Title: Percutaneous Lumbar Pedicle Screw Placement Aided by Computer-Assisted Fluoroscopy-Based Navigation: Perioperative Results of a Prospective, Comparative, Multicenter Study

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Conflicts of Interest and Source of Funding

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**Abstract**

**Study Design:** IRB-approved, prospective, multicenter, comparative study.

**Objective:** To assess the accuracy and utility of a computer-assisted fluoroscopic navigation method for percutaneous placement of lumbar pedicle screws as compared to conventional fluoroscopic placement.

**Summary of Background Data:** Recent reports indicate that cortical breaches during percutaneous pedicle screw placement can exceed 15%. CT- and fluoroscopy-based navigation systems may facilitate increased placement accuracy with reduced radiation exposure and operative times.

**Methods:** Patients were alternately assigned to either the Guidance or Control group. The Guidance group underwent lumbar pedicle screw placement using the oblique visualization technique and computer-assisted fluoroscopic navigation. The Control group underwent lumbar pedicle screw placement per standard percutaneous technique aided by fluoroscopy alone. Baseline demographics, Visual Outcome Scores (VAS), and American Spinal Injury Assessment (ASIA) scores were obtained preoperatively and in the immediate postoperative period. Fluoroscopy times and guidewire insertion times were recorded intraoperatively. All postoperative CT scans were reviewed by an independent spine surgeon to grade screw placement accuracy.

**Results:** 42 patients (210 screws) were assigned to the Guidance group, 34 patients (152 screws) were assigned to the Control group. Use of Guidance resulted in reduced average fluoroscopy usage per pedicle (6.6 sec (SD 5.1) vs. 9.6 sec (SD 6.2), p<0.001) and more expedient placement of guidewires per pedicle (3.65 min (SD 2.31) vs. 4.43 min (SD 2.56), p=0.003). The Guidance group experienced less than half of the breach rate of the Control group (3.0% vs. 7.2%, p=0.055) and reduced breach magnitudes. None of the breaches resulted in a corresponding neurological deficit or required revision. All patient-reported outcomes were significantly improved after surgery and there were no significant differences in average postoperative VAS scores between treatment groups.

**Conclusions:** Use of Guidance reduces fluoroscopy and insertion times with increased accuracy when compared to conventional fluoroscopic methods of percutaneous pedicle screw insertion.
**Key Points:** 1. The use of a fluoroscopy-based computer navigation system reduced fluoroscopy use during percutaneous pedicle screw insertion compared to screw insertion with fluoroscopy alone.

2. The fluoroscopy-based pedicle screw navigation system presented in this manuscript resulted in a low percutaneous pedicle screw breach rate with small breach magnitude. None of the malpositioned screws in either study group resulted in neurologic deficits.

3. The fluoroscopy-based navigation platform presented in this manuscript is not intended to be purchased by the hospital and can be used in most operating rooms without additional capital expenditures. As such, this system may serve as a low-cost alternative to CT-based navigation systems which are often only available in select hospitals with sufficient funding to purchase and house such platforms.
Mini Abstract/Précis: This prospective, multicenter, comparative study reports the placement accuracy, fluoroscopic exposure, procedure time, and perioperative clinical outcomes of patients treated with percutaneous pedicle screws using either a fluoroscopy-based computer navigation system for placement of pedicle screws or traditional pedicle screw placement using fluoroscopy alone.
Fluoroscopy-Based Navigation

Introduction

Percutaneous placement of pedicle screws is becoming routine in spine surgery with the advent and maturity of minimally invasive techniques. The reported benefits of minimally invasive over open procedures include reductions in blood loss, length of hospital stay, infection rates, postoperative pain, and time to return to work. Placement of percutaneous pedicle screws using the conventional fluoroscopic technique with anteroposterior and lateral images is time-consuming and exposes the patient and surgical team to considerable radiation. Recent reports indicate that cortical breaches during percutaneous pedicle screw placement can exceed 15%, with neurologic injury as high as 15%. A number of CT- and fluoroscopy-based navigation systems have been developed with demonstrated ability to increase screw accuracy, decrease radiation exposure, and reduce operative times. Unfortunately, these systems have not seen widespread adoption because they require time-consuming planning and invasive fixation of a reference arm, they are unable to compensate for positional change, and are expensive capital investments.

