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Freehand screw insertion technique without image guidance for the cortical bone trajectory screw in posterior lumbar interbody fusion: what affects screw misplacement?

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OBJECTIVE Cortical bone trajectory (CBT) screw insertion using a freehand technique is considered less feasible than guided techniques, due to the lack of readily identifiable visual landmarks. However, in posterior lumbar interbody fusion (PLIF), after resection of the posterior anatomy, the pedicles themselves, into which implantation is performed, are palpable from the spinal canal and neural foramen. With the help of pedicle wall probing, the authors have placed CBT screws using a freehand technique without image guidance in PLIF. This technique has advantages of no radiation exposure and no requirement for expensive devices, but the disadvantage of reduced accuracy in screw placement. To address the problem of symptomatic breaches with this freehand technique, variables related to unacceptable screw positioning and need for revisions were investigated.

METHODS From 2014 to 2020, 182 of 426 patients with single-level PLIF were enrolled according to the combined criteria of L4–5 level, excluding cases of revision and isthmic spondylolisthesis; using screws 5.5 mm in diameter; and operated by right-handed surgeons. We studied the number of misplaced screws found and replaced during initial surgeries. Using multiplanar reconstruction CT postoperatively, 692 screw positions on images were classified using previously reported grading criteria. Details of pedicle breaches requiring revisions were studied. We conducted a statistical analysis of the relationship between unacceptable (perforations > 2 mm) misplacements and four variables: level, laterality, spinal deformity, and experiences of surgeons.

RESULTS Three screws in L4 and another in L5 were revised during initial surgeries. The total rate of unacceptable screws on CT examinations was 3.3%. Three screws in L4 and another in L5 breached inferomedial pedicle walls in grade 3 and required revisions. The revision rate was 2.2%. The percentage of unacceptable screws was 5.2% in L4 and 1.7% in L5 ($p < 0.05$), whereas other variables showed no significant differences.

CONCLUSIONS A freehand technique can be feasible for CBT screw insertion in PLIF, balancing the risks of 3.3% unacceptable misplacements and 2.2% revisions with the benefits of no radiation exposure and no need for expensive devices. Pedicle palpation in L4 is the key to safety, even though it requires deeper and more difficult probing. In the initial surgeries and revisions, 75% of revised screws were observed in L4, and unacceptable screw positions were more likely to be found in L4 than in L5.

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KEYWORDS posterior lumbar interbody fusion; cortical bone trajectory screw; freehand technique; screw misplacement; complication; surgical technique

In lumbosacral fusion surgery, cortical bone trajectory (CBT) screws are usually implanted under image guidance, mostly using fluoroscopy.[1–3] A freehand technique for CBT screw insertion without image guidance is considered less feasible, due to the lack of readily identifiable and reproducible visual landmarks compared to the well-defined identifiable landmarks for traditional pedicle screw insertion.[4] In posterior lumbar interbody fusion (PLIF), laminotomy combined with facetectomy enables pedicle wall palpation from the spinal canal or neural foramen as well as neural decompression and creation of a pathway to the disc space. Pedicle walls provide the most reliable landmarks for screw insertion, because they represent the borders that should not be breached. In PLIF

ABBREVIATIONS CBT = cortical bone trajectory; MPR = multiplanar reconstruction; PLIF = posterior lumbar interbody fusion.

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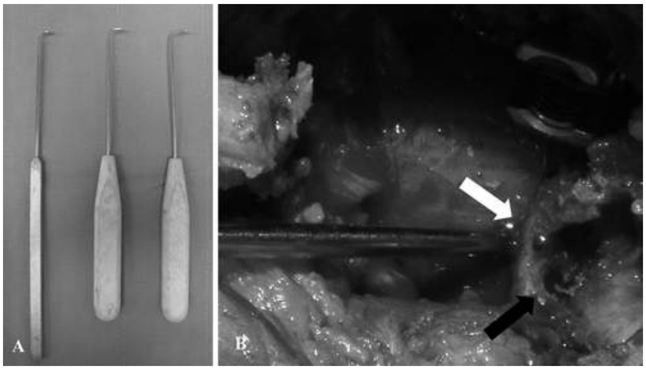

