Usefulness of Preoperative Planning by Three-Dimensional Planning Software for Pedicle Screw Placement in Thoracolumbar Surgeries: *Misplacement Rate and Associated Risk Factors*

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Abstract:

Introduction: A number of imaging technologies have been developed to reduce the risk of pedicle screw (PS) misplacement. For example, preoperative three-dimensional (3D) planning can reportedly enhance implant placement accuracy in some orthopedic surgeries. However, no study has investigated the effect of preoperative 3D planning on PS placement without intraoperative 3D navigation. Thus, in this study, we aim to examine the accuracy of PS placement and identify the risk factors for PS misplacement in thoracolumbar surgeries performed using preoperative 3D planning software with intraoperative fluoroscopic guidance in a retrospective study.

Methods: In total, 25 consecutive patients (197 PSs) underwent thoracic or lumbar spinal fusion surgeries using preoperative 3D planning with intraoperative fluoroscopic guidance. PS misplacement was graded based on the degree of perforation (Grade 0, no perforation; Grade 1, <2 mm; Grade 2, 2-4 mm; Grade 3, >4 mm) observed in postoperative computed tomography (CT). Deviations between planned and actual PSs were evaluated by matching preoperative and postoperative CT volume images for each vertebra.

Results: The overall PS misplacement rate was 6.6% (Grade 1: 4.0%, Grade 2: 1.5%, Grade 3: 1.0%). The median linear deviations of PS entry points between planned and actual locations were determined to be 3.3 mm and 3.3 mm for the horizontal and vertical axes, respectively. The median angular deviations of the PS axis were 6.2° and 4.5° for the transverse and sagittal planes, respectively. Multivariate analysis revealed that horizontal deviation of the PS entry point was the sole factor associated with Grade ≥1 PS misplacement (odds ratio=2.47, p<0.001).

Conclusions: Preoperative 3D planning software without intraoperative 3D navigation was able to achieve a relatively low PS misplacement ratio among the reported ratio of conventional techniques without navigation. Surgeons should carefully ensure that the entry point is consistent with preoperative planning, especially in the mediolateral direction to avoid misplacement in this method.

Keywords:

Pedicle screw, Misplacement, Accuracy, Three-dimensional, Planning software, Risk factor, Deviation, Computed tomography

Spine Surg Relat Res 2022; 6(3): 279-287
dx.doi.org/10.22603/ssrr.2021-0185

Introduction

Pedicle screw (PS) has been widely regarded as the strongest vertebral anchor for spinal fusion procedures in patients with various spinal pathologies[1)]. However, PS misplacement during spinal surgery can lead to unsatisfactory biomechanical properties[2,3)] and severe complications, such as neurological deficits, vascular injury, and pneumothorax[4,5)]. Therefore, accurate PS placement is essential to achieve the surgical goals.

When using conventional techniques, PS misplacement rates reportedly range from 5% to 41% in the lumbar spine and from 3% to 55% in the thoracic spine[6,7)]; thus, a number of techniques have already been developed to improve PS placement accuracy and reduce morbidity associated with misplacement[8)]. In addition to two-dimensional (2D) fluoros-

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Received: September 10, 2021, Accepted: October 2, 2021, Advance Publication: November 4, 2021

copy, fluoroscopy-based or computed tomography (CT)-based navigation systems have been reported to improve PS placement accuracy[7,9]. In the past decade, patient-specific PS template guides[10-12] and robotic-assisted technology[13] have been developed. However, implementation of these products involves greater costs as well as a learning curve for inexperienced surgeons[14].

We have introduced preoperative three-dimensional (3D) planning software for spinal fusion surgery to enable more detailed preparation for PS placement. This software allows surgeons to visualize the 3D relationship between the spinal structure and ideal PS location, thus minimizing screw misplacement. The main objective of this software is to plan for the appropriate screw length and diameter. However, additional benefits include visualization of the entry point and visualization of the ideal screw setting in virtual fluoroscopic images[15]. Preoperative planning using 3D analysis software could reduce the risk of PS misplacement. To our knowledge, no study has investigated the effects of preoperative 3D planning software in PS placement, although it has been applied in orthopedic procedures such as hip arthroplasty[16], knee arthroplasty[17], shoulder arthroplasty[18,19], and surgeries of fractures[20,21].

