

Original Research Article

Accuracy of pedicle screw fixation under O-arm and navigation guidance in thoracolumbar spine surgery

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ABSTRACT

Background: Accurate pedicle screw placement is critical for successful thoracolumbar spine fixation. Misplacement can lead to complications such as neurological injury, vascular damage, and the need for revision surgeries. The use of 3D intraoperative imaging and navigation systems, such as the O-arm and Stealth system, has been proposed to improve screw placement accuracy. This study evaluates the efficacy and safety of these systems for pedicle screw insertion in the thoracolumbar spine.

Methods: A prospective, non-randomized study was conducted with 118 patients who underwent thoracolumbar spine fixation between July 2022 and April 2024. A total of 512 pedicle screws were inserted using the O-arm navigation system. Preoperative assessments included X-ray, MRI, and neurological evaluation using the ASIA scale and VAS. The O-arm system was used for real-time 3D imaging, guiding screw placement. Postoperative accuracy was evaluated with an O-arm confirmation scan and classified using the Gertzbein and Robbins scale.

Results: The study group included 46 male and 72 female patients, with the mean age of 49.22 years. Degenerative diseases were the most common aetiology. Pedicle screw fixation was performed alone in 32 cases and in combination with decompression or TLIF in 86 cases. Of the 512 screws inserted, 486 (95%) were classified as Grade A (accurate placement). The overall breach rate was 5.07%, with 2.34% requiring intraoperative revision. Notably, no postoperative revisions or neurovascular injuries occurred, and there was no deterioration in ASIA grading or VAS scores.

Conclusions: The use of 3D intraoperative imaging and navigation significantly enhances the accuracy and safety of pedicle screw placement in thoracolumbar spine surgery. Routine use of this technology minimizes complications, reduces the need for revision surgeries, and ensures optimal patient outcomes.

Keywords: 3D imaging, Accuracy, Intraoperative navigation, O-arm, Pedicle screw fixation, Stealth navigation, Thoracolumbar spine

INTRODUCTION

The use of screws for internal spinal fixation has its origins in King's 1948 description, with significant advancements in technique over the years. Pedicle screws, first documented by Boucher in 1959 and refined by Roy-Camille et al. in the 1960s, have become standard for thoracolumbar spine fixation due to their biomechanical

advantages in correcting spinal deformities. Their widespread use spans degenerative, traumatic, infectious, and oncological conditions, providing three-column stability and effective fixation for the vertebral body.¹

However, accurate placement of pedicle screws is crucial to avoid complications such as dural tears, neural damage, and vascular or visceral injury, particularly in the cervical

and thoracic spine.² Despite various techniques, misplacement rates remain high, reaching up to 30% in the lumbar and 55% in the thoracic spine, even with X-ray guidance. To address these challenges, innovative methods involving real-time image processing and computer systems have been explored since the early 1990s.³

Several navigation systems assist in pedicle screw insertion, including CT-based navigation (CT Nav), 2D fluoroscopy-based navigation (2D FluoroNav), 3D fluoroscopy-based navigation (3D FluoroNav), and O-arm-assisted navigation (O-arm Nav). CT Nav utilizes preoperative CT scans, while 2D FluoroNav and 3D FluoroNav provide intraoperative 2D and 3D imaging, respectively. O-arm Nav integrates a 3D CT-like system with real-time surgical navigation.⁴

The O-arm® system (Medtronic) represents a cutting-edge imaging platform designed to optimize spine surgeries. It provides 3D imaging, which, when integrated with the Stealth Station® navigation system, enhances pedicle screw placement accuracy and minimizes radiation exposure. The O-arm captures up to 400 images in just 30 seconds, offering real-time, multidimensional views of the spine. This technology eliminates the need for fluoroscopy, reducing radiation risks for both patients and surgeons.⁵

Despite the growing body of research on CT-based and fluoroscopy-based navigation systems, there is limited data on the O-arm and Stealth system's effectiveness. This study aims to evaluate the accuracy of pedicle screw placement in the thoracolumbar spine using the O-arm and Stealth system.

METHODS

This prospective, non-randomized study aimed to evaluate the accuracy of pedicle screw placement in the thoracolumbar spine. Using Andrew Fisher's formula, the sample size was calculated, with a total of 512 pedicle screws placed in patients admitted to the Orthopaedics department between July 2022 and April 2024.

Inclusion criteria

Patients requiring spine fixation in thoraco-lumbar region were included.

Exclusion criteria

Patients with previous surgery or failed surgery to same vertebral level of spine were excluded.