FIG. 1. Pedicle probing after removal of posterior anatomy. **A:** Ball-tip hooks. **B:** Checking the medial breach in the right L4 pedicle. *Right*: Cranial. *Left*: Caudal. *Upper*: Left. *Lower*: Right. A tapped screw hole is seen on the right L4 lamina (*black arrow*). After resection of the posterior anatomy, the pedicle wall can be probed from the spinal canal beside the dural sac (*white arrow*).

surgeries, we have performed a freehand technique for CBT screw insertion with direct pedicle palpation, instead of image guidance, with the aim of avoiding both radiation exposure and the need for expensive equipment. However, our freehand technique sometimes fails in correct screw placements due to misorientation. In some cases, immediate revision surgeries are required because of subsequent neurological symptoms caused by screws protruding into the spinal canal. To confirm the safety of our technique, we analyzed the risk of screw misplacements to prevent further symptomatic pedicle breaches.

Methods

Patient Population

From August 2014 to August 2020, a total of 426 patients underwent single-level PLIF with CBT screw fixation at our institution. To enable statistical risk analysis of a homogeneous population, we set criteria that reduced the enrolled number of patients by excluding the cases with the following features: 1) patients with spinal surgery site other than the L4–5 level (n = 153 patients); 2) patients undergoing revision surgery (n = 15 patients); 3) patients with isthmic spondylolisthesis (n = 13 patients); 4) patients who underwent surgery without the use of screws 5.5 mm in diameter (n = 41 patients); and 5) patients whose operation was performed by a left-handed surgeon (n = 22 patients). After the exclusion of these 244 patients, 182 patients were enrolled in the study, comprising 78 men and 104 women with a mean age of 70 years (range 37–88 years).

Causative conditions were classified into 164 cases of degenerative spondylolisthesis, 16 cases of lumbar canal stenosis, and 2 cases of disc herniation.

Among the total of 728 screws in 182 patients, 692 CBT screws 5.5 mm in diameter were included in the investigation. These comprised 565 Mykres screws (Teijin-Nakashima Medical) and 127 Solera screws (Medtronic). The number of implanted screws in each pedicle was as follows: right L4, n = 164; left L4, n = 165; and right L5, n = 181; left L5, n = 182. The remaining 36 screws were excluded either because they were not 5.5 mm in diameter (33 screws) or because conversion to traditional pedicle screw fixation was performed (3 screws).

In the right L4, 18 screws other than 5.5 mm in diameter were implanted in CBT fashion. In the left L4, 15 CBT screws other than 5.5 mm in diameter were implanted and 2 screws were converted to conventional pedicle screw fixation. In the right L5, 1 screw was converted to the conventional trajectory. Reasons for these conversions were pedicle fracture during screw hole preparation (n = 1) and intraoperative identification of screw malpositioning (n = 2).

Our study protocol was approved by the institutional review board at Kansai Rosai Hospital.

Surgical Technique

Preoperative planning was conducted based on images from multiplanar CT. Screws 5.5 mm in diameter in both L4 and L5, with lengths of 40–45 mm in L4 and 35–40 mm in L5, were routinely selected to yield the maximum purchase and total involvement inside the pedicles. Positional relationships between the surfaces of the pars interarticularis and pedicles, which form screw pathways, were meticulously checked to clarify virtual trajectories. No fluoroscopy was used during surgery. Under general anesthesia, each patient was placed in a prone position on a Hall four-point frame. Surgical level was confirmed by lateral radiography of the 18-gauge injection needle buried in the L4 spinous process before skin incision. Operators, who were all right-handed in this study, stood on the left side of the patient and performed all procedures from the left side. A midskin incision was made at the L4–5 level. Soft tissue was dissected minimally and laterally to the inferomedial aspect of L3–4 facets and the medial aspects of L4–5 facets, and then L4–5 bilateral laminotomy with or without total facetectomy was performed in response to pathological conditions. Following disc curettage, two carbon fiber–reinforced polyetheretherketone cages filled with local bone graft were laterally inserted into the disc space, supplemented by medial grafting of several local bone blocks.