In this study, we performed spinal fusion surgery under conventional 2D fluoroscopic guidance; preoperative planning was carried out with 3D planning software. The purposes of this study were to investigate the accuracy of PS placement and to identify risk factors for PS misplacement, especially with respect to deviations between actual and planned PS locations.

Materials and Methods

This retrospective study has investigated PS placement accuracy using 3D planning software before surgery at a single institution. This study involved 25 consecutive patients who underwent posterior thoracic and/or lumbar spinal fusion using the conventional open PS technique or percutaneous PS (PPS) technique with conventional 2D fluoroscopy guidance between April 2019 and March 2020. All patients were ≥40 years of age and underwent thin-slice CT both before and after surgery. All PS placements were planned using 3D planning software (ZedSpine ver. 14.0; LEXI Co., Ltd., Tokyo, Japan) before surgery. Patients with missing postoperative CT data were excluded from analysis. S-2 alar iliac screws were not evaluated, as the anatomy and screw trajectory differ from those of PSs. The site of PS placement (thoracic or lumbosacral spine), surgical technique (PPS or conventional open technique), and surgeon experience (skilled [≥10 years of experience performing spine surgery] or unskilled [<10 years of experience performing spine surgery]) were examined. Vertebral morphologies are assessed by pedicle size (the smaller of width and height at the pedicle isthmus on preoperative CT), vertebral axial rotation[22]/coronal tilt (referring S1 vertebra on preoperative CT), and anterior slip on preoperative standing radiograph. The study protocol was approved by the institutional review board of Fuchu Hospital (No. 20020012, approval date: December 28, 2020).

Preoperative planning

All CT images were obtained with a slice thickness of 0.5 mm. A 3D model of each vertebra was reconstructed using the 3D planning software. Sagittal and coronal ray-sum rendering images were used to construct virtual fluoroscopic images with anteroposterior and lateral views. A surgical plan for PS placement (i.e., PS length, diameter, and direction in sagittal and transverse planes) was prepared by the attending surgeon (KY) within 1 week before the surgery. The planned PS trajectory was identified as the position in the center of the pedicle, based on assessments of sagittal, transverse, coronal, and ray-sum rendering images (Fig. 1). The planning methods for PS placement were identical between conventional open and PPS techniques.

Surgical procedure

The attending surgeon (KY) determined the surgical technique for PS placement prior to surgery in accordance with each patient's pathology. Generally, a conventional open technique was used for patients who required decompression or augmentation (e.g., sublaminar tape or lamina hook), in addition to the PS, whereas the remaining patients underwent surgery using the PPS technique.

In the conventional open technique, a midline skin incision was made over the corresponding vertebrae. The paraspinal muscles were dissected to expose the lateral borders of the pars interarticularis. PS entry points were determined by reviewing preoperative planning 3D images (Fig. 1A), and a high-speed burr was used to penetrate the outer cortex over the pedicle entry point. Afterward, a curved pedicle probe was used to create the PS trajectory based on the trajectory direction on the transverse plane of the preoperative planning images (Fig. 1B). After palpation of a pedicle tract using a ball-tipped probe to verify the presence of any cortical breaches, a metallic marker was placed; anteroposterior and lateral images were then obtained by fluoroscopy to confirm adequate PS trajectory. Tap and PS placements were then performed using fluoroscopic lateral image guidance to verify the appropriate PS length.

In the PPS technique, a 1- to 2-cm lateral skin incision was made depending on the depth of the tissue between the skin and the pedicle. The fascia and muscle were then dilated to allow PS placement. A Jamshidi needle was placed against the bone at the junction of the base of the transverse process and the facet joints; anteroposterior fluoroscopic preoperative planning images and anteroposterior ray-sum rendering images were then reviewed to confirm an adequate entry point (Fig. 1C, D). The Jamshidi needle was then gently tapped with a mallet to engage its tip in the bone while reviewing the needle trajectory on transverse preoperative planning images. The needle was advanced to the medial pedicle wall using the anteroposterior fluoroscopic view and

