## Computer-Assisted Spinal Navigation Using a Percutaneous Dynamic Reference Frame for Posterior Fusions of the Lumbar Spine

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#### **Abstract**

We report a 6-year retrospective review of screw placement utilizing a percutaneous dynamic reference frame attached to the posterior superior iliac spine performed by a single orthopedic surgeon. We included all lumbar spine procedures utilizing computer-assisted spinal navigation (StealthStation® Navigation System, Medtronic Navigation, Louisville, Colo) performed from 2000 to 2005, with 272 of 289 patients (94.1%) having at least a 4-month follow-up with radiographs. Six hundred seventy-two screws were placed. Following surgery, none of these patients had screw misplacements. One patient (0.4%) had a screw backing out of the pedicle. Eighteen patients (6.6%) had their posterior instrumentation removed. Three had repeat operations but did not have their instrumentation removed. No patient with repeat operations had a screw misplaced.

ccuracy for the spine surgeon is a necessity, but accurate instrumentation placement and effective stabilization can be difficult. In order to obtain a successful fusion in the lumbar spine, correct positioning of screws is essential to avoid injury to the surrounding nerve roots and the spinal cord. In addition, it is necessary to have correct placement in order to optimize the strength of the fixation device.

Computer-assisted spinal navigation has allowed surgeons to ensure precision in instrumentation insertion. Numerous studies have asserted its value in assisting the surgeon in instrumentation placement. Computer-assisted image guidance allows the surgeon to have a multi-planar view of the spine in real time with accurate reference to the spinal anatomy. This

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allows the surgeon to view structures that are not completely exposed during the procedure.

This technology has not been without criticism. There is concern about the length of operative time, learning curve, cost, and disruption in flow of the operative procedure. A recent study showed a reduction in operative time with spinal navigation. With progressive advances in technology and surgeon experience, these limitations and drawbacks are minimized, and the many benefits outweigh the criticisms.

# "Our study included 272 procedures with a total of 674 screws placed under computer-assisted image guidance."

The traditional technique of placing the dynamic reference frame onto a posterior spinous process (Figure 1) has many disadvantages, including:

- 1. The surgeon's hand obscuring the view from the camera to the reference frame during routine work on the spine.
- 2. The surgeon's hand and the instruments striking and moving the reference frame during routine work on the spine.



Figure 1. The traditional reference frame attached to the posterior spinous process. This is a relatively weak fixation technique in which the device is fastened to a flimsy aspect of the vertebrae. Image courtesy of Medtronic. Reproduced with permission.



Figure 2. The strong reference pin driven by a percutaneous technique into the sturdy iliac crest. Image courtesy of Medtronic. Reproduced with permission.

- 3. Weak attachment of the reference frame owing to both the mechanism of clamping and the thin spinous process.
- 4. Inability to attach the reference frame before the procedure begins—thus obviating the ability to plan incisions or to perform percutaneous screw placement.
- 5. The need to halt the operative procedure after exposing the spine and attaching the dynamic reference frame in order to acquire the intraoperative image data set.
- 6. Length of time to acquisition of the image data set by the radiographic technician, whose view of the patient is obscured by the operative drapes, necessitating multiple attempts to find true anterior-posterior and lateral trajectories.
- 7. Suboptimal quality of the image data set because it is obtained after exposure of the spine, which causes air density artifact.

Placing a percutaneous dynamic reference frame in the iliac crest before the spinal incision is made addresses all of the above issues (Figure 2).

This study focuses on our experience with the insertion of both pedicle screws and translaminar facet screws in the lumbar or lumbosacral spine with the use of the StealthStation® Navigation System (Medtronic Navigation, Louisville, Colo) (Figure 3) and a dynamic reference frame (DRF) attached via a percutaneous screw/pin to the posterior superior iliac spine (PSIS).

#### MATERIALS AND METHODS

#### **Patient Population**

From January 2000 to April 2005, 289 consecutive posterior fusions were performed from L3 to the sacrum. Intraoperative computer-assisted spinal navigation using a DRF attached to the PSIS was used in all of these cases, which we have retrospectively studied. All proce-



Figure 3. The StealthStation® Navigation System (Medtronic Navigation, Louisville, Colo). Image courtesy of Medtronic. Reproduced with permission.

dures were performed by one orthopedic spine surgeon at one of 2 institutions. Patients were diagnosed with degenerative disc disease, stenosis, low-grade spondylo-listhesis, or pseudarthrosis; patients with pseudarthrosis underwent fusion for unsatisfactory nonoperative treatment. Sixty-four procedures (22.1%) involved more than one level. If a patient underwent multiple surgeries, each procedure was counted. There were no exclusions due to sex or medical condition. Only those patients who had at least one set of postoperative radiographs at a minimum of 4 months after surgery were included in this study. Demographic data is detailed in Table I.