According to the previously described technique based on morphometric research,[1–4] an entry hole was created on the intersection point 1–3 mm medial to the lateral notch of the pars interarticularis and 1 mm caudal to the inferior edge of the transverse process. However, intraoperative adjustment by fluoroscopy or navigation for optimal location is usually required because of individual variations in the relationship between anatomical landmarks and pedicle shape. In our freehand technique without image guidance, the optimal position of the entry hole located on the inferomedial border of the pedicle wall was explored and adjusted by imagining the virtual shape of the pedicles with the help of both medial L4 pedicle wall probing from the spinal canal and inferior L4 pedicle wall probing from the neural foramen. Ball-tip hooks were used to touch the wall (Fig. 1A). A pilot hole was then drilled on the cortical surface with a 2-mm bar directed 10°–15° laterally in the axial plane and 20°–25° cranially in the sagittal plane. The hole was extended to the opposite upper lateral cortical wall of the vertebra using a straight probe,

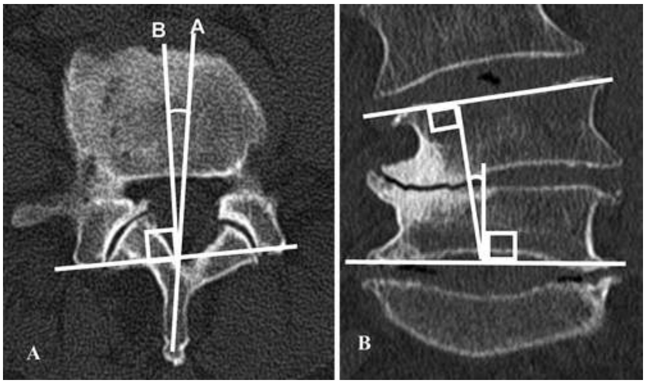

FIG. 2. Measurement of spinal deformity. **A:** L4–5 rotational angle on axial CT. *Line A* bisects the L4 spinous process and *line B* is perpendicular at the midpoint between the bilateral L5 superior articular processes. The rotational angle is defined as the angle between *line A* and *line B*. **B:** L4–5 Cobb angle on coronal CT.

with adequate resistance of cancellous bone against the probe until the opposite cortex was the same as that of the conventional trajectory technique. The hole was dilated by tapping, then checked for breaches using a sounder from inside the pedicle and direct probing from outside the pedicle (Fig. 1B). These procedures were repeated in a step-by-step manner as the diameter of the tap increased. Terminal cortical breach, warranting strong screw purchase, was checked by assessing for the opposite loss of resistance during probing, tapping, and sounding. After final tapping of the planned size, the screw was implanted manually. Screw placements in L5 were performed in a similar manner. Palpation of the medial and superior L5 pedicle wall helped to identify the entry points on the pars interarticularis in L5.

A cranial screw trajectory of 10°–15° lower than that in L4 should be obtained. Rod-screw assembly, wound irrigation, drainage tube placement, and skin closure were routinely performed to complete the surgery. Screw positions were finally confirmed by anteroposterior and lateral plain radiographs in the operation room before exiting.

Radiological Evaluation

Axial helical CT scans 1 mm thick of L4–5 were performed on an 80-line multislice CT scanner (Aquillion ONE; Toshiba), and coronal and sagittal multiplanar reconstruction (MPR)–CT (MPR-CT) images were created before and after surgery, routinely within a week, with the exception of urgent postoperative cases presenting with neurological deterioration.

From the preoperative axial CT, the rotational angle formed between the line bisecting the L4 spinous process and the perpendicular line at the midpoint of bilateral L5 superior articular processes was measured (Fig. 2A). The Cobb angle at L4–5 on coronal CT was also measured as an indicator of coronal deformity (Fig. 2B). Spinal deformity was defined as a Cobb angle or rotational angle > 5°.

