

# Accuracy of Screw Placement and Fusion Rate after Transforaminal Lumbar Interbody Fusion with O-arm Navigation: A Review of 475 Patients

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## Research article

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# Abstract

## Purpose

To evaluate the accuracy of screw placement and fusion rate after the minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF) technique under O-arm navigation.

## Methods

In 475 consecutive patients at a single-center, the accuracy of screw placement was evaluated on intraoperative O-arm imaging. Misplaced screws were investigated to identify the direction of deviation and associated clinical outcomes. The fusion rate was evaluated on postoperative computed tomography scan at 1 and 2 year(s). The assessment of screw placement and fusion level was analyzed for inter-rater reliability and reported as a kappa value. Accuracy of screw placement (Gertzbein-Robbins Classification), extent of fusion (Bridwell Interbody Fusion Grading System), and complications were considered as outcome measures.

## Results

A retrospective data analysis from 2,098 pedicle screws in 475 patients. The mean age of participants was  $56.61 \pm 12.30$  years, and 45.26% were female. Their ethnicities were as follows: Asian (58.74%), Caucasian (20.21%), Middle-eastern (14.32%), and African (6.74%). The final fusion levels were single (80.63%), two (18.11%), three (1.05%), and four (0.21%). There were L4/L5 as the most prevalent placement (55.35%), followed by L5/S1 (36.29%), L3/L4 (5.22%), L2/L3 (2.35%), L1/L2 (0.52%), and S1/S2 (0.26%). Seven out of 2,098 screws were breaches. None of screw needed immediate revision. In total, 99.66% of the screws were grade A (no breach), 0.19% were grade B (breach < 2 mm) and 0.14% were grade C (breach < 4mm).

## Conclusion

The accuracy of pedicle screw insertion was 99.66%, with a fusion rate of 95.45% after MIS-TLIF under O-arm navigation. Breaches were not associated with poor clinical outcomes or fusion rates.

## Background

Since 2000, interbody fusion has become more popular as the technique for lumbar spine fusion [1]. This minimally invasive transforaminal lumbar interbody fusion procedure was first reported by Foley et al. [2] and has been used for a variety of spinal diseases [3, 4] because of the advantages of less operative blood loss, less soft tissue damage, and faster recovery compared to an open technique [5].

Pedicle screw placement can be performed freehand [6], using imaging guidance with 2D fluoroscopy-assisted or 3D O-arm navigation imaging systems [6–14], or with robotic assistance [6, 15]. The accuracy of screw placement has been reported in many studies, varying from 69.6–96.8% [6–10, 16]. Some variations in outcomes may be due to the different techniques of pedicle screw insertion used (e.g. K-wire vs. no K-wire) and small sample size ranging from 20–353 patients among the studies [9, 15, 17].

Like pedicle screw placement, interbody fusion procedures vary across contexts. Our surgical technique for minimally invasive surgical transforaminal lumbar interbody fusion (MIS-TLIF) using pedicle screw placement without K-wire and navigated by a surgical imaging system has been modified from the Wiltse approach [18]. More information regarding the accuracy of screw placement and fusion rate associated with this technique will help clarify the advantage of O-arm navigation.

## Methods

### Patients

The study was approved by the Bumrungrad International Institutional Review Board (approval number 278-01-20 CDEK-H Exp).

We retrospectively reviewed data from 2,098 pedicle screw procedures and the fusion rate in 475 consecutive patients who underwent MIS-TLIF with surgical imaging (O-arm Navigation System, Medtronic Inc., Dublin, Ireland) and computerized navigation (StealthStation Surgical Navigation System, Medtronic Inc.) systems at Bumrungrad International Hospital between October 2013 to December 2017 by the same surgical team. Patients were included if they were diagnosed with spondylolisthesis, disc herniation, recurrent disc herniation, foraminal stenosis, or recurrent facet cyst. The exclusion criteria were incomplete patient data or missing O-arm scan images.

### Surgical procedure

Patients were positioned prone on the operating table with a Jackson frame. A reference pin was fixed securely to the posterior superior iliac spine. Intraoperative 3D images were made after the O-arm scan. The skin incision for screw placement was made according to the optimal entry point for pedicle screw placement indicated by a probe. The Wiltse approach was performed. The size and trajectory of the screw were selected during the tapping procedure by sagittal, axial, and coronal images on the StealthStation [Fig. 1]. The preparation of screw placement was completed before all decompression. However, only pedicle screws on the non-decompression side (non-TLIF approach side) were first manually inserted without K-wire under navigation control before the decompression procedure started.