Study technique

The study was conducted in the Department of Orthopaedics, Apex Hospital Varanasi, after obtaining ethical clearance. A total of 512 pedicle screw placements for thoracolumbar spine fixation surgeries were performed

from July 2022 to April 2024, with informed consent obtained from all participants. Preoperative protocols included routine investigations such as X-ray, MRI, and neurological assessment using the ASIA scale and VAS. The surgical procedure involved accurate localization, attachment of a reference frame to the posterior superior iliac spine (PSIS), and the use of the O-arm for high-resolution imaging and navigation. The O-arm scan was transferred to the navigation system for automatic registration, and pedicle screw placement was guided by the system. Post-surgery, an O-arm confirmation scan was performed to verify screw placement, which was assessed using the Gertzbein and Robbins classification system for accuracy. Post-operative care followed standard hospital protocols.

Statistical analysis

Frequency tables and measures of central tendencies were used for descriptive statistics. Parametric and nonparametric tests were used for continuous quantitative variables and qualitative variables, respectively. The level of statistical significance was set to $p < 0.05$ for all statistical analysis. The accuracy of pedicle screw fixation under O-ARM and navigation guidance in thoracolumbar spine surgery were calculated according to the formula below-

$$\text{Accuracy rate (\%)} = \frac{\text{Number of screws, grade A+B}}{\text{Total number of screws implanted}}$$

RESULTS

The study group consisted of 46 male and 72 female patients, with the largest age group being 61-75 years (48 patients), followed by 46-60 years (36 patients). There were 12 patients aged 31-45, 4 patients aged 15-30, and 18 patients over 75 years old. The mean age of the cohort was 49.22 years.

Degenerative conditions were the most common etiology, affecting 72 patients, followed by traumatic fractures in 22 patients. Pathological fractures accounted for 14 cases, while infections and tumors contributed 6 and 4 cases, respectively (Table 1).

Table 1: Distribution of cases according to aetiology.

Etiology	No. of patients	Percentage
Degenerative diseases	72	61.02
Traumatic fracture	22	18.64
Pathological fracture	14	11.86
Infection	6	5.08
Tumour	4	3.39
Total	118	100

Pedicle screw fixation alone was performed in 32 cases, while combined procedures were also common: 37 cases involved pedicle screw fixation with decompression, and 49 cases involved TLIF with decompression (Figure 1).

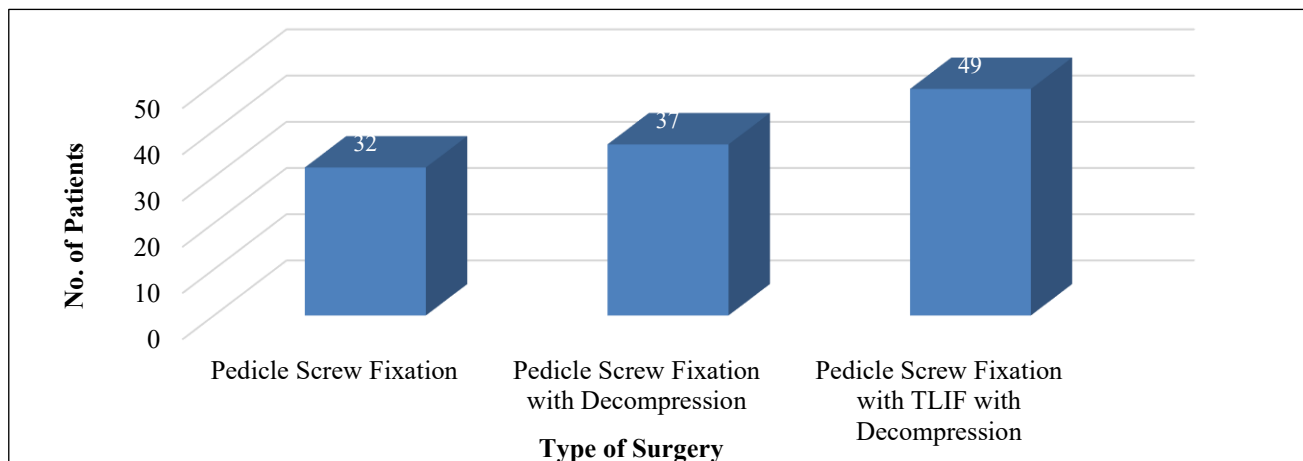


Figure 1: Distribution of cases according to type of surgery.

The table shows the distribution of screws inserted at each spinal level, reflecting the focus of surgical interventions. While no screws were inserted at levels T1 and T2, lumbar regions, particularly L4 and L5, saw the highest number of insertions, with 92 and 128 screws, respectively, indicating a greater emphasis on addressing conditions affecting the lower spine (Table 2).

Table 2: Distribution of pedicle screws according to level of vertebrae.

