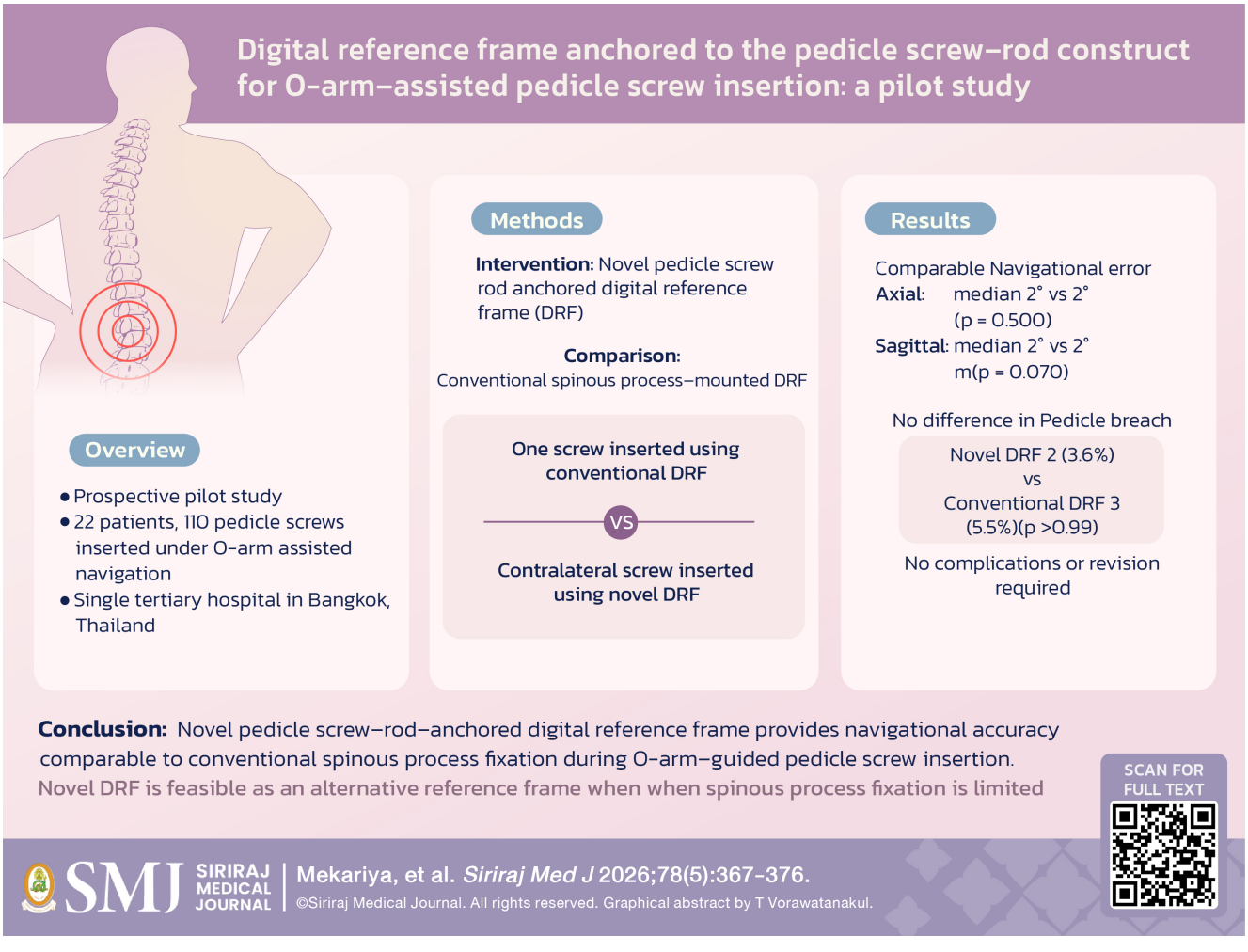
Digital Reference Frame Anchored to the Pedicle Screw–rod Construct for O-arm–Assisted Pedicle Screw Insertion: A Pilot Study

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ABSTRACT

Objective: Accurate pedicle screw placement reduces neurological injury and complications. Although O-arm navigation improves precision, navigation error and digital reference frame (DRF) instability persist. This study aims to develop and evaluate a novel DRF anchored to the pedicle screw–rod construct as an alternative to spinous process–based attachment for O-arm–assisted pedicle screw insertion.