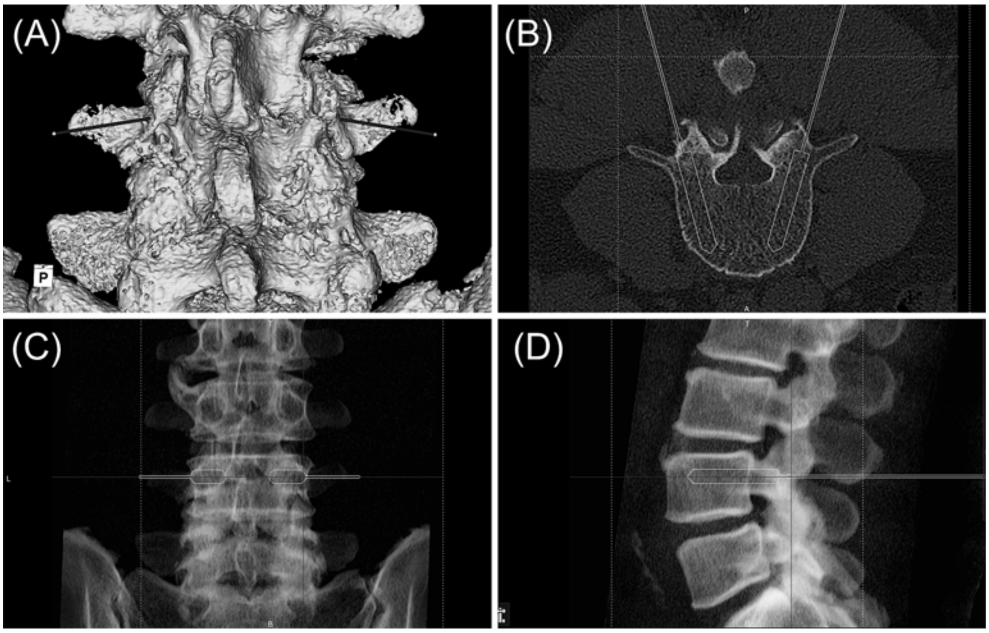

Figure 1. Preoperative pedicle screw trajectory determined using three-dimensional planning software. (A) Three-dimensional view. (B) Transverse plane with planned pedicle screw. (C) Coronal plane depicted by ray-sum rendering image. (D) Sagittal plane depicted by ray-sum rendering image.

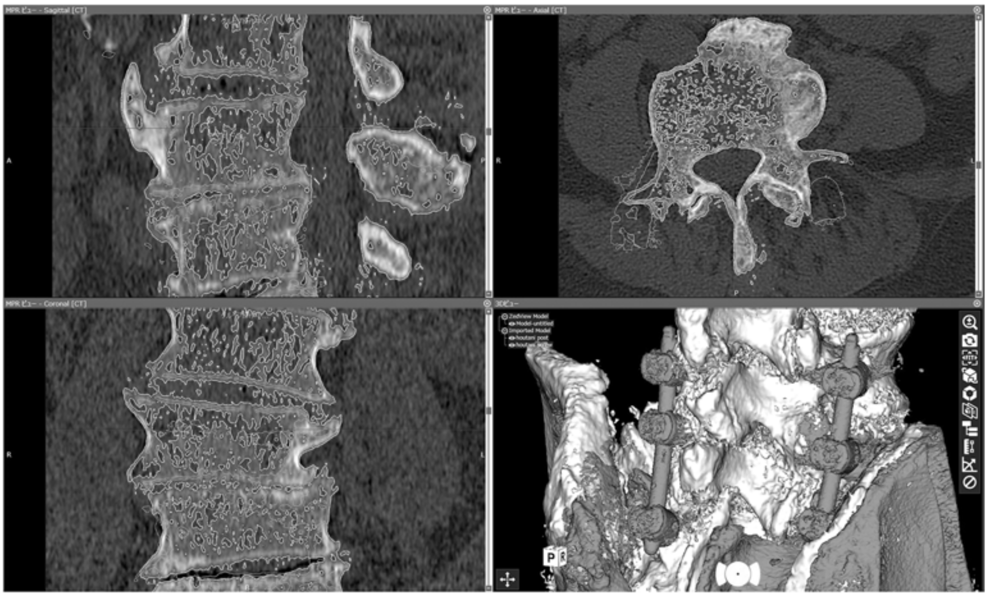

Figure 2. Vertebral matching between preoperative and postoperative computed tomography images. White-colored components indicate preoperative images, whereas gray-colored components indicate postoperative images. Matching was performed by reviewing the vertebral body, lamina, and spinous process locations on transverse, sagittal, and coronal planes.

then advanced using the lateral fluoroscopic view. After preparing the pedicle with a cannulated tap through guidewire, a cannulated PS was placed.

