Original Article

Computer-assisted Spinal Navigation Versus Serial Radiography and Operative Time for Posterior Spinal Fusion at L5-S1

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15 **Objective:** To review the operative time differences between computer-assisted spinal navigation versus serial radiography.

17 Summary of Background Data: There have been multiple studies describing the use of computer-assisted image guided surgery (IGS) in the application of spinal instrumentation. Techniques AQ2 have evolved to allow attainment of multilevel visualization 21 intraoperatively both successfully and safely. These have proven to result in low screw misplacement rates, low incidence of 23 radiation exposure and excellent operative field viewing. As a result, image guidance has become an increasingly accepted and 25 practiced form of intraoperative spinal navigation. However, potential limitations to IGS have been described including 27 longer operating times. Many studies have looked at the success of beneficial outcomes; however, none to our knowledge have 29 reviewed such described operative time increments with IGS. Methods: The authors performed a retrospective database

31 Interactions: The authors performed a retrospective database analysis of 105 patients undergoing posterior L5-S1 spine fusion with pedicle screw instrumentation for isthmic spondylolisthesis with and without the use of fluoroscopy-based image guidance.
35 This was followed by a chart review of anesthesia operative time documentation. Subsequent time calculations and statistical analysis were performed for comparison.

Results: Computer-assisted image-guided spine surgery has overall demonstrated shorter mean operative times when 39 compared with intraoperative serial radiography technique; an average of 40 minutes less per case (P < 0.001). There is also less 41 variation in operative times using image guidance, with 13 of 43 (30%) cases using serial x-ray lasting more than 3.75 hours 43 compared with none of the 57 done via image guidance 45 (P < 0.001). The operative duration for both procedures trended downward over time. For both procedural cohorts operating room time continued to decrease as of the most recent year 47 being performed. Lastly, in an attempt to minimize such a 49 confounding factor as a learning curve, the last 20 cases in each group were compared. There was an average difference of about

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22 minutes less for the image guidance group but missed being statistically significant (P = 0.0503). 59

Conclusions: 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.6163

Key Words: image-guided surgery, FluoroNav, navigation, computer-assisted spine surgery

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71 **S** pine surgery with computer-assisted spinal navigation [image-guided surgery (IGS) with computer technol-73 ogy] versus serial radiography alone (repeated AP and lateral x-ray) is intended to improve surgical accuracy and 75 minimize any morbidity associated with screw misplace-77 ment. The precise 3-dimensional anatomic information provided by image-guided technology improves the safety 79 and accuracy of spinal implant placement. In addition to providing multiplanar visualization it allows for any surgical instrument to be tracked in real time with 81 reference to the anatomy. These beneficial effects have been well documented in the medical literature and 83 subsequently image guidance has become an increasingly 85 accepted and practiced addition to spinal surgery. However, concern regarding added operative time, learning curve, and cost have created some reservations. 87 The requirement for patient registration, preoperative 89 data acquisition, and the intimate system familiarity needed by the surgeon have also hindered the wide acceptance of such advancing technology.^{1,2} Although AO31 these projected limitations may be real, their variability is subject to speculation. Ongoing advances in this field and 93 further in-depth review may defy such limitations. We will examine and hypothesize that total operative time is 95 actually decreased with the use of StealthStation with 97 FluoroNav (Medtronic Navigation, Louisville, CO) and a dynamic reference frame (DRF) attached to a percutaneous screw versus conventional intraoperative imaging 99 methods. 101

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METHODS

A retrospective database analysis was performed to 3 formulate 2 cohorts of patients from 1 surgeon at 1 institution. The diagnosis in all patients was low-grade 5 isthmic spondylolisthesis at L5-S1. One hundred and five patients were identified. All patients underwent Gill 7 laminectomy at L5 with posterior L5-S1 instrumentation and fusion using iliac crest bone graft (ICBG) and pedicle 9 screws and rods. Group 1 (59 patients) used the StealthStation with FluoroNav (Fig. 1) and a percuta-11 neous reference frame placed into the posterior superior iliac spine (PSIS). Group 2 (46 patients) used standard 13 intraoperative radiographic serial imaging. Medical records were reviewed to verify operative procedure and 15 documented operative times. Any patients with revision or added procedures, reported intraoperative complica-17 tions, or different instrumentation used were excluded from our analysis to minimize confounding factors. 19 Operative times were obtained from the anesthesia records. These records demonstrated both room and 21 operative times with precision. Thus, only operative times were used which excluded room arrival, induction of 23 anesthesia, and patient positioning. Operative time for



59 FIGURE 1. StealthStation Treon plus Platform.

both groups began with the initial incision. For the FluoroNav cohort, start time was from the initial incision 61 to place the DRF. Operative time included initial image acquisition to reversal of anesthesia. The DRF is attached 63 to the PSIS of the pelvis before exposure of the spine. A small incision is placed just caudal and lateral to the PSIS 65 and blunt dissection is performed to reach the PSIS. At this point the DRF is attached to the patient via a self-67 tapping percutaneous screw (Fig. 2).

