Accuracy of Intraoperative Computed Tomography–Based Navigation for Placement of Percutaneous Pedicle Screws

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Abstract

MISS techniques have gained recent popularity. The proposed benefits of these techniques include reduced tissue trauma, reduced blood loss, less perioperative pain, and a quicker recovery and return to normal activities. The purpose of this study was to evaluate the accuracy of intraoperative computed tomography (CT)-based navigation for placement of percutaneous pedicle screws in a cadaveric model. Outcome measures included accuracy of screw placement. Two cadaveric specimens were utilized. CT images were obtained using an O-Arm (Medtronic, Memphis, Tennessee, United States) and were coupled to the Stealth navigation system (Medtronic). Computer navigation was used for placement of percutaneous pedicle screws. Screws were placed bilaterally from T5 to S1. Postinsertion CT scans were obtained. Pedicle breach was assessed and classified (I: none, II: < 2 mm, III: 2 to 4 mm, or IV: > 4 mm) with direction of breach. Thirty thoracic screws were placed with 3 (10%) medial breaches and 17 (56.7%) lateral breaches (grade III). Of 20 lumbar screws there were 0 medial breaches and 2 (10%) lateral breaches (1 grade III, 1 grade IV). Four sacral screws were placed without breaches. The real-time computer-aided navigation tool (“simulated screw”) was limited in identifying a breach. Manipulation of the surgeon’s hand or driver could change the orientation of the navigation tool without changing the screw trajectory. CT-based navigation for percutaneous pedicle screw placement appears safe for the lumbar spine. Lateral thoracic breaches appeared commonly but were not felt to be clinically significant. The 10% rate of medial thoracic breach was concerning, but definitive conclusions could not be made due to the small sample size.

Keywords
► minimally invasive spine surgery
► percutaneous pedicle screw
► navigation
► accuracy
► instrumentation

The use of minimally invasive spine surgery (MISS) techniques has gained recent popularity. There are numerous variations of this including the use of tube dilators, endoscopic techniques, muscle-splitting or sparing techniques, and placement of percutaneous pedicle screws. Proposed benefits of these techniques include reduced tissue trauma, reduced blood loss, less perioperative pain, and a quicker recovery and return to normal activities.1–3 Placement of percutaneous pedicle screws can be performed with several different image-guided techniques included C-arm fluoroscopy, 2D computer-assisted fluoroscopy (FluoroNav; Medtronic, Memphis, Tennessee, United States),...
CT-Based Navigation for Placement of Percutaneous Pedicle Screws  
Eck et al.

iso-centric C-arm 3D fluoroscopy, and computed tomography (CT)-based navigation.\textsuperscript{4-7} In a retrospective review of 488 percutaneously placed pedicle screws using traditional C-arm guidance, Kim et al investigated the accuracy of placement and risks factors for pedicle breach.\textsuperscript{5} A cortical breach was identified in 54 (11.1%), and cortical encroachment was found in 61 (12.5%). Only 2 (0.4%) developed symptomatic medial penetration requiring revision surgery. The most significant risk factor for cortical breach was patient obesity with a relative risk of 3.373 (95% confidence interval 1.095 to 10.391).

It is generally believed that more advanced image guidance will increase the accuracy of pedicle screw placement. Nakashima et al performed a retrospective review of 300 percutaneously placed pedicle screws using postoperative CT scans to determine accuracy.\textsuperscript{6} Half of the screws were placed with conventional fluoroscopy, and the other half were placed with iso-centric 3D fluoroscopy. Of the 150 screws placed with traditional fluoroscopy, 18 (12%) were found to be exposed, and 5 (3.3%) were perforated. Of the 150 screws placed with 3D fluoroscopy, 11 (7%) were exposed, and 0 were perforated. This difference was statistically significant ($p < 0.05$).

