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Predictive factors of distal pedicle screw loosening followed posterior corrective surgery for degenerative lumbar scoliosis

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Abstract

Introduction To explore incidence and predictive factors for distal pedicle screw loosening (DPSL) followed posterior corrective surgery for degenerative lumbar scoliosis (DLS).

Methods The diagnostic criteria for DPSL developed by X-ray including radiolucent area around screw and "double halo" sign. According to occurrence of DPSL at two-year follow-up, 153 patients were divided into two groups: study group (screw loosening) and control group (without screw loosening). To investigate predictive factors for DPSL, three categorized factors including general data, surgical data and radiological data were analyzed statistically.

Results DPSL was detected in 72 patients at two-year follow up (study group). Hounsfield unit (HU) value was lower in study group than that in control group. Fusion level was longer in study group than that in control group. Lower instrumented vertebrae on L5 was less in study group than that in control group. Posterolateral fusion was less in study group than that in control group. Preoperative Cobb angle, postoperative Cobb angle, Cobb angle correction, preoperative lumbosacral coronal angle (LSCA), LSCA correction, preoperative thoracolumbar junction (TL), postoperative TL were larger in study group than those in control group. Logistic regression analysis revealed that low Bone mineral density (BMD) (< 169 HU), posterolateral fusion, Cobb angle correction (> 16 degrees), LSCA correction (> 9 degrees) were independently associated with DPSL.

Conclusions The incidence of DPSL following posterior decompression and instrumented fusion for DLS is 47.1%. Low BMD, large correction of both main curve and fractional curve are predictive factors for DPSL, posterolateral fusion is a protective factor.

Keywords Distal pedicle screw loosening, Posterior decompression and instrumented fusion, Degenerative lumbar scoliosis

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Introduction

Posterior decompression and instrumented fusion is supposed to be the most commonly used surgical procedure for degenerative lumbar disease [1]. Screws loosening is one of the frequently reported typical complication of pedicle screws fixation that is associated with the necessity of the revision surgery, and usually occurs in the cranial and caudal vertebrae of the long fusion, much more frequent in caudal screws [2]. The frequency of screw loosening has varied widely in different studies, which ranged from less than 1–15% in non-osteoporotic patients and even up to 60% in osteoporotic spines [3, 4]. Screw loosening may lead to pseudarthrosis, nonunion, loss of correction, revision surgery, and therefore need to be paid specific attention [5]. Bone mineral density (BMD) is supposed to be an important factor influencing the stability of pedicle screws [6]. Wittenberg et al. [7] proved that early loosening of pedicle screws may be expected at a BMD less than 90 mg/mL, as measured by quantitative computed tomography. The majority of studies were focused on impact of BMD on the occurrence of screws loosening, however, it has been proven that bone quality is not the only contributing factor [8, 9]. Several other factors affecting the stability of pedicle screws, such as the length, outer diameter, design, fitness in the pedicle, elasticity of the cancellous bone, were supposed to potentially influence the development of screw loosening. Knowledge of these risk factors is very important for minimizing the occurrence of screw loosening and to allow surgeons to take measures for its prevention when possible.

Degenerative lumbar scoliosis (DLS) is characterized as three-dimensional deformity, including axial rotation, coronal and sagittal vertebral tilting, and presents not only scoliotic deformity on coronal plane, but also lumbar hypo-lordosis on sagittal plane [10]. Scoliosis correction and lumbar lordosis reconstruction mainly depend on pedicle screw compression and distraction. Whether these surgical manipulation increase the risk of pedicle screw loosening is unknown. Although previous reports have alerted spine surgeons about screw loosening subsequent to posterior decompression and instrumented fusion, very few published reports describing specific risk factors that need to be taken into account to avoid this undesirable event for DLS patients. The aim of this study was therefore to explore the incidence and possible predictive factors for distal pedicle screw loosening (DPSL) following posterior decompression and instrumented fusion for DLS, and hope to provide references in decision making and surgical planning for spine surgeons.

