Clinical and radiographic outcomes of minimally invasive percutaneous pedicle screw placement with intraoperative CT (O-arm) image guidance navigation

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Object. Intraoperative CT image-guided navigation (IGN) has been increasingly incorporated into minimally invasive spine surgery (MIS). The vast improvement in image resolution and virtual real-time images with CT-IGN has proven superiority over traditional fluoroscopic techniques. The authors describe their perioperative MIS technique using the O-arm with navigation, and they report their postoperative experience, accuracy results, and technical aspects.

Methods. A retrospective review of 48 consecutive adult patients undergoing minimally invasive percutaneous posterior spinal fusion with intraoperative CT-IGN between July 2010 and August 2013 at Cedars-Sinai Medical Center was performed. Two surgeons assessed 290 screws in a blinded fashion on intraoperative O-arm images and postoperative CT scans for bony pedicle wall breach. Grade 1 breach was defined to be < 2 mm, Grade 2 breach to be between 2 and 4 mm, and a Grade 3 breach to be > 4 mm. Additionally, anterior vertebral body breach was recorded.

Results. Of 290 pedicle screws placed, 280 (96.6%) were in an acceptable position without cortical wall or anterior breach. Of the 10 breaches (3.4%) 5 were lateral (50%), 4 were medial, and 1 was anterior; 90% of breaches were Grade 1–2 and all medial breaches were Grade 1. The one Grade 3 breach was lateral. No vascular or neurological complications were observed intraoperatively, and no significant postoperative complications were noted. The mean clinical follow-up period was 18 months (range 3–39 months). The overall clinical outcomes, measured using the visual analog scale (back pain scores), were improved significantly postoperatively at 3 months compared with preoperatively (visual analog score 6.35 vs 3.57; $p < 0.0001$). No revision surgery was performed for screw misplacement or neurological deterioration.

Conclusions. New CT-IGN with the mobile O-arm scanner has increased the accuracy of pedicle screw/instrumentation placement using MIS techniques. The authors' high (96.6%) accuracy rate in MIS compares favorably with historical published accuracy rates for fluoroscopy-based techniques. Additional advantages of CT-IGN over fluoroscopic imaging methods are lower occupational radiation exposure for the surgical team, reduced need for postoperative imaging, and decreased rates of revision surgery. For now, the authors simply conclude that use of intraoperative CT-IGN is safe and accurate.

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KEY WORDS • minimally invasive surgery • CT navigation • O-arm •
pedicle screw • accuracy

MINIMALLY invasive surgery (MIS) has proven to be a safe and effective alternative to traditional open spinal surgery.^{7,12,43} Increasing evidence has directly pointed to approach-related morbidity associated with traditional open exposures.^{19,24} However, as direct visual access to the bony spine becomes ever smaller with MIS approaches, the opportunity for increased error and improper placement of instrumentation increases, and higher rates of revision (from 6% to 40%) have been reported.^{4,13,21} Consequently, the reliability of

radiography and imaging modalities becomes of paramount importance to the surgeon for indirect visualization and guidance.

The newest generation of navigation technology, with intraoperative 3D CT image-guided navigation (IGN) with the mobile O-arm scanner (Medtronic, Inc.), has made a tremendous impact on spine imaging resolution. By additionally providing real-time virtual images, mapping out planned trajectories, and visualizing deep spine anatomy, CT-IGN has enabled the surgeon to refine MIS techniques.^{2,3,5,8,18,35} By increasing the accuracy of pedicle screw and instrumentation placement in the cervical, thoracic, and lumbar spine, CT-IGN in spine surgery has led to a significant decrease in instrumentation-related morbidity.^{6,9–11,14,15,17,20,22,30,33,34,36,38,40,42,45}

Abbreviations used in this paper: CT-IGN = CT image-guided navigation; MIS = minimally invasive surgery; VAS = visual analog scale.

In the present study, we describe our perioperative MIS technique for placing percutaneous spinal instrumentation utilizing the O-arm with navigation. We also report our postoperative experience including the accuracy results and technical aspects of our MIS navigation experience in our cohort of spine patients.

