Placement of thoracolumbar pedicle screws using three-dimensional image guidance: experience in a large patient cohort

Clinical article

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Object. The goal of this study was to analyze the placement accuracy and complications of thoracolumbar pedicle screws (PSs) inserted using 3D image guidance in a large patient cohort.

Methods. The authors reviewed the charts of 220 consecutive patients undergoing posterior spinal fusion using 3D image guidance for instrumentation placement. A total of 1084 thoracolumbar PSs were placed using either the BrainLAB Vector Vision (BrainLAB, Inc.) or Medtronic StealthStation Treon (Medtronic, Inc.) image guidance systems. Postoperative CT scanning was performed in 184 patients, allowing for 951 screws to be graded by an independent radiologist for bone breach. All complications resulting from instrumentation placement were noted. Using the intraoperative planning function of the image-guided system, the largest diameter screw possible in each particular case was placed. The screw diameter of instrumentation placed into the L3–S1 levels was noted.

Results. No vascular or visceral complications occurred as a result of screw placement. Two nerve root injuries occurred in 1084 screws placed, resulting in a 0.2% per screw incidence and a 0.9% patient incidence of nerve root injury. Neither nerve root injury was associated with a motor deficit. The breach rate was 7.5%. Grade 1 and minor anterolateral “tip out” breaches accounted for 90% of the total breaches. Patients undergoing revision surgery accounted for 46% of the patients in this study. Accordingly, 154 screws placed through previous fusion mass could be evaluated using postoperative CT scanning. The breach rate in this specific cohort was 7.8%. A total of 765 PSs were placed into the L3–S1 levels in this study; 546 (71%) of these screws were ≥7.5 mm in diameter. No statistical difference in breach rate was noted in PSs placed through revision spinal levels versus nonrevision spinal levels (p = 0.499). Additionally, no increase in breach rate was noted with placement of 7.5-mm-diameter screws.

Conclusions. Three-dimensional image guidance is a useful adjunct to placement of spinal instrumentation. The complication rate in this study was low, and accurate placement of instrumentation was achieved despite the high percentage of revision surgery cases in our patient population. Additionally, because active fluoroscopy was not used for instrumentation placement, there was minimal to no radiation exposure to the surgeon or operating room staff.

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Key Words • computer-assisted image guidance • instrumentation • navigation • pedicle screw • spinal fusion

The use of PSs in spinal fusion procedures has been steadily increasing over the past decade. An advantage of using instrumentation in spinal fusion surgery is greater biomechanical stability with subsequent increased fusion rates.8,9,25,48 Complications of spinal instrumentation placement can be serious and include vascular, visceral, and neurological injury.5,7,11,12,26,27,31 Image-guided spinal surgery was introduced in 1995 and has been designed to increase the accuracy of spinal instrumentation placement.1–3,16,30,33,47 We describe our experience with 1084 thoracolumbar PSs placed using 3D image guidance for posterior spinal fusion procedures.

Methods

We obtained approval from the institutional review board for this study. We reviewed the charts of all patients undergoing posterior instrumented spinal fusion by the senior author (E.W.N.) at Mayo Clinic Florida between January 2003 and June 2008. The senior author uses 3D image guidance for thoracic and lumbar PS placement, and all cases involving PS placement into these regions

Abbreviations used in this paper: AP = anteroposterior; cbCT = cone-beam CT; PS = pedicle screw.
of the spine were included in the study. We identified 230 patients who underwent posterior instrumented spinal fusion. An image guidance system was not available for 10 patients. These patients were excluded, leaving 220 patients available for study. A total of 1084 thoracolumbar PSs were placed (Table 1). The BrainLAB Vector Vision (BrainLAB) image guidance system was used to assist placement of instrumentation in the majority of these patients. The Medtronic StealthStation Treon (Medtronic, Inc.) image guidance system was also used for instrumentation in some patients in this study. Vertebral registration was accomplished using a paired point/surface-matching algorithm in 80 patients. In the remaining 140 patients, registration was accomplished using the Arcadis Orbig Isocentric C-arm (Siemens Medical Solutions) or the O-arm (Medtronic, Inc). The Arcadis Orbig Isocentric C-arm and the O-arm are systems that produce intraoperative cbCT images. The cbCT data set is automatically registered to the image-guided system and, therefore, no point-matching steps are needed.