Evaluation of PS placement

Postoperative CT images were collected within 1 week postoperatively. The degree of perforation of the pedicle by PS misplacement was classified into four grades, in accordance with previous reports[23,24]: Grade 0, no perforation; Grade 1, <2 mm; Grade 2, 2-4 mm; and Grade 3, >4 mm. PS misplacements were graded by two authors (TO and KY), who reached agreement by consensus.

To assess PS deviation between planned and actual locations, vector component analysis was performed using an additional function in the 3D analysis software (ZedSpine ver. 14.0). Postoperative image volumes with actual PSs were superimposed on preoperative image volumes with planned PSs for each vertebra (Fig. 2). The deviations be-

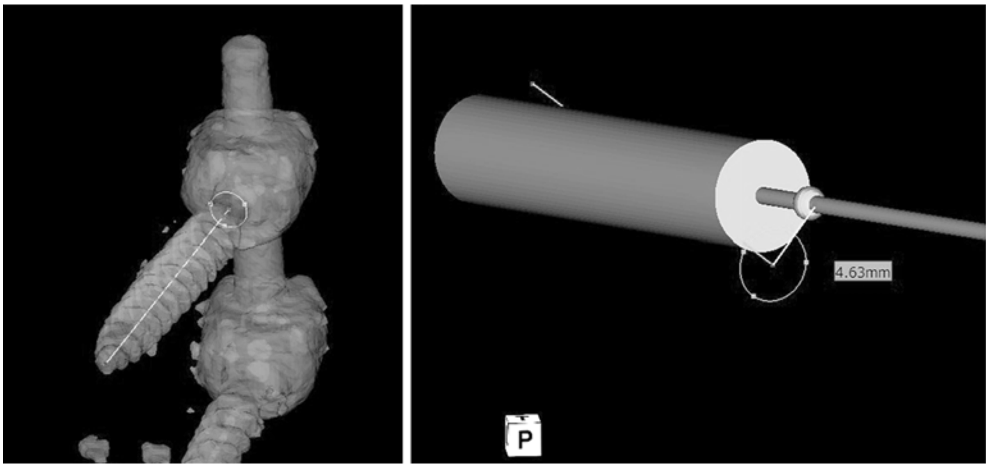

Figure 3. Evaluation of deviation between planned and actual screws on three-dimensional images. (Left) Circle indicates the actual screw entry point, while line indicates the actual screw axis. (Right) Comparison between planned and actual screws. Deviation was evaluated with respect to linear deviation of the entry point and angular deviation of the screw axis.

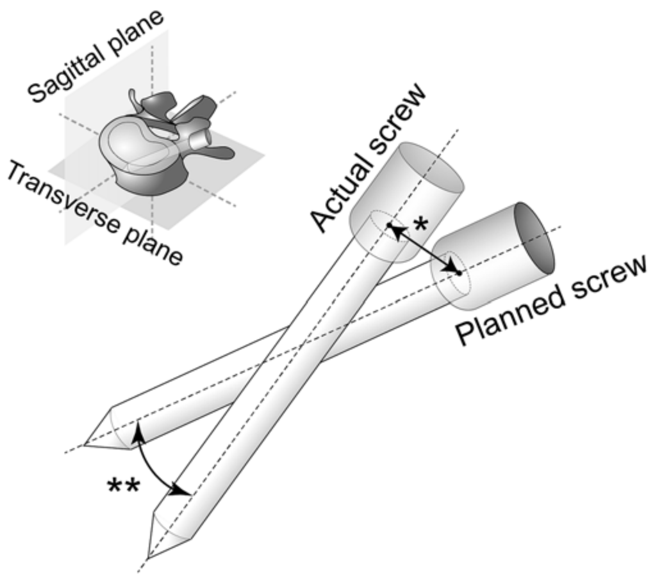

Figure 4. Graphical representation of the software methodology for measuring screw deviation. *Linear deviation of the entry point was measured and calculated on the three-dimensional axis and vertical/horizontal axes of the superior endplate of each vertebra. **Angular deviation of the screw axis was measured and calculated on the three-dimensional plane and transverse/sagittal planes.

tween the planned and actual PS trajectories were then compared (Fig. 3). Deviations of the PS entry point between the planned and actual PSs were examined to determine linear deviations along the 3D, vertical, and horizontal axes of the superior endplate of each vertebra. Deviations of the screw axis between planned and actual PSs were assessed to determine angular deviation along the 3D, sagittal, and transverse planes. Fig. 4 shows the graphical representations of these measurements. To quantify intraobserver and interobserver variabilities of the PS deviation between planned and actual PSs, 20 randomly selected PSs were assessed twice at a 3-month interval by two authors (TO and KY), both of whom were blinded to the patients' data.