Materials and methods

Patients

This was a retrospective study of prospective collected data at our hospital and was approved by the Institutional Review Board of our hospital in accordance with the Declaration of Helsinki before data collection and analysis. This study was approved by the Ethics Committee of the Third Hospital of Hebei Medical University (Ke 2022-128-1). Written consent for participation of this study was available if required at any time. One hundred and fifty-three consecutive DLS patients surgically treated between January 2013 and July 2018 were retrospectively reviewed. Inclusion criteria: (1) DLS patients treated by posterior instrumented fusion with pedicle screws. (2) follow-up duration more than two years with radiological data including antero-posterior (A/P) and lateral X-ray at preoperation, early postoperation, and two-year follow-up. Exclusion criteria: (1) patients with spinal deformities derived from idiopathic scoliosis, ankylosing spondylitis, neuromuscular diseases, infections, or scheuermann kyphosis. (2) patients treated with anterior or lateral lumbar fusion surgery, minimally invasive lumbar fusion surgery. (3) posterior instrumentation include iliac screw (IS) or sacral-alar-iliac (S2AI). Every patient provided a informed consent to participate this study before enrollment.

Clinical and radiological evaluation

The diagnostic criteria for DPSL developed by X-ray include the radiolucent area (thicker than 1 mm) around screw and the "double halo" sign defined as the presence of radiolucent area and radiopaque rim at the same X-ray [11, 12]. (Fig. 1) The first three authors resolved all ambiguities by consensus. According to the occurrence of DPSL at two-year follow-up, patients were divided into two groups: study group (screw loosening) and control group (without screw loosening). To investigate predictive factors for distal pedicle screw loosening, three categorized factors were analyzed statistically.

Patient general data including age, sex, body mass index (BMI), BMD, comorbidity (hypertension, diabetes, coronary heart disease) were investigated. BMD was evaluated by Hounsfield unit (HU) value on L1, which was performed via a previously described technique using Philips Easy Vision Picture Archiving and Communication System (PACS) [13]. This protocol records HU on axial images at three levels within the vertebral body: immediately caudal to the superior end plate, mid-body, and cranial to the inferior end plate. (Fig. 2) For each measurement, the largest possible elliptical region of interest was drawn, excluding the cortical margins to prevent volume averaging.

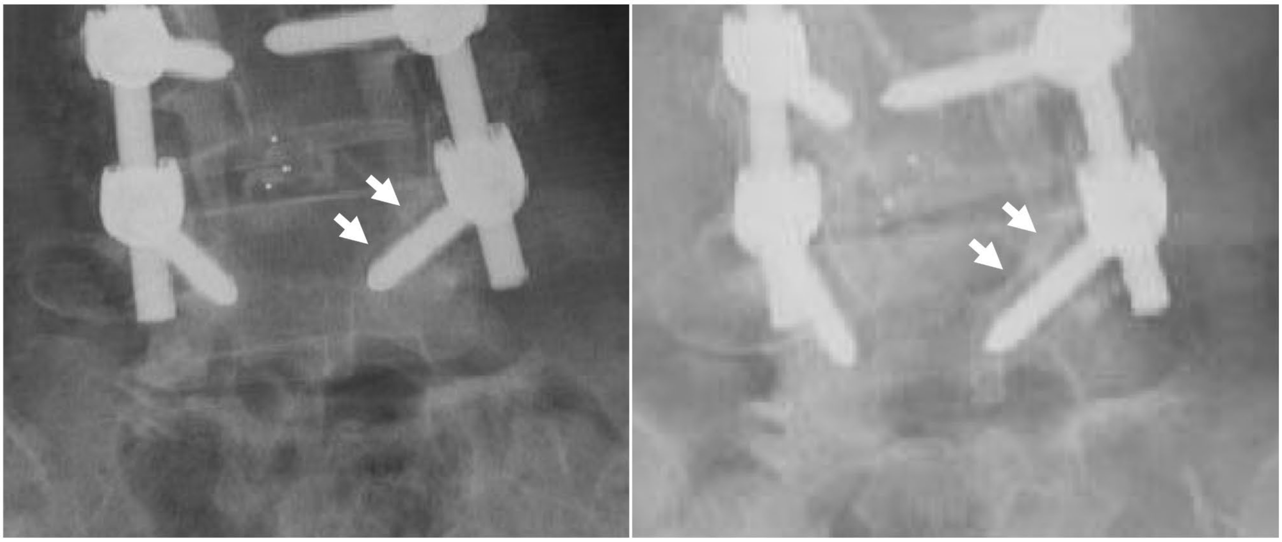

Fig. 1 **Left: A** halo zone sign (arrows) was defined as radiolucent area (thicker than 1 mm) around screw, indicated loosening of the left L5 pedicle screw. **Right: A** double halo sign (arrows) further confirmed the loosening, described as a radiolucent rim surrounding the screw that is framed by the rim of radiopaque dense bone trabiculae