The senior author placed or supervised placement of all 1084 screws. The technique of screw placement was the same in all patients. After registration was accomplished, navigation accuracy was confirmed by touching anatomical landmarks with the image-guided probe. The intraoperative planning function on the image-guided system, which places a phantom screw on the tip of the probe, was then used to ascertain the entry point and trajectory of the screw (Fig. 1). The optimal length and diameter of the screw were also determined using this function, and it should be noted that in each case effort was made to place the maximum diameter screw that the anatomy could accommodate. This intraoperative plan was locked into place, and all subsequent drilling/probing was done with image-guided instruments through this plan (Fig. 2). In screws placed above the T-4 level, a hole was typically drilled into the pedicle using a high-speed drill through an image-guided drill guide. After the pedicle was either probed or drilled, a pedicle feeler was then used to confirm that there was no pedicle breach, and the hole was then tapped in the same trajectory. After a pedicle feeler again confirmed no pedicle breach, the screw was placed. Navigation accuracy was briefly checked again prior to placement of the next screw by touching anatomical landmarks. In most cases, the tap and screwdriver were not image guided.

Patients routinely underwent AP and lateral radiography in the operating room prior to the end of the procedure to check instrumentation placement. Another intraoperative cbCT scanning procedure was performed if there was any uncertainty regarding screw position or when it was thought that AP and lateral radiographs would not suffice in determining appropriate instrumentation position. Patients who experienced exacerbation of preoperative extremity pain, onset of a different type of extremity pain, or any new-onset neurological complaints underwent evaluation of the operated levels using MR imaging and thin-cut CT scanning. Patients were followed up at 3- to 6-month intervals with flexion-extension radiographs and thin-cut CT scans that included sagittal and coronal reconstructions. Some patients were lost to follow-up or could not undergo CT scanning. Subsequently, 951 screws could be analyzed using postoperative CT scanning. An independent radiologist graded the placement of the screws using the system described by Mirza et al.29 In this system, a breach of < 2 mm is considered Grade 1, a breach of 2–4 mm is considered Grade 2, and a breach of > 4 mm is considered Grade 3. The direction of perforation was also noted, including anterior bone perforation by the tip of the screw. In the senior author’s practice, the “in-out-in” technique is used for placement of PSs into narrow pedicles, and S-1 PSs are typically placed bicortically. Accordingly, these intentional breaches were not counted in the breach analysis.

**Table 1: Breakdown per level of thoracolumbar PSs placed with the aid of 3D image guidance**

<table>
<thead>
<tr>
<th>Level</th>
<th>No. of PSs</th>
</tr>
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<tbody>
<tr>
<td>T-1</td>
<td>64</td>
</tr>
<tr>
<td>T-2</td>
<td>50</td>
</tr>
<tr>
<td>T-3</td>
<td>30</td>
</tr>
<tr>
<td>T-4</td>
<td>12</td>
</tr>
<tr>
<td>T5–10</td>
<td>40</td>
</tr>
<tr>
<td>T-11</td>
<td>20</td>
</tr>
<tr>
<td>T-12</td>
<td>16</td>
</tr>
<tr>
<td>L-1</td>
<td>35</td>
</tr>
<tr>
<td>L-2</td>
<td>52</td>
</tr>
<tr>
<td>L-3</td>
<td>122</td>
</tr>
<tr>
<td>L-4</td>
<td>224</td>
</tr>
<tr>
<td>L-5</td>
<td>273</td>
</tr>
<tr>
<td>S-1</td>
<td>146</td>
</tr>
<tr>
<td>total</td>
<td>1084</td>
</tr>
</tbody>
</table>

**Statistical Analysis**

Breach rates were estimated as binomial proportions with exact binomial confidence intervals. The associations between pedicle breach in PSs placed during nonrevision and revision surgery cases were assessed using the Fisher exact test. Associations between pedicle breaches in patients undergoing registration by point matching versus registration via cbCT were also assessed in this fashion. Results were considered statistically significant at a probability value < 0.05. All statistical analysis was performed using SAS version 9.1 (SAS Institute, Inc.).