Materials and Methods: This pilot study enrolled patients undergoing O-arm–assisted thoracolumbar pedicular screw instrumentation between November 2024 and February 2025. At each instrumented level, one pedicle screw was placed using the conventional DRF, and the contralateral pedicle screw was placed using the novel pedicle screw–rod–anchored DRF. We compared the 2 DRF systems within each level. Navigational error was defined as the angular deviation between the intraoperative virtual trajectory and the screw position on postoperative computed tomography. Pedicle breaches were identified and graded.

Results: Twenty-two patients (110 pedicle screws) were included. The median navigational error did not differ between novel and conventional DRF in axial (2°, $P = 0.500$) or sagittal (2°, $P = 0.070$) planes. Subgroup analyses by level and pathology (degenerative, tumor, trauma) showed no significant differences. Minor pedicle breaches (< 2 mm) occurred in 2 screws with the novel DRF and 3 screws with the conventional DRF, all mid-thoracic and without clinical complications.

Conclusions: The novel pedicle screw–rod–anchored DRF provides navigational accuracy comparable to the conventional system. These findings support its feasibility as an alternative reference frame for O-arm–guided spinal procedures when spinous process fixation is limited.

Keywords: Digital reference frame; O-arm navigation; pedicle screw placement; pilot study; spinal surgery (Siriraj Med J 2026;78(5):367-376)

INTRODUCTION

Pedicle screws are the cornerstone of modern spinal fixation and are used extensively across degenerative disease, deformity correction, and spinal trauma. Instrumentation with a pedicle screw–rod system improves construct strength and fusion rates in spinal fusion surgery.[1,2] The use of pedicle screws has increased markedly over recent decades.

Accurate pedicle screw placement with optimal pedicle purchase is essential to prevent neurologic injury and instrumentation failure. Traditional techniques report misplacement rates as high as 15% - 40%[3,4], leading to nerve root injury, vascular or visceral damage, and reoperation for pedicle breaches.[5] To address these risks, guidance strategies include C-arm fluoroscopy, 3-dimensional (3D) O-arm navigation, and robotic-assisted methods.[4,6] Among these, 3D O-arm navigation is widely accepted. It has been used in Thailand for more than 10 years and yields superior accuracy, faster insertion, and lower complication rates compared to conventional methods.[7]

The 3D O-arm navigation system integrates real-time intraoperative 3D imaging with trajectory guidance for pedicle screw placement. Intraoperative 3D images are obtained using 2 components: a digital reference frame (DRF) attached to the patient for automated registration and the O-arm system (Medtronic Surgical Technologies, Louisville, CO, USA), which generates computed tomographic–like images. The navigation platform then processes these images, enabling simultaneous visualization of screw trajectories and spinal anatomy during surgery.

Despite the high accuracy of O-arm–assisted techniques, navigational error and pedicle screw misplacement persist in up to 3% of cases.[8,9] These events are often attributed to "navigation drift"—a deviation of the navigated trajectory from the true pedicle path—reported particularly in deformity surgery.[10] Contributing factors include increased DRF–to–instrumented-level distance, DRF displacement, inadequate neuromuscular blockade with patient movement, and obstruction between the DRF and the optical tracking cameras.[10-12] Conventional DRF fixation—typically to the spinous process or, via an additional incision, to the iliac bone—faces additional challenges in specific contexts. These include pediatric cases with small, unstable spinous processes; scoliosis procedures requiring intraoperative neuromonitoring without muscle relaxation; and revision surgery when the spinous process has been removed.[13]

To address these limitations, we developed a novel DRF for O-arm navigation that attaches directly to the

pedicle screw–rod construct to improve stability. We hypothesized that this design would deliver navigational accuracy comparable to, or greater than, traditional DRF systems. This pilot study evaluated the novel DRF with a modified attachment mechanism in patients undergoing elective surgery for degenerative and deformity conditions of the spine.

MATERIALS AND METHODS

Study design and registration

This single-center pilot study was conducted at a tertiary hospital in Bangkok, Thailand, from November 1, 2024 to February 28, 2025. The protocol received Institutional Review Board approval before enrollment. The trial was registered with the Thai Clinical Trials Registry (TCTR20250506005). All participants provided written informed consent after receiving detailed study information.

Participants and eligibility

Adults aged > 18 years who underwent open posterior thoracolumbar instrumentation requiring 3D O-arm–navigated pedicle screw insertion were eligible. The exclusion criteria were spinal infection (e.g., spondylodiscitis or spinal epidural abscess), revision spine surgery, pedicle screw insertion extending to the cervical level, or planned pelvic fixation. Baseline demographics and clinical characteristics were recorded after enrollment.