The purpose of this prospective, multicenter study is to compare a fluoroscopy-based navigation system with conventional fluoroscopy alone for the percutaneous placement of lumbar pedicle screws. The navigation technique described herein takes advantage of the oblique “owl’s eye” fluoroscopic pedicle view and has been previously published with favorable placement accuracy and clinical outcomes in a single-cohort, retrospective study.

Materials and Methods

The NVM5™ Guidance System (NuVasive®, Inc, San Diego, CA) applied to a standard two-dimensional C-arm forms the navigation platform in this study and has been previously described. A portable reticle with integrated central laser beam is attached to the image-intensifier surface of the C-arm and tracks the angular position of the fluoroscope in real time. A micro-accelerometer integrated into a clip-on
attachment enables real-time calculation of the angular position of the pedicle cannulation needle. The pedicle cannulation needle is also continuously stimulated to enable evoked electromyography (EMG) monitoring of potential cortical breaches. Preoperative CT or MRI images are used to calculate the targeted medial-lateral angle of each pedicle trajectory. A single intraoperative lateral fluoroscopic image is used to calculate the targeted cranial-caudal angle of each pedicle trajectory. With the medial-lateral and cranial-caudal angles programmed, the reticle-equipped C-arm is then brought into an oblique view down the central axis of the pedicle. After an incision is made, the micro-accelerometer-attached pedicle cannulation needle is then brought into the programmed angles using feedback displayed on the Guidance system (Figure 1.), as well as light emitting diodes (LED) on the cannulation needle (Figure 2.) to direct impaction into the pedicle. A guidewire is placed and the remaining steps of screw insertion are identical to conventional percutaneous methods.

Enrollment in this institutional review board-approved, multicenter, prospective, comparative study was limited to patients between the ages of 20 and 79 with a preoperative diagnosis requiring treatment with pedicle screw fixation in the lumbar spine. Patients were excluded from study participation if they had previous instrumented surgery at the targeted lumbar level(s). At each study site, after obtaining written informed consent, patients were assigned to alternating treatment groups according to the order of enrollment. At each site, the first patient treated was assigned to the Guidance group. The Guidance group underwent percutaneous pedicle screw placement aided by fluoroscopy-based navigation. The Control group underwent percutaneous pedicle screw placement aided by conventional fluoroscopy alone. Demographic data collected included age, sex, height, weight, and body mass index (BMI). Patient-reported clinical outcomes were collected using the visual analog scale for back (VAS\textsubscript{back}) and leg (VAS\textsubscript{leg}) pain at baseline and within 1 week after surgery. A neurological exam, including evaluation of lower extremity motor strength and sensory function was performed at baseline and within 1 week after surgery using the American Spinal Injury Association (ASIA) classification. If motor or sensory deficits
were identified at the first postoperative visit, patients were evaluated again 4-6 weeks postoperatively to
determine whether the deficit was transient.

Intraoperative data include levels treated, operative time, estimated blood loss, intraoperative
complications, number and location of screws, screw diameters and lengths, and time to guidewire
insertion in the pedicle. The EMG thresholds of the final position of each pedicle cannulation needle and
each pedicle screw were recorded. Total fluoroscopy time was collected as well as subset fluoroscopy
times for preincisional skin marking and guidewire placement for each pedicle. Additional data collected
in the Guidance group included Guidance system set-up time, preoperative measured pedicle angles, and
actual pedicle cannulation needle angles after impaction into the pedicle. Postoperative complications
and duration of hospital stay were noted.

Pedicle screw placement was assessed by a single, independent, blinded spine surgeon based on a
postoperative CT scan obtained within 1 week after surgery. The magnitude of pedicle perforation was
categorized as no breach, breach less than 2 mm, breach 2-4 mm, breach 4-6 mm, and breach greater than
6 mm. The direction of the perforation was categorized as lateral, medial, inferior, or superior.

