Comparison of Radiation Exposure in Lumbar Pedicle Screw Placement With Fluoroscopy Vs Computer-Assisted Image Guidance With Intraoperative Three-Dimensional Imaging

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Received January 22, 2008; accepted June 17, 2008

Abstract

Background/Objective: Little is known about the long-term effects of chronic exposure to ionizing radiation. Studies have shown that spine surgeons may be exposed to significantly more radiation than that observed in surgery on the appendicular skeleton. Computer-assisted image guidance systems have been shown in preliminary studies to enable accurate instrumentation of the spine. Computer-assisted image guidance systems may have significant application to the surgical management of spinal trauma and deformity. The objective of this study was to compare C-arm fluoroscopy and computer-assisted image guidance in terms of radiation exposure to the operative surgeon when placing pedicle screw-rod constructs in cadaver specimens.

Methods: Twelve single-level (2 contiguous vertebral bodies) lumbar pedicle screw-rod constructs (48 screws) in 4 fresh cadavers were placed using standard C-arm fluoroscopy and computer-assisted image guidance (Stealth Station with Iso-C^{3D}). Pedicle screw-rod constructs were placed at L1–L2, L3–L4, and L5–S1 in 4 fresh cadaver specimens. Imaging was alternated between C-arm fluoroscopy and computer-assisted image guidance with StealthStation Iso-C^{3D}. Radiation exposure was measured using ring and badge dosimeters to monitor the thyroid, torso, and index finger. Postprocedure CT scans were obtained to judge accuracy of screw placement.

Results: Mean radiation exposure to the torso was 4.33 ± 2.66 mRem for procedures performed with standard fluoroscopy and 0.33 ± 0.82 mRem for procedures performed with computer-assisted image guidance. This difference was statistically significant ($P = 0.012$). Radiation exposure to the index finger and thyroid was negligible for all procedures. The accuracy of screw placement was similar for both techniques.

Conclusions: Computer-assisted image guidance systems allow for the safe and accurate placement of pedicle screw-rod constructs with a significant reduction in exposure to ionizing radiation to the torso of the operating surgeon.

J Spinal Cord Med. 2008;31:532–537

Key Words: C-arm fluoroscopy; Radiation exposure; Minimally invasive surgery, computer-assisted, Image-guided; Pedicle screw; Intraoperative imaging; Surgical navigation systems

INTRODUCTION

Fractures of the spine that necessitate reduction or decompression or are biomechanically unstable may in the course of management necessitate posterior instrumentation for both reduction and fusion. Particularly in the patient with traumatic injury, pedicle screw place-

ment is technically demanding and requires meticulous attention to both surgical technique and patient anatomy because a misplaced screw may cause vascular or neurologic compromise. Intraoperative imaging with fluoroscopy is used by many surgeons to confirm both the anatomic starting point for screw entry and to assess screw trajectory, depth, and position.

During imaging, the surgeon is often in close proximity to the fluoroscope; however, little is known about the long-term health effects of chronic exposure to low doses of ionizing radiation. Prior studies investigating radiation exposure to orthopedic surgeons in the trauma setting have shown that, for surgery on the appendicular skeleton, exposure levels are well within established

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safety limits (1,2). Recent work by Rampersaud et al (3) showed that, for spine surgeons, radiation exposures may be significantly more than that in other orthopedic procedures and may approach or exceed guidelines for cumulative exposure. Ul Haque et al (4) showed that the fluoroscopically assisted placement of pedicle screws in adolescent idiopathic scoliosis may expose the spine surgeon to radiation levels that exceed established lifetime dose equivalent limits. In the traumatically injured spine, this is of particular concern, because intraoperative imaging requirements may be significantly greater because of alterations in anatomic landmarks and decreased visibility caused by fracture displacement and overlap.

Computer-assisted surgical navigation systems (5) have been introduced as a potential means to both increase surgical accuracy and decrease reliance on intraoperative imaging. Improved accuracy has been shown in pedicle screw and C2–C1 transarticular screw placement with computer-assisted image guidance systems (6,7). In preliminary studies in the cadaver laboratory setting, computer-assisted image guidance systems have shown potential for equivalent or improved accuracy relative to standard C-arm fluoroscopy for the placement of sacroiliac screws (8), thoracic vertebral body screws (5), and lumbar intervertebral disk prosthesis (9). Decreased fluoroscopy time with fluoroscopy-based image navigation systems has been shown for the placement of odontoid screws in a cadaveric study (10).