Ravi et al placed 161 screws in 41 consecutive patients using 2D computer-assisted fluoroscopy and assessed accuracy with CT scans at 6 months postoperatively.\textsuperscript{7} They identified 37 (23%) pedicle breaches (30% medial, 60% lateral, 10% superior), of which 1 medical breach at L5 was clinically significant causing radiculopathy. They also identified 8 (5%) vertebral body breaches, none of which was clinically significant.

Computer-based systems couple imaging (either CT or fluoroscopy) to intraoperative navigation probes referenced to fixed anatomic points on the patient. First-generation CT-based navigation systems coupled preoperative CT imaging to the patient’s anatomy after a “registration” step. Intraoperative cone beam CT scanners now have the capability to take an intraoperative set of images and register the anatomy directly to the navigation system. This technology is utilized by the O-arm (Medtronic) and Stealth navigation system (Medtronic). Best et al performed a retrospective review of 672 lumbar screws placed percutaneously using computer-assisted navigation.\textsuperscript{8} Based on postoperative plain radiographs, none of the screws were misplaced; however, postoperative CT scans were not obtained.

One drawback of most image-guided pedicle screw placement is the increased amount of radiation exposure to the surgeon, operating room staff, and patient. Mroz et al performed a cadaveric study to determine the total fluoroscopy time for percutaneous placement of pedicle screws using traditional fluoroscopy.\textsuperscript{9} The total fluoroscopy time for placement of 10 screws was 4 minutes 56 seconds (29 seconds per screw). The authors additionally calculated the radiation exposure to the hands to be 10.3 mrem/screw and 2.35 mrem/screw exposure to the eye.

A major potential benefit of intraoperative CT-based navigation systems is the ability of the surgeon and much of the operating room staff to temporarily leave the room during imaging to reduce their risk of radiation exposure. It is possible that the use of surgical navigation for percutaneous placement of pedicle screws could provide a safe and effective technique while reducing the radiation exposure to the surgeon and operating room staff. The purpose of the current study was to quantify the accuracy of percutaneous placement of thoracolumbar pedicle screws using computer-assisted navigation and intraoperative CT imaging.

Methods

Two fresh-frozen cadaveric specimens were utilized for this study. Initial CT images were obtained using the O-arm. The Stealth navigation system was used for percutaneous placement of pedicle screws bilaterally from T5 to S1 in one specimen and T6 to S1 in the other specimen. All screws were placed according to the specific instruction of the technique guide by a single spine surgeon. Specifically, under navigation guidance a Jamshidi needle was placed percutaneously through the skin and through the pedicle into the vertebral body. A guide wire was placed through the Jamshidi needle, and the Jamshidi needle was removed over the guide wire. The screw hole was then tapped over the guide wire to a diameter 1 mm less than the screw to be placed. The tap was then removed, and the screw was placed over the guide wire. All screw sizes were selected based on measurements of pedicle size from the initial CT scans. A snapshot of the pedicle screw located in the pedicle was obtained for each screw using the real-time computer-aided navigation tool (“simulated screw”).

Following placement of the pedicle screws, a repeat CT scan was obtained using the O-arm to evaluate the placement of the screws. The O-arm is able to scan $\sim 5$ levels. To scan the entire length of the thoracolumbar spine, three separate scans needed to be performed. The reference frame was firmly attached in the posterior superior iliac crest for placement of screws from L2 to S1. The reference frame was firmly attached the spinous process of L1 for screws placed from T9 to L1, and to the spinous process of T8 for screws placed from T5 to T8.

The final CT images were analyzed to assess for accuracy of pedicle screw placement. Screws were graded based on the presence of pedicle breach (I: no breach, II: $< 2$ mm, III: 2 to 4 mm), IV: $> 4$ mm).\textsuperscript{7} The direction of breach was recorded. Breaches of the vertebral body were also recorded. The location of screws on the final CT scan was compared with the location shown on the real-time computer-aided navigation tool (simulated screw).

