Original Article
Clinics in Orthopedic Surgery 2023;15:92-100 • https://doi.org/10.4055/cios21229

Computed Tomography Evaluation of Percutaneous Pedicle Screws Inserted during Minimally Invasive Transforaminal Lumbar Interbody Fusion: Long-term Follow-up Results of Screw Violation

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Background: To evaluate the accuracy of percutaneous pedicle screw (PPS) insertion in degenerative lumbar disease treated with minimally invasive transforaminal lumbar interbody fusion (MI-TLIF) and to analyze risk factors and long-term clinical outcomes of screw violation.

Methods: Sixty-two consecutive patients (262 screws) were included. Based on postoperative computed tomography (CT) axial images, a PPS that perforated out of the pedicle was classified into a violation group, while screws surrounded by pedicular cortical bone were classified into a correct group. A logistic regression model was used for risk factor analysis of violation. We also observed the long-term clinical outcomes using the Oswestry disability index and visual analog scale.

Results: Of the 262 screws, 14 (5.3%) were considered to be violated (10 medial violations and 4 lateral violations). All violations of S1 and L5 were in the medial direction. In contrast, entire violations of L4 were always lateral and of the 2 violations of L3, one was lateral and the other was medial. There were no cases of superior or inferior violation. The mean pedicle convergence angle (CA) was significantly higher in the violation group (mean ± standard deviation, 27.0° ± 6.2°) than in the correct group (21.7° ± 5.4°). There were no significant differences according to vertebral rotational angle, body mass index, bone mineral density, and surgical timing (learning curve) between the two groups. Logistic regression analyses demonstrated that a high CA was a significant risk factor for pedicle wall violation ($p = 0.002$). There were no significant differences in clinical or radiographic results between the two groups in 60 patients who were followed up for more than 1 year and in 40 patients who were followed up for more than 5 years. There were 2 patients who required reoperation to replace a screw due to leg pain.

Conclusions: With PPS insertion during MI-TLIF, the rate of pedicle violation was 5.3% (14/262). An understanding of the anatomical characteristics of each vertebra and the unique structures of the patient is essential to prevent pedicle violations. Even in the violation group, PPS fixation was found to be a safe and useful procedure with successful long-term radiographic and clinical outcomes.

Keywords: *Lumbar vertebrae, Percutaneous pedicle screws, Transforaminal lumbar interbody fusion, Minimally invasive surgical procedures, Adverse effects*

Received December 4, 2021; Revised May 4, 2022; Accepted June 6, 2022

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Percutaneous pedicle screw (PPS) fixation was first introduced by Magerl[1] for temporary external fixation of spinal fractures and treatment of infections in 1977. The technique was revisited for the fixation of the spine upon the development of an advanced instrument system.[2] Recently, minimally invasive transforaminal lumbar interbody fusion (MI-TLIF) supplemented with PPS fixation has been recognized as an effective alternative to traditional open posterior spinal fusion surgery.[3,4] The combination of MI-TLIF and PPS fixation has many advantages, including minimal tissue damage, less intraoperative bleeding, improved postoperative morbidity, and shorter postoperative recovery time.[5]

During PPS fixation, direct observation of anatomical landmarks is not feasible, which raises doubts about safety and accuracy.[6] Misplacement of pedicle screws may result in neurological, vascular, or visceral injury. Intraoperative image guidance has been developed rapidly in recent years; however, two-dimensional (2D) fluoroscopy remains one of the most widely used image guidance methods thanks to its simplicity, rapidity, and familiarity to surgeons.

There have been several studies on computed tomography (CT) assessment of pedicle screw placement.[7-16] However, there is a lack of data concerning the risk factors associated with screw violation and their impact on long-term clinical and radiographic outcomes. In this study, we radiographically evaluated the accuracy of PPS insertion followed by MI-TLIF and analyzed the long-term outcomes and risk factors for screw violation.

METHODS

The study protocol was approved by the Institutional Review Board of Soonchunhyang University Seoul Hospital (No. 2016-08-024-001). Informed consent was not required due to the retrospective study design.

Data Collection

This study is a retrospective case series with prospective data collection. The inclusion criteria were degenerative lumbar disease treated with TLIF and PPS fixation under fluoroscopy and postoperative CT between 2005 and 2009. All operations were performed by a single senior spine surgeon (JCL). Patients with trauma, myelopathy, infection, tumors, or scoliosis were excluded. Overall, 62 patients were included (mean age, 57 years). Clinical data such as age, sex, diagnosis, bone mineral density (BMD), body mass index (BMI), perioperative blood loss, fusion level, Oswestry disability index (ODI), and visual analog scale (VAS) were reviewed (Table 1).