Because of the concerns of radiation exposure from intraoperative imaging in spine procedures and the emerging evidence that surgical navigation systems offer a safe and effective means to accurately instrument the spine, the aim of this study is to measure radiation exposure to the surgeon in placing lumbar pedicle screws in both the standard fashion and with computer-assisted image guidance.

METHODS

Four fresh-frozen cadavers with ages ranging from 63 to 81 years (mean, 71.5 years) were obtained. Each cadaver was placed prone on a radiolucent operating table. The spine of each cadaver was exposed in standard posterior fashion from T12 to the sacrum. To simulate a posterior 1-level instrumented fusion, screws were placed bilaterally at L1–L2, L3–L4, and L5–S1 in each cadaver (total of 12 screws per cadaver). Each spinal segment was treated as a separate procedure. Two cadavers were instrumented with the use of standard fluoroscopy, and two cadavers were instrumented with computer-assisted image guidance using StealthStation (Medtronic Navigation, Louisville, CO) with Iso-C^{3D} (Siemens Medical Systems, Inc. Malvern, PA). One surgeon placed all pedicle screws with C-arm fluoroscopy and a different surgeon placed all pedicle screws with image guidance.

Pedicle Screw Instrumentation With C-arm Fluoroscopy

An OEC model 9600 C-arm fluoroscope was used (GE Medical Systems, New York, NY). An anteroposterior image was used to identify the starting point for each pedicle screw. After decortication of the starting point with a high-speed burr, the screw path was prepared in standard fashion with either a cervical curette or a blunt pedicle probe. A lateral fluoroscopic view was taken during path preparation to confirm path trajectory and depth. The path was probed in standard fashion with a ball-tipped probe to confirm that there was no breach, and after path preparation with the tap, screws were placed. In addition to the standard fluoroscopic views, additional images were obtained if requested by the surgeon during the procedure. After the placement of all 4 screws, their final position was confirmed with AP and lateral fluoroscopic views (Figure 1).

StealthStation With Iso-C^{3D}

The StealthStation with Iso-C^{3D} performs intraoperative three dimensional (3D) dataset acquisition and automatic registration of that dataset. To relate instrumentation to the patient's anatomy, the system uses a patient reference frame; in this application, the reference frame was secured to a percutaneous pin and tapped into the posterior superior iliac spine (PSIS; Figure 2). The cadaver was scanned using the 190-degree rotational scanner (Siremobil Iso-C^{3D}; Siemens Medical Solutions, Erlangen, Germany) for registration. During the registration scan, the surgeon stood outside of the room. Pedicle screws were placed in standard fashion solely with computer-assisted navigation; no intraprocedure fluoroscopy was used.

Radiation Dosimetry

Before each procedure (instrumentation of a single interspace or segment), dosimeters with a minimum 1-mRem reporting capability (Luxel Radiation Monitor Badges; Landauer, Glenwood, IL) were placed on the operative surgeon. The dosimeters were attached to the outside of the thyroid shield and the outside of the torso at the level of the beltline. After each procedure, the badges were removed and changed. Removed badges were quarantined outside of the room to ensure that they were not contaminated. A single index ring dosimeter with a minimum 30-mRem reporting capability (Landauer) was worn for each cadaver, measuring the total exposure to the surgeon's hand for all 3 levels instrumented.

Screw Placement Confirmation

Postprocedure conebeam CT images of all instrumented levels in both cadavers were obtained using the O-arm System (Breakaway Imaging, Littleton, MA) (Figure 3). Conebeam computed tomography uses a cone-shaped x-ray beam to generate volumetric datasets. Pedicle screws were graded according to prior established classification

Figure 1. Anteroposterior (AP) and lateral fluoroscopic views confirming final screw position.

methods used to evaluate optimal pedicle screw placement (11,12): Grade 0, no perforation; Grade 1, perforation of <2 mm; Grade 2, perforation between 2 and 4 mm; Grade 3, perforation >4 mm (Figure 4). The pedicle screw grading was done by 1 observer, and images were blinded with regard to instrumentation technique.