Clinical and radiographic data were analyzed using PASW Statistics 18.0 (SPSS Inc., Chicago, IL). An
independent t-test was used to compare mean results between treatment groups, the paired t-test was used
to compare mean results in the same treatment group across different time points, and the Fischer’s exact
test was used to compare categorical data between treatment groups. The significance level was defined
as p<0.05.

Results

79 patients were consented for study participation at 5 sites. Three control patients from two different
sites withdrew consent prior to treatment. Ultimately, 76 patients were included in the study; 42 patients
were assigned to the Guidance group and 34 were assigned to the Control group. The difference in patients per group can be attributed to enrollment of an odd number of patients at each site, and patients who withdrew consent prior to treatment. The average age at surgery was 52 years (range 20-79) and the average body mass index (BMI) was 31.0 kg/m² (range 19.1-45.9). Indications for surgery included degenerative disc disease (85.5%), central or foraminal stenosis (69.7%), loss of disc height (55.3%), spondylolisthesis (44.7%), herniated nucleus pulposus (17.1%), degenerative scoliosis (13.2%), and post-laminectomy instability (5.3%). Baseline patient-reported pain scores were VAS_{back} 75.5 mm (SD 17.9), VAS_{left_leg} 38.5 mm (SD 35.2), and VAS_{right_leg} 46.9 mm (SD 33.3). Prior to surgery 60 (78.9%) patients had at least one lumbar motor or sensory deficit. Baseline variables including sex, age, BMI, and indications for surgery were well matched between cohorts (p>0.05) and are reported in Table 1. Surgical data are reported by group in Table 2.

A total of 362 screws were placed, (210 Guidance, 152 Control) from L2 to S1. Patients were treated with an average of 4.8 screws (range 2-10) and screw diameters ranged from 5.5 to 7.5 mm. The average screw diameter and number of screws placed per patient were not statistically different between treatment groups (p=0.294 and p=0.083, respectively). On average the Guidance group used less fluoroscopy per pedicle (6.6 sec (SD 5.1) vs. 9.6 sec (SD 6.2), p<0.001) (Figure 3.), and resulted in more expedient placement of guidewires per pedicle (3.65 min (SD 2.31 vs. 4.43 min (SD 2.56), p=0.003) (Figure 4.). The Guidance system set-up can be done without surgeon supervision and averaged 5.0 min (SD 5.6). Pre-incision fluoroscopy included skin marking in both groups and an additional lateral registration image in the Guidance group. Pre-incision fluoroscopy time was not significantly different between groups.

Estimated blood loss was less than 200 cc in 71.6% of patients, 200-300 cc in 18.9% and greater than 300 cc in 9.5%. There were no intraoperative complications and all screws were placed percutaneously without transition to an open technique. Postoperative CT scans of 75 patients were available for review by an independent spine surgeon. CT data was available for 354 screws (202 Guidance, 152 Control). There were 17 pedicle breaches, including 6 (3.0%) in the Guidance group and 11 (7.2%) in the Control.
group (p=0.055). All breaches in the Guidance group and 10 of 11 in the Control group were less than 2 mm. The remaining Control group breach was 2-4 mm. One Guidance group breach occurred at the endplate and two Control group breaches occurred at the lateral cortex of the pedicle. All remaining breaches occurred at the medial cortex of the pedicle. None of the breached pedicle screws required revision. There was no significant association between treatment side or vertebral level and incidence of breach.

No neurologic complication could be attributed to screw malposition. Complications included 7 postoperative motor deficits (5 Guidance, 2 Control) and 4 sensory deficits (3 Guidance, 1 Control). One motor and 1 sensory deficit occurred together in a Guidance group patient with a breached pedicle screw; however, the breach was remote from the symptomatic nerve roots and all deficits resolved within 4 weeks. It is suspected that the deficit was related to the patient’s anterior surgery. All other deficits occurred in patients without pedicle screw breaches. One sensory deficit in a Guidance group patient was persistent at 8 weeks, and one motor deficit was not further assessed as the patient was lost to follow-up. All other deficits resolved by the 8 week visit. Clinical outcomes are reported by group in Table 3. Average postoperative patient-reported pain scores were not significantly different between treatment groups and were significantly improved compared to baseline scores.