**Results**

**Surgical Complications**

Overall, 1084 PSs were placed using 3D image guidance in 220 patients. No vascular or visceral complications occurred as a result of screw placement. Two nerve root injuries occurred in 1084 screws placed, resulting in a 0.2% screw incidence and a 0.9% patient incidence of nerve root injury. Neither injury was associated with a motor deficit. One of the nerve root injuries resulted in

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permanent numbness for the patient in an S-1 distribution. In this case, the pedicle hole was probed and tapped in the correct trajectory using image guidance; however, the patient had a low-set lumbosacral junction that made it difficult to place instrumentation in the sacrum, and the entry point of the PS was close to the dorsal aspect of the sacral foramina. The PS was inadvertently placed down the dorsal foramina. The AP and lateral radiographs obtained prior to wound closure revealed the screw misplacement, and the screw was subsequently placed into the correct location. In the other case, the patient had a previous L3–S1 fusion for high-grade spondylolisthesis and required fusion that extended up to the thoracic spine. Instrumentation was placed through her previous fusion mass down to the L-5 level. The right L-5 PS had a minor inferior breach in an already narrowed foramen (Fig. 3), which resulted in postoperative lower-extremity pain without neurological deficit. The radiculopathy did not improve with conservative measures, and the screw was subsequently removed in a minimally invasive fashion, resulting in abatement of symptoms.

**Pedicle Breach**

Thirty-six patients in this study did not undergo postoperative CT scanning because they were lost to follow-up or because CT scans were pending at the time of submission of this study. Subsequently, 951 screws were evaluated by postoperative thin-cut CT scans with sagittal and coronal reconstructions. The overall breach rate in our study was 7.5%. The degree and direction of breaches are summarized in Table 2. Grade 1 breaches accounted for 61% of all breaches. Anterolateral breaches, also referred to as “tip-out” breaches, accounted for 29% of the breaches. Grade 2 and 3 breaches accounted for 7 and 3% of the total breaches, respectively. The most common breach type and level in this series was the anterolateral ("tip out") perforation at the L-5 level.

A review of the operating room records revealed 3 medial breaches that were discovered intraoperatively after probing the pedicle. In these cases, the screw was placed in a different trajectory with no adverse sequela. In another patient, AP and lateral radiographs that were obtained intraoperatively suggested a medially placed screw in the L-3 pedicle. A spin of the isocentric C-arm was accomplished and confirmed this. The screw was subsequently placed in a more lateral trajectory. The patient had no symptoms stemming from the initial screw placement.

Two hundred thirty-eight thoracic PSs were placed in this study spanning from T-1 to T-12. There were 22 unintentional breaches in this group, yielding a 9% breach rate. Grade 1 breaches accounted for 21 (95.5%) of these breaches. The other breach was a Grade 2 breach (4.5%) with no clinical sequelae. The “in-out-in” technique was used for 16 thoracic screws, and these intentional breaches were not included in the analysis.

Forty-six percent of the patients undergoing fusion in this study had previous laminectomy or laminectomy fusion over the levels to be instrumented. Accordingly, 333 screws were placed through these spinal levels, and 282 of these screws could be graded based on postoperative CT scanning. The overall breach rate of screws placed into these revision spinal levels was 6.7%. When breaking down this group further, 154 PSs that were placed through an actual fusion mass could be evaluated by postoperative CT scanning, and 12 of these screws demonstrated a breach, resulting in a 7.8% breach rate in this group (Fig. 4). Seven of the 128 screws placed through spinal levels that had undergone previous laminectomy without fusion demonstrated a breach, resulting in a 5.5% breach rate in this group. There was no significant difference in breach rates in screws placed into spinal levels with laminectomy defects versus screws placed through fusion mass (p = 0.4833). Additionally, there was no significant difference in breach rate between screws placed in nonrevision surgery spinal levels and revision surgery spinal levels (p = 0.499).

A paired point/surface-matching algorithm was used for vertebral registration in 80 patients. Three hundred fourteen screws were placed in this group with a breach rate of 9.2%. One hundred forty patients had 637 screws placed using cbCT scanning for vertebral registration, and the breach rate in this group was 6.6%. The difference in breach rates between these 2 groups was not statistically significant (p = 0.0936).
Pedicle Screw Diameter

Using the intraoperative planning function of the image-guided system, the senior author placed the largest diameter screw possible in each particular case. The diameters of screws placed from the L3–S1 levels were determined. A total of 765 PSs were placed into the L3–S1 levels in this study, and 546 screws (71%) were ≥ 7.5 mm in diameter. Table 3 demonstrates the breakdown of screw size per level in this cohort. Compared with smaller diameter screws, there was no increase in breach rate when ≥ 7.5-mm-diameter screws were placed into the L3–S1 levels.

