An Evaluation of the Accuracy, Efficiency, and Safety of Pulse® Navigation Percutaneous Pedicle Screw Placement: A Randomized, Cadaveric Study

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Introduction

The safety and effectiveness of pedicle screw implantation can be enhanced by enabling technologies such as advanced imaging, radiation reduction algorithms, and navigation. Separately, lack of systems integration in the operating room (OR) can lead to procedural inefficiencies, crowding of limited OR space, and creation of a suboptimal workflow. The integration of multiple technologies into a single platform has the potential to address these issues, however, the utility and benefits of such a platform have yet to be quantified.

Figure 1: NuVasive Pulse system displaying navigation tools and capabilities

The NuVasive® Pulse® platform (Figure 1) is the first fully integrated OR system that combines advanced imaging, radiation reduction, and navigation technology, along with intraoperative neuromonitoring, spinal alignment assessment technology, and patient-specific rod bending, to address the various challenges that are unique to spinal surgery procedures. The purpose of this study was to evaluate the accuracy, efficiency, and radiation safety of NuVasive Pulse navigation versus traditional free-hand fluoroscopy-guided techniques for percutaneous thoracolumbar pedicle screw (PS) placement.

Methods

Sample

A total of 12 fellowship-trained spine surgeons each placed 22 percutaneous pedicle screws from T8 to S1 bilaterally (11 on each side) in 12 non-pathologic cadaver specimens. The Reline® MAS® pedicle screw system (NuVasive, Inc., San Diego, CA, USA) was used for all screw placements. PS placement was randomized per side to: NuVasive Pulse paired with 3D imaging, 2D fluoroscopy, and C-arm tracking with the Cios Spin® (Siemens Healthineers, Inc., Erlangen, Germany) vs. free-hand fluoroscopy (FHF) with OEC 9900 Elite® C-Arm System X-ray (General Electric, Fairfield, CT, USA). The technique sequence was also randomized and the complete first side was performed prior to moving on to the second side. Additionally, prior to starting Pulse navigation, patient arrays were placed on the spinous processes in order to track devices during navigation (Figure 2).

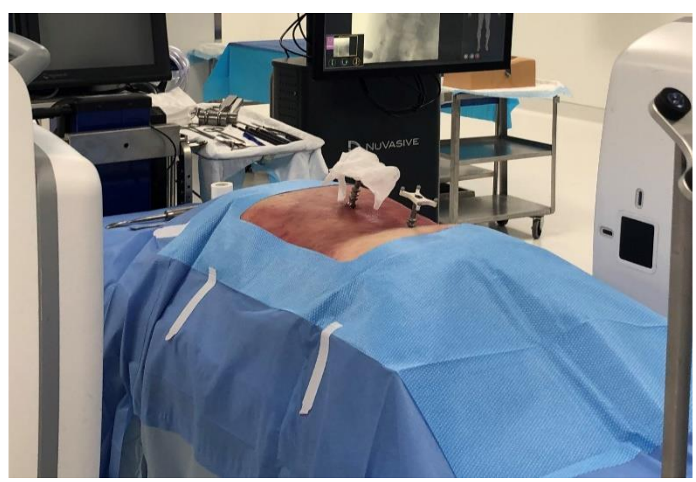

Figure 2: Photograph showing spinous process placement of patient arrays for Pulse navigation

Variables

Following the procedure, intraoperative 3D scans were taken using the Siemens Cios Spin (Figure 3). These scans were assessed by an independent reviewer to determine the accuracy of each PS placement using the Gertzbein-Robbins breach grading method (score 0: none (0 mm); score 1: minor (<2 mm); score 2: moderate (2-4 mm); or score 3: severe (>4 mm)). Additionally, navigation registration time, overall screw placement time, fluoroscopy emission (measured from each respective system), and surgeon radiation exposure captured by a RaySafe™ dosimeter (Fluke® Biomedical, Billdal, Sweden) worn outside the front of the surgeon's lead apron, were compared between the groups.

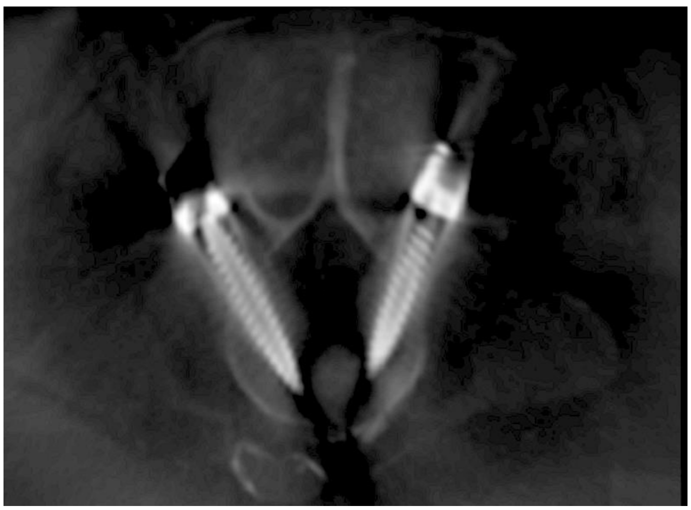

Figure 3: Axial view of a cadaveric lumbar vertebra using Cios Spin intraoperative 3D scan after placing percutaneous pedicle screws (left: free-hand fluoroscopy screw, right: Pulse navigation screw)

Statistical Analyses

The McNemar test was used to analyze concordance in screw placement accuracy across the two screw placement techniques, by examining the breach rate at each level as pairs. Using this test, concordant breach at a level is suggestive of confounding factors (e.g., anatomy) that may have affected screw placement accuracy per level. As such, only breaches that were unique to either Pulse or FHF levels were used in the McNemar's calculation of comparative accuracy between Pulse navigation and FHF. Similarly, paired t-tests were used to analyze the efficiency and safety of Pulse navigation vs. FHF.