From postoperative MPR-CT images, the extent of pedicle perforations by screws was assessed using the grading system of Gertzbein et al. and Rao et al. (grade 0, no violation; grade 1, < 2 mm; grade 2, 2–4 mm; grade 3, > 4 mm)[5,6] (Figs. 3A–D and 4A–D). The slice with the largest deviation was chosen for grading. Grade 2 and grade 3 were defined as clinically unacceptable screw positions.[7] All measurements were performed by one of the authors (M.I.), who was not enrolled as a surgeon in this study due to being left-handed.

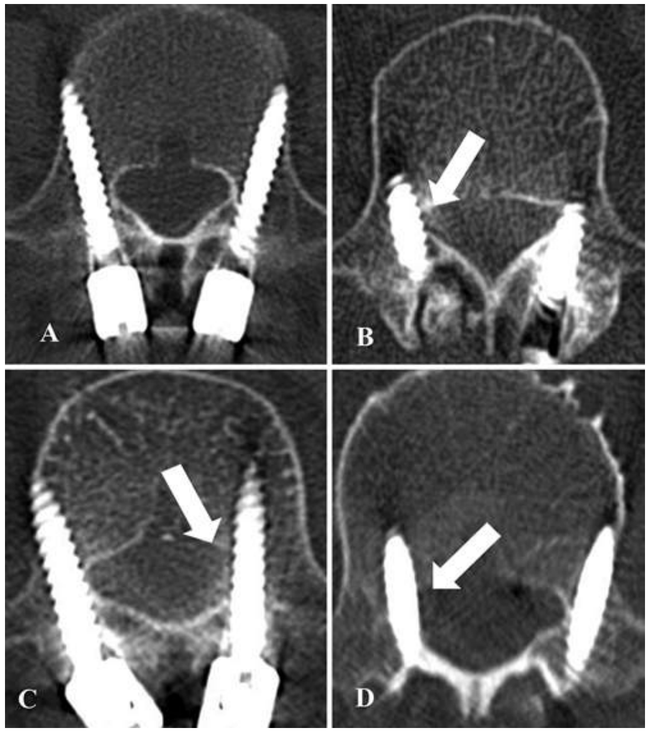

FIG. 3. Grading of screw misplacement on axial CT. **A:** Grade 0 (no violation). **B:** Grade 1 (< 2 mm). **C:** Grade 2 (2–4 mm). **D:** Grade 3 (> 4 mm). *White arrows* indicate the extent of screw misplacement.

Investigation of Screw Misplacement

We investigated intraoperative screw misplacements found on postoperative radiographs and immediately salvaged in initial surgeries before exiting from the operation room. The number of grade 2 and grade 3 perforations missed by postoperative radiographs but revealed on postoperative CT was counted. The directions, levels, and extents of misplaced screws were also investigated in revision cases.

Statistical Analysis

To clarify what affects screw misplacements, associations between unacceptable breaches and the four variables of pedicle level, laterality, spinal deformity, and surgeon experience were calculated by Fisher's exact test. Six surgeons, who met the criterion of being right-handed, were divided into the experienced group (n = 2) and the inexperienced group (n = 4). The criterion for the experienced group was work as a spinal surgeon for more than 10 years. Statistical analysis was performed using Statcel 4 software (OMS Publishing Inc.).

