

PATIENT LEVEL CT CLASSIFICATION AFTER NAVIGATION GUIDED VERSUS FLUOROSCOPY GUIDED PERCUTANEOUS PEDICLE SCREW FIXATION FOR THORACOLUMBAR FRACTURES

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ABSTRACT

Thoracolumbar fractures often require posterior stabilization, and the limited exposure in percutaneous fixation makes accurate pedicle screw placement especially important. We compared navigation guided and fluoroscopy guided percutaneous transpedicular fixation in 50 patients with T11-L2 fractures treated at Nishtar Hospital Multan. Adults aged 18-60 years with intact neurology, an AO Spine thoracolumbar injury score above 5, and presentation within 72 hours of injury were included; 25 patients received each approach. The navigation group underwent CT-based trajectory planning with Brainlab, whereas the comparison group underwent placement under anteroposterior and lateral fluoroscopy. Postoperative CT with three dimensional reconstruction was obtained within 24 hours. Our postoperative outcome table recorded an accurate or inaccurate classification for each patient, rather than a grade for every implanted screw. We compared these patient level proportions and examined the baseline and exploratory subgroup counts. The groups had similar mean ages (47.20 ± 9.30 versus 48.76 ± 9.72 years) and body mass indices (28.40 ± 2.61 versus 29.32 ± 2.50 kg/m²). Twenty-four of 25 navigation patients (96%) and 19 of 25 fluoroscopy patients (76%) were classified accurate, an absolute difference of 20.0 percentage points (95% Agresti-Caffo confidence interval, -0.7 to 37.8). The risk ratio was 1.26 (approximate 95% confidence interval, 0.999 to 1.597). Pearson chi-square gave $p=0.042$; a two-sided Fisher exact test, used because there were only seven inaccurate classifications, gave $p=0.098$. Navigation was associated with a higher observed patient level classification rate, although the interval was wide and the exact test did not establish a clear difference. Because individual screw counts and CT grades were unavailable, these results do not estimate screw level placement accuracy or clinical safety.

Keywords: Thoracolumbar fracture; pedicle screw; neuronavigation; fluoroscopy; CT; accuracy

INTRODUCTION

The thoracolumbar junction joins the relatively rigid thoracic spine to the more mobile lumbar spine. Fractures in this region can compromise alignment and stability, especially when the

posterior ligamentous structures are disrupted. Posterior pedicle screw fixation provides immediate mechanical support and is commonly used when an unstable fracture requires surgical treatment. The choice of an open or percutaneous

approach changes the exposure of the posterior elements, but both approaches depend on a reliable path through each pedicle.

Percutaneous fixation limits muscle dissection and allows screws and rods to be placed through small incisions. It also removes the direct view of bony landmarks that helps orient the surgeon during an open procedure. The pedicle is a narrow three dimensional corridor; its size, orientation and cortical boundaries vary by vertebral level and patient. A misplaced screw can breach medially toward the canal, laterally beyond the vertebral body, or superiorly or inferiorly toward adjacent structures. CT-based assessment is therefore useful after instrumentation, even when the intraoperative images appear satisfactory [1,2]. Conventional fluoroscopy displays projections of the vertebra and instruments in real time. During percutaneous placement, anteroposterior imaging helps locate the pedicle and lateral imaging helps assess depth and trajectory. The surgeon must integrate these two views while advancing a needle or guidewire through a three dimensional structure. Image overlap, patient habitus and the need to reposition the C-arm can make interpretation more difficult. Fluoroscopy remains practical and widely used, but the quality of placement depends on both image quality and the operator's interpretation.

Navigation combines preoperative or intraoperative imaging with instrument tracking so that the planned trajectory can be viewed against reconstructed anatomy. It may help identify a pedicle entry point and show the relation of the instrument to the cortical walls before the screw is fully advanced. The value of that information depends on accurate registration and a stable reference frame. A navigation display can be misleading if the patient or reference array moves after registration, and imaging used to establish or verify navigation adds steps to the operation. These technical differences justify comparing navigation with fluoroscopy in the same clinical setting. The endpoint chosen for such a comparison matters as much as the guidance method. Gertzbein-Robbins grades describe the extent of cortical breach for each screw: grade A has no breach, grade B has less than 2 mm, and higher grades indicate progressively greater

deviation [1]. The proportion of grade A or B screws is a screw level measure. A patient may receive several screws, however, and a single patient level label cannot reveal how many were placed or which one breached. Published placement rates should be interpreted with their imaging method, threshold and denominator in view [3,4,7].