Development and design of the novel DRF

The novel DRF was manufactured from certified medical-grade titanium (Orthopesia Co., Bangkok, Thailand), similar to the conventional DRF. Instead of a claw-tooth spinous process clamp, the device uses a straight, rod-shaped lower base, 5.0-6.0 mm in diameter, that connects to polyaxial or monoaxial pedicle screw heads. The connection is secured when the screw nut is tightened (Figs 1, 2). Standard sterilization protocols were applied to the DRF set before surgery.

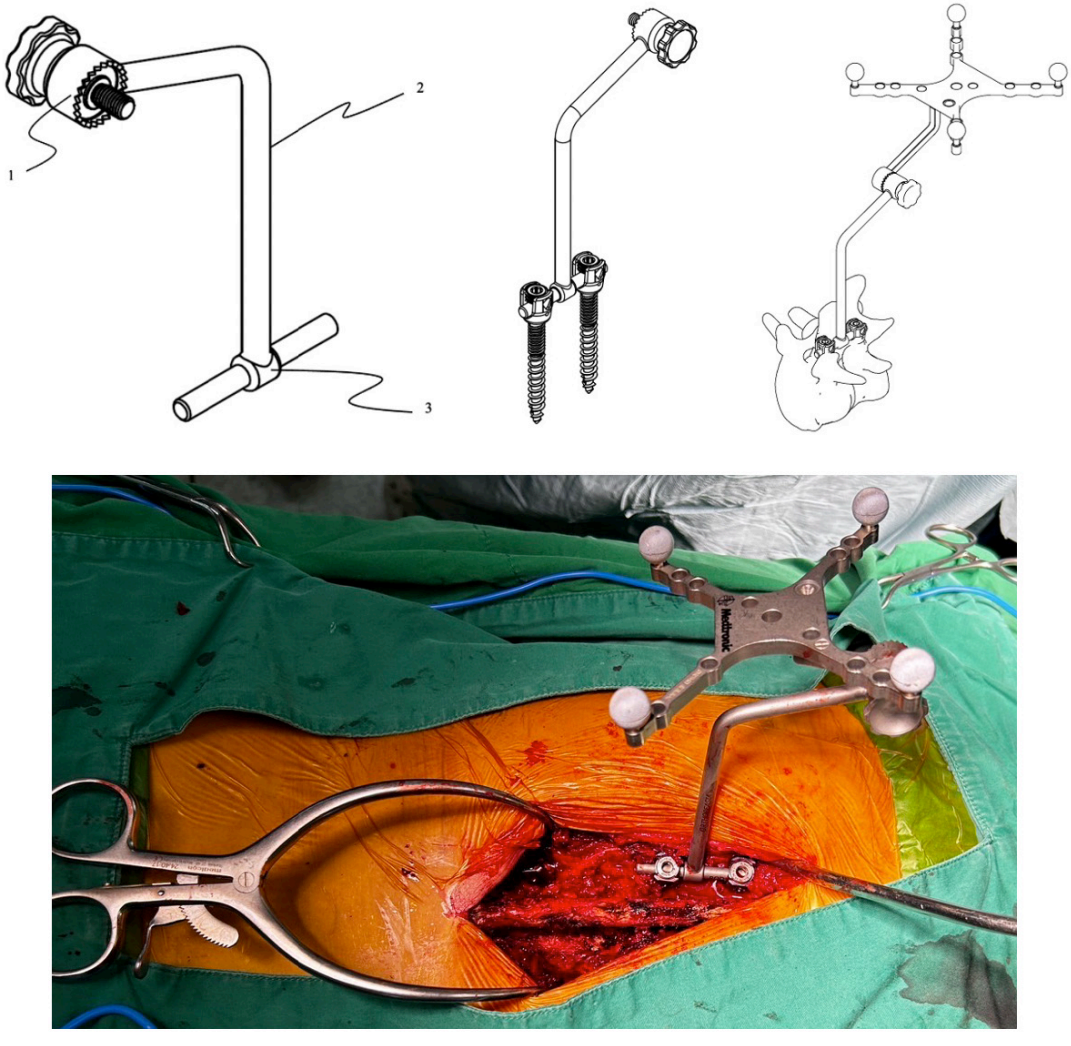


Fig 1. Design and Dimensions of the Novel Digital Reference Frame (DRF) with a Straight Rod-Like Base Attachment for Pedicular Screw head. The novel dynamic reference frame (DRF) consists of three main components: (1) A Hirth joint connector with tapered teeth, designed to connect with standard reference markers (light-reflecting spheres). (2) An arm of the DRF angled at 110°. (3) A rod-shaped base connector that attaches to pedicle screw heads.