Surgical Technique

After standard MI-TLIF procedures, the PPS was inserted with the assistance of conventional fluoroscopy. Anterior-posterior (AP) and lateral fluoroscopy projections were located parallel to the body endplates and the spinous process was located at the midline between both pedicles to ensure a true AP image. When a tilted vertebral body was observed in the coronal plane, the C-arm fluoroscope was adjusted to make true lateral images. The entry point for the screws was the lateral margin of the pedicle on the AP view. The Jamshidi needle (J-needle) was advanced according to the predetermined convergence angle (CA) until it nearly contacted the medial border of the pedicle. The K-wire was advanced by passing through the trochar of the J-needle and inserted to two-thirds of the vertebral body under lateral fluoroscopic control. A tapper was advanced along the K-wire, and a cannulated pedicle screw was inserted. The pedicle screws and rods were 94.2% Sextant (Medtronic Sofamor Danek, Minneapolis, MN, USA) and 5.8% Viper (DePuy Spine, Raynham, MA, USA) products. After the contralateral instrument was inserted

Table 1. Demographic Characteristics and Distribution of Lumbar Segments and Pedicle Screws

Variable	Value
Age (yr)	57.45 ± 12 (23–81)
Male : female	21 : 41
Diagnosis	
Spinal stenosis	40
Spondylolisthesis	16
Herniated intervertebral disc	4
Degenerative disc disease	1
Segmental instability	1
Fusion level	
Single level	55
Double level	7
Level	Screw (n = 262)
L3	20
L4	94
L5	110
S1	38

Values are presented as mean ± standard deviation (range) or number.

in the same fashion, the cranial and caudal vertebrae were compressed along the rod, after which the rods were tightened using a torque wrench.

Accuracy of PPS Placement

The accuracy of screw placement within the pedicle was assessed via CT postoperatively within 2 weeks in all patients. CT scans were performed after the patient's general condition was stabilized during hospitalization in all cases. High-speed helical CT (Somatom Sensation, Siemens, Erlangen, Germany) was utilized with settings of 120 kV, 160 mA, exposure time 750 ms, and slice thickness 3 mm. The location of the screw was assessed via axial CT images and sagittal and coronal reconstructed images. A PPS that perforated out of the pedicle was classified into a violation group, while screws surrounded by pedicular cortical bone were classified into a correct group. Violated screws were divided into two subgroups (lateral and medial) according to the direction of violation. Based on the classification of Schizas,[17)] the degree of pedicle violations was subdivided as grade I (minor, less than half of the screw thread, < 3 mm), grade II (moderate, less than the full screw thread, 3–6 mm), and grade III (severe, more than the screw diameter, > 6 mm). Radiographic measurements were performed by two spinal surgeons (JCL and HDJ) in the same manner. Agreement was assessed via kappa statistics, and the kappa value of the two observers was 0.714.

Risk Factor Analysis of PPS Violation

For risk factor analysis of violation, multiple variables were assessed. The CA was defined as the angle between the vertebral body center line and the line in the middle of the screw tract in the axial CT image (Fig. 1). The rotational angle of the vertebral body was defined as the angle between the vertebral body centerline bisecting the spinous process and vertebral body and the vertical axis line (Fig. 2). The relationship between pedicle wall violation and BMD or BMI was also evaluated to assess the effect of intraoperative C-arm fluoroscopic image quality on the accuracy of PPS placement. To analyze the change in violation frequency according to the learning curve of the surgeon, participants were divided into early and late groups based on the previous studies regarding the learning curve of MI-TLIF.[18-20)]

Relationship between Radiographic/Clinical Outcomes and PPS Violation

For 60 patients who were followed up for more than 1 year, the degree of radiographic fusion was evaluated using modified Bridwell criteria as follows: grade I, fused with bony bridging and trabeculae remodeling; grade II, not fully bony bridged and remodeled, but with no lucency above or below the cage; grade III, definite lucency at the top or bottom of the cage and screw; and grade IV, definitely not fused with false motion.[21,22)] Grades I and II were considered to indicate solid fusion. Two independent investigators (JCL and HDJ) reviewed the radiographic