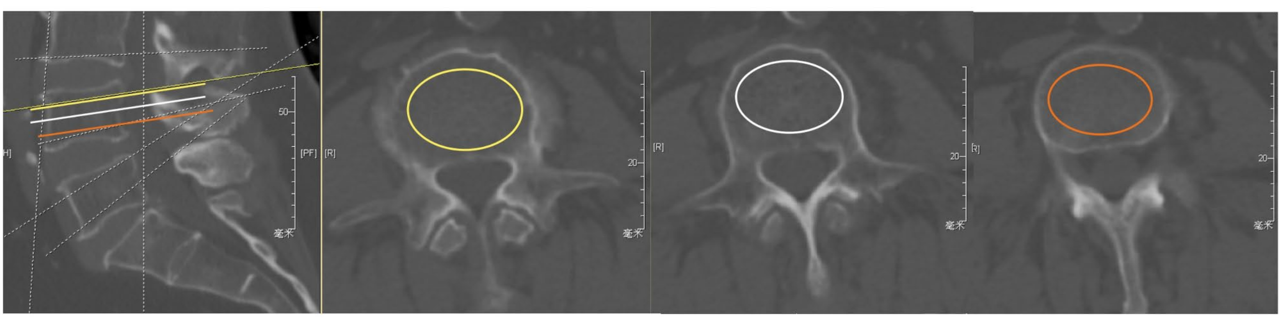

Fig. 2 The trabecular HU measurement was performed on axial images at three levels within the vertebral body: immediately caudal to the superior end plate, mid-body, and cranial to the inferior end plate. For each measurement, the largest possible elliptical region of interest was drawn, excluding the cortical margins to prevent volume averaging

Surgical data including surgery time, estimated blood loss, fusion level, lower instrumented vertebrae (LIV), Posterolateral fusion were reviewed.

Radiological data were evaluated at pre-operation, early post-operation, two years post-operation. Cobb's angle was measured using lines projected from the upper border of the most tilted vertebra above and lower border of the most tilted vertebra within the main curve. Lumbosacral coronal angle (LSCA) was measured using lines projected from the upper border of L4 and upper border of S1 on P/A X-ray. Coronal balance distance (CBD) was measured as the distance between C7 plumb line and center sacral vertical line. Lumbar lordosis (LL) was measured from T12 inferior endplate to S1 superior endplate by the Cobb method on lateral X-ray. Thoracolumbar junction (TL) was measured from T10 superior endplate to L2 inferior endplate on lateral X-ray. Pelvic incidence (PI) was defined as the angle between the line perpendicular to the sacral plate and the line connecting the midpoint of the sacral plate to the bicoxofemoral axis. Sacral slope (SS) was the angle between the S1 superior endplate and a horizontal line. Sagittal vertical axis (SVA) was the distance from C7 plumb line to the perpendicular line drawn from superior posterior endplate of S1. (Fig. 3)

Statistical analysis

Data were analyzed using Statistical Product and Service Solutions software (version 17; SPSS, Chicago, IL). Continuous variables were measured as mean ± standard deviation, and categorical variables were expressed as frequency or percentages. An independent t test was used to analyze the difference of continuous variables between two groups. An χ2 analysis and Fisher's exact test were used to examine the differences among categorical variables. Binary Logistic regression analysis was used to analyze the assumed predictive factors with backward elimination, in which variables with a significance