Discussion

Perhaps the most important attribute of any navigation system is that it facilitates safe and accurate screw placement. In this study, 97% of navigated screws were entirely intrapedicular and 100% of navigated screws were less than 2 mm breached, commonly considered to be within the ‘safe zone’ around the pedicle. The breach rate was less than half of that using conventional fluoroscopy. According to a recent meta-analysis, average pedicle screw placement accuracy was 92.1% in navigated and 87.3% in un navigated cases. Although many clinical studies report a low incidence of neurologic injury
associated with misplaced screws, there is evidence that small cortical breaches can impact the biomechanical strength of a construct.\textsuperscript{12,21,25-27} George et al. demonstrated the importance of cortical containment of pedicle screws in their findings that the pull-out strength of pedicle screws with a cortical breach was 11\% less than that of screws contained wholly within the pedicle.\textsuperscript{28} Similarly, Acikbas et al. observed that patients with malpositioned screws had reductions in early correction, increased long-term loss of correction, and greater non-union rates.\textsuperscript{29}

As long as fluoroscopy remains an integral part of percutaneous pedicle screw placement, radiation exposure to the surgical team will remain a legitimate concern. Cumulative radiation dose can exceed regulatory occupational limits.\textsuperscript{4,30} This study confirmed that the use of the Guidance system significantly reduced fluoroscopy time per pedicle. Additionally, the central laser beam from the reticle denotes the target in the oblique pedicle view and enables the surgeon to step back from the C-arm during skin marking. In contrast, during conventional anteroposterior and lateral fluoroscopy, the surgeon typically stands next to the patient and C-arm and holds a guidewire against the skin to localize anatomical landmarks. With current CT- and three-dimensional fluoroscopy-based navigation systems, the patient is exposed to significant amounts of radiation during image acquisition even if the surgeon is able to step away.\textsuperscript{20,31} The Guidance system takes advantage of routine preoperative imaging without requiring extensive reimaging of the patient intraoperatively.

Many surgeons have been hesitant to embrace navigation technologies because of early experience with tedious matched-pair point registration of numerous anatomical landmarks, excessive operative set-up times, and prolonged screw placement times.\textsuperscript{13,15,32} Some navigation platforms mandate the attachment of a reference arc through a separate incision.\textsuperscript{12,18,20} With newer generation systems, more recent reports describe image registration and set-up times between 14 and 18 minutes.\textsuperscript{5,11,20} Results from the current study demonstrated a relatively short set-up time of approximately 5 minutes by ancillary staff as well as reductions in screw placement time. Before starting the case, the surgeon need take only a few moments
to measure the medial-lateral pedicle angles on the patient’s preoperative CT or MRI scan. With the Guidance system, no reference arc is attached to the patient since no additional point registration or calibration is necessary. This portable navigation system is designed to integrate with a standard C-arm and does not require any additional capital expenditures by the hospital; this is critical when one considers that CT-based navigation platforms require hospitals to purchase the platform. Once a CT-navigation system is purchased, implementation the system may also require permanent modification of the operative suite to integrate intraoperative CT scans for automated system registration. In the example of small community hospitals with limited funding or operative suites that must be reconfigured frequently for multipurpose use, a CT navigation system may not be a realistic option. The technology presented in this manuscript represents an innovative step toward a simpler, more efficient, and more cost-effective fluoroscopy-based navigation platform for percutaneous placement of pedicle screws.

Conclusions

Computer-assisted fluoroscopic navigation of percutaneous lumbar pedicle screws effectively reduces fluoroscopy times and shortens screw insertion times without compromising accuracy when compared to conventional fluoroscopic methods. Further study may show the utility of this technology in the placement of thoracic pedicle screws where breach rates are typically elevated in the setting of lower tolerance for error. As navigation technologies become more advanced, they will be increasingly employed to aid in the placement of pedicle screws. Future studies directly comparing different systems will need to be performed to evaluate the advantages of one over another.