We studied patients with T11-L2 fractures at Nishtar Hospital Multan to compare postoperative CT classifications after navigation guided and fluoroscopy guided percutaneous fixation. We describe the treatment groups, the recorded outcomes and the uncertainty of their difference. Because the outcome table classifies patients rather than individual screws, our principal question is whether the observed patient level classification differs between groups. We do not equate that comparison with a screw level accuracy or complication rate.

LITERATURE REVIEW

The method used to assess a pedicle screw determines what an accuracy estimate means. Gertzbein and Robbins established a CT-based description of screw position and canal encroachment [1]. Laine and colleagues prospectively examined screw placement on CT and showed the importance of postoperative cross-sectional imaging [2]. Plain radiographs or intraoperative fluoroscopic views may show a satisfactory projected trajectory without resolving a small cortical breach. CT studies can describe both the amount and direction of deviation, although thresholds for an acceptable screw differ between reports.

Kosmopoulos and Schizas brought together 130 studies comprising 37,337 screws and found substantial differences across spinal regions and insertion techniques [3]. Gelalis and colleagues focused on prospective in vivo comparisons of freehand, fluoroscopic and navigated insertion [4]. These reviews show why the apparent advantage of one technique can change with case mix, anatomy, imaging and study design. A pooled per-screw estimate is not directly comparable with the percentage of patients receiving a binary label after multiple screws have been inserted. Waschke and colleagues compared CT navigation and

fluoroscopic placement in a single centre series of 4,500 thoracolumbar screws [5]. In their thoracic subgroup, the reported accuracy was 95.5% with navigation and 79.0% with fluoroscopy. Those values informed the initial sample-size assumptions for our study. The earlier series assessed screws, however, whereas our outcome table has one observation per patient. It would be incorrect to treat a numerically similar proportion as evidence of the same endpoint or effect size. Brunken and colleagues examined three dimensional navigations against fluoroscopic guidance specifically in percutaneous fixation of traumatic fractures at the thoracolumbar junction [6]. This population is closer to ours than series dominated by deformity or degenerative disease. Even among trauma cohorts, the extent of fracture displacement, pedicle morphology, number of instrumented levels and imaging platform can differ. These features may alter the technical difficulty of placement and should be reported when results are compared across centres.

Aoude and colleagues reviewed the methods used to judge placement and noted that accuracy depends on the grading definition [7]. Bilhar and colleagues compared fluoroscopy and navigation in cadaveric thoracic specimens [8], while Charles and colleagues described technical limits of percutaneous placement across the thoracolumbar region [9]. Cadaveric studies allow closer control of anatomy and instrumentation, but they cannot measure clinical consequences such as new neurological deficit or reoperation in injured patients. Revision for malposition was the distinct outcome assessed by Fichtner and colleagues [10]. Perdomo-Pantoja and colleagues pooled results from 51,161 screws placed by different methods [11]. Rajasekaran and colleagues compared navigated and non-navigated thoracic screws in deformity correction [12]. Tabaraee and colleagues studied cone-beam CT navigation and conventional C-arm fluoroscopy in a cadaveric comparison that also considered efficiency and radiation [13], and Tian and Xu reviewed image guided accuracy across studies [14]. Collectively, these reports address related but separate questions: where the screw lies on CT, whether a patient needs revision, and what imaging or operating burden accompanies placement. Our

analysis addresses the first question only through a patient level classification. It contains no comparative revision, radiation or operative time endpoint.

MATERIALS AND METHODS

Study design and setting: We conducted a two group comparative study in the Department of Neurosurgery, Nishtar Hospital Multan, during a twelve month study period. Fifty patients were enrolled, with 25 treated by navigation guided and 25 by fluoroscopy guided percutaneous transpedicular fixation. The initial sample-size calculation used 80% power, a 5% significance level and the 95.5% and 79.0% placement proportions reported by Waschke and colleagues [5]; it called for 50 patients per group. Fewer eligible patients were recruited, and the final study enrolled half that number per group. We report confidence intervals to show the precision achieved by the actual sample.