For decompression, an incision was made according to the intraoperative imaging. The microscopic decompression started from the facet removal on the side of the symptoms to identify the traversing and exiting nerve roots. After decompression, the polyetheretherketone cage with the autogenous bone graft and the bone substitute was packed into the disc space. Cross decompression, if needed, was performed.

The pedicle screw on the decompression side, prepared and selected according to size, was then inserted under navigation control. The O-arm scan was redone to check the accuracy of all screw placements. The positions of the screws were evaluated based on the O-arm scan images in the sagittal, axial, and coronal planes. Any unacceptable pedicle breach; >4mm breach lateral direction or > 2 mm breach medial direction detected was revised immediately and another O-arm scan, which was performed to confirm the final pedicle screw position. Once the positions of the screws were accepted by the surgical team, rods were inserted. All wounds were closed in layers [Fig. 2].

## Evaluation of screw placement

The intraoperative O-arm images were evaluated by two independent reviewers. If the cortical layer was breached by the pedicle screw, the breaches were assessed in the axial, sagittal, and coronal planes using the Gertzbein-Robbins classification system[11]. Specifically, pedicles that did not breach the cortical layer were defined as grade A, breaches < 2 mm as grade B, breaches < 4 mm as grade C, breaches < 6 mm as grade D, and breaches  $\geq$  6 mm as grade E [Fig. 3a,b,c]. The direction of screw misplacement was defined as medial, lateral, inferior, or superior [Fig. 3b, c]. In cases where the breach grade was questionable, the poorer grade was selected for data analysis.

## Evaluation of fusion rate

The postoperative computed tomography (CT) scan at the 2-year follow-up was assessed by two independent reviewers. The fusion was graded according to Bridwell et al. as follows [19]: fused with remodeling and present trabeculae (grade I) [Fig. 4a]; graft intact, not fully remodeled or incorporated, but no lucency present (grade II) [Fig. 4b]; **and** graft intact, potential lucency present at top and bottom of the graft (grade III) [Fig. 4c], and fusion absent with collapse/resorption of the graft (grade IV) [13].

## Statistical analysis

Frequency tables and measures of central tendencies were used to summarize descriptive statistics. Parametric and nonparametric tests were used for continuous quantitative (visual analog scale [VAS] back, VAS leg, Oswestry Disability Index [ODI] score, length of hospital stay, operative time, and radiation time) and qualitative (intraoperative and postoperative complications) variables, respectively. The level of statistical significance was set to  $p < 0.05$  for all statistical analyses. Statistical analysis was performed using Stata Statistics Version 14 software (StatCorp LLC, College Station, TX, USA).

## Results

A total of 475 international patients with 2,098 pedicle screws were included. The mean age was  $56.61 \pm 12.30$  years and 45.26% were female. Ethnicities included Asian (58.74%), Caucasian (20.21%), Middle-eastern (14.32%), and African (6.74%). The final fusion levels were single (80.63%), two (18.11%), three (1.05%), and four (0.21%). There were L4/L5 as the most prevalent placement (55.35%), followed by L5/S1 (36.29%), L3/L4 (5.22%), L2/L3 (2.35%), L1/L2 (0.52%), and S1/S2 (0.26%) as shown in Table 1.

Table 1  
Characteristics of patients

<b>Variables</b>	<b>Total</b>
Age (Years), mean $\pm$ standard deviation	56.61 $\pm$ 12.30
Sex (female)	45.26%
<b>Ethnicity</b>	
Asian	58.74%
Caucasian	20.21%
Middle-Eastern	14.32%
African	6.74%
<b>Diagnosis</b>	
Foraminal stenosis	45.05%
Spondylolisthesis	37.26%
Disc Herniation	11.37%
Recurrent Disc Herniation	6.11%
Recurrent Facet Cyst	0.21%
<b>Fusion level</b>	
1 level	80.63%
2 levels	18.11%
> 2 levels	1.26%
<b>Level of screw</b>	
L1-L2	0.52%
L2-L3	2.35%
L3-L4	5.22%
L4-L5	55.35%
L5-S1	36.29%
S1-S2	0.26%
<b>Total screws</b>	2,098

The radiologic assessment of pedicle screw placement showed that seven out of 2,098 screws were breaches. None of screw needed immediate revision. In total, 99.66% of the screws were grade A (no breach), 0.19% were grade B (< 2 mm breach) and 0.14% were grade C (< 4mm breach). None of the cases were grade D, or E. The breaches occurred more often on the left side and mostly on L4. The most deviated direction was medial as shown in Table 2.