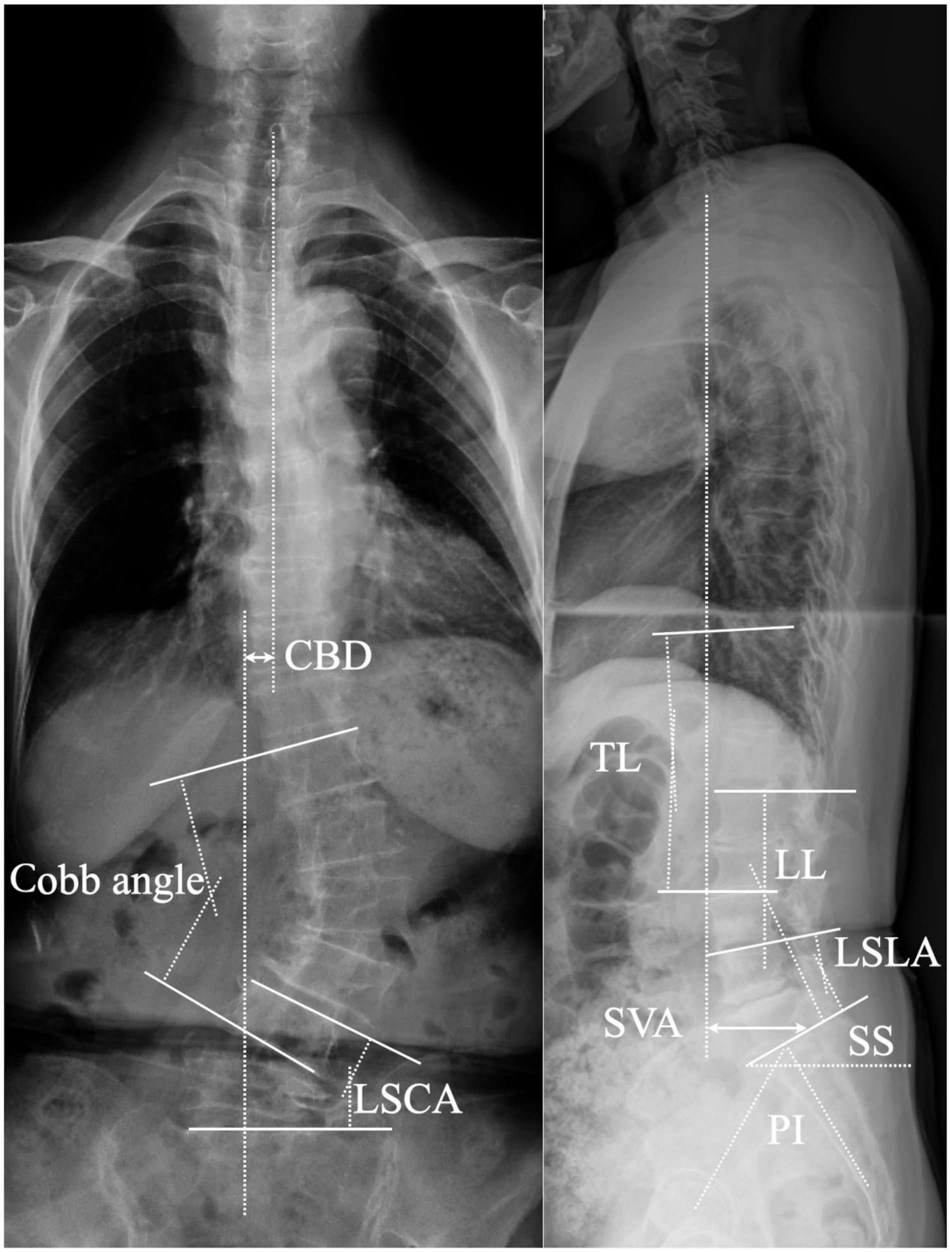

Fig. 3 The radiological data measured on the P/A X-ray include Cobb's angle, lumbosacral coronal angle (LSCA) and coronal balance distance (CBD). The radiological data measured on the P/A X-ray include lumbar lordosis (LL), thoracolumbar junction (TL), pelvic incidence (PI), sacral slope (SS) and sagittal vertical axis (SVA)

level of >0.10 were removed. The confidence interval of the odds ratio (OR) was 95%.

Result

DPSL was detected in 72 of 153 patients (47.1%) at two-year follow up, and were enrolled as study group. Another 81 patients presented no screw loosening at two-year follow up, and were enrolled as control group. (Figures 4 and 5)

There was no statistically significant difference between the two groups in age at operation, sex, BMI, comorbidity. The HU value on L1 was lower in study group than that in control group. (Table 1)

There was no statistically significant difference between the two groups in mean surgery time, estimated blood loss. Fusion level was longer in study group than that in control group. The LIV on L5 was less in study group than that in control group. Posterolateral fusion was less in study group than that in control group. (Table 2)

The preoperative Cobb angle, postoperative Cobb angle, correction of Cobb angle, preoperative LSCA, correction of LSCA, preoperative TL, postoperative TL were

