

Radiation-Free Machine-Vision Navigation Achieves $\geq 99\%$ Accuracy in Thoracolumbar Pedicle Screw Placement

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Disclosures: The authors do not have any financial interests or affiliations with institutions, organizations, or companies relevant to the manuscript. None of the authors received payment or funding support in kind for any aspect of the submitted work. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

INTRODUCTION: Pedicle screw fixation is integral to spinal fusion but risks malposition and breach that can cause serious neurologic complications. Although 3D fluoroscopy improves accuracy, it adds radiation exposure and equipment burden. The 7D FLASH machine-vision system offers radiation-free navigation using visible light and structured illumination. However, the accuracy of machine vision-based navigation remains poorly characterized in the adult spinal degeneration literature. As such, this study aims to assess the positional accuracy of 7D FLASH Navigation for pedicle screw placement in patients undergoing thoracolumbar fusion. We hypothesize that 7D FLASH will have high accuracy in placing pedicle screws.

METHODS: This was a single-surgeon retrospective series of patients who underwent thoracolumbar fusion using the 7D FLASH Navigation System with Cios Spin cone-beam computed tomography (CBCT) confirmation. Inclusion was limited to cases using CPT 61783; revision cases were included if screws were placed during the revision. Screw placement accuracy was assessed using Gertzbein-Robbins (GR) classification, with grades A or B considered accurate (Figure 1). GR grades C, D, and E were considered not accurate. Radiation exposure and patient demographics were collected as secondary outcomes. A one-proportion z-test was used to compare observed accuracy to the 97% benchmark. Power analysis ($\alpha = 0.05$, power = 0.80) estimated a required sample size of 283 screws, assuming 99% expected accuracy. The study included 58 patients (35 male, 60.3%, 23 female, 39.7%) with 288 pedicle screws placed.

RESULTS SECTION: Patient demographics included the following: median age 64 years (IQR 15), BMI 27.4 kg/m² (IQR 6.6); 65.5% single-level fusions; 25.9% with a prior fusion. Of 288 screws, 287 (99.65%) were GR A and 1 (0.35%) was GR B. Overall accuracy (GR A/B) was 100%. Median total intraoperative radiation dose was 104.9 mGy (majority from one confirmatory spin of the Cios Spin C-arm used for screw accuracy confirmation). No patients returned to the operating room for malpositioned hardware. Of note, the one patient with a GR B screw did not experience any complications or require revision. The single GR B screw was repositioned intraoperatively due to surgeon preference. No screws received GR grades C, D, or E, indicating that none were considered inaccurate.

DISCUSSION: The 7D FLASH Navigation achieved near-perfect thoracolumbar pedicle-screw accuracy. Our finding of 100% accuracy is consistent with other studies reporting accuracy rates of 94.2% to 98.7%, highlighting that 7D FLASH Navigation is highly accurate for thoracolumbar pedicle-screw placement across multiple surgeons and centers.^{1,2} The system enables surgeons to quickly register anatomy in seconds, re-register quickly, and operate free of bulky equipment with equivalent safety to 3D fluoroscopic navigation without the radiation or time involved in that method. While larger, prospective comparisons are warranted, our data, in the context of the literature,^{1,2} support 7D FLASH as a compelling, radiation-free navigation methodology to aid in pedicle screw placement for open thoracolumbar fusion procedures. Limitations of this study include its design as a retrospective single-surgeon series, which may limit generalizability. In addition, as all screws in this study were verified with intraoperative CBCT, the reported intraoperative radiation dose overestimates what would be observed if 7D FLASH Navigation were used without confirmatory imaging. Although 7D FLASH demonstrated near-perfect accuracy in this series, future studies are warranted to evaluate how it compares with 3D fluoroscopy and robotic platforms in diverse clinical contexts, including complex deformity, minimally invasive approaches, and cost-utility analyses. In conclusion, 7D FLASH Navigation achieved near-perfect accuracy in open thoracolumbar pedicle-screw placement, validating its role as a safe and effective navigation platform.

SIGNIFICANCE/CLINICAL RELEVANCE: 7D FLASH Navigation enables highly accurate pedicle-screw placement while eliminating navigation-related radiation to patients, surgeons, and operating room staff, thereby improving workplace safety.

REFERENCES:

[1] Dorilio J, Utah N, Dowe C, Avrumova F, Alicea D, Breceovich A, et al. Comparing the Efficacy of Radiation Free Machine-Vision Image-Guided Surgery With Traditional 2-Dimensional Fluoroscopy: A Randomized, Single-Center Study. *HSS J.* 2021;17(3):274-280.

[2] Malham GM, Munday NR. Comparison of novel machine vision spinal image guidance system with existing 3D fluoroscopy-based navigation system: a randomized prospective study. *Spine J.* 2022;22(4):561-569.

ACKNOWLEDGEMENTS: None

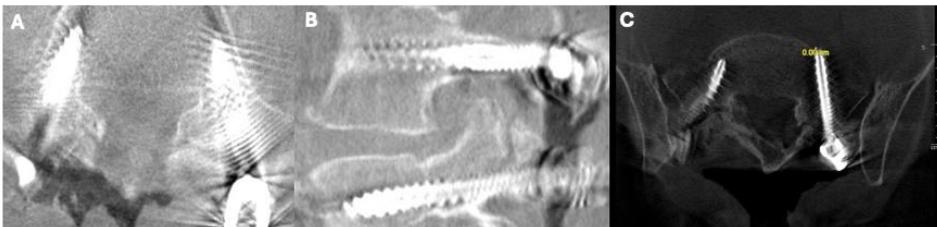


Figure 1: Representative CT images of Gertzbein-Robbins (GR) classification grading. Axial (A) and sagittal (B) views, respectively, of screws that has been assigned GR grade A with no breach. Axial image (C) of GR grade B screw showing 0.09 cm breach of the screw beyond the anterior vertebral cortex. Both GR grades A & B are considered accurate.