Eligibility and enrollment: We included men and women aged 18-60 years with a fracture from T11 through L2, presentation within 72 hours of injury, intact neurological examination and a thoracolumbar AO Spine injury score above 5. The AO Spine system describes fracture morphology, neurological status and modifiers [15]. We excluded fractures outside the thoracolumbar region, bleeding disorders, a history of malignancy, repeat surgery, open or pathological fractures and multiple trauma. Eligible patients were enrolled by non-probability convenience sampling after assessment in the outpatient or emergency service.

Group assignment: Assignment was described by lottery in one passage and by odd or even enrollment number in another. Both descriptions lead to two groups of 25, but they do not establish the same allocation process. We cannot verify sequence generation or concealment from the study records, and therefore interpret the comparison without assuming a concealed random allocation. We do not have surgeon level or fracture-morphology data to assess whether these features were balanced.

Navigation assisted planning and placement: For patients in the navigation group, preoperative two and three dimensional CT images were loaded

into Brainlab software. We reviewed the vertebral anatomy, selected the pedicle entry region and planned the path and depth of instrumentation. During surgery, the navigation display provided a reconstructed view of the instrument in relation to the vertebra. We did not document the registration procedure, reference array verification, image acquisition hardware or a measured navigation error. These details constrain replication of the exact workflow.

Fluoroscopy guided placement: In the comparison group, percutaneous access was guided by anteroposterior and lateral fluoroscopic images. A Jamshidi needle was advanced through the pedicle into the vertebral body. Guidewires were passed through the needles, after which the needles were removed and the paraspinal muscles were dilated serially. The pedicle and proximal vertebral body were prepared before cannulated screws were advanced over the guidewires. Rods were introduced through the percutaneous screw extenders and secured after alignment and tightening. The general procedure also describes lateral fluoroscopy, so the amount of fluoroscopy used during navigation-assisted surgery cannot be assumed to be zero.

Postoperative imaging and endpoint: CT with three dimensional reconstruction was performed within 24 hours of surgery. The operative accuracy definition considered Gertzbein-Robbins grades A and B acceptable for a screw [1,16]. Our results table, however, gives a single “accurate” or “inaccurate” entry for each patient and does not include the grade or number of individual screws. We used the recorded patient level binary classification as the outcome. The rule by which the individual screw assessments were combined into that patient label was not documented, so we do not present the percentages as per-screw grade A/B rates.

Data and statistical analysis: We summarized age, body mass index and time to presentation as mean $\pm$ standard deviation, and sex, age band, injury mechanism and CT classification as counts and percentages. We initially used SPSS version 25 and a Pearson chi-square comparison, with a nominal p threshold of 0.05. Because only seven patients were classified inaccurate, we also calculated a two sided Fisher exact p value. We

estimated the navigation-minus-fluoroscopy difference in proportions with a 95% Agresti-Caffo interval and the risk ratio with an approximate log scale 95% interval. Age, sex and injury mechanism subgroup counts are descriptive; we did not fit an adjusted model or a screw level model from these aggregate tables.

Ethics: Institutional ethical approval was obtained before enrollment. Written informed consent was obtained from the participants.

DATA DESCRIPTION

The study dataset comprises 50 treated patients, 25 in each guidance group. The aggregate baseline tables report age in three bands, sex, body mass index, elapsed hours from injury to presentation and one of four injury mechanisms. Age eligibility began at 18 years, but every patient tabulated was 31-60 years old. The two groups had similar mean ages, while falls were more frequent in the fluoroscopy group and violence related injury was more frequent in the navigation group. Table 1 presents the recorded group summaries without treating these baseline comparisons as proof of equivalence.

The available postoperative CT outcome is binary at the patient level. Table 2 contains 24 accurate and one inaccurate classification in the navigation group and 19 accurate and six inaccurate classifications in the fluoroscopy group. The 43 accurate classifications divided by all 50 participants yield 86% for the combined cohort. That pooled percentage is distinct from the fluoroscopy group rate of 19/25, or 76%. We use the denominators in the outcome table consistently in the abstract, results and Figure 1.

The age and sex cross tabulations retain the number of accurate classifications within each stratum (Table 3). We also tabulated the outcome by injury mechanism (Table 4). These are aggregate summaries, not patient level records that can be linked across covariates. We cannot determine whether a given patient had one or several malpositioned screws, the direction and size of any cortical breach, the vertebral level of each screw, or a grade A-E distribution. Neurological change, revision, radiation dose and operative time were not supplied as comparative outcomes.