Methods

Data Collection

After obtaining institutional review board approval, we performed a retrospective review of 48 consecutive adult patients undergoing MIS percutaneous posterior spinal fusion performed by the first author (T.T.K.) at Cedars-Sinai Medical Center between July 2010 and August 2013. Patients included in this study underwent surgery for the following reasons: degenerative disc disease, isthmic spondylolisthesis, idiopathic scoliosis, pseudarthrosis, and infection. All cases involving MIS percutaneous posterior fusion were included in the study.

Patient medical charts were reviewed to document age, sex, body mass index, diagnosis, procedure, levels of fixation, intraoperative or postoperative complications, and follow-up data. Screw repositioning was documented and reviewed. The pre- and postoperative pain status was assessed using the visual analog scale (VAS) scoring system for back pain. Computed tomography and/or conventional anteroposterior and lateral radiographs were obtained prior to the end of the procedure and at follow-up to assess instrumentation and fusion. Using an established grading system previously described,²⁶ 2 surgeons in a blinded fashion assessed the screws for breach and direction of perforation. A Grade 1 breach was recorded to be < 2 mm, a Grade 2 breach to be between 2 and 4 mm, and a Grade 3 breach to be > 4 mm.

Statistical Analysis

Descriptive statistics were reported for continuous variables, while independent and paired t-tests were used for clinical outcome data. Breach rates were assessed and reported per group characteristics. Using SPSS (SPSS, Inc.), VAS assessments (mean $\pm$ SD) and breach statistics (Grades 1–3) were performed depending on the diagnosis group. Statistically significant results were considered at a probability level < 0.05.

Surgical Technique

All patients were placed prone on a Jackson radiolucent spinal operating table and all pressure points were padded appropriately. The lumbar spine was prepared and draped under sterile conditions. A percutaneous reference pin was placed in the left ilium inferior to the level of the posterior superior iliac spine for short-segment percutaneous pedicle screw instrumentation. For patients requiring a midline incision and transfascial pedicle screw delivery, a spinous process bone clamp attached to the reference frame was selected. Three-dimensional CT images were obtained using an O-arm and were transferred to the computer-assisted StealthStation surgical navigation workstation (Medtronic, Inc.). All instrumentation was calibrated, and lateral-based

percutaneous stab incisions were made as determined by navigated planned pedicle screw trajectories. For patients in whom a midline incision was necessary (in the case of a decompression), a transfascial or separate percutaneous stab incision was selected for pedicle screw insertion. A navigated dilator was inserted through the Wiltse paraspinal muscle interval and docked onto the ideal pedicle screw starting point, lateral to the facet joint (Fig. 1). Serial dilators were inserted, and a navigated awl was used to enter the center of the bony pedicle canal as determined by the navigated axial, coronal, and sagittal planes (Fig. 2). Once the pedicle was cannulated, a navigated tap was used to tap the bony pedicle tract, and the desired size and length screw was determined via the StealthStation measurements. The largest-sized pedicle screw with 1–2 mm of circumferential bony containment was finally inserted into the pedicle with a navigated screwdriver and was confirmed on the StealthStation computer screw projection. In short-segment lumbar fixation (1–3 levels) we connected the percutaneous incisions, inserted a quadrant retractor, and inserted the rod under direct visualization. This eliminated additional radiation exposure as well as decortication and dorsal onlay of bone on the lateral lamina, facet, and transverse processes. For longer-segment scoliosis cases ($\geq$ 4 levels), we used reduction MIS towers (Medtronic, Inc.) and brief fluoroscopic imaging solely for rod delivery. The

FIG. 1. Intraoperative image of the initial navigated dilator inserted through a transfacial stab incision. The navigated dilator is bluntly placed through the paraspinal muscle interval and docked onto the ideal pedicle screw starting point as determined by navigation.

