Pedicle Screw Placement With O-arm and Stealth Navigation

SUresh patil, MD; Emily m. Lindley, PhD; Evalina l. Burger, MD; Hiroyuki Yoshihara, MD; Vikas V. Patel, MA, MD

abstract

Various navigation systems are available to aid pedicle screw placement. the O-arm replaces the need for fluoroscopy and generates a 3-dimensional volumetric dataset that can be viewed as transverse, coronal, and sagittal images of the spine, similar to computed tomography (CT) scanning. the dataset can be downloaded to the Stealth system (medtronic Navigation, Louisville, Colorado) for real-time intraoperative navigation.

The main objectives of the current study were to assess (1) accuracy of pedicle screw placement using the O-arm/stealth system, and (2) time for draping, positioning of the O-arm, and screw placement. of 188 screws (25 patients), 116 had adequate images for analysis. the average time for O-arm draping was 3.5 minutes. Initial O-arm positioning was 6.1 minutes, and final positioning was 4.9 minutes. Mean time for screw placement, including O-arm draping and positioning and array attachment, was 8.1 minutes per screw. Mean time for screw placement alone was 5.9 minutes per screw. Screw placements on final O-arm images were on average 3.14 mm deeper than on the snapshot navigation images. Three screws (2.6%) breached the medial cortex, and 3 screws (2.6%) were misaligned and did not follow the pilot hole trajectory.

the use of the O-arm/stealth system was associated with a low rate of pedicle screw misalignment. the time to place screws was less than previously reported with CT navigation, but longer than conventional techniques. It is important to be aware of the potential discrepancy between snapshot navigation images and actual screw placement on final O-arm images. our findings suggest that final screw positions may be deeper than awl positions appear on navigation images.

---

Dr. Patil, Lindley, Burger, Yoshihara, and Patel are from the Spine Center, Department of Orthopaedics, University of Colorado, Denver, Colorado.

Dr. Patil, Lindley, Burger, Yoshihara, and Patel have no relevant financial relationships to disclose.

Correspondence should be addressed to: Vikas V. Patel, MA, MD, The Spine Center, Department of Orthopaedics, University of Colorado, Mail Stop B202, 12631 E 17th Ave, Aurora, CO 80045 (vikas.patel@ucdenver.edu).

doi: 10.3928/01477447-20111122-15
Pedicle screw placement is a commonly used technique for posterior stabilization in the thoracolumbar spine. Misplacement of screws can lead to vascular injury, neurological injury, dural tear, and pedicle fractures that can compromise stable fixation. The incidence of neurological complications associated with pedicle screw placement has been reported to be 1% to 3%.\(^1\)\(^,\)\(^2\) Techniques for pedicle screw placement include the use of anatomic landmarks, laminotomy with palpation of the pedicle, plain radiography, standard fluoroscopic imaging, fluoroscopic image guidance, and computed tomography (CT) image guidance. Intraoperative fluoroscopy and portable radiographs are routinely used during pedicle screw placement to help guide correct surgical placement of pedicle screw instrumentation. Although these imaging procedures are commonly used to aid pedicle screw placement, their accuracy has been debated. Using conventional techniques, Vaccaro et al\(^3\) placed 90 screws in the T4-T12 pedicles and reported 41% misalignment of screws. Weinstein et al\(^4\) placed 128 screws in the T11-S1 pedicles of 8 cadaver specimens and reported 21% screw misalignment.

Various navigation systems have been introduced to improve the accuracy of screw placement and to prevent vascular and neurological injury. A CT-based navigation system allows for 3-dimensional visualization of the pedicle to facilitate placement of screws. The primary disadvantage of this system is the need for preoperative CT scans and intraoperative registration. Several studies have reported misplacement rates of 4.5% to 8% using CT navigation.\(^5\)\(^,\)\(^6\) Other studies of computerized isocentric 3-D fluoroscopy reported improvements in the accuracy of screw positioning and the ability to detect misplaced screws prior to wound closure. Misplacement rates with isocentric 3-D fluoroscopy were reported to be 1.7% to 5%.\(^7\)\(^,\)\(^8\) and Villavicencio et al\(^9\) reported a significant reduction in radiation exposure for the patient and surgical staff.

The O-arm generates a 3-D dataset of the spine, similar to CT scanning, that can be downloaded to the Stealth system (Medtronic Navigation, Louisville, Colorado). The image data can be viewed on the O-arm screen in standard transverse, coronal, and sagittal planes or in any oblique plane desired. When combined with the Stealth system, the image data can be viewed relative to the image-guided probes to help to accurately navigate the awl into the pedicle (Figures 1, 2). If a navigated screwdriver is available, pedicle screws can be navigated during placement. After screw placement, the O-arm can generate a final 3-D data volume to confirm the position of the screws. In <30 seconds, it can take up to 400 images, which are reconstructed on a flat panel monitor for the surgeon to review before the patient leaves the operating room. These images can be saved and recalled at any time. The O-arm and Stealth navigation technology replaces the need for fluoroscopy and thus reduces radiation exposure.