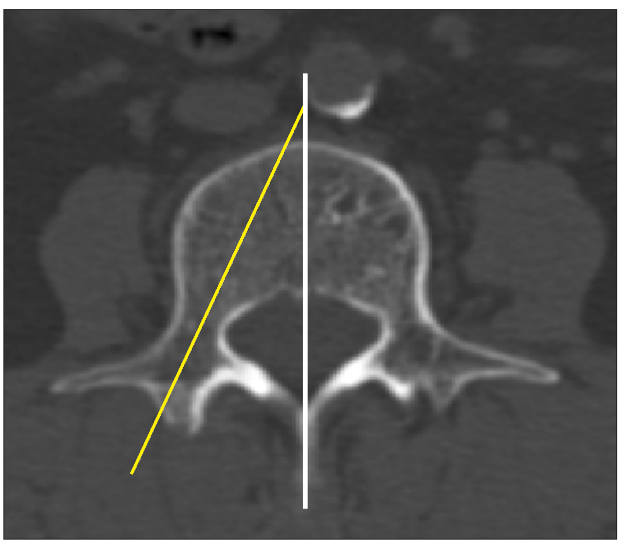

Fig. 1. Measurement of the pedicular convergence angle defined as the angle between the vertebral body center line (white line) and the line in the middle of the screw tract on the axial computed tomography image (yellow line).

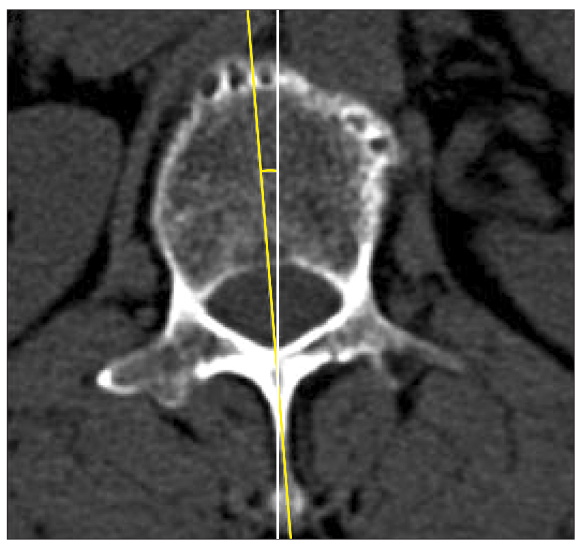

Fig. 2. Measurement of the vertebral rotation angle defined as the angle between the vertebral body centerline bisecting the spinous process and vertebral body (yellow line) and the vertical axis line (white line).

data, and agreement was assessed using kappa statistics. The Kappa value of the two observers was 0.785. The impact of violation on patients' clinical outcomes, including ODI and VAS assessments (lower back and leg pain) at the 1-year (n = 60), 5-year (n = 40), and final follow-ups (mean follow-up period of 64 months; range, 12–114 months) was evaluated.

Statistical Analysis

Variables were analyzed using the Student *t*-test and chi-square test. For risk factor analysis of violation, logistic regression analysis was performed using a stepwise backward elimination based on the Wald statistic. We identified candidate variables for each regression model via univariate screening using $p < 0.20$. The statistical program IBM SPSS ver. 21.0 (IBM Corp., Armonk, NY, USA) was used with a two-tailed *p*-value of less than 0.05 to indicate statistical significance.

RESULTS

Evaluation of PPS Accuracy

In all, 262 PPSs were inserted in 131 vertebrae, comprising 20 screws in L3, 94 in L4, 110 in L5, and 38 in S1. Fourteen screws violated the pedicle wall (violation rate, 5.3%). There were 10 medial violations (3.8%) and 4 lateral violations (1.5%) (Table 2). All violations of S1 and L5 were in medial directions, all of L4 were lateral, and one violation in L3 was lateral and another one was medial. The degree of medial violations ranged from 0.5 to 4.1 mm, and that of lateral violations was 2.2–4.9 mm. The medial violations (n = 10) comprised 5 cases in the minor group, 5 cases in the moderate group, and none in the severe group. The lateral violations (n = 4) comprised 2 cases in the minor group, 2 cases in the moderate group, and none in the severe group. Obtaining an appropriate lateral image in intraoperative C-arm fluoroscopy prevented both superior and inferior violation. As a result, there were no superior or inferior violations on intraoperative fluoroscopic images, and there were no cases of superior or inferior violations on the postoperative CT scan.