Statistical analysis

Results are shown as median (interquartile range). Univariate analysis of Grade ≥1 PS misplacement was conducted using Pearson's χ^2 test for categorical variables and the Mann-Whitney U test for continuous variables. Multivariate analysis of Grade ≥1 PS misplacement was performed using logistic regression analysis. Factors included in the model were age, sex, and factors of clinical interest among factors with $p<0.10$ in univariate analyses. For all analyses, p-values of <0.05 were considered statistically significant. Statistical analysis was performed using IBM SPSS Statistics, version 19.0 (IBM Corp., Armonk, NY, USA).

Results

Patient demographics are shown in Table 1. The patients comprised 12 men and 13 women, with a median age of 75 years. The mean number of fused levels was 3±1.9. In total, 16 patients (123 PSs) and 9 patients (74 PSs) underwent screw insertion with PPS and open surgery, respectively. PS misplacements were noted in 13 PSs (6.6%) in the overall analysis of 197 PSs. Misplacement types were Grade 1, eight PSs (4.0%); Grade 2, three PSs (1.5%); and Grade 3, two PS (1.0%). Each misplacement screw by vertebral level is shown in Fig. 5. No patients developed postoperative neurological complications or required revision surgery due to PS misplacement.

Linear and angular deviations of the PS entry point and trajectory between planned and actual PSs are shown in Table 2. The intraobserver and interobserver variabilities of the deviation measurements ranged from 0.702 to 0.99 in each parameter (Table 3); therefore, the measurements were con-

Table 1. Patient Demographics.

Patients (screw)	25 patients (197 screws)
Age (years), median (interquartile range)	75 (69–80)
Sex (male/female)	12 patients/13 patients
Fused levels (mean±standard deviation)	3±1.9
Pathology	
Degenerative disorders	12 patients
Vertebral fracture	10 patients
Pyogenic spondylitis	2 patients
Spinal metastasis	1 patient
Site of screw placement	
Thoracic spine	72 screws
Lumbosacral spine	125 screws
Surgical technique	
Percutaneous pedicle screw technique	16 patients (123 screws)
Open technique	9 patients (74 screws)
Surgeon experience	
Skilled (≥10 years performing spine surgery)	126 screws
Unskilled (<10 years performing spine surgery)	71 screws

Data are present as numbers of patients or screws unless otherwise indicated.

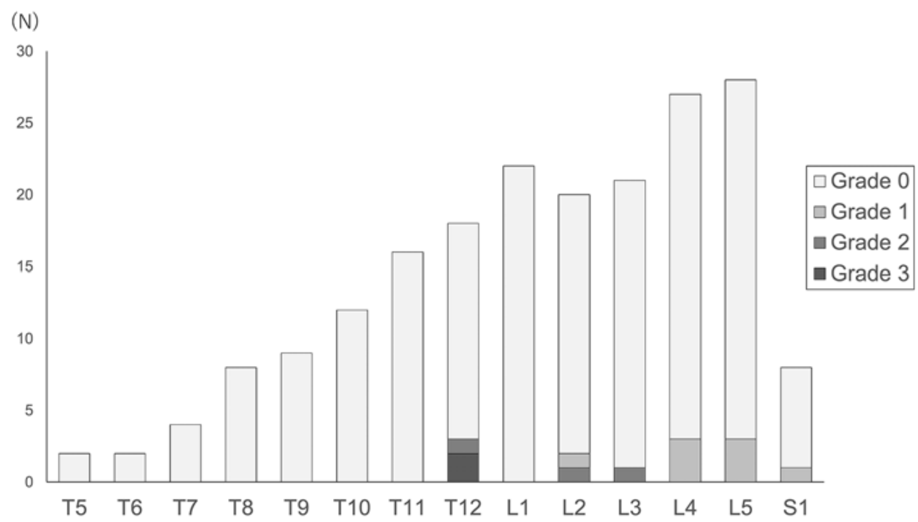

Figure 5. Screw misplacement by vertebral level. Grade 2 or Grade 3 misplacements occurred in the thoracolumbar junction level (T12, L2, and L3), whereas Grade 1 misplacements frequently occurred in the lower lumbar level.