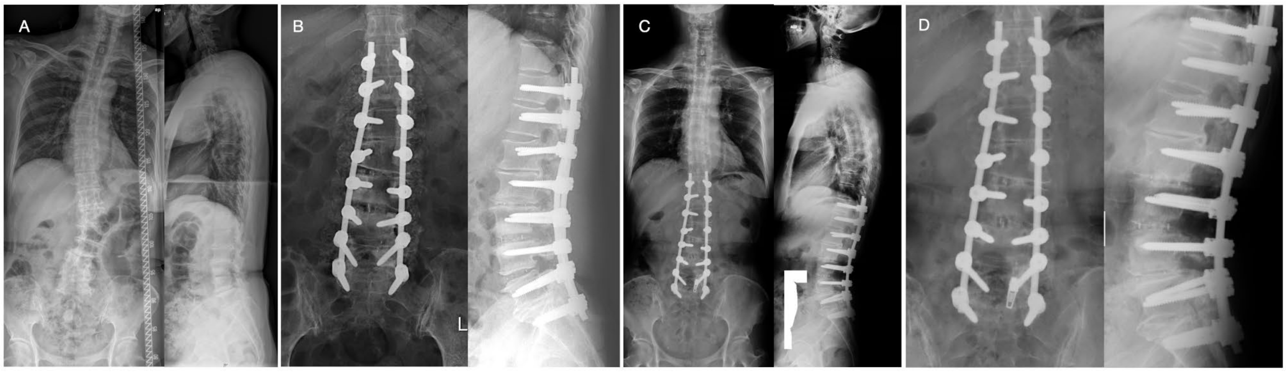

Fig. 4 The patient, BMD on L1 vertebrae = 178 HU. (**A**) Preoperative Cobb's angle was 31 degrees, CBD was 47 mm, LSCA was 22 degrees, LL was 26 degrees. (**B**) He underwent posterior decompression and instrumented fusion (T11-S1) with bilateral posterolateral fusion. At postoperative, Cobb's angle was 8 degrees, LSCA was 7 degrees. (**C**) At one-year follow up, Cobb's angle was 7 degrees, CBD was 18 mm, LL was 34 degrees. (**D**) At two-year follow up, posterolateral arthrodesis was satisfactory, and no distal pedicle screw loosening was detected

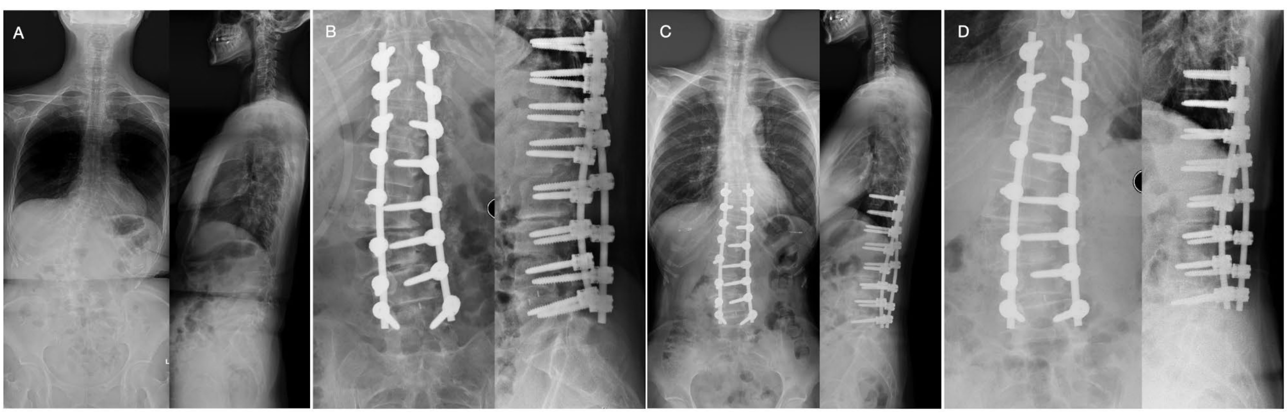

Fig. 5 The patient, BMD on L1 vertebrae = 129 HU. (**A**) Preoperative Cobb's angle was 55 degrees, CBD was 23 mm, LSCA was 23 degrees, LL was − 14 degrees. (**B**) He underwent posterior decompression and instrumented fusion (T10-L5) with left posterolateral fusion. At postoperative, Cobb's angle was 22 degrees, LSCA was 7 degrees. (**C**) At one-year follow up, Cobb's angle was 24 degrees, CBD was 10 mm, LL was 6 degrees. (**D**) At two-year follow up, posterolateral arthrodesis was not satisfactory, loosening of bilateral L5 pedicle screw was detected