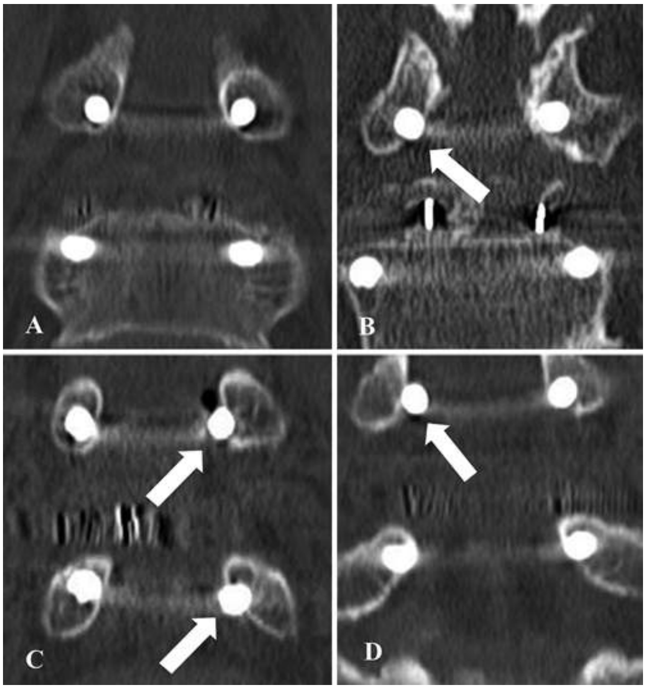

FIG. 4. Grading of screw misplacement on coronal CT. **A:** Grade 0 (no violation). **B:** Grade 1 (< 2 mm). **C:** Grade 2 (2–4 mm). **D:** Grade 3 (> 4 mm). *White arrows* indicate the extent of screw misplacement.

Results

Four screws (2 in right L4, 1 in left L4, 1 in right L5) were found to be unacceptably misplaced on postoperative radiographs in the operation room. All were immediately reimplanted into correct positions before exiting. The final positions of screws were confirmed later on CT images. These misplaced screws caused no residual symptoms. The numbers of grade 0, 1, 2, and 3 positioned misplaced screws on postoperative CT images were 134, 24, 4, and 2 in the right L4; 127, 27, 8, and 3 in the left L4; 170, 8, 1, and 2 in the right L5; and 170, 9, 3, and 0 in the left L5, respectively. The total rate of unacceptable screws was 3.3% (Table 1). Two screws in the right L4, 1 in the left L4, and another in the right L5 pedicle required revision surgeries, because they caused severe leg pain or motor weakness the next day. The rate of symptomatic screws in unacceptable positions was 17% (4/23 screws). All screws were in grade 3 and breached the inferomedial pedicle walls into the spinal canal. All revision surgeries were performed on either the day of or the day after CT examinations. After replacement of screws, symptoms resolved immediately. The revision rate was 2.2% (4/182 surgeries).

TABLE 1. Misplaced and revised screws in each pedicle

	Rt L4	Lt L4	Rt L5	Lt L5	Total (n = 692)
Misplacement grade					
0	134	127	170	170	601 (86.9)
1	24	27	8	9	68 (9.8)
2	4	8	1	3	16 (2.3)
3	2	3	2	0	7 (1.0)
Revised screws	2	1	1	0	4

Values are number (%) of screws.

TABLE 2. Statistical analysis of unacceptable screws and related variables

Variables	Screw Placement		p Value*
	Acceptable	Unacceptable	
Level			<0.05
L4	312 (94.8)	17 (5.2)	
L5	357 (98.3)	6 (1.7)	
Side			>0.05
Rt	336 (97.4)	9 (2.6)	
Lt	333 (96.0)	14 (4.0)	
Deformity			>0.05
Yes	168 (97.7)	4 (2.3)	
No	501 (96.3)	19 (3.7)	
Surgeon experience			>0.05
Experienced	450 (96.0)	18 (4.0)	
Inexperienced	219 (97.8)	5 (2.2)	

* Fisher's exact test. Each p value refers to the statistical difference associated with the level, side, deformity, and surgeon experience, respectively, of unacceptable compared with acceptable screws.

There were 329 screws implanted into L4 pedicles, 363 into L5 pedicles, 345 on the right side, and 347 on the left side. In cases with spinal deformity (rotation or Cobb angle > 5°), patients received 172 screws. Twenty-three cases presented with coronal deformities (10.0° ± 4.1°) only, while 4 cases showed rotational deformities (8.0° ± 1.0°) only. Seventeen cases showed both deformities (Cobb angle, 10.8° ± 4.8°; rotation, 7.7° ± 2.1°). Experienced surgeons inserted 468 screws, while inexperienced surgeons inserted 224 screws.