Risk Factor Analysis of PPS Violations

The mean pedicle CA was significantly higher in the violation group (mean ± SD, 27.0° ± 6.2°) than the correct group (21.7° ± 5.4°) ($p = 0.001$). It was also significantly higher for lateral violations in L4 (27.6°) than in the correct group (21.9°) ($p = 0.003$), and for medial violations in S1 (29.5°) than in the correct group (22.9°) ($p = 0.010$) (Table 2). The mean vertebral rotational angle was not significantly different between the two groups ($p = 0.647$). The violation group had lower mean BMD and higher mean BMI; however, the difference was not statistically significant. For the learning curve, there were 5 violations

Table 2. Direction of Screw Violation and Mean Convergence Angle According to Lumbar Levels

Level	Correct	Violation		Total violation	Total screw
		Medial	Lateral		
Screw violation					
L3	18	1	1	2 (10)	20
L4	91		3	3 (3.2)	94
L5	107	3		3 (2.7)	110
S1	32	6		6 (15.8)	38
Total	248 (94.7)	10 (3.8)	4 (1.5)	14 (5.3)	262
Convergence angle					*p*-value
L3	20.7 ± 3.6	36.1	12.7		0.805
L4	21.9 ± 5.5		27.6 ± 1.4		0.003*
L5	21.4 ± 5.4	23.0 ± 4.3			0.618
S1	22.9 ± 5.7	29.5 ± 4.1			0.010

Values are presented as number (%) or mean ± standard deviation.
*Statistically significant, $p < 0.05$.

in both the early (n = 31) and late (n = 31) groups, with no significant difference (p = 0.590). Logistic regression analyses demonstrated that a high CA was a significant risk factor for pedicle wall violation (p = 0.002). Details are shown in Table 3.

Revision Surgery Due to PPS Violation

Two patients (3.2%) required revision surgeries for screw repositioning due to persistent leg pain after surgery. According to CT, both patients had a moderate violation of the medial pedicle of S1, and after revision surgery, their pain was completely relieved. The first patient was a 61-year-old woman with spondylolytic spondylolisthesis at L5–S1, who was experiencing persistent postoperative leg pain. During the initial surgery, it was quite difficult to observe the cortical margin of the pedicle due to anterior translation and deformity, and an overly short pedicle with a very wide base. Postoperative CT revealed medial violation of the S1 screw. We repositioned the left S1 screw. The second case was a 50-year-old obese woman (BMI, 37.8 kg/m^2) with spondylolytic spondylolisthesis at L5–S1, a shorter left leg caused by polio sequelae, and lumbar scoliosis. Postoperative CT revealed the violation, so we performed a revision surgery (Fig. 3).

Assessment of Radiographic Union and Clinical Results

Of the 50 cases of correct placement with a 1-year follow-up, 48 patients showed solid fusion (96%), and 2 patients showed pseudarthrosis. However, none of the violation groups had pseudarthrosis at the 1-year follow-up. The correct placement and violation groups showed no significant difference in the occurrence of pseudarthrosis (Table 4). Mean ODI decreased from 24.1 preoperatively to 10.4 at the 1-year follow-up (n = 58), 8.5 at the 5-year follow-up (n = 40), and 6.9 at the final follow-up. Mean lower back pain and leg pain VAS of all patients decreased from 5.3 and 6.8 preoperatively to 2.3 and 0.7 at 1 year, 2.5 and 0.6 at 5 years, and 2.3 and 0.7 at the final follow-up, respectively. There were no significant differences in clinical results between the two groups in any follow-up period (Table 4). Therefore, there were no significant impacts of PPS violation on clinical outcomes.

Table 3. Logistic Regression Analysis for Risk Factor Assessment of Percutaneous Pedicle Screw Violation

Risk factor	Univariable analysis			Multivariable analysis*		
	OR	95% CI	*p*-value	Adjusted OR	95% CI	*p*-value
Convergence angle (°)	1.189	1.072–1.318	0.001†	1.178	1.063–1.305	0.002†
Rotational angle (°)	0.999	0.763–1.308	0.994	1.008	0.760–1.336	0.957
BMI (kg/m^2)	1.037	0.900–1.195	0.613	1.078	0.919–1.264	0.355
BMD (T score)	0.833	0.555–1.250	0.377	0.853	0.564–1.290	0.452

OR: odds ratio, CI: confidence interval, BMI: body mass index, BMD: bone mineral density.
*Statistics were analyzed by a backward stepwise method in logistic regression analysis. †Statistically significant, $p < 0.05$.