Table 2. Deviation between Planned and Actual Screws.

Linear deviation of screw entry point	
Three-dimensional axis, mm	4.2 (3.2–5.4)
Horizontal axis, mm	3.3 (2.2–4.7)
Vertical axis, mm	3.3 (2.2–4.4)
Angular deviation of screw axis	
Three-dimensional plane, degrees	8.3 (5.8–10.7)
Transverse plane, degrees	6.2 (4.3–9.6)
Sagittal plane, degrees	4.5 (2.6–6.7)

Data are presented as median (interquartile range).

sidered reliable.

Table 4 shows the results of univariate analysis for Grade ≥1 PS misplacement. No significant differences were noted in terms of age, sex, laterality, PS placement site, surgical technique, surgeon experience, pathology, or vertebral morphology. Deviations between planned and actual PSs were associated with Grade ≥1 PS misplacement in each entry point axis (3D axis: 7.6 [7.0-10.2] vs. 4.1 [3.1-4.5] mm, $p<0.001$; horizontal axis: 6.9 [6.0-8.8] vs. 3.2 [2.1-4.5] mm, $p<0.001$; vertical axis: 5.0 [3.6-6.6] vs. 3.1 [2.2-4.2] mm, $p=0.001$). Angular deviation was only associated with Grade ≥1 PS misplacement in the 3D and transverse planes (3D plane: 12.1 [6.9-15.2] vs. 8.2 [5.8-10.4]°, $p=0.04$). After adjustment for potential confounders, only horizontal entry point deviation was independently associated with Grade ≥1 PS misplacement (adjusted odds ratio=2.47, $p<0.001$) (Table 5).

Differences between surgical techniques (open and PPS)

Table 3. Intraobserver and Interobserver Variabilities for Deviation Measurements.

	Intraobserver reliability			Interobserver reliability		
	ICC	95% CI	P	ICC	95% CI	P
Entry point						
Three-dimensional axis	0.99	0.974–0.996	**<0.001**	0.958	0.893–0.984	**<0.001**
Horizontal axis	0.973	0.931–0.99	**<0.001**	0.968	0.915–0.988	**<0.001**
Vertical axis	0.892	0.741–0.958	**<0.001**	0.783	0.506–0.913	**<0.001**
Screw trajectory						
Three-dimensional plane	0.962	0.904–0.986	**<0.001**	0.955	0.831–0.985	**<0.001**
Transverse plane	0.964	0.909–0.986	**<0.001**	0.968	0.916–0.988	**<0.001**
Sagittal plane	0.799	0.547–0.919	**<0.001**	0.702	0.286–0.885	**<0.001**

Significant p-values are indicated in bold font.
ICC, interclass correlation coefficient; CI, confidence interval

Table 4. Univariate Analysis for Grade ≥1 Screw Misplacement.

	Misplacement (+)	Misplacement (–)	P
	N=13	N=184	
Backgrounds			
Age, years	77 (71–81)	75 (69–81)	0.688
Sex, male	5 (38.5)	87 (47.3)	0.538
Laterality, left	7 (53.8)	91 (49.5)	0.76
Site of screw placement, thoracic	3 (23)	69 (37.5)	0.297
Surgical technique, PPS	8 (61.5)	115 (62.5)	0.945
Surgeon experience, ≥10 years	7 (53.8)	119 (64.7)	0.307
Pathology			0.262
Degenerative disorders	7 (53.8)	59 (32)	
Vertebral fracture	4 (30.8)	95 (51.6)	
Infection	2 (15.4)	18 (9.8)	
Spinal metastasis	0 (0)	12 (6.5)	
Vertebral morphology			
Pedicle size, <5 mm	0 (0)	29 (15.8)	0.117
Vertebral axial rotation, >5 degrees	3 (23.1)	37 (20.1)	0.797
Vertebral coronal tilt, >5 degrees	3 (23.1)	45 (24.4)	0.932
Vertebral anterior slip, >3mm	4 (30.8)	22 (12)	0.074
Linear deviation of screw entry point			
Three-dimensional axis, mm	7.6 (7.0–10.2)	4.1 (3.1–5.1)	**<0.001**
Horizontal axis, mm	6.9 (6.0–8.8)	3.2 (2.1–4.5)	**<0.001**
Vertical axis, mm	5 (3.6–6.6)	3.1 (2.2–4.2)	**0.001**
Angular deviation of screw axis			
Three-dimensional plane, degrees	12.1 (6.9–15.2)	8.2 (5.8–10.4)	**0.04**
Transverse plane, degrees	8.3 (4.9–14.1)	6.1 (4.3–9.4)	0.138
Sagittal plane, degrees	5.6 (3.7–7.0)	4.5 (2.6–6.7)	0.393