The percentage of unacceptable screws was 5.2% in L4 and 1.7% in L5 ($p < 0.05$), 2.6% in the right side and 4.0% in the left side ($p > 0.05$), 2.3% in deformity cases and 3.7% in no-deformity cases ($p > 0.05$), and 4.0% in experienced surgeon cases and 2.2% in inexperienced ($p > 0.05$) (Table 2).

Discussion

A risk of increased radiation exposure has been raised in minimally invasive surgery.[8] CBT fixation is classified as less invasive, because it requires minimal lateral soft-tissue dissection due to the laterally directed pathway from a more medialized start point compared to the traditional pedicle screw. However, this divergent trajectory of the CBT screw against the pedicle shape makes accurate screw placement more difficult, in contrast to the convergent trajectory of traditional pedicle screws. Moreover, a freehand technique is reportedly unreliable in CBT fixation, because readily identifiable and reproducible visual landmarks are lacking. Obscuration of patient anatomy secondary to degenerative changes resulted in a 22% rate of unsafe screw placement.[4] For these reasons, radiological image guidance is thought to be required for correct CBT screw implantation, at the expense of health risks caused by radiation exposure.

Some authors have tried to reduce irradiation during screw placement by using robotic guidance,[9] CT navigation,[10] and patient-matched 3D-printed guidance,[11] instead of conventional fluoroscopy. However, acceptance and uptake of expensive navigation devices is less practicable, and even more cost-conscious printed guidance systems require initial investments into software and 3D printers.

A freehand technique without image guidance is widely accepted for traditional pedicle screw fixation. Parker et al.[12] examined 6816 freehand-placed pedicle screws in the thoracic and lumbar spine and concluded that freehand pedicle screw placement based on the external anatomy can be performed with acceptable safety and accuracy and allows avoidance of radiation exposure encountered in fluoroscopic techniques. In systematic reviews of the accuracy of pedicle screw placement comparing freehand and fluoroscopy guidance and navigation techniques, although the navigation technique exhibited higher accuracy and increased safety compared to freehand and fluoroscopy, a higher accuracy for fluoroscopy guidance than for the freehand technique was not established.[13]

In PLIF surgeries, the freehand technique of CBT screw insertion can be performed not only based on surface landmarks, but also based on the most reliable anatomical landmarks, the pedicle walls themselves, because they are identified by direct probing after removing the posterior anatomy.

Laminotomy in combination with facetectomy, to decompress neural elements and expose the disc space beside the dural sac, is routinely performed in the PLIF procedure. After resection of the posterior anatomy, pedicle walls can be probed from the spinal canal and neural foramen. For example, in L4–5 surgery, medial and inferior walls of the L4 pedicles and medial and superior walls of the L5 pedicles can be probed. This helps the surgeon identify the shapes of pedicles and determine entry points and screw trajectories inside the pedicles, despite degenerative changes to the posterior surfaces. Our results of 3.3% for grade 2 and grade 3 positions and 2.2% of revisions were satisfactory and as good as those of the fluoroscopy-guided CBT technique, with 0%–13.1% of unacceptable screws and a 0%–5.2% revision rate.[1,3,9,14] However, these findings were no match for the absolute accuracy of the navigation-guided technique. Le et al.[9] reduced the rate of unacceptable screws from 13.1% to 4.7% and the revision rate from 5.2% to 0% by replacing the fluoroscopy for robot navigation. Khan et al.[10] reported the excellent accuracy of no screws in grade 2 and grade 3 with no revision using robotic guidance and 3D CT navigations (Table 3). Plain radiographs reportedly offer lower detection power than reconstruction CT in pedicle screw misplacement.[15–17] In our series, although 4 misplaced screws were found on postoperative radiographs and immediately replaced in the initial surgeries, the rest of the 23 screws in unacceptable positions were missed and found on reconstruction CT images later. On anteroposterior plain radiographs, inferomedial pedicle lines overlapped and were concealed by the proximal part of CBT screws even in grade 0 screw positions on MPR-CT.