Results

The results of pedicle screw breaches are summarized in Table 1. A total of 30 thoracic pedicle screws were placed. There were 3 (10%) medial breaches and 17 (56.7%) lateral breaches. A total of 20 lumbar pedicles screws were placed. There were no medial breaches and 2 (10%) lateral breaches. Four sacral pedicle screws were placed without any breaches. There were two extravertebral breaches: one at T5 and the other at L4. None of the lateral pedicle breaches were felt to be
clinically significant as the screws were located in the costo-vertebral joint. The two medial pedicle breaches were into the spinal canal at the spinal cord level and were both considered to be likely clinically significant.

The real-time computer-aided navigation tool (simulated screw) was found to be limited in identifying a pedicle breach. Manipulation of the surgeon’s hand or driver could change the orientation of the navigation tool without changing the screw trajectory. However, when no force is being applied to the driver or other instrument, the error in the simulated screw appears to be much less.

Fig. 1 shows an example of a grade IV lateral pedicle screw breach and extravertebral breach on the right side (a). The corresponding “simulated screw” navigation tool predicted a perfectly placed pedicle screw (b).

**Table 1** Summary of pedicle screw breaches

<table>
<thead>
<tr>
<th>Level</th>
<th>Cadaver 1</th>
<th>Cadaver 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Left</td>
<td>Right</td>
</tr>
<tr>
<td>T5</td>
<td>I</td>
<td>III lateral/extravertebral</td>
</tr>
<tr>
<td>T6</td>
<td>I</td>
<td>III lateral</td>
</tr>
<tr>
<td>T7</td>
<td>I</td>
<td>III lateral</td>
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<tr>
<td>T8</td>
<td>I</td>
<td>III lateral</td>
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<tr>
<td>T9</td>
<td>I</td>
<td>III lateral</td>
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<td>T11</td>
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<td>III lateral</td>
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<td>III lateral</td>
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<td>L1</td>
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<td>I</td>
<td>I</td>
</tr>
<tr>
<td>S1</td>
<td>I</td>
<td>I</td>
</tr>
</tbody>
</table>

Abbreviation: N/A, not available.

Note: Breaches graded as: I, no breach; II, < 2 mm; III, 2–4 mm; IV, > 4 mm. “Extravertebral breach” means the tip of the screw was outside the vertebral body.

**Discussion**

With the advancement of new technologies, the use of minimally invasive techniques for spine surgery continues to increase. Prior to the routine integration of these techniques into clinical practice, it is crucial to fully understand the associated risks and benefits. The purpose of this study was to define the accuracy of using a CT-based navigation system for the percutaneous placement of pedicle screws in a cadaveric model.

Our results suggest that intraoperative CT-guided navigation is a safe and effective technique for placement of lumbar and sacral pedicle screws. We identified only two (10%)
lumbar screws with a lateral breach. Based on final CT imaging, neither of these pedicle breaches was considered to be clinically significant.

The use of this technique for placement of percutaneous thoracic pedicle screws was found to be less accurate. There was a 56.7% rate of lateral pedicle breaches; however, these screws passed through the costovertebral joint and were not thought to be clinically significant. More worrisome, however, was the 10% rate of medial pedicle screw breach in the thoracic spine. These screws were found in the spinal canal at spinal cord level and felt to possibly be clinically significant. However, due to the small sample size of the current study, it is difficult to make definitive conclusions.

We utilized strict criteria of defining all pedicle screws that were not completely within the boundaries of the pedicle as a breach regardless of the potential clinical significance of the breach. Previous studies have classified pedicle screw position as optimal if the central axis is in the plane and axial of the pedicle and the tip is completely within the vertebral body; acceptable if the majority of the shank of the screw is outside the central axis of the pedicle but not potentially unsafe; or potentially unsafe if the screw traverses the canal or if the tip of the screw is extravertebral with the screw outside the central axis of the pedicle and the tip is completely within the vertebral body; acceptable if the majority of the shank of the screw is extravertebral with risk for vascular perforation. Adopting this criteria to the current study would change our results to 100% optimal or acceptable screws in the lumbar spine and 90% in the thoracic spine.