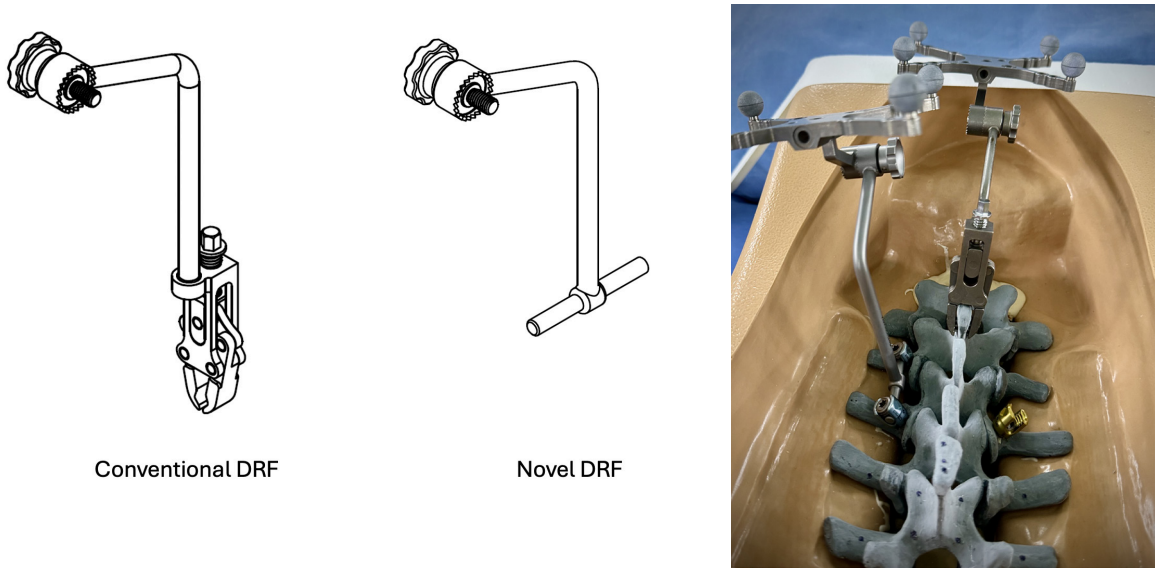


Fig 2. Comparison Between the Conventional Digital Reference Frame (DRF) Using Spinous Process Attachment and the Novel DRF Using Pedicular Screw Attachment.

Surgical procedure

All patients underwent open posterior surgery with 3D O-arm–navigated guidance. After induction of general anesthesia, patients were positioned prone on a Jackson frame. The operative field was prepped and draped, followed by a midline longitudinal incision and subperiosteal detachment of paraspinal musculature. The index level was confirmed with C-arm fluoroscopy. Dissection proceeded to the spinous process, lamina, and facet joints. A conventional DRF was attached to the spinous process 1–2 levels adjacent to the planned instrumented level. The O-arm and StealthStation navigation system (Medtronic Navigation, Louisville, CO, USA) were used.

Imaging, registration, and accuracy verification

After the first intraoperative computed tomography, scan image processing and instrument registration were performed. Accuracy was verified with a navigated light-reflecting ball probe pointing to 8 anatomical landmarks: superior and inferior spinous processes; superior laminar borders (left/right); inferior laminar borders (left/right); transverse processes (left/right). The probe's true position was compared with the navigation display. If the discrepancy was > 1 mm, registration was deemed unsuccessful ("not passed"), and image acquisition and registration were repeated.

DRF allocation, pedicle screw insertion, and surgical procedure

After passing accuracy verification, half of the planned pedicle screws were inserted under guidance from the conventional DRF. The conventional DRF was removed, and the novel DRF was attached to the inserted screws nearest the spinous process previously used for conventional attachment. A second intraoperative scan and registration were performed using the novel DRF as the reference, and the remaining pedicle screws were inserted. Final intraoperative computed tomography was obtained to assess pedicle screw position. Based on the preoperative plan and the patient's diagnosis, the procedures after pedicle screw insertion were done as indicated, including laminectomy, posterior spinal fusion, or interbody fusion.