Fig. 3. (A) A 61-year-old female patient with spondylolytic spondylolisthesis underwent minimally invasive transforaminal lumbar interbody fusion (MI-TLIF) and percutaneous pedicle screw insertion at L5–S1. Postoperative computed tomography (CT) showed a medial violation of the S1 pedicle screw on the left side. (B) A 50-year-old female patient with spondylolytic spondylolisthesis and polio underwent MI-TLIF at L5–S1. Postoperative CT showed a medial violation of the S1 pedicle screw on the right side.

Table 4. Correlation of Radiographic and Clinical Results of the Two Different Pedicle Screw Placements

Variable	Correct group	Violation group	*p*-value
Radiographic result (> 1-year follow-up)			0.223
Solid fusion	48	10	
Pseudarthrosis	2	0	
Total	50	10	
Clinical result			
1-Year follow-up			
LBP VAS	2.4	2.4	0.970
Leg pain VAS	1.4	0.3	0.125
ODI	11.6	11.6	0.989
5-Year follow-up			
LBP VAS	2.3	2.4	0.924
Leg pain VAS	1.3	0.4	0.153
ODI	11.3	11.5	0.975
Final follow-up			
LBP VAS	2.2	2.3	0.915
Leg pain VAS	1.2	0.5	0.283
ODI	10.9	11.2	0.929

LBP: lower back pain, VAS: visual analog scale, ODI: Oswestry disability index.

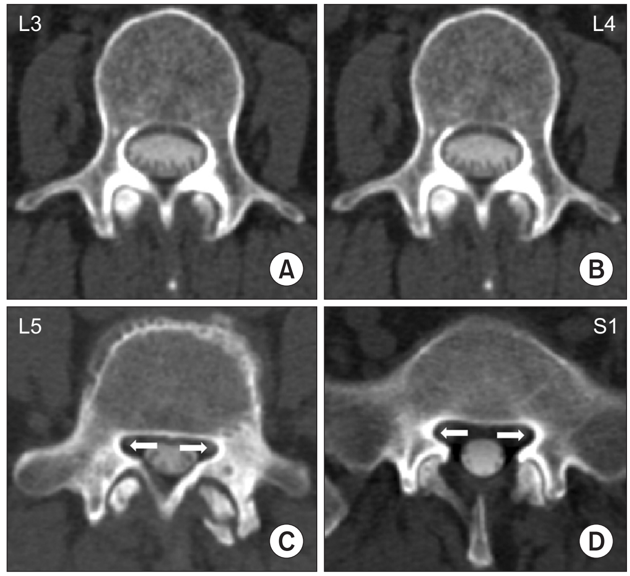

Fig. 4. Differences in the shape of the spinal canal and a lateral recess between the lumbar vertebrae. L5 and S1 vertebrae have deeper lateral recess than L3 and L4 vertebrae (white arrows).

DISCUSSION

In this analysis of 262 PPS, 14 violations of the pedicle wall (5.3%) were observed. However, mild or moderate violation did not affect radiographic fusion or long-term clinical outcomes. In the present study, the authors evaluated the radiographic fusion of 60 patients who had more than a 1-year follow-up out of 62 consecutive case series. Furthermore, we analyzed the impact of PPS violation on long-term clinical outcomes in the 40 patients who were followed up for more than 5 years.

In a previous study that used postoperative CT, the percentage of incorrectly placed traditional open pedicle screws was up to 40%.[23] In PPS instrumentation, bony structures cannot be observed visually for use as landmarks. Moreover, there are also limitations in palpating the boundary of the pedicle wall directly through pilot pedicle holes or laminectomy sites as an open surgical technique. Due to these limitations, and because accurate placement of the PPS during the procedure is crucial, it must be performed exclusively under intraoperative C-arm fluoroscopy. Reported violation rates of PPS vary greatly depending on the insertion method and evaluation modality.[24-27] Our study was based on data from a consecutive case series, all of whom received postoperative CT. PPS fixation cannot be assessed accurately in plain radiographs; CT is 10 times more reliable to assess placement.[28]