Table 1. Baseline and injury characteristics.

Variable	Navigation	Fluoroscopy
Patients	25	25
Age, years	47.20 ± 9.30	48.76 ± 9.72
Age 31-40 / 41-50 / 51-60	9 / 4 / 12	7 / 3 / 15
Male / female	16 / 9	18 / 7
BMI, kg/m ²	28.40 ± 2.61	29.32 ± 2.50
Presentation, hours	43.28 ± 14.75	48.92 ± 13.61
Motor vehicle / fall	7 / 5	8 / 10
Violence / sports	7 / 6	3 / 4

RESULTS

Enrollment and baseline characteristics: We analyzed all 50 patients, with 25 in each group. Mean age was 47.20 ± 9.30 years after navigation assisted fixation and 48.76 ± 9.72 years after fluoroscopy guided fixation. Nine versus seven patients were aged 31-40 years, four versus three were aged 41-50 years, and 12 versus 15 were aged 51-60 years. Thus, 27 of the 50 patients were in the oldest recorded band. The navigation group included 16 men and nine women; the fluoroscopy group included 18 men and seven women (Table 1).

Body mass index and presentation: Mean body mass index was 28.40 ± 2.61 kg/m² in the navigation group and 29.32 ± 2.50 kg/m² in the fluoroscopy group. Mean time from injury to presentation was 43.28 ± 14.75 and 48.92 ± 13.61 hours, respectively. All participants met the criterion of presentation within 72 hours. We recorded p=0.209 for body mass index and p=0.166 for time to presentation. We do not interpret a non-significant baseline comparison as evidence that fracture severity or instrumentation complexity was balanced.

Injury mechanism: Motor vehicle injuries occurred in seven navigation and eight fluoroscopy patients. Five versus ten patients had fallen, seven versus three had violence-related injury, and six versus four had sports related injury (Table 1 and Figure 2). Across both groups, motor vehicle injury and falls each accounted for 15 of 50 cases; violence and sports accounted for ten each. The tabled mechanism comparison was p=0.292. Fracture morphology by mechanism and the number of treated levels were not available, so these counts cannot be used to adjust the primary contrast.

Postoperative CT classification: Navigation patients had 24 accurate and one inaccurate classification, compared with 19 accurate and six inaccurate classifications after fluoroscopy (Table 2). The respective proportions were 96% and 76%, an observed absolute difference of 20.0 percentage points (Figure 1). The 95% Agresti-Caffo interval for the difference extended from -0.7 to 37.8 percentage points. The estimated risk ratio was 1.26 with an approximate 95% interval of 0.999 to 1.597. These intervals reflect considerable uncertainty around the apparent group difference.

Comparison tests: Pearson chi-square without a continuity correction gave p = 0.042. Its expected number of inaccurate classifications in each group was 3.5. With so few events, the two sided Fisher exact test is a useful check and gives p = 0.098. The two tests therefore cross the conventional 0.05 threshold in different directions. We report both rather than presenting the chi-square result alone as a definitive treatment effect.

Age and sex strata: In the 31-40 year group, all nine navigation and seven fluoroscopy patients were classified accurate. For ages 41-50 years, the counts were 4/4 and 1/3; for ages 51-60 years they were 11/12 and 11/15. Among men, 15/16 navigation and 14/18 fluoroscopy patients were classified accurate. Among women, the corresponding counts were 9/9 and 5/7 (Table 3). These strata contain few inaccurate classifications, so differences within them are unstable and should not be interpreted as evidence of age or sex specific effects.

Injury mechanism strata: Accurate classifications for motor vehicle injuries were 6/7 after navigation and 7/8 after fluoroscopy. The corresponding counts were 5/5 and 6/10 for falls,

7/7 and 2/3 for violence-related injury, and 6/6 and 4/4 for sports injury (Table 4). The four strata are descriptive and involve very small denominators. We could not assess per-screw

grades or clinical sequelae of malposition because those observations were unavailable in our aggregate analysis.

Table 2. Reported patient level CT classification.