Navigational error and pedicle breaches

Two spine surgeons evaluated navigational error and pedicle breaches for the conventional and novel DRF. The navigational error angle was defined as the angular difference between the StealthStation navigation system's virtual screw trajectory and the actual pedicle screw trajectory shown on postoperative computed tomography at each vertebral level (Fig 3). On axial images, the angle was measured between the screw axis and the midsagittal vertebral axis (Figs 3A, B).[14] The midsagittal axis is a line that bisects the vertebral body and aligns with the laminar base and spinous process. On sagittal images, the angle was measured between the screw axis and the superior endplate of the corresponding vertebral body (Figs 3C, D). Pedicle breaches were identified on the final computed tomographic images. Each screw was assessed by perforation direction in 6 anatomical categories: anterior, lateral, medial, inferomedial, inferolateral, and superior. Pedicle breach severity was graded as follows: Grade 0, no breach (0 mm); Grade 1, > 0 mm and ≤ 2 mm; Grade 2, > 2 mm and ≤ 4 mm; and Grade 3, > 4 mm.[15]

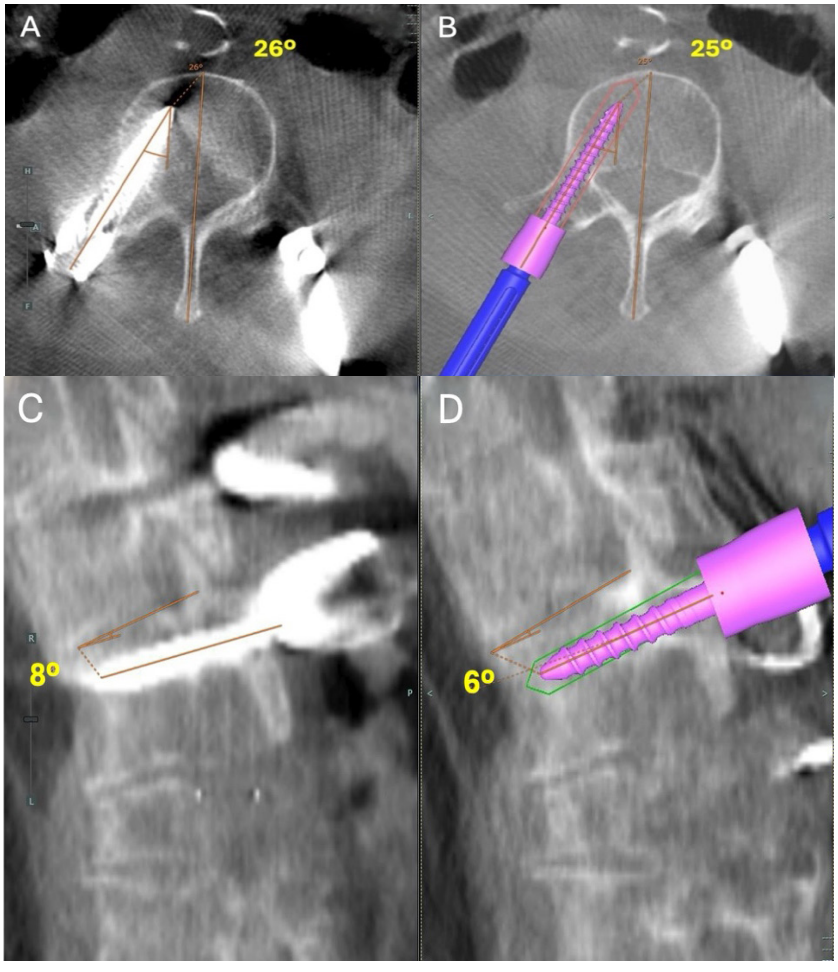


Fig 3. Measurement of navigational error in axial and sagittal planes.

Angles are measured in degrees. Navigational error is the absolute angular difference between the navigated and postoperative CT angles. Actual postoperative screw angle relative to the midsagittal vertebral axis (A) and the corresponding O arm–navigated trajectory (B). The axial navigational error in this example is 1°. Actual postoperative screw angle relative to the superior endplate (C) and the navigated trajectory (D). The sagittal navigational error in this example is 2°.

Statistical analysis

Data were analyzed with Stata version 17 (StataCorp LLC, College Station, TX, USA). Categorical variables were summarized as frequencies and percentages. Normality was assessed with the Shapiro–Wilk test. Continuous variables were summarized as means with standard deviations or medians with interquartile ranges, as appropriate. Group comparisons used the independent *t* test or the Mann–Whitney *U* test, as appropriate. All tests were two-sided, and $P < 0.05$ denoted statistical significance.

Sample size calculation

The sample size for this pilot study was determined according to the guidelines proposed by Viechtbauer et al..[16] Assuming a true event rate of 10% and a 90% confidence interval for identifying issues in navigation accuracy, a total of 22 participants was required.