Table 1 Comparison of general data between study and control groups

	Study group	Control group	statistic	*p* value
Number of cases	72	81	—	—
Age	62.8 ± 6.6	64.7 ± 6.7	-1.657	0.100
Sex (M/F)	17/55	21/60	0.109	0.741
BMI	25.7 ± 3.3	26.7 ± 3.4	-1.119	0.268
BMD (HU value on L1)	135.8 ± 57.8	198.9 ± 66.6	-6.222	< 0.001
Comorbidity				
Hypertension (yes/no)	27/45	32/49	0.065	0.799
Diabetes (yes/no)	18/54	19/62	0.050	0.824
Coronary heart disease (yes/no)	9/63	11/70	0.039	0.843

Table 2 Comparison of surgical data between study and control groups

	Study group	Control group	statistic	*p* value
Surgery time (min)	226.2 ± 37.6	215.5 ± 83.9	0.638	0.527
Estimated blood loss (mL)	792.5 ± 371.5	711.2 ± 386.5	0.805	0.424
Fusion level	6.8 ± 1.8	5.5 ± 1.5	4.940	< 0.001
LIV (L5/S1)	25/47	45/36	6.666	0.010
Posterolateral fusion (yes/no)	4/68	43/38	40.463	< 0.001

Table 3 Comparison of peri-operative radiological data between study and control groups

	Study group	Control group	statistic	p value
Cobb angle				
Preoperative value	32.1 ± 11.1	25.3 ± 11.6	3.618	< 0.001
Postoperative value	12.8 ± 7.4	8.9 ± 6.3	2.837	0.005
Correction	21.9 ± 10.9	17.6 ± 10.8	2.440	0.016
Lumbosacral coronal angle	LSCA			
Preoperative value	17.7 ± 5.9	13.3 ± 3.8	5.528	< 0.001
Postoperative value	6.7 ± 3.7	6.3 ± 2.9	0.745	0.458
Correction	10.9 ± 4.4	7.0 ± 2.6	6.835	< 0.001
CBD				
Preoperative value	19.4 ± 13.2	23.4 ± 19.5	-1.076	0.285
Postoperative value	8.5 ± 7.3	10.4 ± 7.6	-0.810	0.422
Correction	7.1 ± 13.6	7.3 ± 16.2	-0.083	0.934
LL				
Preoperative value	-3.1 ± 29.7	3.0 ± 30.2	-1.227	0.222
Postoperative value	10.9 ± 38.7	17.5 ± 36.4	-4.242	0.427
Correction	12.5 ± 21.6	15.7 ± 18.7	-1.569	0.519
TL				
Preoperative value	18.7 ± 14.7	13.5 ± 12.5	2.278	0.024
Postoperative value	16.3 ± 9.2	11.8 ± 11.3	2.307	0.023
Correction	-5.9 ± 14.8	-4.5 ± 11.1	-0.671	0.503
PI	46.5 ± 10.9	47.7 ± 11.6	-0.593	0.554
SS				
Preoperative value	24.7 ± 9.8	24.3 ± 10.6	0.019	0.985
Postoperative value	28.7 ± 8.0	30.1 ± 8.1	-0.899	0.370
Correction	-0.4 ± 14.4	-1.3 ± 14.8	0.344	0.731
SVA (mm)				
Preoperative value	50.6 ± 57.1	37.9 ± 39.4	1.582	0.116
Postoperative value	28.4 ± 28.9	16.2 ± 30.1	1.880	0.064
Correction	30.5 ± 53.2	28.1 ± 42.1	0.316	0.752

Table 4 Risk factors for pedicle screw loosening, identified by logistic regression analysis

Risk factors	Odds ratio [95% CI]	p value
BMD (HU value on L1)	10.672 [2.064–55.188]	0.005
Posterolateral fusion	0.013 [0.001–0.126]	< 0.001
Fusion level	0.223 [0.038–1.299]	0.095
Preoperative Cobb angle	3.504 [0.349–35.176]	0.287
Postoperative Cobb angle	0.158 [0.014–1.785]	0.136
Correction of Cobb angle	7.197 [1.028–50.389]	0.047
Preoperative lumbosacral coronal angle	1.708 [0.324–9.105]	0.528
Lumbosacral coronal angle correction	7.202 [1.075–48.260]	0.042
Preoperative TL	0.262 [0.048–1.450]	0.215
Post-operative TL	2.491 [0.226–27.457]	0.456
LIV (L5/S1)	1.379 [0.965–1.971]	0.077

larger in study group than those in control group. There was no statistically significant difference in postoperative LSCA, preoperative CBD, postoperative CBD, correction of CBD, preoperative LL, postoperative LL, correction of LL, correction of TL, PI, preoperative SS, postoperative SS, correction of SS, preoperative SVA, postoperative SVA, correction of SVA between the two groups. (Table 3)