Measure	Navigation	Fluoroscopy
Recorded accurate	24/25 (96%)	19/25 (76%)
Recorded inaccurate	1/25 (4%)	6/25 (24%)
Risk difference	20.0 points	95% CI -0.7 to 37.8
Risk ratio	1.26	95% CI 0.999 to 1.597
Statistical comparison	Pearson p=0.042	Fisher p=0.098

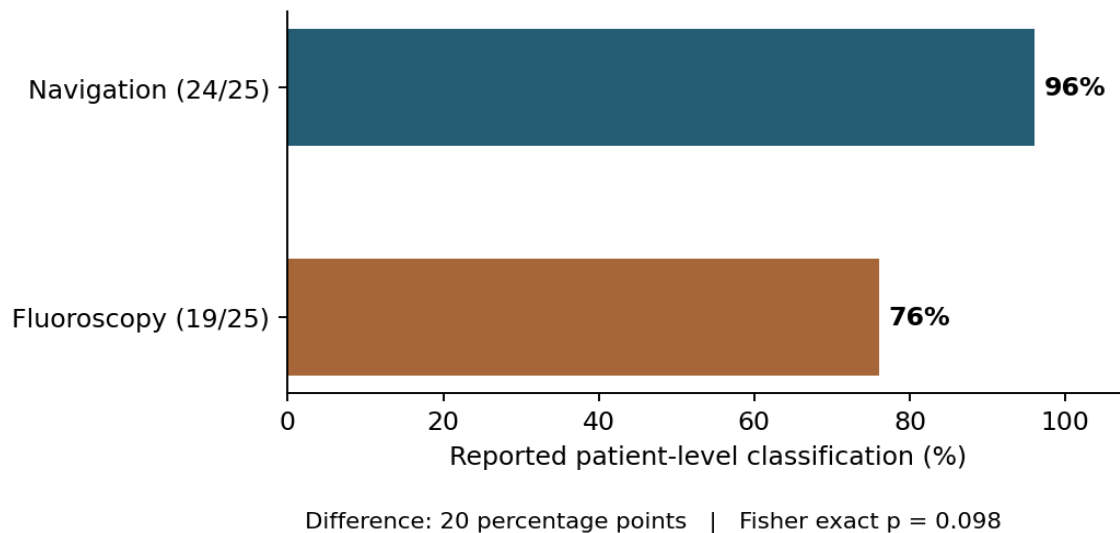


Figure 1. Reported patient classifications; denominator is patients, not screws.

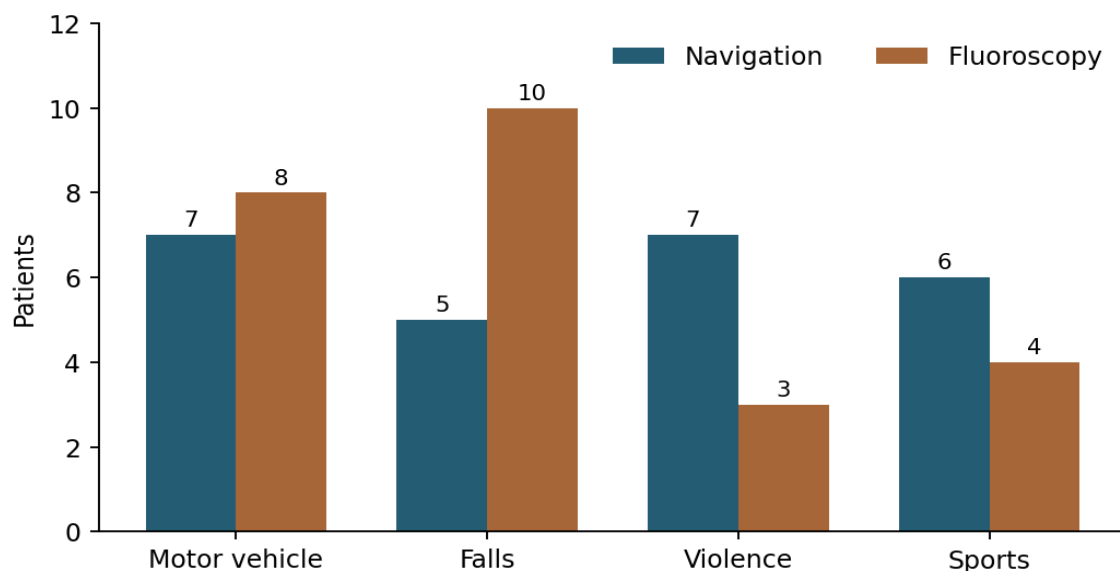


Figure 2. Injury mechanisms by treatment group.