Although various studies have reported on the use of CT-based and isocentric 3-D fluoroscopy-based navigation, a paucity of data exists on the use of the O-arm and Stealth system. Thus, the purpose of the current study was (1) to evaluate the accuracy of pedicle screw placement in the thoracolumbar spine using the O-arm and Stealth system; (2) to assess the time required for draping, positioning the O-arm, and screw placement; and (3) to compare the results of intraoperative neuromonitoring with the actual number of screws that breached the medial cortex on CT images.

**MATERIALS AND METHODS**

After Institutional Review Board approval, we analyzed data from 25 patients who underwent pedicle screw placement using the O-arm and Stealth system between February 2010 and August 2010. The exclusion criteria were poor quality of snapshot navigation or final O-arm images and missing images.

After standard preparation and surgical exposure, a reference array was attached to a spinous process for registration, and the O-arm was brought in for initial imaging. Images were transferred to the Stealth system for navigation, and a navigated awl and navigated probe were used to find the pedicles. Pedicle entry points were found with the help of the navigated pedicle probe, and pilot holes were made with a high-speed burr to enter the cortex. The navigated pedicle probe was then used to create a path down the pedicle into the vertebral body to the ideal screw position. The screw length was then chosen based on the depth marks etched on the probe. A snapshot picture was saved at that time for analysis. The pedicle tract was then palpated using a ball-tipped feeler probe, and screws were placed. Although navigated screwdrivers are available for the Medtronic pedicle screw system, we used...
other screw systems and, thus, all of our screws were placed freehand in the pathway created by the O-arm navigated awl.

After all screws were placed, a final intraoperative O-arm image of the region was obtained to confirm proper placement of the screws. Somatosensory-evoked potential and stimulus-evoked electromyography (EMG) were monitored intraoperatively in all patients. Screws were stimulated before obtaining the final O-arm image, and neuromonitoring results were recorded. Rods and set screws were then placed on each side to complete the screw–rod construct.

The following time points were recorded: (1) length of time for the operating room technician to drape the O-arm, (2) length of time for initial positioning and spinning of the O-arm, (3) length of time to place all screws, (4) length of time for final positioning and spinning of the O-arm to confirm screw placement, and (5) overall length of time from attachment of the array to last screw placement.

All images were reviewed by 1 independent observer (S.P.) to compare O-arm navigation snapshot images with final intraoperative O-arm images. Image J software (National Institutes of Health, Bethesda, Maryland) was used to measure final O-arm images. The distance from the tip of the awl to the anterior and lateral cortex of the vertebrae were measured on the navigation images and compared with those measured on the final intraoperative O-arm images (Figure 3). Misalignment angle, which was defined as the angle between the pilot hole and the screw, was also calculated (Figure 4).

RESULTS

In this study, 188 pedicle screws were placed in 25 patients (11 men, 14 women; age range, 26-75 years) (Table) using the O-arm and Stealth system. Of the 188 screws, adequate images were available for analysis in 116 screws; the remaining screws were excluded from measurement due to poor image quality or missing images. Of the 116 screws analyzed in the study, 37 were placed in the thoracic spine and 79 in the lumbosacral spine.

Average time required to drape the O-arm was 3.5 minutes (range, 2-8 minutes), average time for initial positioning of the O-arm was 6.1 minutes (range, 2-10 minutes), and average time for final positioning of the O-arm was 4.9 minutes (range, 2-8 minutes). Average time required for screw placement was 5.9 minutes per screw. Average time for screw placement when including the time for array attachment and obtaining O-arm images was 8.1 minutes per screw.

On snapshot navigation images, the average distance from the tip of the awl to the anterior cortex was 8.06 mm, and...
the distance from the tip of the awl to the lateral cortex was 7.66 mm. On final intraoperative O-arm scans, the average distance from the tip of the screw to the anterior cortex was 4.88 mm and from the tip of the screw to the lateral cortex was 4.56 mm. This resulted in errors of 3.18 mm and 3.10 mm (average, 3.14 mm) using the navigation images.

Intraoperative postinstrumentation O-arm images revealed that 3 screws (2.6%) breached the medial cortex, all by <2 mm. These screws were all located in the lumbar spine and were revised and confirmed with an additional O-arm image and neuromonitoring. No intra- or postoperative neurological injuries, vascular injuries, or dural leaks occurred. Intraoperative stimulation of all screws was normal, despite the 3 screws that breached the medial cortex. Thus, the false negative rate of neuromonitoring was 1.59% (3/188 screws).

Three screws (2.6%) were misaligned and did not follow the pilot hole trajectory. Their average misalignment angle was 13.76°, and all 3 screws were lateral to the pilot holes. These misalignments did not result in pedicle fracture or any neurological or vascular injuries.