The following variables were entered into the Logistic regression model: BMD (HU value on L1), fusion level, LIV, posterolateral fusion, preoperative Cobb angle, postoperative Cobb angle, correction of Cobb angle, preoperative LSCA, correction of LSCA, preoperative TL, postoperative TL. Binary Logistic regression model revealed that BMD (< 169 HU), posterolateral fusion, correction of Cobb angle, LSCA correction were independently associated with DPSL. (Table 4)

Table 5 Comparison of back/leg pain between study and control groups

	Study group	Control group	statistic	*p* value
Back pain VAS				
Preoperative	6.39 ± 0.92	6.53 ± 0.89	-1.857	0.204
2-week postoperative	3.28 ± 0.44	3.45 ± 0.51	-1.689	0.225
Final follow up	1.19 ± 0.15	1.27 ± 0.18	-1.801	0.218
Leg pain VAS				
Preoperative	7.84 ± 1.14	7.98 ± 1.30	-1.069	0.342
2-week postoperative	2.85 ± 0.36	2.98 ± 0.51	-1.137	0.319
Final follow up	0.73 ± 0.09	0.88 ± 0.11	-1.574	0.283

There was no statistically significant difference between the two groups in age at operation, sex, BMI, comorbidity. The HU value on L1 was lower in study group than that in control group. (Table 5)

Discussion

In the current study, 47.1% of the patients (72/153) presented DPSL followed posterior decompression and instrumented fusion for DLS, we found that low BMD, large correction of both main curve and fractional curve, posterolateral fusion was significantly and independently associated with the occurrence of DPSL, and can be assessed before surgery, these results were not confounded by other variables potentially affect DPSL. Notably, the DPSL did not affect the recovery of lower back pain and leg pain.

A critical point for the investigation of screw loosening is the assessment of whether a screw is loosened or not, planar radiographs are most commonly used, whereas a significant minority of papers employed clinical CT or low-dose CT [14]. Potential health risks associated with increased radiation exposure as well as financial costs limit postoperative CT use to selected patients with persistent symptoms or where there is specific concern regarding the possibility of implant-related complications. Wu et al. proved that CT might not be superior to X-ray in assessment of screw loosening, especially considering its higher cost and radiation exposure, as X-ray had a sensitivity of 24% and a specificity of 98%, while CT scan had a sensitivity of 22% and a specificity of 95% regarding extraction torque as criterion of screw loosening [15]. Sanden et al. reported that a radiolucent zone around a PS is a good indicator of screw loosening [16]. That is the reason why we chose plain radiographs to evaluate pedicle screw loosening in the present study.

Since its first description by Watkins in 1953, the technique of posterolateral fusion (PLF) has evolved into the widely adopted method of lumbar arthrodesis for degenerative disease [17]. Tsirikos et al. proved that posterolateral arthrodesis in situ with autologous iliac crest bone without instrumentation achieved a solid fusion and produced excellent clinical outcomes and high patient satisfaction [18]. Moreover, the use of pedicle screw fixation to support the PLF could achieve fusion rates as high as 96% [19]. Addition of interbody fusion via a transforaminal approach (TLIF) has become a popular surgical option for treatment of degenerative lumbar conditions. Although technically more complicated than PLF, it has been suggested that TLIF provides superior immediate stability and protects against early pedicle screw loosening. Kim et al. proved that TLIF appears to have a protective effect in reducing rates of early screw loosening by approximately 60% versus PLF [20]. A retrospective study comparing the outcomes between TLIF and PLF found that the PLF construct was more prone to induce instrument breakage and pseudoarthrosis compared with the TLIF technique, indicating the importance of anterior column support in the maintenance of construct stability [21]. In recent years, TLIF has replaced PLF to be the most commonly used lumbar fusion surgery [22]. However, postoperative screw loosening was not completely avoided, especially in patients undergoing long segment pedicle screw fixation. Results from the current study suggest that supplementing the TLIF with PLF potentially reduces the rates of DPSL followed corrective surgery for DLS. Following decortication of transverse processes and posterolateral bone, morselized local autograft was placed in the posterolateral intertransverse space in order to create posterolateral arthrodesis, which could reduce the segmental motion of posterior spinal column, and minimize the risk of screw loosening. This is particularly important in patients with poor bone quality, such as those with osteoporosis, where the risk of screw loosening is inherently higher.