TABLE 3. Misplacement and revision rate under fluoroscopic guidance and navigations

Authors & Year	No. of Pts	No. of Screws	Guidance Modality	Grade (%) 1	Grade (%) 2	Grade (%) 3	Revision (%)
Ohkawa et al., 2015[1]	54	366	Fluoroscopy	NR	NR	NR	1.9
Marengo et al., 2018[3]	101	418	Fluoroscopy	NR	NR	NR	3.9
Penner et al., 2019[14]	82	328	Fluoroscopy	3.6	0	0	0
Le et al., 2018[9]	38	145	Fluoroscopy	20	9.0	4.1	5.2
Le et al., 2018[9]	20	86	Robot navigation	8.1	4.7	0	0
Khan et al., 2020[10]	18	74	CT navigation	6.8	0	0	0
Khan et al., 2020[10]	22	92	Robot navigation	0	0	0	0

NR = not reported; pt = patient.

In contrast, screw heads projected onto the lateral area of pedicle lines in the traditional trajectory, resulting in easy assessment of inferomedial lines. Disturbed evaluation on inferomedial pedicle lines concealed by the proximal part of screws, where symptomatic breaches happen, may be the reason why unacceptable placements were sometimes missed on plain radiographs in CBT. MPR-CT assessment is the most reliable method for final confirmation of screw positions in the operation room. Taking no account of costs, navigations with higher accuracy and lower irradiation are ideal for both intraoperative guidance and final assessment in the operation room, but these options are not affordable to all institutions. Under the limitations of budget and requests for no radiation exposure, we have investigated the accuracy and safety of the freehand technique by risk analysis of revision and variables related to unacceptable screw positions. To ensure a homogeneous population for reliable statistical analysis, we set strict inclusion criteria of the single level of L4–5 only, excluding cases with exceptional pathologies, uniform usage of screws with a diameter of 5.5 mm, and insertion performed by right-handed surgeons only. In addition to our observational findings in which 75% (6 of 8) of revised screws in initial surgeries and revisions were found in L4, our statistical results indicated that screws in L4 were at greater risk of misplacement, regardless of laterality, spinal deformity, and surgeon experience. Ohkawa et al.[1] reported that in their 54 cases using a fluoroscopy-assisted technique, half of their misplacements occurred at the L5 level and on the right side in cases of right-handed surgeons. These authors considered the association between misdirection and dominant hand, development of the lateral recess of the spinal canal at L5, and medial penetration. To simplify the analysis of handedness, we only included those surgeries performed by right-handed surgeons based on the hypothesis by Ohkawa et al.[1] that right-handed surgeons were more likely