Data are presented as median (interquartile range) or n (%).
Significant p-values are indicated in bold font.
PPS, percutaneous pedicle screw

were examined as a sub-group analysis of PS misplacement (Supplemental Table 1). There was no difference in misplacement ratio (open 6.8% vs. PPS 6.5%, P=0.945) and deviations between planned and actual screws, although patients' backgrounds or vertebral morphologies were noted to differ.

Discussion

In this study, we have determined the rate of PS misplacement and associated risk factors in thoracolumbar surgeries performed using preoperative 3D planning with intraoperative fluoroscopic assistance. The Grade ≥1 misplacement rate was 6.6%. Horizontal deviation of the entry point from the planned PS location was associated with PS misplacement. To our knowledge, this study is the first to inves-

Table 5. Multivariate Analysis for Grade ≥1 Screw Misplacement.

	aOR	95% CI	P
Age, per 1 year	1.009	0.925–1.101	0.839
Sex, male	0.394	0.069–2.252	0.295
Vertebral anterior slip, >3 mm	4.781	0.803–28.471	0.086
Linear deviation of screw entry point (horizontal axis), per 1mm	2.466	1.514–4.017	**<0.001**
Linear deviation of screw entry point (vertical axis), per 1mm	1.304	0.833–2.040	0.245

Multiple logistic regression analysis was performed using age, sex, and factors of clinical interest among factors with p<0.10 in univariate analysis.
Significant p-values are indicated in bold font.
aOR, adjusted odds ratio; CI, confidence interval

tigate PS accuracy using 3D analysis with respect to preoperative 3D planning.

The proportion of PSs fully located in the pedicle without perforation ranged from 69% to 94% with free-hand technique[6]. Advances in imaging technologies have enabled reduction of PS misplacement risk. In recent years, the navigation system has been developed to obtain more accurate screw setting. The CT-based or fluoroscopic-based 3D navigation system has become the most popular spine navigation system. A systematic review showed that 3D navigation system attributed higher placement accuracy of less than 5% and reduced higher-grade deviation such as Grade 3[6,7]. However, 3D navigation is expensive: a study using the 2011 Medicare reimbursement rate showed that intraoperative navigation using O-arm imaging carries a cost of $233.35 per patient, with an additional cost of $59.49±$24.93 for confirmatory scans[25]. Furthermore, 3D navigation involves radiation exposure. Surgeries performed by an experienced surgeon using a fluoroscopy-guided free-hand technique were reportedly safe, with a significant decrease in patient radiation exposure, compared with the use of a 3D navigation technique, among patients with idiopathic scoliosis[26].

The guidance using 2D fluoroscopy remains to be the technique commonly used in most centers for being practical, ubiquitous, and cost effective. However, the proportion of PSs fully located in the pedicle without perforation with fluoroscopic assistance ranged from 28% to 85%, which was lower than that with 3D navigation[6]. Moreover, PPS technique using fluoroscopic guidance did not improve screw placement accuracy compared with conventional free-hand technique[27,28], despite its ability to save screwing time in minimally invasive spine stabilization[29].

In this study, the Grade ≥1 misplacement rate was 6.6% during surgeries performed with preoperative 3D planning and intraoperative fluoroscopic assistance. This misplacement rate was relatively low compared with previous reports by conventional intraoperative fluoroscopic guidance[6,7]. Notably, PS misplacement was noted to not vary between thoracic and lumbar spine locations or skilled and unskilled surgeons in this study. This result is presumably because preoperative 3D planning combined with virtual fluoroscopic image construction allowed surgeons to understand each patient's spinal anatomy and ideal PS trajectory. This approach might contribute to a reduced PS misplacement risk for inexperienced surgeons and thoracic spine locations with narrow pedicles. Benefits of this method include the absence of a requirement for additional hardware in the conventional surgical room, although new computer software may be needed; therefore, the operating cost is waived for each patient. Furthermore, the improved understanding of patient anatomy and PS trajectory could reduce radiation exposure.