It has been widely accepted that osteoporosis is a potential risk factor for pedicle screw loosening. Fixation failure rates due to screw loosening range from 1 to 15% and can rise in osteoporotic spines for which the strength of fixation with pedicle screws decreases along with lower bone density [3, 4]. In a study of osteoporotic cadavers, pedicle screw pullout strength was found to be highly correlated with BMD [23]. BMD measuring with DEXA scans could not perform differentiation of the cancellous bone from the cortical bone, T-scores can be overestimated due to abdominal vessel wall calcification, degenerative bony spurs, and facet hypertrophy. It has been proved that older patients or patients with degenerative lumbar scoliosis are more likely to have unreliable lumbar T-scores [24]. Measuring HU from computed tomography has been proposed as a useful technique for assessing vertebral bone quality, the reliability and accuracy of HU to determine osteoporosis have been proved in the literature with many reports [25, 26]. In the current study, our findings are consistent with Jan et al. that the determination of bone density by HU value could predict the risk of screw loosening and inform the decision to use cement augmentation to reduce the incidence of screw loosening [27]. Preoperative routine HU-based BMD assessments for all patients undergoing interbody fusion procedures is recommended, which could identify potential risk of pedicle screw loosening and take necessary vertebral reinforcement measures to reduce these risks at preoperative. Screw augmentation with bone cement as well as expandable screws demonstrated improved screw pullout stability, better fixation strength and clinical results in comparison with standard pedicle screws in human cadaver material in vitro [28, 29].

The typical major curve of DLS always lies in the mid-lumbar spine, it is always compensated by a distal curve at the lumbosacral region as the body attempts to maintain coronal balance, named the fractional curve. Both pedicle screws compression at the convex side and pedicle screws distraction at the concave side could achieve correction of the main curve and fractional curve. No matter which technique is used, the cutting effect of pedicle screw on bone should not be ignored. The more scoliosis correction, the greater the cutting effect of pedicle screw on bone, and the greater the risk of pedicle screw loosening. Based on our previous study, we put forward two suggestions. Firstly, asymmetrical vertebral degeneration in DLS patients is manifested as high HU value within concavity and low HU value within convexity both in major and fractional curve. Concave side of the vertebrae theoretically withstand more cutting forces than convex side based on the HU value measurement, distraction of pedicle screws at concave side should be a priority to correct both main curve and fractional curve [30]. Secondly, inadequate release of the posterior spinal bone elements in PLIF or TLIF technique may hinder the correction of the fractional curve, because the lumbosacral junction tends to be particularly rigid and may already be fused into an abnormal position. Posterior column osteotomy facilitates effective correction of the scoliosis through complete release of dural sac as well as the asymmetrical intervertebral reconstruction by cage is recommended [31].

There are several potential limitations in this study. First, the number of patients is relatively small, and the study may be under powered to detect the significance of some risk factors. Second, the study was conducted retrospectively by case selection, and was not randomized and controlled, the subjects selected are all Chinese Han individuals, whether the conclusion is applicable to other ethnic groups needs to be further investigated in the future. Based on the findings in the current study, three suggestions are provided for surgical planning. Firstly, screw augmentation with bone cement or expandable screws is recommended for patients with patients with low BMD, especially when the BMD less than 169HU. Secondly, posterior column osteotomy plus unilateral cage strutting technique on the concavity is recommended for scoliosis correction, screw distraction instead of compression should be preferred. Thirdly, posterolateral fusion is recommended for DLS patients that underwent posterior long segment fusion.

Conclusion

The incidence of DPSL following posterior decompression and instrumented fusion for DLS is 47.1%. Low BMD, large correction of both main curve and fractional curve are predictive factors for DPSL, posterolateral fusion is a protective factor.

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This research was performed in Hebei Medical University Third Hospital only.

Author contributions
HRY was responsible for interpreting results and writing this article. YLL, CJD and PXY was responsible for data collection, statistics analysis. YCH and DZ were responsible for English editing. HW were responsible for designing the search strategy, evaluating the articles and English editing.

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Data availability
The datasets will be available from the corresponding author if required.

Declarations

Ethics approval and consent to participate
Ethics Committee of the Hebei Medical University Third Hospital approved this study in accordance with the Declaration of Helsinki before data collection and analysis (Ke 2022-128-1). Every patient provided a informed consent to participate this study before enrollment.

Competing interests
The authors declare that they have no competing interests

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