FIG. 2. A navigated awl is passed through the soft tissue dilator and enters the center of the bony pedicle canal as determined by the navigated axial, coronal, and sagittal planes.

decision of whether to use K-wires in the MIS was dependent on the attending's preference.

Postoperative Course

Intraoperative confirmatory O-arm images and postoperative CT scans were analyzed for evidence of bony pedicle wall breach. The majority of postoperative CT scans were obtained in the outpatient setting for diagnosis purposes or to confirm evidence of bony fusion. Whenever possible, immediate postoperative CT scans were generally not obtained on asymptomatic patients secondary to concern for undue radiation exposure.

Results

Table 1 summarizes the preoperative baseline characteristics of the patients undergoing CT-IGN MIS posterior spinal fusion. Overall, 290 pedicle screws were placed in 48 patients (24 males and 24 females) with a mean age of 54.75 years (range 15–84 years) and an average body mass index of 27 (range 19–47). Degenerative disc disease with stenosis was the most common preoperative diagnosis, representing 68.8% of the series. Other reasons for fusion included isthmic spondylolisthesis (20.8%), idiopathic scoliosis (6.2%), infection (2.1%), and pseudarthrosis (2.1%).

TABLE 1: Summary of the preoperative demographics of patients undergoing minimally invasive percutaneous pedicle screw placement with intraoperative CT-IGN

Characteristic	Value*
no. of patients	48
no. of screws	290
sex	
male	24 (50)
female	24 (50)
age in yrs	
mean	54.75
range	15–84
body mass index	
mean	27
range	19–47
preop diagnosis	
degenerative disc disease	33 (68.8)
isthmic spondylolisthesis	10 (20.8)
idiopathic scoliosis	3 (6.2)
pseudarthrosis	1 (2.1)
infection	1 (2.1)

* Values are number of patients (%) unless noted otherwise.

Pedicle Breach and Clinical Outcome

In the 48 patients, 9 (18.8%) underwent a 1-level, 31 (64.6%) underwent a 2-level, 7 (14.6%) underwent a 3-level, and 1 (2.1%) underwent a 5-level fusion. A total of 97 levels were instrumented in 48 patients and the distributions were as follows: 2 (2.1%) at L3–4; 4 (4.1%) at L4–5; 3 (3.1%) at L5–S1; 1 (1.0%) at L2–4; 5 (5.2%) at L3–5; 25 (25.8%) at L4–S1; 2 (2.1%) at L2–5; 25 (25.8%) at L3–S1; and 1 (1.0%) at L1–S1. Of the 290 pedicle screws placed, 280 (96.6%) were placed without a breach and 10 breaches (3.4%) occurred unintentionally. Of the 10 breaches, 3 occurred in one patient and 2 occurred in another patient; both cases with multiple breaches were patients with idiopathic scoliosis who were treated early in the learning curve of this technique. Upon further imaging review, 5 breaches were lateral (50%), 4 were medial (40%), and 1 was in the anterior vertebral body. Grade 1 breaches accounted for the largest group at 70%, Grade 2 breaches were 20%, and Grade 3 breaches were 10%. Of the patients with medial breaches, all were Grade 1 and had preoperative small atrophic pedicles that could not be avoided because those levels were at the top of the construct.

The patient with 3 breaches was a 61-year-old woman with adult idiopathic scoliosis who underwent an L2–5 fusion. In this patient, 2 breaches were medial (Grade 1) at L-2 (Fig. 3), and 1 breach was anterior (Grade 2) at L-5. In this particular case, the two L-2 screws that breached medially were because of small atrophic pedicles (1-mm pedicle diameter on the left and 2.8-mm diameter on the right) (Fig. 4). The anterior breach at L-5 was explained by the prominent iliac crest limiting the lateral to medial trajectory of that pedicle (Fig. 5).

FIG. 3. Computed tomography image obtained in a 61-year-old woman with adult idiopathic scoliosis with two Grade 1 medial pedicle wall breaches.