In the current study, 5.3% of PPSs had violation. Although this is somewhat greater than previous reports, it partly results from the fact that we did not use special methods such as intraoperative navigation or electromyography monitoring. These newer techniques require specialized, expensive equipment, and usually additional time for procedures. Our 2D fluoroscopy-guided screw-insertion technique is the most popular method used in real clinical practice and we believe that it still has clinical relevance. Another reason for our relatively higher incidence of pedicle violation is that we performed postoperative CT on all patients, and minor violations were meticulously evaluated even in patients with no clinically significant symptoms. Violations were mainly of the medial direction (3.8%), while 1.5% were of lateral violation. Lateral violations observed in the proximal end screws of construct were presumed to be due to the laterally located entry point. These technical errors happen because of an attempt to prevent cranial facet joint violation caused by screw shaft or facet compression by screw head. In contrast, we found that there were mainly medial violations in S1. Anatomically, in the lower lumbar and S1 vertebrae, the more lateral recess of the spinal canal tends to be deeper, and then even the same CA seems to generate more medial violation at the lower lumbar and S1 vertebrae (Fig. 4). Our results are consistent with previous studies.[3,12)]

Logistic regression analysis indicated that the CA of the PPS was a significant risk factor for violation. This is a notable result because no study to date has addressed the association between CA and PPS violations. A high CA has advantages in improving screw pull-out strength; however, there is a risk of medial violation considering the anatomical features of the pedicle. In our study, the CA was significantly higher in the medial violation group than in the correct group, and both patients who required the revision surgery showed medial violation. In the procedures that included conventional open pedicle screw insertion, we were able to determine whether or not a violation had occurred by direct palpation of the medial cortical wall of the pedicle. In contrast, because it is not possible to directly palpate the cortical wall in the PPS procedure, it is particularly necessary to pay attention to the medial violation according to the high CA.

In obese patients with a high BMI, the quality of fluoroscopy imaging is poor due to scattering of the radiation beam caused by excessive subcutaneous fat tissue. Additionally, three-dimensional (3D) orientation of spinal anatomy is quite difficult due to the long distance from skin to screw entry point at the specific bony landmark. Moreover, in patients with severe osteoporosis, the incidence of pedicle violations may increase because observation of the pedicle is complicated due to its faint cortical margin. In our study, the violation group tended to have lower mean BMD and higher mean BMI values. However, no statistical evidence could be found, possibly due to the small cohort size. Mild to moderate screw violation of the pedicle did not affect the fusion rate in our study. There has been a concern of malpositioning of pedicle screws influencing the fixation quality and fusion rate, especially if it occurs at both the proximal and distal ends of the construct.

The strengths of this study that distinguish it from other studies were the long-term (greater than 5 years) clinical and radiological follow-up results. Most previous studies have focused on radiological assessments performed in the immediate postoperative period and on short-term clinical data.[7,16,27,29,30)] In the field of spinal fusion surgery in particular, long-term follow-up data are essential because clinical and radiological outcomes significantly change over time. Additionally, pedicle screw validation can cause transient neurological deficits, even necessitating revision surgery in certain cases, then postoperative clinical observation is crucial.[16)] Considering these facts, our study had a considerably strong follow-up rate (40 patients of 62 consecutive patients, 64.5%) of 5 years.

There were several limitations of this study. First, the number of patients was not sufficient for risk factor analysis. Second, it was a retrospective study without randomization. However, we collected the radiographic and clinical data prospectively. Third, this study was based on cases treated by a single spinal surgeon.

Based on our results and in terms of clinical relevance, most PPS violations were asymptomatic. Because long-term clinical and radiographic results of the violation group were not inferior to the correct group, it was clinically acceptable to keep cases of violation under observation without early revision. Two cases of PPS violation developed related neurological deficits and underwent revision surgery. In severe obesity and osteoporosis cases, this technique has some technical difficulties. Nonetheless, this procedure is worthwhile to attempt if proper preoperative planning and care are employed because the accuracy of PPS placement does not significantly decrease in severely obese or in osteoporosis patients. Our study identified several risk factors for violation of PPS: pedicles with a high CA, an overly laterally placed entry point in the cranial screw, and S1 screw insertion with too high a CA.

In conclusion, with PPS insertion during MI-TLIF, the incidence of pedicle violations was relatively low (5.3%) using the conventional fluoroscopic technique without computer guidance. An understanding of the anatomical characteristics of each vertebra and the unique 3D structures of the patient is essential to prevent pedicle violations. Even in the violation group, PPS fixation was found to be a safe and useful procedure with successful long-term radiographic and clinical outcomes.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

ACKNOWLEDGEMENTS

This work was supported by the Soonchunhyang University Research Fund (Asan, South Korea).

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