–4.55)	0.034
Postoperative PT	0.92 (0.85–0.99)	0.034
Preoperative PI-LL	0.94 (0.90–0.96)	0.033
Postoperative PI-LL	0.92 (0.85–0.98)	0.016

OR, odds ratio; CI, confidence interval; PT, pelvic tilt; PI, pelvic incidence; LL, lumbar lordosis.

shorter length than the lumbar pedicles, and the bone–screw interface is usually located in the weaker trabecular bone of the sacrum. Therefore, screw loosening is a common complication in patients with osteoporosis undergoing pedicle screw fixation across the lumbosacral junction.

Recent studies have also found that abnormal spinal-pelvic parameters limit the effectiveness of spinal surgeries. The increase of local stress in the sagittal curves would lead to the increased risk of screw loosening and pseudo articulation formation.^{13,23} It is generally accepted that PI is unchangeable in adulthood, and the sagittal balance of the spine is maintained mainly by the changes in LL, SS, and PT.^{8,13} High PI is normally associated with early-stage degeneration, and the recovery of LL after surgery contributes to reducing the incidence of low back pain and screw loosening.¹³ Therefore, **when LL is smaller and PI is larger, the imbalance between the spine sagittal alignment increases the load on the screws, which may lead to loosening.**^{8,22} Excessive PT leads to hyperflexion and increases the load on the lumbosacral segments, leading to screw loosening.^{13,23} Therefore, patients with such risk factors as

lumbosacral fixation and larger preoperative and postoperative PI-LL and PT should be treated with a cautious surgical strategy, as well as close follow-up and regular antiosteoporosis treatment.

The small number of patients and the retrospective study design are the major drawbacks of the present study. The sagittal parameters were incomplete in some patients, and we did not analyze adjacent segment degeneration, fracture, or cage subsidence. The loosening rate might be lower in clinical practice, considering that our data are mainly from symptomatic patients or those with obvious implant failure, whereas patients without screw loosening may be reluctant to pursue follow-up and thus are rarely enrolled in studies. Moreover, we prefer to use polymethylmethacrylate-augmented pedicle screws for patients with lower BMD.

CONCLUSION

As the spinal fusion length increased, the rate of screw loosening and fusion, as well as VAS and ODI scores at follow-up, were significantly increased in osteoporotic patients with double-level or multilevel pedicle screw fixation, and thus the clinical effect decreased during the follow-up. Therefore, an instrument with stronger holding strength at cranial and caudal pedicle screws is recommended for those patients, especially in cases with larger PI-LL, larger PT, and lumbosacral fixation.

CRediT AUTHORSHIP CONTRIBUTION STATEMENT

Hui-zhi Guo: Conceptualization, Methodology. **Yong-chao Tang:** Conceptualization, Methodology. **Dan-qing Guo:** Data curation, Writing - original draft, Writing - review & editing. **Yan-huai Ma:** Data curation, Writing - original draft. **Kai Yuan:** Visualization, Investigation. **Yong-xian Li:** Data curation, Writing - original draft. **Jian-cheng Peng:** Supervision. **Jing-lan Li:** Visualization, Investigation. **De Liang:** Supervision. **Shun-cong Zhang:** Writing - review & editing.

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