The second patient with two Grade 1 medial breaches was a 58-year-old woman with adult idiopathic scoliosis who underwent an L1–S1 fusion. The breaches were both at the L-1 and were explained again by small atrophic pedicles (0.9 mm and 2 mm). Neither patient had symptoms stemming from the malpositioned screws.

No vascular or neurological complications were ob-

FIG. 4. Preoperative CT image of the L-2 pedicle anatomy obtained in the same patient as in Fig. 3, demonstrating small atrophic pedicles (1-mm pedicle diameter on the left and 2.8-mm diameter on the right).

FIG. 5. Computed tomography image showing the anterior breach at L-5 in the same patient as in Figs. 3 and 4 without significant encroachment on the surrounding neurovascular structures.

served intraoperatively, and no significant postoperative complications were noted. The mean clinical follow-up period was 18 months (range 3–39 months). The overall clinical outcomes, measured by the VAS (back pain scores), were improved significantly postoperatively at 3 months compared with preoperatively (6.35 vs 3.57; $p < 0.0001$). No revision surgery was performed for screw misplacement or neurological deterioration.

Discussion

The use of intraoperative CT-IGN for pedicle screw instrumentation has increasingly gained in popularity. The literature contains several reports on this newest generation imaging technology (O-arm) in MIS. Baaj et al.² recently published a feasibility and technique study on O-arm technology and its use in MIS. Analyzing 14 patients and 110 screws placed using a percutaneous technique with CT-IGN, they reported an accuracy rate of 94.5% with a total of 6 screw breaches (4 lateral and 2 medial) without clinical neurological deficits or revision surgery. Oertel et al.²⁹ presented 10 patients who underwent instrumentation through a percutaneous MIS with intraoperative CT-IGN; of the 40 total pedicle screws inserted, 5 screws (12.5%) breached, but none of the patients had clinical symptoms of nerve root injury. Although both early studies were limited by a short follow-up period, they each concluded that intraoperative CT image-guided MIS was practical and consistently reliable at providing insertion accuracy.

In a more recent study, Houten et al.¹⁵ presented a larger clinical series of MIS percutaneous screw placements using O-arm image-guided navigation. All patients in that study underwent MIS lumbar interbody fusion (MIS transforaminal lumbar interbody fusion, direct lateral interbody fusion, and extreme lateral interbody fusion) for degenerative spondylolisthesis. The O-arm

O-Arm MIS

group had 52 patients with 205 screws, and the fluoroscopy-based group had 42 patients with 141 screws. The perforation rate was 3% versus 12.8% ($p < 0.001$). This high accuracy rate is statistically significant when compared with the accuracy rates published for fluoroscopy-based techniques.^{15,29,36,42}

Of the 290 pedicle screws analyzed in our study, 280 were placed without a breach. This accuracy rate of 96.6% is in line with the findings of previously published reports and adds to the body of literature supporting O-arm intraoperative CT-IGN MIS techniques.^{2,3,5,8,18,35} Our study did find a correlation between the accuracy of pedicle screw delivery translating into improved clinical outcomes. No vascular or neurological complications were observed intraoperatively, and no significant postoperative complications were noted. There were no revision surgeries performed for screw misplacement or neurological deterioration. Although our only clinical metric was VAS (back pain scores), we did find significant postoperative improvement at 3 months compared with the preoperative group.

One of the greatest risks of O-arm CT-IGN MIS lies in the inability to track the “real-time” location of the K-wires or guidewires that are used as position markers in the bony spine. With classic fluoroscopic techniques, changing between cannulated instruments requires guidewires to facilitate in delivery of the instruments down the same trajectory. Tracking the distal position of the guidewire is confirmed using sequential fluoroscopic images to prevent advancement into the abdomen, especially during bony tap and screw insertion. In our early experience, we found that intraoperative CT navigation could not account for the exact location of the distal guidewire in the vertebral body. On intraoperative CT images, however, we are able to visualize deep soft-tissue and 3D bony spine anatomy. By combining our ability to mark and save our starting point with the imaging software on the StealthStation monitor and using customized CT-image navigation tools (Figs. 1 and 2), we have been able to find our trajectory and starting point consistently without undue loss of accuracy or an increase in overall operating room time.