Discussion

Image-guidance techniques began to be implemented in spinal surgery procedures in 1995 and have been designed to increase the accuracy of spinal instrumentation placement.1–3,30,34–37 Standard techniques of PS insertion have included fluoroscopic guidance, as well as the freehand technique. A 14–55% misplacement rate for PSs using standard techniques has been reported.4,21,44,46 Additionally, injury from PS placement has been reported to occur at a rate of 1–8%.7,17,20,27,48 To our knowledge, our study represents the largest analysis in the literature of PS placement using 3D image guidance.

In a meta-analysis of the published literature on accuracy of PS placement, Kosmopoulos and Schizas38 reported a median accuracy of 90.3% in 12,299 PSs placed in vivo without navigation versus a median accuracy of 95.2% in 3059 PSs placed in vivo with navigation. This meta-analysis did not include studies published after 2006 and also did not specify navigation techniques. Since this time, several studies have been published reporting accuracy of PS placement with the aid of 3D navigation. In a randomized clinical trial comparing thoracic PS placement using fluoroscopic assistance versus 3D fluoroscopy–based navigation in patients with spinal deformity, Rajasekaran et al.33 found a 23% breach rate in the fluoroscopic group compared with a 2% breach rate in the navigation group. In another recent study, Kotani et al.39 reported an 11% breach rate in PSs placed with fluoroscopic guidance versus a 1.8% breach rate in PSs placed with 3D image guidance in patients with scoliosis. We consider the 7.5% breach rate in our study quite acceptable given the fact that nearly half of the patients in this study were revision surgery cases and that minor Grade 1 breaches and the anterolateral “tip out” breach constituted 90% of the breaches in our study. This latter breach type was found mostly at the L-4 and L-5 levels in which the pedicles were angled medially, and there was difficulty obtaining a medial trajectory of the screws due to patient anatomy, resulting in minor anterolateral breaches of these screws. The remaining 10% of the breaches in our study were either Grade 2 or 3 breaches representing an overall breach rate of 0.7% for screws of a Grade 2 or higher breach. Additionally, only 1 (0.5%) of 220 patients in this study required reoperation for a misplaced screw.

Of the 220 patients undergoing posterior spinal fusion in this study, 102 patients (46%) were undergoing revision surgery after either a previous laminectomy (32 patients) or a previous laminectomy and fusion (70 patients) over the spinal levels to be instrumented. Accordingly, 179 PSs were placed through previous fusion masses in this cohort; 154 of these screws could be assessed by postoperative CT scanning. Austin et al.2 demonstrated improved accuracy of PS insertion using 3D image guidance compared with standard techniques in a simulated posterior fusion cadaver model. In 1 of 2 in vivo studies in the literature assessing accuracy of PS insertion through mature fusion masses, Rampersaud and Lee37 reported a 20% breach rate in 102 PSs placed through mature fusion masses in revision spine surgery cases using 2D fluoroscopy–based image guidance. Lim et al.22 reported a 4.1% breach rate in 122 PSs placed through fusion mass using 3D image guidance. The 154 PSs placed using 3D image guidance in our study represent the largest in vivo series in the literature assessing accuracy of PS placement.
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through mature fusion mass using 3D image guidance. Our breach rate of 7.8% in these screws is lower than that described by Rampersaud and Lee who used 2D image guidance, but higher than that reported by Lim et al. who used 3D image guidance.

We believe that using the 3D planning function of the image guidance system allows larger diameter screws to be placed into the spine and can result in screws being placed in a more medial trajectory than standard techniques. Linhardt et al. demonstrated increased pullout strength in PSs placed with computer-assisted techniques compared with screws placed with conventional techniques. Several studies have demonstrated that wider diameter screws, as well as screws placed in a more medial trajectory, have greater pullout strength and resulting increased construct stability. In a detailed study on pedicle morphometry, Krag et al. reported that pedicle diameter steadily increased from the L-3 to the S-1 level. Our study has demonstrated that ≥ 7.5-mm-diameter screws could be placed in approximately half of the L-3 levels and that the frequency of placement of these larger diameter screws gradually increased in lower spinal levels to a 79% frequency at L-5 and a 99% frequency at S-1. Krag et al. also reported that the average pedicle diameter at L-5 in their series was 13 mm. Our series demonstrated that only 79% of PSs placed at L-5 could be ≥ 7.5 mm in diameter. We believe that the reason a higher percentage of larger diameter screws could not be placed in our study is two-fold. First, the study by Krag et al. concentrated only on the axial diameter of the pedicle. In the senior author’s experience, a pedicle that may accommodate a larger diameter screw in the axial plane cannot always accommodate this larger diameter in the sagittal plane, and the 3D planning functions used in spinal image guidance can help determine this. Second, the patient’s anatomy sometimes limits the trajectory of the PS, resulting in a smaller diameter screw being placed to avoid a pedicle breach.