32. Laine T, Lund T, Ylikoski M, Lohikoski J, Schlenzka D. Accuracy of pedicle screw insertion with and without computer assistance: a randomised controlled clinical study in 100 consecutive patients. 

### Table 1. Patient demographics.

<table>
<thead>
<tr>
<th></th>
<th>Guidance (SD)</th>
<th>Control (SD)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>42</td>
<td>34</td>
<td>N/A</td>
</tr>
<tr>
<td>Age</td>
<td>52.7 (16.3)</td>
<td>51.9 (11.9)</td>
<td>0.804</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>30.7 (6.8)</td>
<td>31.4 (6.9)</td>
<td>0.685</td>
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</table>

### Table 2. Surgical results.

<table>
<thead>
<tr>
<th></th>
<th>Guidance (SD)</th>
<th>Control (SD)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total screws placed</td>
<td>210</td>
<td>152</td>
<td>N/A</td>
</tr>
<tr>
<td>Screws per patient placed</td>
<td>5.0 (1.3)</td>
<td>4.7 (1.3)</td>
<td>0.083</td>
</tr>
<tr>
<td>Fluoroscopy time before incision (sec)</td>
<td>13.8 (7.5)</td>
<td>16.5 (12.9)</td>
<td>0.277</td>
</tr>
<tr>
<td>Fluoroscopy time per pedicle (sec)</td>
<td>6.6 (5.1)</td>
<td>9.6 (6.2)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Incision to guidewire placement time per pedicle (min)</td>
<td>3.65 (2.31)</td>
<td>4.43 (2.56)</td>
<td>0.003</td>
</tr>
</tbody>
</table>

### Table 3. Baseline and postoperative Visual Analog Scale results. All results are in millimeters.

<table>
<thead>
<tr>
<th></th>
<th>Guidance (SD)</th>
<th>Control (SD)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Back</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>73.2 (18.8)</td>
<td>78.5 (16.7)</td>
<td>0.197</td>
</tr>
<tr>
<td>Postoperative</td>
<td>57.2 (25.4)</td>
<td>56.0 (29.0)</td>
<td>0.857</td>
</tr>
<tr>
<td>Left Leg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>35.0 (33.1)</td>
<td>42.8 (37.8)</td>
<td>0.347</td>
</tr>
<tr>
<td>Postoperative</td>
<td>21.8 (25.7)</td>
<td>21.1 (26.7)</td>
<td>0.907</td>
</tr>
<tr>
<td>Right Leg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>46.8 (32.6)</td>
<td>47.1 (34.7)</td>
<td>0.969</td>
</tr>
<tr>
<td>Postoperative</td>
<td>23.1 (30.0)</td>
<td>29.9 (28.0)</td>
<td>0.308</td>
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</tbody>
</table>
Figure Legends

Figure 1. Graphical user interface of the Guidance System. By centering the pedicle an oblique “owl’s eye” fluoroscopic image, the C-arm reticle laser becomes co-linear with the pedicle axis. The laser projection on the patient aids skin marking and pedicle cannulation. Instrument and C-arm angles are continuously updated and displayed at the right of the screenshot. Evoked EMG thresholds are also reported.

Figure 2. Pedicle cannulation needle with micro-accelerometer attachment. LED arrows on the attachment direct angulation toward the pre-programmed cranial-caudal and medial-lateral angles.

Figure 3. Fluoroscopy use per pedicle. Error bars represent 95% confidence interval for the mean.

Figure 4. Guidewire placement time per pedicle. Error bars represent 95% confidence interval for the mean.
Figure 1
Figure 2
Figure 3

Fluoroscopy per Pedicle

seconds

Control  Guidance

Error bars represent standard deviation.
Figure 4

Guidewire Placement per Pedicle

- Control vs. Guidance

Y-axis: Minutes
X-axis: Control vs. Guidance

Error bars indicate variability.
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