RESULTS

Screw Placement

Seven screws (6 placed with standard fluoroscopy and 1 placed with image guidance) had a cortical breach of <2 mm. Two screws (1 placed with standard fluoroscopy

and 1 placed with image-guidance) had cortical breaches of 2 to 4 mm. One screw (placed with standard fluoroscopy) did not have a cortical perforation but was located in the sacral ala (Table 1).

Radiation Exposure

Torso. Mean exposure to the torso per procedure was 4.33 ± 2.7 mRem with C-arm fluoroscopy and $0.33 \pm$

Figure 2. Intraoperative photograph showing the patient reference frame secured to a percutaneous pin in the posterior superior iliac spine.

Figure 3. Postprocedure conebeam CT image acquired with the O-arm system (Breakaway Imaging, Littleton, MA).

Figure 4. Example of a Grade 2 (Left) and Grade 1 (Right) screw placement score.

0.8 mRem with StealthStation. This difference was statistically significant ($P = 0.012$).

Thyroid. Mean exposure to the thyroid per procedure was 0.33 ± 0.52 mRem with C-arm fluoroscopy and 0.66 ± 1.6 mRem with StealthStation. This difference was not statistically significant ($P = 0.65$).

Finger. Exposure to the ring dosimeters was below the measurable threshold for both procedures done with C-arm fluoroscopy and StealthStation (Table 2).

DISCUSSION

In this cadaveric study of a 1-level instrumentation spinal segment with 4 pedicle screws, average exposure to the

torso was approximately 4 mRem per procedure (1-level fusion) and to the thyroid was approximately 1 mRem per fluoroscopy procedure. For a spine surgeon performing 250 such cases a year, annual cumulative exposure would approach 1 Rem. Surgeons performing high volumes of cases that involve multiple levels could approach the annual cumulative exposure limit of 5 Rem (Occupational Safety & Health Administration, Regulations Standards–29 CFR; Ionizing radiation–1910.1096) to the thyroid or torso. This study investigated screw placement in the lumbar spine; it is conceivable that instrumentation of the thoracic spine with its more variable pedicle anatomy may result in higher radiation exposure. Because little is known about the long-term effects of chronic exposure to low doses of ionizing radiation, the surgeon should consider all available options to limit radiation exposure.

The position of the surgeon and assistant relative to the fluoroscope has a significant impact on radiation exposure. As shown by Rampersaud et al (3), standing on the same side as the radiation source exposes one to greater doses of radiation. Radiation exposure decreases exponentially with distance from the source, so whenever possible, both surgeon and assistant should strive to maximize their distance from both the radiation source and the patient because of Compton scatter. Compton scatter is the noncoherent reflection of the radiation beam and is largest at the surface on the same side as the radiation source. In spine surgery, the surgeon often is in close proximity to both the patient and fluoroscope because of the need to hold an instrument during image acquisition, and Compton scatter is a significant exposure source. Every effort should be made to stand on the opposite side of the radiation source with lateral radiographs and to be cognizant of the scatter of radiation across the plane of tissue with AP radiographs. Rampersaud et al (3) recommended limiting fluoroscopy time, protecting the surgeon with a lead shield, and

Table 1. Screw Placement Scores

	Cadaver 1 Fluoroscopy	Cadaver 2 Image Guidance	Cadaver 3 Fluoroscopy	Cadaver 4 Image Guidance
L1 Right	Grade 0	Grade 0	Grade 0	Grade 0
L1 Left	Grade 1	Grade 0	Grade 0	Grade 0
L2 Right	Grade 0	Grade 0	Grade 0	Grade 0
L2 Left	Grade 0	Grade 2	Grade 0	Grade 0
L3 Right	Grade 1	Grade 0	Grade 0	Grade 0
L3 Left	Grade 1	Grade 0	Grade 0	Grade 0
L4 Right	Grade 0	Grade 0	Grade 1	Grade 0
L4 Left	Grade 1	Grade 0	Grade 0	Grade 0
L5 Right	Grade 0	Grade 0	Grade 1	Grade 0
L5 Left	Grade 0	Grade 1	Grade 2	Grade 0
S1 Right	Grade 0	Grade 0	Sacral Ala	Grade 0
S1 Left	Grade 0	Grade 0	Grade 0	Grade 0

Grade 0, no perforation; Grade 1, perforation <2 mm; Grade 2, perforation 2 to 4 mm; and Grade 3, perforation >4 mm.