#### **Data Collection**

A retrospective review was done for all patients by examining their medical records, obtained through surgeon's office and hospital records. A comprehensive study was done, recording demographic information, diagnosis, level of surgery, and any complications. In addition, it was noted whether there were any complications due to the screw placement or any problems with screw stability. All patients included in the study had at least one set of postoperative radiographs. An assessment was also performed postoperatively on the percutaneous reference frame pin site to evaluate adequate healing. Two hundred seventy-two patients included in the final population had at least a 4-month follow-up with radiographs. The average time for follow-up was 15.5 months, with a range of 4 to 59 months.

#### **Table I. Demographic Information (N = 289)**

Mean age, y 48.1 (SD, 14; range, 14-88) Sex

 Male
 150 (51.9%)

 Female
 139 (48.1%)

 Multiple-level procedures
 64 (22.1%)

#### Table II. Demographic Information for Final Study Population (N = 272)

Mean age, y 48.3 (SD, 14; range, 14-88)

Sex

 Male
 141 (51.8%)

 Female
 131 (48.2%)

 Multiple-level procedures
 64 (23.5%)

#### Surgical Procedure

All procedures were fusions of the lumbar spine with either translaminar facet screws or pedicle screws and were visualized with intraoperative computer-assisted spinal navigation. Specifically, the StealthStation Navigation System was used for all procedures (Figure 3). A DRF was placed in the PSIS of the pelvis for initial image registration (Figure 4). A small incision was made just caudal and lateral to the PSIS, and blunt dissection was performed to reach the PSIS. At this point, the DRF was attached to the patient via either a Schanz screw or a quad-flanged percutaneous pin. The Schanz screw was used until February 2002, when we began to use a quad-flanged percutaneous pin (Figure 5). Subsequent intraoperative images of the spine were obtained before surgical exposure and relayed to the computer workstation for processing. The electrooptical camera tracks both the location of the DRF and the working instrument (Figure 6).

#### Statistical Methods

Summary statistics (number, mean, frequency, standard deviation, percentage, and range) were provided for age, sex, and the number of levels fused. Frequency tables were provided for each of the categorical variables (number of instrumentation removals, number of reoperations, number of complications, and any screw misplacements).

#### Table III. Demographic Information for Translaminar Facet Screw and Pedicle Screw Populations

#### Translaminar Facet Screw Population (N = 93)

Mean age, y 42.3 (SD, 11.2; range, 15-66) Sex

 Male
 46 (49.5%)

 Female
 47 (50.5%)

 Multiple-level procedures
 37 (36.3%)

#### Pedicle Screw Population (N = 179)

Multiple-level procedures

Mean age, y 50.8 (SD, 14.4; range, 14-88) Sex Male 95 (53.1%) Female 84 (46.9%)

27 (14.4%)

Figure 4. The percutaneous posterior superior iliac spine pin with the dynamic reference frame attached.

#### **RESULTS**

#### Study Population

Two hundred eighty-nine posterior lumbar fusion operations were performed with computer-assisted intraoperative navigation from January 2000 to April 2005. Two hundred seventy-two procedures with postoperative radiographs at follow-up were included in the final study population. Ninety-three procedures were performed with translaminar facet screws, and 179 were performed with pedicle screws. A total of 674 screws, 258 translaminar screws, and 416 pedicle screws were placed. The demographic information for these patients is presented in Tables II and III by instrumentation. One hundred forty-one patients (51.8%) were men and 131 patients (48.1%) were women; the mean age was 48.3 years.

#### Screw Placement

Out of the 272 procedures and 674 screws, no screws were misplaced following surgery, as indicated by the review of postoperative radiographs. One patient (0.4%) had a screw backing out of the pedicle at follow-up. Adequate screw placement was determined at follow-up through evaluation of postoperative radiographs and review of final reports by an independent radiologist. Eighty-four procedures were performed with the original Schanz screw (55 pedicle screw procedures and 29 translaminar facet screw procedures). In 2 patients, the Schanz screw was unstable in the iliac crest, which necessitated removal. Both patients were elderly women with osteoporosis. Since we began using the quad-flanged nail, there have been no complications with percutaneous-pin stability, even in the osteoporotic patient.

### Reoperations and Removals of Instrumentation

Twenty-one (7.7%) of all patients had a second operation at the fused level. Reoperations were due to pain or possible pseudarthrosis. Three of these were explorations of the fused site without the removal of instrumentation.



Figure 5. Footprint of the quad-flanged nail (top) compared with the Schanz screw (bottom). The quad-flanged nail is pictured at left.



Figure 6. Intraoperative planning of the incision based upon guidance from the image navigation system.

The remaining 18 (6.6%) patients had their instrumentation removed. None of these patients had misplaced screws as judged intraoperatively during the reoperation. All screws were in the pedicle or in the lamina with no interference of any nerve root or dural/nerve root sleeve structure. One patient had pseudarthrosis and underwent a subsequent anterior lumbar interbody fusion operation. All of the pin placement sites were examined postoperatively to ensure adequate healing. All incisions healed completely with no associated pain and were essentially imperceptible at follow-up.

#### Complications

Five patients had a complication related to their operation. These were separate complications than the reoperations for exploration of the fusion site. Three patients had incisional infections that were irrigated and débrided at a later date. One patient had a cerebrospinal fluid leak that was repaired at a later date, and one patient had urinary retention following surgery.