RESULTS

Characteristics of participants

Twenty-four participants were enrolled; 2 were excluded for spondylodiscitis, leaving 22 eligible. Table 1 presents their demographic and clinical characteristics. Most participants (77.3%) underwent surgery for degenerative conditions—spondylolisthesis, spinal stenosis, or adult spinal deformity correction. Three (13.6%) had spinal tumors, and 2 (9.1%) had thoracolumbar fractures. A total of 110 pedicle screws within 55 levels of vertebral bodies were inserted—55 guided by the novel DRF and 55 by the conventional DRF—across different spinal levels. Distribution by level was thoracic 30 (27.3%) and lumbosacral 80 (72.7%).

Comparison of novel versus conventional DRF

Table 2 summarizes the navigational errors for the novel versus the conventional DRF. In the axial view, the median error was 2° for both systems—novel range 0°–6°, conventional range 0°–5°; $P = 0.500$. In the sagittal view, the median error was 2° for both systems—novel range 0°–4°, conventional range 0°–5°; $P = 0.070$. Subgroup analyses by spinal level and patient's diagnosis showed no significant differences in navigational error between the DRF systems. Five Grade 1 pedicle breaches occurred (5/110; 4.5%) with no significant difference between groups (Table 4). In the novel DRF group, there was one 1-mm anterior perforation and one lateral breach. In the conventional DRF group, there were two 1-mm anterior perforations and one 1.5-mm lateral breach. All breaches occurred at mid-thoracic levels (T3–T10); no complications or revisions were required.

TABLE 1. Baseline demographics and characteristics of the participants (n=22, 110 pedicle screw).

Baseline characteristics	N (%)/ Median (Q1, Q3)
Male	13 (59.1)
Age (years) [median (Q1, Q3)]	63.5 (56.3, 71.3)
Body mass index (kg/m^2) [median (Q1, Q3)]	22.4 (20.0, 25.7)
<18.5	4 (18.2)
18.5-22.9	8 (36.4)
≥23.0	10 (45.5)
Medical comorbidities	
Hypertension	11 (50.0)
Diabetes	6 (27.3)
Dyslipidemia	5 (22.7)
Patient's diagnosis	
Degenerative disease	17 (77.3)
Tumor	3 (13.6)
Fracture	2 (9.1)
Level of screw placement (n=110)	
Thoracic	30 (27.3)
Lumbosacral	80 (72.7)

TABLE 2. Comparison of navigation error between novel and conventional digital reference frame (DRF) (total n=110 screws)

Plane of measurement	Novel DRF (n=55)			Conventional DRF (n=55)			*p*-value[a]
	Navigation angle (°) median (Q1, Q3)	Real angle (°) median (Q1, Q3)	Navigation error (°) median (min-max)	Navigation angle (°) median (Q1, Q3)	Real angle (°) median (Q1, Q3)	Navigation error (°) median (min-max)	
Axial	12 (7, 19)	11 (6, 17)	2 (0, 6)	10 (7, 17)	10 (6, 17)	2 (0, 5)	0.500
Sagittal	4 (2, 6)	3 (2, 4)	2 (0, 4)	4 (2, 6)	2 (2, 6)	2 (0, 5)	0.070

[a] Navigation errors between novel and conventional DRF screw placements were compared using Mann–Whitney U test

TABLE 3. Subgroup analysis of navigation error between novel and conventional digital reference frame (DRF) by screw placement and patient's diagnosis (N=110 screws)

Characteristics	No. of compared screws	Novel DRF (n=55)			Conventional DRF (n=55)			*p*-value[a]
		Navigation angle (°)	Real angle (°)	Navigation error (°)	Navigation angle (°)	Real angle (°)	Navigation error (°)	
		median (Q1, Q3)		median (min-max)	median (Q1, Q3)		median (min-max)	
Level of screw placement								
Thoracic level								
Axial	30	7 (6, 9.5)	7.5 (5, 10)	2 (0, 4)	7.5 (6, 9.5)	6.5 (4.5, 9)	1 (0, 4)	0.359
Sagittal		3.5 (2, 5)	2 (1, 3)	2 (0, 3)	3 (2, 4)	2 (1, 2)	2 (0, 3)	0.703
Lumbosacral level								
Axial	80	15 (8, 20)	14 (8, 19)	2 (0, 6)	12 (8, 19)	14 (7, 19)	2 (0, 5)	0.169
Sagittal		4 (3, 6)	3 (2, 6)	2 (0, 4)	4 (2, 6)	3 (2, 6)	2 (0, 5)	0.070
Patient's diagnosis								
Degenerative								
Axial	90	14 (8, 19)	13 (7, 17)	2 (0, 6)	10 (8, 17)	13 (7, 17)	2 (0, 5)	0.458
Sagittal		4 (3, 6)	3 (2, 6)	2 (0, 4)	4 (3, 6)	3 (2, 6)	2 (0, 5)	0.070
Tumor								
Axial	12	7 (6, 12)	7 (6, 8)	1 (0, 4)	7.5 (6, 8)	5 (4, 6)	2 (0, 3)	0.625
Sagittal		3 (2, 4)	1 (1, 2)	2 (0, 3)	2.5 (1, 3)	0.5 (0, 6)	2 (0, 3)	>0.999
Fracture								
Axial	8	16.5 (7.5, 26)	16.5 (5.5, 28)	2 (2, 4)	17.5 (5, 32.5)	16.5 (3.5, 30)	1.5 (1, 4)	0.500
Sagittal		1.5 (1, 4)	1 (1, 2)	0.5 (0, 3)	1.5 (0.5, 3.5)	1 (0.5, 1.5)	0.5 (0, 3)	>0.999