Table 2. Radiation Exposure (mRem)* and Fluoroscopy Time (seconds)

	Thyroid	Fluoroscopy Time (s)	Belt	Ring
C-arm Fluoro				
Cadaver 1 L1-L2	1	25	3	
Cadaver 3 L1-L2	M	37	4	
Cadaver 1 L3-L4	M	18	1	
Cadaver 3 L3-L4	1	38	4	
Cadaver 1 L5-S1	M	40	9	
Cadaver 3 L5-S1	M	43	5	
Fluoro Nav				
Cadaver 2 L1-L2	M	N/A	M	
Cadaver 4 L1-L2	M	N/A	M	
Cadaver 2 L3-L4	M	N/A	2	
Cadaver 4 L3-L4	4	N/A	M	
Cadaver 2 L5-S1	M	N/A	M	
Cadaver 4 L5-S1	M	N/A	M	
C-arm Fluoro				
Cadaver 1				M
Cadaver 3				M
Fluoro Nav				
Cadaver 2				M
Cadaver 4				M

*Exposure below the measurable threshold for the dosimeter is noted as M.

attempting to have the surgeon maintain a distance of 3 to 4 feet from the radiation source. Using longer instruments if needed for marking images will reduce radiation exposure to the hand; an additional 5 to 10 cm of instrument length may reduce hand exposure by up to 45% (3).

A weakness of this study is the low number of pedicle screws placed ($n = 48$), which limits its power. Individual cadavers were not alternated between imaging systems, which raises the possibility that relative differences between cadavers in anatomy or bone density may have affected the amount of fluoroscopy needed. The design of this study links the comparison of methods with the comparison of cadavers and surgeons. It is possible that some of the variation in results may be related to differences related to the surgeon or anatomic variation between cadavers. The surgeon placing pedicle screws in standard fashion with C-arm fluoroscopy was allowed to ask for additional images if he felt it to be necessary; this was an attempt to simulate clinical conditions in which fluoroscopy images are frequently repeated when visualization or C-arm placement is suboptimal.

As per the study design, radiation dosimetry was measured. However, we did not record of fluoroscopy time or total number of fluoroscopy images requested per procedure. It was felt that, because the surgeon was placing the screws with the same method used in clinical practice, radiation dosimetry was an accurate representation of exposure. We acknowledge that, because a

record was not maintained of total number of fluoroscopy images requested, it may impede the ability to extrapolate or compare results to clinical practice of a surgeon who uses more or less fluoroscopy. On average, the clinical practice of the surgeon placing these screws was to request 2 AP images in obtaining the starting point and 2 to 3 lateral images during screw advancement, for a total of 4 to 5 fluoroscopy images per screw. We acknowledge the failure to record this data during the surgery as a weakness of this study.

The incidence of Grade 2 or larger cortical breaches was similar with both standard C-arm fluoroscopy and image-guided placement (1 screw in each group.) However, we did observe more Grade 1 (<2 mm) breaches in the 2 cadavers instrumented with C-arm fluoroscopy. This suggests that the accuracy of pedicle screw placement with image guidance was at least equivalent to pedicle screw placement with C-arm fluoroscopy with respect to cortical breach in this cadaveric study. Cortical breaches <2 mm are generally considered to be clinically insignificant (11,13). The higher rate of Grade 1 perforation with C-arm fluoroscopy found in this study may not be clinically significant; the design of this study does not allow for any further conclusion regarding the accuracy of each method. Other studies have found that image guidance for pedicle screw placement is as accurate as or more accurate than standard fluoroscopy (6,7).

CONCLUSION

This study, while preliminary in nature, suggests that computer-assisted navigation may enable safe spinal instrumentation without the use of intraoperative ionizing radiation.

With the increasing prevalence of less invasive spine procedures and pedicle screw instrumentation of the thoracic spine that necessitate a high reliance on intraoperative imaging, further study of computer-assisted image guidance systems is warranted.

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