Table 3. Exploratory age and sex strata, recorded accurate/total.

Stratum	Navigation	Fluoroscopy
Age 31-40	9/9	7/7
Age 41-50	4/4	1/3
Age 51-60	11/12	11/15
Male	15/16	14/18
Female	9/9	5/7

Table 4. Patient CT classification by injury mechanism, accurate/total.

Mechanism	Navigation	Fluoroscopy
Motor vehicle	6/7	7/8
Fall	5/5	6/10
Violence	7/7	2/3
Sports	6/6	4/4

DISCUSSION

Navigation assisted fixation was associated with a higher observed proportion of patients classified accurate on early postoperative CT: 24/25 versus 19/25. The 20-point difference is clinically interesting, but only seven patients in the entire cohort were classified inaccurate. Its confidence interval spans a small difference in the opposite direction and a much larger advantage for navigation. The exact p value of 0.098 also differs from the original Pearson chi-square p value of 0.042. We consider the magnitude and uncertainty together rather than assigning the result a binary label based on one test.

The discrepancy between tests follows from the sparse 2×2 table. The chi-square approximation uses expected counts, which are 3.5 in each inaccurate cell; Fisher's test calculates the probability directly for the observed margins. Neither test repairs uncertainty in how the patient level outcome was defined or how patients were allocated. The effect estimate and confidence interval are therefore more informative than a threshold alone. With 25 patients per arm instead of the planned 50, the study has less precision than the initial calculation anticipated.

Our endpoint also differs from those in much of the literature. Waschke and colleagues reported CT accuracy for individual screws [5], as did several reviews that pool screw level estimates [3,4,11]. The current table classifies patients. A patient with four screws and a patient with six each contribute one observation, although their

opportunities for a breach differ. We cannot reconstruct grade A/B

screw counts or the direction and size of any breach. Re-examination of the CT images with one grade per screw and an analysis that accounts for clustering within patients would permit a more direct technical comparison.

The observed injury distribution deserves attention. Falls occurred twice as often in the fluoroscopy group, while violence related injuries were more frequent in the navigation group. Mechanism is an imperfect proxy for fracture morphology, pedicle disruption or the number of levels instrumented, but it suggests that the groups may have differed in ways that the aggregate tables cannot measure. The age, sex and mechanism subgroup counts show how the classifications are distributed, yet their small cells do not support a reliable interaction analysis. Adjustment would require the original patient level data and relevant anatomical or injury variables.

The workflow has further limits. Navigation was based on CT images and Brainlab planning, but registration, reference frame verification and instrument tracking details were not documented in the study dataset. Our operative procedure includes lateral fluoroscopy during percutaneous placement, and we cannot quantify imaging use in either arm. We therefore do not attribute the result to the elimination of fluoroscopy or infer a radiation advantage. We also cannot compare operating time, postoperative neurological status or revision because these outcomes were not available as group data.

Group assignment was described both by lottery and by odd/even enrollment number. Those are different procedures, and we cannot establish concealment. In conjunction with convenience enrollment and absent fracture morphology, this prevents a strong causal conclusion. The strengths of the study are a defined T11-L2 fracture population, equal patient group sizes, and postoperative CT obtained within 24 hours. The finding merits testing in a larger cohort with a documented allocation sequence and complete CT grading.

A subsequent study should retain each patient's vertebral levels, pedicle dimensions, number of screws, CT breach grade and breach direction. It should prespecify whether the primary outcome is the proportion of acceptable screws, the proportion of patients with any unacceptable screw, or a clinical event. Radiation exposure, operative duration, neurological change and revision should be measured separately. This would clarify whether an improvement in CT placement translates into a benefit that matters to patients and would allow fairer comparison with published screw level series.

CONCLUSION

In 50 patients with T11-L2 fractures, an accurate patient level CT classification was recorded for 96% after navigation assisted fixation and 76% after fluoroscopy guided fixation. The observed difference was 20 percentage points, but the confidence interval was wide and the two sided Fisher exact test gave $p=0.098$. Pearson chi-square gave $p=0.042$. Individual screw grades, clinical complications and complete allocation details were unavailable; the present comparison therefore suggests a possible advantage in the recorded patient classification but does not establish a definitive screw level or safety benefit.

ETHICS AND CONSENT

Institutional ethical approval was obtained, and written informed consent was obtained from all participants.

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