[a] Navigation errors between novel and conventional DRF screw placements were compared using Mann–Whitney U test

TABLE 4. Incidence of pedicle breaches between novel and conventional digital reference frame (DRF)

Pedicle breaches (No. of screws)	Novel DRF (n=55) n (%)	Conventional DRF (n=55) n (%)	*p*-value[a]
Grade I (≤2mm)	2 (3.6%)	3 (5.5%)	*p*>0.999
Grade II and above (>2mm)	0 (0)	0 (0)	-

[a] Fisher's exact test was used to compare the incidence of pedicle breeches between novel and conventional DRF screw placements

DISCUSSION

This pilot study demonstrated the feasibility of a novel DRF attachment for O-arm–assisted pedicle screw insertion. By fixing the DRF to the screw–rod construct rather than the spinous process, accuracy remained comparable to the conventional approach without increasing navigational error.

The median navigational error was 2° in both axial and sagittal planes for the novel and conventional DRF. These values are consistent with prior O-arm–assisted pedicle screw insertion studies. Oertel et al reported a mean navigational error of 2.8° ± 1.9°.[8] Mathew et al evaluated 104 screws during L4–5 fusion and found mean deviations of 2.31° and 3.11° in the axial and sagittal planes, respectively.[17] Comparable performance was reported for computer-assisted placement using preoperative computed tomography, with a mean angular deviation of 2.28° ± 1.92°.[18] Our minor anterior perforation rate (2.7%) and lateral pedicle breach rate (1.8%) align with prior O-arm navigation studies reporting breach rates of 1.0%–3.2%.[8,9,17] Collectively, these data support the conclusion that O-arm navigation improves screw placement accuracy and reduces misplacement compared with conventional freehand techniques.[9]

Intraoperative computed tomography with O-arm navigation provides precise visualization of spinal anatomy in the surgical position, enabling real-time, image-guided instrumentation. However, because the DRF is mounted intraoperatively, the mounting process can introduce navigational error. Deviations between planned and actual screw trajectories—termed navigational error or the "drift phenomenon"—have been reported in up to 16.7% of O-arm–guided cases.[10] Contributing factors include reference frame–to–target level distance due to intervertebral flexibility, movement due to inadequate neuromuscular blockade or respiration, and DRF displacement.[10-12] To mitigate these issues, we developed a DRF that attaches to the screw–rod construct to enhance intraoperative stability and aim reduce error sources.

In the present study, navigational error and pedicle breach rates did not differ significantly between the novel and conventional DRF in either plane. This finding likely reflects that conventional spinous process clamp fixation may provide sufficient stability for accurate tracking in our cohort, which predominantly comprised adult degenerative, trauma, and tumor cases. In this population, residual navigational error may be driven primarily by factors other than DRF attachment, including intrinsic system-related error during image acquisition, processing, or tracking, as well as iatrogenic micro-movement during instrumentation. Therefore, a construct-based DRF may not confer a measurable advantage in standard anatomy where conventional fixation performs reliably. Notably, the absence of a significant difference may also represent a Type II error given the pilot design and the limited proportion of highly complex cases in which dynamic shift is more pronounced and DRF instability is most problematic. Future studies should therefore focus on higher-complexity cohorts, such as severe scoliosis or high-grade spondylolisthesis, to more definitively evaluate whether construct-based fixation provides a stability-related benefit. In addition, the numerical differences in median angular error between groups were small, and modest reductions may not translate into clinically meaningful differences in routine adult anatomy. Nevertheless, even minor angular deviations may be more consequential in high-risk settings, such as severe scoliosis with narrow or dysplastic pedicles or patients with compromised bone quality, underscoring the need for targeted evaluation in these populations.