Discussion

The proper placement of pedicle screws is important to avoid neurological and vascular injury and pedicle fractures. Previous literature has shown the rate of misplacement to range from 20% to 41% using conventional techniques.\(^3\)\(^,\)\(^4\) Computer-assisted image guidance has been shown to achieve overall higher rates of accuracy. Park et al\(^10\) reported a misplacement rate of 7.5% (3/40) using the O-arm in conjunction with the Stealth system. All breaches were graded as 0 to 2 mm and asymptomatic. Fraser et al\(^11\) reported no pedicle perforations in 90.9% of screws when using Iso-C/stereotactic 3-D navigation (Siemens Medical Solutions, Erlangen, Germany) and no perforations in 73.3% of screws when using conventional fluoroscopy. Tormenti et al\(^12\) also reported a significantly lower rate of pedicle screw misplacement when using an intraoperative CT operative suite (not the O-arm) vs conventional techniques (1.2% vs 5.2%, respectively). In the current study, 3 screws (2.6%) were misplaced and breached the medial cortex, all by <2 mm. These screws were revised and resulted in no complications. Three screws were also misaligned (2.6%) by an average of 13.76°. In all 3 instances, the screws were lateral to the pilot holes. These misalignments did not result in pedicle fracture or other complications.

In the current study, the time required to drape the O-arm ranged from 2 to 8 minutes, depending on the experience of the scrub technician. In 1 case, draping took 8 minutes because the scrub technician had not previously worked with the O-arm and had to drape it twice. The time required to position the O-arm ranged from 2 to 10 minutes and was also dependent on the experience of the radiology technician. In this study, the system needed rebooting in 2 cases due to an error in transmitting images to the Stealth, and in 1 case there was difficulty positioning the O-arm for the upper thoracic spine because of the arm board. The average time for draping and initial positioning of the O-arm in the current study was 9.6 minutes. Nakashima et al\(^13\) reported the average time required for scanning and image analysis when using Iso-C navigation was 10 minutes; they also reported that the average time to set up the Iso-C and assemble tools was approximately 15 to 20 minutes. We found the overall time required for screw placement to be 8.1 minutes per screw, including the time for attaching the array, initial positioning of the O-arm, and acquiring images for navigation. This was less than the previously reported times for registration and screw placement using CT navigation (11 minutes per screw; 44.6 minutes for 4 screws).\(^14\) In our study, the mean time for screw placement was 5.9 minutes, which was slightly longer than previously reported times for screw placement using conventional techniques (5.1 minutes), but shorter than the reported times with CT navigation (7.5 minutes per screw).\(^3\)

Because we are located at a teaching institution, our times may be longer because residents and fellows are taught to place approximately half of the screws.

We found a mean difference of 3.14 mm between the length of the awl and the length of the screw as measured on snapshot navigation and final O-arm images. Several potential explanations exist for this disparity, including registration error, which has been reported to be approximately 2 mm with CT navigation.\(^15\)\(^,\)\(^16\) The error could also be related to the fact that the tip of the awl is curved but the screws are straight (Figure 5). Another possibility is that soft tissue present above the bone during awl navigation placement led to an underestimation of the true screw depth, ie, the screws may have been placed beyond the soft tissue and in direct contact with the bone and thus ended up deeper than the awl. The discrepancy in measurements could also be due to observer error during calculations. However, a single investigator (S.P.) performed all measurements in a systematic manner in this study.

Electromyographic stimulation of pedicle screws has been shown to improve accuracy during open screw placement in both the thoracic and lumbar spines.\(^17\)\(^-\)\(^19\) Wood and Mannion\(^20\) reported that the
trajectory of the pedicle access needle was altered intraoperatively on 20 occasions (9.4% of the pedicle screws) based on positive EMG responses. In the current study, a false negative rate of 1.59% was found with neurmonitoring. Alemo and Sayadipour reported a 3.48% false negative rate with EMGs and misplaced screws that were later detected postoperatively by new neurologic deficits and abnormal CT. Schwartz et al reviewed 1121 consecutive patients with adolescent idiopathic scoliosis who had intraoperative neuro-monitoring and reported no false positives or false negatives in their series. In our series, we may have found more false negatives if we had experienced more breaches (3 of 116 screws breached the medial cortex). However, the relevance of this is uncertain since no direct negative sequelae of the breaches existed.

This study had several limitations. First, we did not compare the accuracy of screws placed with the O-arm and Stealth system to those of screws placed without intraoperative navigation. However, at our institution, the spine surgeons (E.L.B., V.V.P.) regularly use intraoperative navigation of screws as a standard of care, and thus did not feel comfortable including a control group of patients without navigation. Second, although navigated screwdrivers are available for the O-arm system, we used other screw systems and, thus, all of our screws were placed freehand. It is possible that the use of navigated screwdrivers along with the O-arm and Stealth system would result in better placement accuracy. To overcome this limitation, we are currently initiating a new study to evaluate the accuracy of screw placement using the combination of navigated instruments and the O-arm.

**CONCLUSION**

The use of the O-arm and Stealth system led to a low rate of pedicle screw misalignment in this study. The time to place the screws was longer than that of conventional methods but shorter than with CT navigation. It is important to be aware that final screw positions were generally deeper than awl positions on the navigation image. Great care should also be taken to follow the pathway created by the awl when placing screws without a navigated screwdriver.

**REFERENCES**