Table 2  
Description of pedicle screw placement[11]

<b>Accuracy (%)</b>	<b>Total</b>
Grade A	2,091/2,098(99.66)
Grade B	4/2,098(0.19)
Grade C	3/2,098(0.14)
Grade D	0
Grade E	0
<b>Direction of Screw Misplacement (%)</b>	
Medial	4/7(57.14)
Lateral	3/7(42.86)
Superior	0
Inferior	0
<b>Level (%)</b>	
L1	0
L2	0
L3	2/7(28.57)
L4	4/7(57.14)
L5	0
S1	1/7(14.28)
<b>Side (%)</b>	
Right	2/7(28.57)
Left	5/7(71.42)

## Fusion rate

From the 2-year CT scans, the grade I fusion rate was 95.45% and grade II was 4.54%. In total, 80.63% of the cases were single-, 18.11% were two-, 1.05% were three-, and 0.21% were four-level fusions. L4/L5 was the most prevalent (55.35%), followed by L5/S1 (36.29%), L3/L4 (5.22%), L2/L3 (2.35%), L1/L2 (0.52%), and S1/S2 (0.26%) (Table 3).

Table 3  
Fusion rate according to the Bridwell Interbody Fusion Grading System at 2-year CT scan [19]

Grade	Total
Grade I	95.48%
Grade II	4.51%
Grade III	0
Grade IV	0

## Complications

Pedicle screw perforations may lead to serious complications, such as neurovascular injury and neurologic complications. In the present study, 1.68% of patients(7cases) had a pedicle breach. However, there was no effect on the neurological status or ODI score in these patients.

## Discussion

This study aimed to evaluate the accuracy of screw placement and fusion rate after MIS-TLIF under O-arm navigation. Results show that accuracy of pedicle screw insertion was 99.66% with a 95.45% fusion rate. Of the breach cases, none were associated with complications.

Pedicle screw fixation has been widely used due to the three-column control of the vertebral body in spinal surgeries. The malposition of a screw may violate the nearby vital structures and lead to neurovascular injury. Intraoperative assistance, such as O-arm navigation, has the potential to improve the accuracy of screw placement [7–10, 20]. Therefore, we used O-arm navigation to optimize the pedicle screw placement in MIS-TLIF procedures.

# Accuracy of pedicle screw placement

Studies from surgeries using O-arm imaging with StealthStation navigation have reported increased accuracy of screw placement compared to other techniques. A retrospective review of 191 screws showed 95.81% accuracy in placement [11]. Kleck et al. showed 97% accuracy [21]. Feng et al. showed 97.22% accuracy in the lumbar spine [13]. Van et al. evaluated 1922 screws in an international, multicenter study and found 97.5% correct placements and 1.8% needing immediate revision. Sadrameli et al. (2018) conducted wireless percutaneous pedicle screw placement for 182 screws and demonstrated 90.1% screw accuracy [22]. Higher than in previous reports, the present study showed 99.66% accuracy. Since the surgeries included in the present study were mainly single-level surgeries, the high rate of accuracy could be because the distance between the reference frame and surgical site was short. In addition, not using K-wire for the surgeries in this study eliminated the risk of K-wire difficulty and complications. Furthermore, we started using O-arm navigation in 2013, thus, the learning curve may not be a factor in more recent results. For the misplacement recorded in the present study, they occurred similarly in both sides and among the ethnic groups.

Obtaining the O-arm scan after pedicle screw insertion could reduce reoperation rates. A previous study showed a 3.6% intraoperative revision rate [12] and Van et al. reported a 1.0% intraoperative revision rate [15]. In this study, there was no intraoperative revision (0%). The indication for immediate screw revision was the detection of a > 4-mm breach lateral direction or > 2-mm breach medial direction on the O-arm images. None of the 2,098 screws needed intraoperative revision, and the reoperation rate for screw revision was also 0%.