Results

A total of 262 screws (131 screws per subgroup—1 surgeon did not place PSs on T8) were placed in 12 cadavers by 12 surgeons. The screw breach rate (any magnitude) was significantly lower with Pulse navigation (9%) compared to FHF (18%) ($p=0.048$). Of the 131 screw pairs assessed, accuracy was consistent for 100 screw pairs on both sides (76% concordance), with 98 pairs unbreached and two pairs breached with both Pulse navigation and FHF. There were 10 levels with a Pulse navigation breach but not a FHF breach compared to 21 levels with a FHF but not a Pulse navigation breach.

Of the 12 total breaches with Pulse navigation, 9 (75%) breaches were graded as minor (score 1), while 3 (25%) breaches were graded as moderate (score 2) or severe (score 3). The 23 screw breaches in the FHF arm were graded as minor in 14 (61%), and moderate or severe in 9 (39%) breaches. Additionally, Pulse navigation had fewer medial (3% vs. 9%, $p=0.044$) and lateral (6% vs. 8%, $p=0.491$) breaches compared to FHF.

Figure 4 summarizes the rate, direction, and magnitude (moderate to severe) of breaches for each treatment group. As illustrated in this figure, the results show breaches with FHF were twice as likely as breaches with Pulse navigation. These results also showed that on average, Pulse navigation had less severe breaching and fewer medial breaches compared to screws placed using the traditional FHF technique ($p<0.05$). Additionally, the severity of the medial breaches on the Pulse navigation side was less than FHF ($p=0.037$) (Table 1).

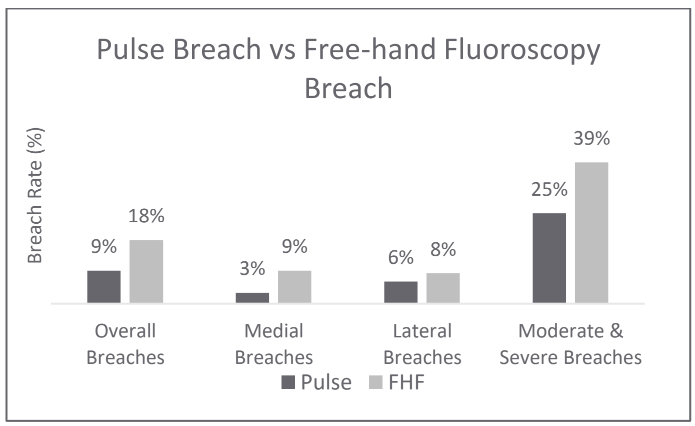

Figure 4: Breach rates, by Pulse navigation and free-hand fluoroscopy (FHF), for direction and severity of breach.

Table 1: Severity of medial breaches of Pulse navigation vs free-hand fluoroscopy (FHF). Average severity score (ASA) was calculated by averaging each subgroup's Gertzbein-Robbins grading scores (0-3), including the 127 screws for Pulse and 119 screws for FHF that had a score of 0 (no medial breaching).

Magnitude of Medial Breaches by Study Arm

	Total # of Screws Breached	Minor Breach (Score 1)	Moderate Breach (Score 2)	Severe Breach (Score 3)	ASA
Pulse	4	3	1	0	0.04
FHF	12	7	4	1	0.14

Surgical efficiency was assessed between Pulse navigation and FHF by comparing the overall procedural time, as well as screw placement time. Median total procedural time was similar between FHF (44.22 min) and Pulse navigation (49.03 min; inclusive of average navigation registration time (24.94 min)) (p=0.424). The median screw placement time, however, was significantly less with Pulse navigation (29.72 min) than with FHF (44.22 min) (p=0.012). Per screw, the median time for Pulse navigation was 2.7 minutes and 4.1 minutes for FHF (p=0.012).

Total mean radiation emission for Pulse navigation was higher compared to FHF (270.8 mGy vs. 69.0 mGy, p=0.0001). However, 97.6% (264.1 mGy) of Pulse radiation emission occurred during registration from Cios Spin 3D scans with the surgeon and OR team out of the room, consistent with clinical workflow. As such, median surgeon radiation exposure was significantly lower for the Pulse navigation treatment group compared to FHF (1.1 uGy vs 43.8 uGy; p=0.020).

Conclusion

The results of this randomized, multi-surgeon study illustrate that the accuracy of thoracolumbar PS placement with Pulse navigation is superior to free-hand fluoro-guided thoracolumbar PS placement, with improved screw placement efficiency and lower radiation exposure.

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