The use of intraoperative cbCT scanning for vertebral registration has been a significant advance in 3D image-guided spinal surgery compared with traditional point-matching registration techniques. With intraoperative cbCT scanning registration, multiple vertebral levels can be registered at once with the patient in the prone position, which is an advantage over point-matching techniques where typically only 1 vertebral level at a time can be registered. Additionally, contrary to point-matching techniques, vertebral registration with the aid of intraoperative cbCT scanning does not require dorsal elements, making it quite useful when placing instrumentation in patients who have undergone previous laminectomy. Mayo Clinic Florida acquired cbCT scanning technology in May 2005. Prior to this date, all 3D image-guided PS placement was accomplished using a paired point/surface-matching algorithm for vertebral registration. After May 2005, cbCT scanning was used for vertebral registration in all cases of image-guided PS placement with the exception of cases that required placement of instrumentation into the upper thoracic levels (T1–3). A disadvantage of cbCT technology is that it can be difficult to visualize the upper thoracic area of the spine, necessitating a point/surface-matching algorithm for vertebral registration in cases involving PS placement into these levels.

The image guidance systems used in our study use optical tracking of instruments, and a potential disadvantage of this is line-of-sight issues between the system camera and the image-guided instrument. Electromagnetic instrument tracking can decrease some of the line-of-sight issues that can arise with optical tracking of instruments and has been implemented successfully in otolaryngological surgery. However, its use has been limited in image-guided spinal surgery because the metallic instruments and implants that are typically used in spinal fusion procedures can cause interference in the electromagnetic field, resulting in inaccurate navigation.

Radiation exposure to the surgeon and operating room staff is a concern when placing instrumentation with the aid of active fluoroscopy. Accordingly, the reported fluoroscopy time used to place a PS varies in the literature from 3.4 to 66 seconds per screw. When using 3D spinal image guidance in our practice, there is minimal to no radiation exposure to the surgeon or operating room staff. When registration is being accomplished with the aid of isocentric fluoroscopy, or when intraoperative radiographs are obtained to check instrumentation placement, the surgeon and operating room staff stand back from the radiation source and are protected by lead aprons or a lead shield, resulting

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**TABLE 3: Diameters and percentages of L3–S1 PSs placed**

<table>
<thead>
<tr>
<th>Level (no. of PSs)</th>
<th>5.5</th>
<th>6.5</th>
<th>7.5</th>
<th>8.5</th>
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<tr>
<td>L-3 (122)</td>
<td>8%</td>
<td>43%</td>
<td>47%</td>
<td>2%</td>
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<tr>
<td>L-4 (224)</td>
<td>2%</td>
<td>41%</td>
<td>54%</td>
<td>3%</td>
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<tr>
<td>L-5 (273)</td>
<td>0%</td>
<td>21%</td>
<td>73%</td>
<td>6%</td>
</tr>
<tr>
<td>S-1 (146)</td>
<td>0%</td>
<td>1%</td>
<td>64%</td>
<td>35%</td>
</tr>
</tbody>
</table>

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**Fig. 4.** Screen shot from an image-guided system showing intraoperative planning of a PS placement through a previous fusion mass using 3D image guidance.
in minimal to no radiation exposure. A point-matching registration algorithm uses a preoperative CT scan so no radiation exposure in the operating room is encountered with this mode of registration.

Conclusions

As technology continues to advance, 3D spinal image guidance is becoming more user friendly to the surgeon. Advantages of this technology in our practice include safe and accurate placement of spinal instrumentation with little to no radiation exposure to the surgeon and operating room staff. The complication and breach rates in our study were low, particularly given the large percentage of revision surgery cases in this series. Additionally, large-diameter screws could be placed with high frequency in the lower lumbosacral spine.

Disclosure

Eric W. Nottmeier, M.D., is a paid consult for BrainLAB and Globus.

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References


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