One potential explanation for the higher accuracy of screw placement in the lumbar spine as compared with the thoracic spine involves the placement of the reference frame for the navigation system. For the lumbar spine, the frame was more rigidly attached in the posterior superior iliac crest. For the thoracic spine, this location of the reference frame is outside the field of view so the frame is clamped to the spinous processes of the vertebral bodies within the field of view. This method of attachment is less rigid and could potentially increase the risk of screw breach due to the potential motion of the reference frame that the navigation is based on.

These results are consistent with the previous published literature. Gelalis et al performed a systematic review of the literature comparing the accuracy of pedicle screw placement using freehand, fluoroscopy guidance, and navigation techniques. They reviewed 26 prospective studies consisting of 1,105 patients and 6,617 pedicle screws and determined an accuracy rate of fully contained pedicle screws ranged from 69 to 94% using the freehand technique, 28 to 85% using fluoroscopy, 89 to 100% using CT navigation, and 81 to 92% using fluoroscopy-based navigation. The wide variation in results was felt to be related to the variation in diagnosis and surgeon experience. Another finding of the study was a tendency for freehand placed screws to deviate the cortex medially versus lateral breaches being more common with CT navigation guidance. This trend was also found in the current study with a significantly greater rate of lateral breach compared with medial breach.

Santos et al performed a cadaveric study on the accuracy of the O-arm for assessment of pedicle screw position. In their study, nine cadaveric specimens were used for placement of pedicle screws through a traditional open exposure under CT-based navigation. Screws were randomized to be intentionally placed in the pedicle, outside the pedicle laterally, or outside the pedicle medially. The overall accuracy of the O-arm in identifying whether or not there was a pedicle breach present was reported to be 73% compared with surgical dissection and visualization of the pedicle.

Our findings also suggested that the real-time computer-aided navigation tool (simulated screw) was limited in identifying a pedicle breach. Manipulation of the surgeon’s hand or screwdriver could change the orientation of the navigation tool without changing the screw trajectory within the pedicle. We found the safest use of the system was to use the navigation tool to identify the ideal starting point and trajectory of the screw. We felt that the “navigated screw” feature was less reliable to judge the “postinsertion” position of the screw. There was enough segmental motion of the vertebral bodies that adjusting the surgeon’s hand and the frame attached to the screwdriver could move the simulated screw while the “simulated vertebral body” stayed stationary. This discrepancy could lead to the appearance of the screw changing its position or trajectory within the pedicle while in reality there was no relative change in position of the screw with respect to the vertebral body. However, when no force was being applied to the driver or other instruments, this discrepancy appeared to be much less.

Other potential sources of error could include a small change in position of the vertebral bodies after dissection especially in open cases, segmental motion between the reference frame and the vertebral bodies being navigated, bent or distorted instruments, and improperly applied screws on the driver.

Limitations of the current study include the relatively low number of screws placed and the potentially poor bone quality of the cadaveric specimens. The specimens had no history of spinal surgery, but they were not screened with bone density studies. Poor bone quality could potentially increase the risk of pedicle breach or poor placement of the screws. Additionally, in the current study we utilized the Jamshidi needle for creation of the path through the pedicle followed by placing the screws over a wire. Newer techniques utilizing an awl followed by the tap and pedicle screw under direct navigation using precalibrated instruments might further improve accuracy.

Based on the results of the current study, we can recommend the use of CT-guided navigation for the placement of percutaneous pedicle screws in the lumbar spine, but there might be an increased risk associated with this technique in the thoracic spine. It is possible that combining the use of navigation for percutaneous placement of pedicle screw with neurophysiologic monitoring could significantly increase the safety of this technique.

Disclosures
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Anthony Lapinsky, None
Christian P. DiPaola, Consulting: Allen Medical

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