Levels	No. of screw inserted	Percentage
T1	0	0.00
T2	0	0.00
T3	4	0.78
T4	4	0.78
T5	4	0.78
T6	8	1.56
T7	8	1.56
T8	6	1.17
T9	8	1.56
T10	8	1.56
T11	34	6.64
T12	42	8.20
L1	30	5.86
L2	66	12.89
L3	70	13.67
L4	92	17.97
L5	128	25.00
Total	512	100

The Figure 2 provides an overview of pedicle screw breaches across spinal levels, classified by the Gertzbein and Robbins scale. Grade A, indicating perfect screw placement, accounted for 486 screws, while 14 screws were classified as grade B (breach <2 mm). Four screws were graded as grade C (2-<4 mm), six as grade D (4-<6 mm), and two screws as grade E (>6 mm), reflecting varying degrees of screw misplacement within the patient cohort (Figure 2).

The Table 3 provides an analysis of screw insertion and revision across various vertebral levels, detailing the total number of screws inserted, breaches (classified as Grade B, C, D, or E), and revised screws. Of the 512 screws inserted, 26 breaches were observed, with 12 requiring revision. The data highlights patterns of breach occurrence and revision across different spinal levels, emphasizing the need for targeted interventions to address breaches and improve patient outcomes.

Table 3: Distribution according to revised screws.

Vertebral levels	No. of screws inserted	Total Breach (Grade B, C, D, E)	No. of revised screws (Grade C, D, E)
T1	0	0	0
T2	0	0	0
T3	4	0	0
T4	4	0	0
T5	4	0	0
T6	8	0	0
T7	8	0	0
T8	6	1	0
T9	8	1	0
T10	8	0	0
T11	34	3	2
T12	42	2	1
L1	30	3	2
L2	66	3	2
L3	70	2	0
L4	92	4	2
L5	128	7	3
Total	512	26	12

The Figure 3 provides a comprehensive breakdown of screw insertion statistics across different vertebral levels, along with the incidence of breaches classified as Grade B, C, D, or E, and the corresponding percentage of breaches relative to the total number of screws inserted. Notably, the

data indicates that out of the total 512 screws inserted, 26 breaches occurred, resulting in an overall breach rate of 5.07%. Analysis by vertebral level reveals varying rates of breaches, with some levels experiencing higher percentages compared to others. For instance, at T8 and T9 levels, where 6 and 8 screws were inserted respectively, the breach rates were 16.6% and 12.5%. In contrast, lower breach rates were observed at levels such as L3, where 70

screws were inserted with only 2 breaches, resulting in a breach rate of 2.85%. The data table presents a comprehensive analysis of breach severity across various vertebral levels. It reveals that out of a total of 26 breaches observed, 14 screws were categorized as clinically acceptable/insignificant breach (Grade B), while the remaining 12 screws were considered unacceptable/significant breach (Grade C, D, or E).

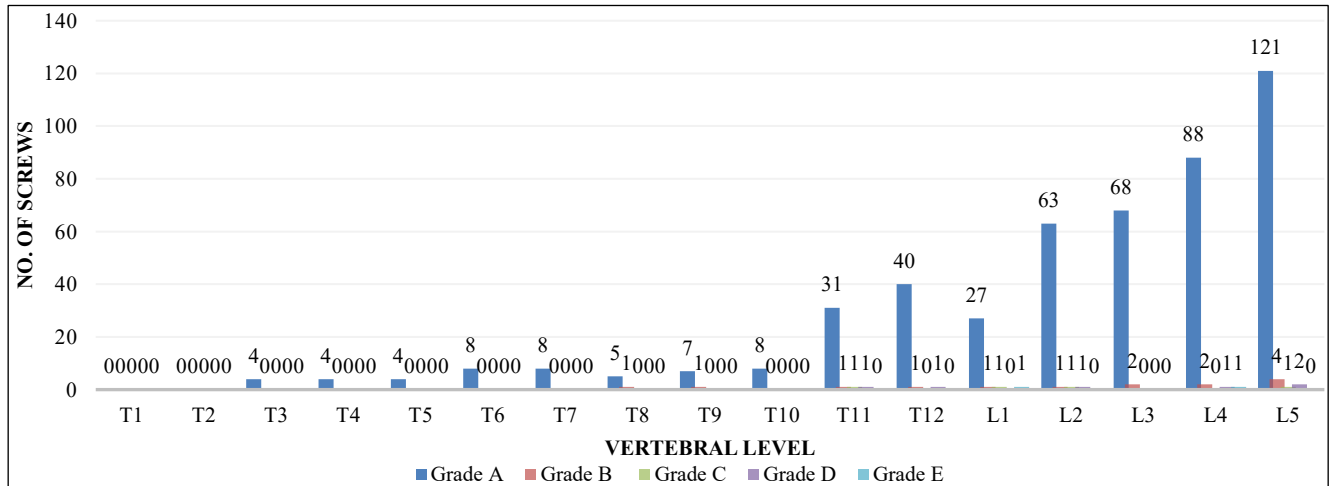


Figure 2: Distribution of pedicle screws according to severity of breach in pedicle using Gertzbein and Robbins classification.