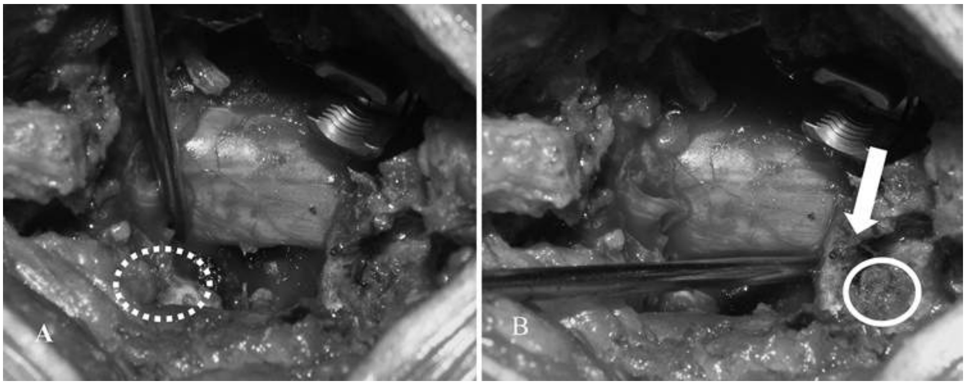

FIG. 5. Lower accessibility to L4 pedicle than L5 pedicle. **A:** Easy access to the L5 pedicle. Outline of right L5 pedicle (*dotted-line circle*). Removing the inferior articular process of L4 and marginal resection of the L5 superior articular process enable easy probing of the L5 pedicle. **B:** Deeper probing blocked by unresected lamina at L4. Outline of right L4 pedicle (*solid-line circle*). Deeper probing is blocked by the unresected lamina (*white arrow*).

to misplace screws on the right side. Our statistical results revealed no significance in laterality and more misplacements at L4, unlike their findings. A learning curve exists for the placement of pedicle screws in the thoracic spine of patients with scoliosis. Samdani et al.[18,19] reported that as the experience of the surgeon increased, an overall decrease in the breach rate was seen in the surgeries for adolescent idiopathic scoliosis presenting with a preoperative thoracic Cobb angle of 62.6°. However, our results showed no association between screw misplacement and deformity, although the magnitude of the curve per single level reported by Samdani et al. was similar to our curve of 10°. Moreover, there was no relationship between malposition and surgeon experience. Differences in misplacement might be hard to identify, because the broader pedicle diameter at L4 and L5 compared to the thoracic spine allowed a lower breach rate, irrespective of deformity and surgeon experience. Regarding the greater frequency of misplacements in L4, we considered two reasons for this. One is the pedicle size. Despite the development of the lateral recess in the spinal canal, the broader pedicle diameter at L5 than at L4 is associated with a lower frequency of breach if an appropriate medial-lateral direction is applied. Another reason is the lower accessibility of the L4 pedicles. In the PLIF procedure, the medial margin and top of the L5 superior articular process are usually excised to visualize the lower end of the L4–5 disc, resulting in easy access to the pedicle wall in L5 (Fig. 5A). On the other hand, when performing posterior decompression, the upper one-third of the lamina and pars interarticularis in L4 must be left in CBT fixation, because this part is critical for drilling the entry point and gaining purchase on the cortical surface. Consequently, L4 pedicles require deeper, more difficult probing than L5 pedicles, because palpation upward occurs over a larger distance, blocked by the unresected upper lamina and pars (Fig. 5B). Removal of greater amounts of the lamina and pars facilitates access to L4, but increases the risk of pedicle fracture because of the insufficient bony margin around the screw hole.

Once the cortical purchase of a CBT screw is not achievable, good fixation is not expected. Conversion to the conventional trajectory screw was sometimes required as salvage. To achieve safe screw placement avoiding pedicle fracture, reduced accessibility is the required tradeoff. Therefore, in the freehand technique, which depends on direct palpation of the pedicle walls, less accessibility to the L4 pedicles results in less accuracy.

Conclusions

Our freehand technique has a disadvantage of inferior accuracy compared to navigation methods using image guidance, but can represent a feasible technique for CBT screw insertion in PLIF, balancing the 3.3% rate of unacceptable misplaced screws and 2.2% rate of revisions with the lack of both radiation exposure and the need for expensive devices. Pedicle palpation in L4 is the key to safely avoiding symptomatic breaches in our technique, even though deeper and more difficult probing is required. Seventy-five percent of revised screws in initial surgeries and revisions were observed in L4, and unacceptable screw positions were more likely to be found in L4 than in L5.

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Disclosures

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Author Contributions

Conception and design: Ishii. Acquisition of data: Ishii. Analysis and interpretation of data: Ishii. Drafting the article: Ishii. Critically revising the article: Ohnishi, Yamagishi, Ohwada. Reviewed submitted version of manuscript: Ohnishi, Yamagishi, Ohwada. Approved the final version of the manuscript on behalf of all authors: Ishii. Statistical analysis: Ishii. Study supervision: Ohwada.

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