## Fusion rate

In a systematic review and meta-analysis, lumbar fusion rates were reported at 95.7% at 24-months when recombinant human bone morphogenetic protein-2 was used for TLIF/posterior lumbar fusion (PLF) [23]. According to another systematic review, the 93-93.3% fusion rate associated with MIS-TLIF seemed to be higher compared to lateral lumbar interbody fusion, anterior lumbar interbody fusion, and PLF [24]. Khan et al. reported 92.3% and 92.7% fusion rates for the BMP and non-BMP groups, respectively [25]. Our results showed 95.45% grade I and 4.54% grade II fusions on the 2-year CT scan.

No comparative statistical analysis is done between Grade A vs Grade B breaches although this is likely not possible given the rarity of breaches. Among different ethnicities, Africans tended to have more cases classified as grade II fusions.

## Limitations

There are limitations to this study to consider. First is the retrospective and single-center design that limits the generalizability of the results. To reduce these limitations, the evaluators were blinded to the clinical results and the O-arm images were independently reviewed. Second, some O-arm images were not clear because of the material of the inserted pedicle screws. In cases where the breach was questionable, the poorer grade was selected for data analysis.

## Conclusions

The accuracy of pedicle screw insertion was 99.66% and the fusion rate was 95.45% under O-arm navigation. Pedicle screw breaches were not associated with poor clinical outcomes, and there was no evidence of a relationship with fusion rate.

## Abbreviations

CT, computed tomography; MIS-TLIF, minimally-invasive surgical transforaminal lumbar interbody fusion; ODI, Oswestry Disability Index; PLF, posterior lumbar fusion VAS, visual analog scale

## Declarations

**Ethic approval and consent to participate:** The study was approved by the Bumrungrad International Institutional Review Board.

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**Consent for Publication:** Not applicable

**Availability of data and material:** All data generated or analysed during this study are included in this published article

**Competing interests:** The authors declare that they have no competing interests.

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### Authors' contributions:

WK and KW contributions to the conception. KP and KW design of the work. KW, KM collect the data. KW, KM and WK provide figures. KP acquisition, analysis, KP, KW interpretation of data; KW have drafted the work or substantively revised it

All authors have approved the submitted version and agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature.

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## Figures



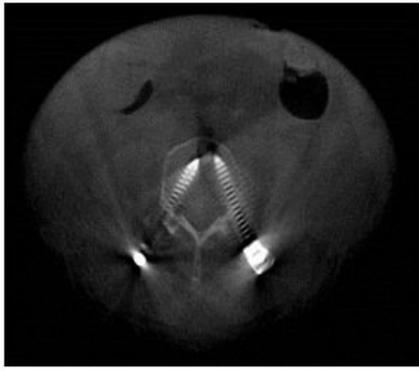
**Figure 1**

Pedicle Screw Insertion using Intra-operative O-arm Navigation. The position and size of the pedicle screw are decided intra-operatively



**Figure 2**

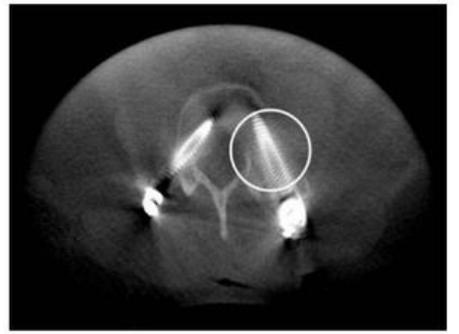
Surgical Wounds



**a**



**b**



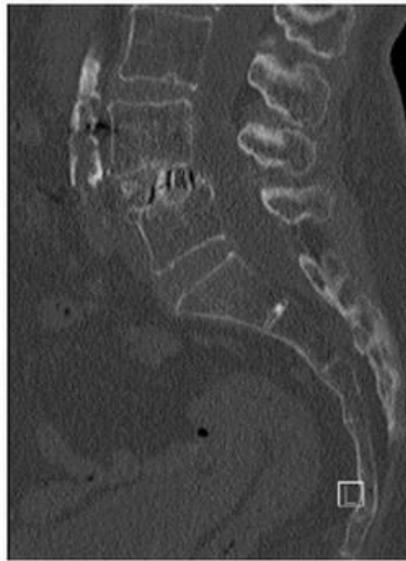
**c**

**Figure 3**

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**a**



**b**



**c**

**Figure 4**

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