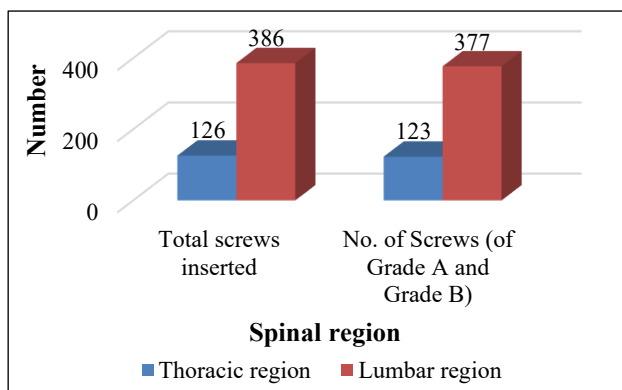


Figure 3: Percentage accuracy.

DISCUSSION

Since the early 1990s, image-guided navigation systems have become increasingly common in spine surgery, evolving from traditional radiography and C-arm fluoroscopy methods. Advances in computer technology have enhanced their accuracy, safety, and effectiveness, especially in complex cases like scoliosis, malignancy, and deformity correction. Navigation allows for precise screw placement, reducing neurological injuries and the need for screw revisions. In the lumbar region, it facilitates the use of more medially angulated screws, improving fixation strength. The O-arm combined with Stealth Station navigation offers real-time 3D imaging, ensuring accurate screw insertion with minimal radiation exposure. While

screw misplacement rates vary, misplacements under 2 mm are generally safe and unlikely to cause neurological harm.⁶ This combination of advanced technology ensures safer and more reliable spinal surgeries.

In the present study, a total of 512 pedicle screws were inserted across various levels of the thoracolumbar spine in 118 patients, with no screw insertions at T1 and T2. The lumbar regions, particularly L4 and L5, showed the highest number of screw insertions, with 92 and 128 screws, respectively, reflecting a focus on conditions affecting the lower spine. These findings are consistent with other studies, such as Lu J et al, who implanted 573 screws in 97 patients, Winder et al, who placed 614 screws in 108 patients from T2 to S1, and Miller et al, who conducted a study with 153 patients, placing 240 screws from T1 to S1, with 146 screws in the thoracic spine and 94 in the lumbosacral region.⁷⁻⁹

In this study, Grade A pedicle screw placements were the most frequent, with 486 screws placed correctly across various vertebral levels. Grade B breaches occurred in 14 screws, Grade C in 4, Grade D in 6, and Grade E in 2 screws. Overall, 26 breaches were observed, resulting in a breach rate of 5.07%. Breach rates varied by vertebral level, with higher rates seen at T8 and T9 (16.6% and 12.5%, respectively), while lower rates were observed at L3, where 2 breaches occurred out of 70 screws, resulting in a breach rate of 2.85%. These findings align with the results of Kosmopoulos et al, who conducted a meta-analysis involving 37,337 pedicle screws and reported an

overall misplacement rate of 8.3%.¹⁰ Their study also highlighted the lower misplacement rate of 4.8% with navigation-assisted techniques compared to 9.7% with non-navigation methods. Another meta-analysis of 7,533 screws found a misplacement rate of 10.8%, with rates ranging from 2.8% to 14.5% depending on the navigation system used.

In our study, the thoracic region demonstrated high precision, with 123 out of 126 screws accurately placed, yielding an accuracy rate of 97.61%. In the lumbar region, 377 out of 386 screws were accurately inserted, resulting in an accuracy rate of 97.69%. Overall, in the thoracolumbar region, 500 out of 512 screws were placed correctly, achieving an overall accuracy rate of 97.65%. This is consistent with findings from Sundaram et al, who reported a first-pass accuracy rate of 97.41% for thoracolumbar pedicle screw insertion.¹¹ Similarly, Waschke et al achieved a 94.5% accuracy rate across 2,422 screws without any revision surgeries, while Rivkin and Yocom reported a 94.7% accuracy in 1,651 screws, with a 1.5% revision rate.^{12,13}

CONCLUSION

Our analysis of 512 thoracolumbar pedicle screw insertions highlights the efficacy and safety of using 3D intraoperative imaging and navigation, achieving a 97.65% first-pass accuracy with a total breach rate of 5.07%, of which 2.34% were significant breaches revised intraoperatively. Importantly, no revisions were required postoperatively, and there were no neurovascular injuries or deterioration in ASIA grading or VAS scores, even in cases of screw malposition. The prompt revision of significantly breached screws during the same surgical setting eliminated the need for subsequent revision surgeries. These findings underscore the effectiveness of routine navigation and intraoperative 3D scanning in enhancing the safety and precision of thoracolumbar spinal instrumentation, particularly in complex cases.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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