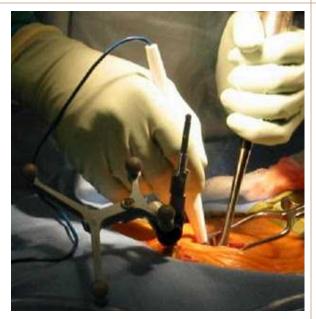


Figure 7. The reference frame is positioned out of the way of the surgeon, facilitating the operative procedure.

#### **DISCUSSION**

Several studies have evaluated the use of computerassisted spinal navigation in cadavers<sup>2,4,6,8,10,11</sup> and in clinical experience. 1,3,7,12,13,15 However, all of these studies were smaller populations of 22 to 100 patients. Our study included 272 procedures with a total of 674 screws placed under computer-assisted image guidance.

Under standard techniques without image guidance, studies have shown high pedicle-screw misplacement rates ranging from 5.5% to 41% in both cadaver and clinical studies. 16-20 With image guidance, this rate decreases to 5% to 19%.1-4,7,10,21 In our clinical experience following surgery, there were no screw misplacements at follow-up. With intraoperative image guidance, the surgeon is able to verify accurate screw alignment prior to placement and immediately following placement while still in the operating room. If misplacement is identified while in the operating room, accurate placement can still be accomplished, preventing subsequent operations.

Although other studies have shown misplacement rates higher than ours, 1-4,7,10,21 their misplacements were determined from computed tomography (CT) or magnetic resonance imaging following surgery. Our study, instead, has shown that, clinically, both translaminar facet screws and pedicle screws can be adequately placed with intraoperative image navigation using a percutaneous DRF in the iliac crest. A limitation with this study is the fact that CT scanning was not done routinely with this population. While some patients had CT scans done for other indications, these scans were not included because of an incomplete population.

There were no complications directly relating to screw placement. All reoperations determined the screws to be placed correctly with no complications related to nerve, vascular, or cortical compromise. Twenty-one (7.7%) patients had a second operation at their fused level. These

operations were due to back pain following surgery, which was thought to be hardware induced or secondary to pseud-arthrosis. After exploration, it was determined that none of the screws were misplaced in these patients. All patients in the study population had at least one postoperative radiograph, which also verified correct screw placement.

Our study is one of the few that also evaluated the use of translaminar facet screws with image navigation. One previous study showed near optimal placement of translaminar facet screws implanted by percutaneous technique with use of the SteathStation Navigation System and a percutaneous DRF driven into the PSIS.<sup>11</sup> In fact, as seen in our study's cohort, no screws were placed in the spinal canal or near an exiting nerve root, placing neither at risk.

Fluoroscopy has many drawbacks to its use, including radiation exposure.<sup>22</sup> In addition, conventional fluoroscopy allows the surgeon to view only one plane at a time. The C-arm must be repositioned before another view can be captured, and the machine can impede the surgical field.

An improvement on fluoroscopy, virtual fluoroscopy (SteathStation), has changed the way surgeons visualize the spine. There is a significant reduction in radiation exposure with virtual fluoroscopy versus conventional C-arm<sup>23</sup> with no demonstrated radiation exposure to the surgeon during image acquisition.<sup>24</sup> Images can be obtained in multiple planes without repeated adjustments. However, there have been criticisms, including bulkiness of the standard reference frame, 14,21 increased operating time, and a learning curve for the surgeon. With the DRF placed in the PSIS out of the surgeon's operative field, the procedure is profoundly simplified (Figure 7). Incisions are made with navigation guidance, allowing truly minimally invasive approaches, and operative flow is not hampered by stopping to take intraoperative radiographs. A recent study showed a decrease in operative time with spinal navigation versus serial radiography in posterior spinal fusions at levels L5-S1.15 Computer-assisted image-guided spine surgery overall demonstrated shorter mean operative times when compared with intraoperative serial radiography technique, an average of 40 minutes less per case (P<0.001). There is also less variation in operative times using image guidance. In an attempt to minimize such a confounding factor as a learning curve, the last 20 cases in each group were compared. There was an average difference of about 22 minutes less for the image guidance group, but this finding was not statistically significant (P=0.0503).

In conclusion, image-guided spinal surgery did not cause an increase in operative time. In the best scenario, image navigation saved a statistically significant (P<0.001) amount of time in the operating room. At its worst, fluoroscopy-based image-guided navigation is not significantly different from standard serial radiography in the length of operating time.<sup>15</sup>

#### **AUTHORS' DISCLOSURE STATEMENT**

Dr. Sasso wishes to note the following: he is a paid consultant to and receives royalties from Medtronic; he has received research grants from Stryker, AO (Arbeitsgemeinschaft für Osteosynthesefragen), Medtronic, CeraPedics, and Lilly; and he owns stock in Biomet.

Dr. Best and Dr. Garrido report no actual or potential conflict of interest in relation to this article.

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This paper will be judged for the Resident Writer's Award.