From an occupational perspective, the advantage of CT-IGN over prevailing fluoroscopic imaging methods lies in radiation exposure. Numerous reports have documented the harmful effects of radiation exposure to the surgeon and the operative team,^{16,23,27,31,37,39} including cases of cancer and sarcoma from cumulative fluoroscopic radiation exposure,^{1,28,32,44} and grave concerns exist regarding the stochastic effects of ionizing radiation.^{15,27,31} Even with the protection of lead aprons, thyroid shields, and lead glasses, many parts of the surgeon’s body remain unprotected during fluoroscopy and can accumulate a significant amount of scatter ionizing radiation exposure. The distinguishing feature in CT image-based navigation systems for MIS is the complete lack of radiation exposure during the acquisition of the CT images. The surgeon and operative team are positioned outside the room during intraoperative CT scan acquisition, so there is theoretically no risk or exposure to ionizing radiation. The complete removal of this occupational risk with new

CT image-based navigation systems appears to have very important and beneficial health implications for MIS.

Radiation exposure to the patient also needs to be considered. Certainly, a decision between fluoroscopy versus CT imaging for MIS must be made in the light of a priori “first, do not harm” concern for the patient. Although strict annual limits of occupational radiation exposure are well defined by federal and state regulatory committees—the Environmental Protection Agency and Nuclear Regulation Commission—patient radiation exposure in the context of medical treatment and diagnostics is not clearly defined. The Nuclear Regulation Commission, in its code of federal guidelines, recommends ALARA, an acronym for “as low as (is) reasonably achievable,” which means making every reasonable effort to maintain exposures to ionizing radiation as far below the dose limits as practical, consistent with the purpose for which the licensed activity is undertaken. The O-arm manufacturer’s dosimetry report estimates that for 1 intraoperative CT scan, approximately 9 mGy is delivered, which is the equivalent of 35 seconds of fluoroscopy time.²⁵ Several reports have documented approximately 7–20 seconds of fluoroscopy time for the delivery of 1 screw;^{16,22,41} these estimated times are often lower than what is required for MIS procedures. For a 1-level fusion with 4 pedicle screws, the clear superiority of one imaging modality over the other is not as evident. Recent developments in low-level radiation dose protocols for pediatric patients, and adjustments in collimation and body habitus can further reduce the amount of radiation exposure to the patient. Additionally, with the added increase in accuracy with CT-IGN, the need for postoperative radiation exposure in the form of CT scans for confirmation of fluoroscopy directed screws is greatly mitigated.

Conclusions

The newest generation CT-IGN with O-arm technology has been shown to increase the accuracy of placing pedicle screws and instrumentation when using MIS techniques. Using this technology, our accuracy rate was 96.6%, and 90% of the breaches were Grade 1–2 with only one Grade 3 breach in this study. This high accuracy rate is statistically significant when compared with accuracy rates historically published for fluoroscopy-based techniques. Additionally, clinical VAS outcome scores show a statistically significant improvement at 3 months from the preoperative state. From an occupational and patient perspective, the advantage of CT-IGN over fluoroscopic imaging methods is a reduction in the amount of radiation exposure without compromising the quality outcome. For now, we simply conclude that use of intraoperative CT-IGN for minimally invasive spine surgery is safe and accurate.

Disclosure

Dr. Kim is a consultant for DePuy Synthes.

Author contributions to the study and manuscript preparation include the following. Conception and design: Kim, Drazin. Acquisition of data: Drazin. Analysis and interpretation of data: Drazin,

Shweikeh. Drafting the article: Kim, Drazin, Shweikeh. Critically revising the article: Kim, Drazin. Reviewed submitted version of manuscript: Kim, Drazin, Pashman, Johnson. Approved the final version of the manuscript on behalf of all authors: Kim. Study supervision: Johnson.

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