Although conventional fixation appeared adequate in our cohort, traditional spinous process attachment poses limitations, particularly in revision surgery where a laminectomy has removed suitable bony landmarks. In such settings, surgeons may secure the DRF at a distant level with an intact spinous process, which increases navigational error. Alternatively, iliac fixation can be used, but it requires an additional incision. One feasibility of the novel DRF design is that it permits DRF attachment through existing pedicle screws, avoiding the need for additional incisions with comparable accuracy.

Similarly, pediatric deformity surgery poses challenges for conventional DRF fixation because spinous processes are often small or underdeveloped, limiting stable DRF fixation and increasing intraoperative motion that can cause navigational error. Prior O-arm navigation studies in this population report malposition rates of 8.5%–9.8% in complex deformity and scoliosis, with a tracker placement of more than 3 levels from the target identified as a notable risk factor.[19,20] One study documented Grade 2–3 pedicle breaches in up to 21% of patients with dystrophic scoliosis secondary to neurofibromatosis type 1.[20] Although multiple factors contribute—including small, rotated, dysplastic pedicles and optical tracking signal deviation—we hypothesize that instability of DRF attachment is a key driver of navigational error in this cohort. A stronger, screw–rod–anchored DRF reduces susceptibility to displacement from patient movement or inadvertent instrument contact.[21] To our knowledge, this is the first study to evaluate DRF fixation through pedicle screws. Although our cohort did not include pediatric deformity cases, the comparable accuracy observed in

typical adult indications might support the feasibility of construct-based fixation and provide a rationale for future evaluation in pediatric and complex deformity in which conventional placement is difficult or unfeasible.

Nonetheless, several limitations must be acknowledged. First, as a pilot investigation, this study was designed to assess feasibility and characterize navigational accuracy rather than to demonstrate the superiority of the novel DRF over conventional attachment. Accordingly, the findings primarily inform sample size calculations for adequately powered comparative studies. Second, although the device targets challenging scenarios, such as revision surgery and pediatric deformity, our cohort predominantly comprised degenerative, tumor, and trauma indications only. Consequently, performance of the device in more complex settings remains unvalidated, and navigational accuracy may be lower with higher pedicle breach rates in such populations. Third, the study had limited ability to evaluate differences in the most clinically consequential safety outcome. Specifically, no Grade II or higher pedicle breaches (>2 mm) occurred in either group, resulting in a very low event rate and minimal statistical power to detect between-group differences in clinically significant breaches. Therefore, the absence of severe breaches difference and any potential safety benefit of this pilot study should be interpreted cautiously. Finally, we did not evaluate the biomechanical stability of the DRF under dynamic loading. Future cadaveric or benchtop biomechanical studies could quantify stability, characterize failure modes, and define any mechanical advantages in simulated surgical environments.

CONCLUSIONS

This pilot study demonstrates that a novel DRF attached to the pedicle screw–rod construct achieves navigational accuracy comparable to a conventional spinous process–mounted DRF during O-arm–assisted pedicle screw insertion. These results provide a foundation for future trials and support continued development of alternative DRF strategies, particularly for complex spinal deformity surgery and revision cases.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request. The data are not publicly available due to privacy or ethical restrictions.

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DECLARATIONS

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Conflict of Interest

The authors declare that there are no conflicts of interest. No financial support was received from companies that produce or distribute the drugs, devices, or materials described in this report.

Registration Number of Clinical Trial

The trial was registered with the Thai Clinical Trials Registry (TCTR20250506005).

Author Contributions

KM: Conceptualization, Project administration, Writing – original draft, Investigation, Formal analysis, Writing – review & editing; PL: Conceptualization, Project administration, Writing – original draft, Investigation; DA: Conceptualization, Project administration, Writing – original draft, Formal analysis; MR: Conceptualization, Project administration, Writing – original draft, Investigation, Formal analysis, Writing – review & editing; CR: Investigation, Formal analysis; EK: Investigation; CC: Investigation; SW: Investigation; WS: Investigation.

Ethics approval and consent to participate

This prospective cohort study was approved by the Siriraj Institutional Review Board (COA no. Si 610/2024). All methods were performed in accordance with relevant guidelines and regulations. Written informed consent was obtained from all participants.

Use of Artificial Intelligence

None.

Abbreviations

3D: 3-dimensional
DRF: Digital reference frame

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