Preoperative 3D planning outcomes have been comparable with the outcomes of navigation and patient-specific guides in knee arthroplasty[17] and shoulder arthroplasty[18]. Our data support their results in terms of PS placement in the thoracolumbar spine; the use of preoperative 3D planning could achieve a PS misplacement rate comparable with that attained by 3D navigation guidance.

Our study has also examined factors associated with Grade ≥1 PS misplacement. A systematic review showed that PSs positioned using a free-hand/fluoroscopic technique tended to exhibit medial perforation, whereas PSs placed with CT navigation guidance tended to exhibit lateral perforation[6]. Even experienced surgeons misdirected the PSs medially in 5% of patients[30]. Our investigation of factors responsible for pedicle perforation indicated that the PS entry point was more important than the PS trajectory for achieving accurate PS placement.

Xu et al.[31] reported that the error rate of a mediolateral entry point (65.7%) was larger than the error rate of a superior/inferior entry point (34.3%) in a study with a simulated free-hand method using intraoperative navigation. They have also indicated that the error rate of a transverse PS trajectory angle (55.6%) was larger than the error rate of a sagittal PS trajectory angle (44.5%). These tendencies were consistent with our results despite the use of preoperative 3D planning and intraoperative fluoroscopic guidance; surgeons could adjust the sagittal angle during PS insertion by reviewing lateral fluoroscopic images to avoid perforation of the pedicle wall if the entry point is deviated in the vertical axis. Therefore, surgeons should carefully ensure that the entry point is consistent with preoperative planning, especially in the mediolateral direction, during PS insertion.

This study has several limitations. First, the sample size was insufficient to perform a detailed analysis of PS misplacement according to severity because the rate of substantial misplacement was low. Second, this study included diverse patient pathologies and lacked a comparison with other techniques such as fluoroscopic guidance without preoperative 3D planning or 3D navigation system; thus, additional studies are needed to confirm the usefulness of preoperative 3D planning without navigation. Third, surgeons involved in this study had previously performed preoperative 3D planning with the software used in this study; thus, we cannot generalize the results of this study to surgeons who have not used this type of software or to surgeons who have used comparable software from other manufacturers. Despite these limitations, this study had multiple strengths. To our knowledge, this was the first study to perform a detailed analysis of deviations between planned and actual PSs by matching preoperative and postoperative CT volume data from patients who had undergone PS placement without navigation or patient-specific guides; thereby, this study has elucidated points to note at the screw insertion to avoid misplacement without navigation. Additionally, because the preoperative planning and surgical procedures were supervised by one senior surgeon, the surgical indications and PS diameter/length selection considerations involved uniform criteria. Therefore, the findings of this study should be useful for clinical practice, especially for low-volume institutions without access to navigation or patient-specific guides.

In conclusion, preoperative 3D planning software with intraoperative fluoroscopic guidance achieved a low PS misplacement ratio; thus, it seems to be a good alternative method when intraoperative navigation is not available. Increased horizontal deviation of the actual PS entry point from the planned PS entry point was most strongly associated with PS misplacement. Surgeons should carefully ensure that the entry point is consistent with preoperative planning, especially in the mediolateral direction, during PS insertion.

Conflicts of Interest: Hiroaki Nakamura has received speaker fees and/or research grants from Taisho Toyama Pharmaceutical Co., Ltd., Daiichi Sankyo Co., Ltd, Shionogi Co., Ltd, Eli Lilly Japan K.K, Hisamitsu Pharmaceutical Co. Ltd., and Japan Society for Promotion of Science. The other authors declare no conflict of interest.

Sources of Funding: This study was funded by grants from the Alumni Association of the Department of Orthopaedic Surgery in Osaka City University.

Author Contributions: Conception and design: KY. Acquisition of data: TO and KY. Analysis and interpretation of data: TO and KY. Drafting the article: TO. Critically revising the article: KY. Reviewed submitted version of manuscript: TO, KY, and HN. Approved the final version of the manuscript on behalf of all authors: TO, KY, and HN. Statistical analysis: TO and KY. Administrative/technical/material support: KY. Study supervision: HN

Ethical Approval: This study was approved by the Institutional Review Board of Fuchu Hospital (No. 20020012, approval date: December 28, 2020).

Informed Consent: Informed consent was obtained in the form of opt-out on the website of Fuchu Hospital.

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