Fluoroscopic images of the patient are then 69 obtained before exposure of the spine and relayed to the computer workstation for processing. The electro-optical 71 camera tracks both the location of the DRF and working 73 instrument. For the serial imaging cohort, operative time was recorded as initial incision, to reversal of anesthesia. In this cohort serial x-rays were obtained as needed 75 throughout the case, both for level localization and final pedicle screw placement views. Usually, 2 spot radio-77 graphs were obtained for each procedure: the first to verify proper location (this was performed with a small 79 curette at the base of one of the pedicles to also assess the sagittal trajectory of the pedicles) and the second spot x-81 ray verified the final construct. The spot films were obtained with either a fluoroscope or a portable x-ray 83 machine depending upon which was quicker to obtain. With the inclusion of all surgical and image acquisition 85 steps for each cohort and the exclusion of cases with intraoperative complications, operative time differences 87 are reflective of alternative imaging techniques.

Database query resulted in 59 patients that underwent L5-S1 fusion via pedicle screw instrumentation with the use of ICBG and FluoroNav image navigation for isthmic spondylolisthesis. Surgery dates spanned from January 2000 to February 2004. After review of operative reports, 2 patients were excluded from the analysis, one for the performance of a concomitant posterior lumbar interbody fusion and the other had a revision surgery. This left 57 patients in the image navigation group.

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FIGURE 2. Dynamic reference frame on the percutaneous screw in the PSIS.

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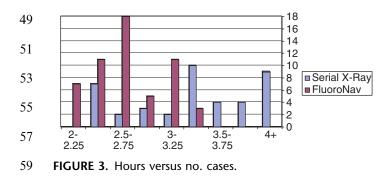
- 1 Database query resulted in 46 patients that also underwent L5-S1 fusion, pedicle screw instrumentation, and
- 3 ICBG for isthmic spondylolisthesis, but instead had serial radiography performed throughout the case. Surgery
- 5 dates ranged from February 1995 to December 2002. Nine of these patients had surgery after January 2000,
- 7 which marked the beginning of our image-guided use. After reviewing these operative reports for the entire
- 9 cohort, 2 patients were excluded for the use of experimental instrumentation and 1 for concomitant posterior
 11 lumbar interbody fusion procedure performed. This left
 43 patients in the serial x-ray group.
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RESULTS

17 There was a significant (P < 0.001) decrease in operative time for the FluoroNav image navigation 19 cohort, averaging 40 minutes less per case. There was also less variation in operative times using FluoroNav 21 versus serial radiography with 30% of serial x-ray cases lasting more than 3.75 hours and none of the image 23 navigation group lasting more than 3.75 hours (Fig. 3). The operative time duration for both procedures trended 25 downward over time with a greater decrease in time with the serial x-ray procedure (Fig. 4). It would be difficult to 27 identify whether this effect was due to a learning curve (ie, surgeon skill) or other factors and operating room (OR)-29 related inefficiencies (dedicated scrub nurse/tech, etc). When analyzing the initial learning curve of the image-31 guided technique (year 2000), the average operative time of 186 minutes or 3.1 hours is greater than serial imaging 33 at its best, 143 minutes or 2.4 hours (year 2002). However, serial imaging at its best was not faster than image 35 guidance at its best, year 2004 at 127 minutes or 2.1 hours. Throughout the use of both techniques it does not 37 seem that a plateau occurred with either type as the OR time was still trending downward at the most recent year 39 of use. In an attempt to eliminate confounding variables such as learning curve, surgeon experience, or other OR 41 technical variables, a comparison was made for the last 20 cases performed in each procedure group. This assess-43 ment demonstrated an average difference of 22 minutes less for the image-guided group but missed being 45 statistically significant (P = 0.0503).





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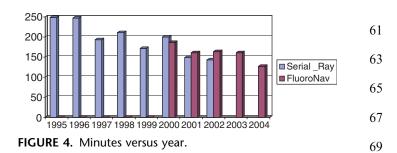


Image-guided Group

The resulting 57 patients had times ranging from 120 to 218 minutes, with an average of 161.8 ± 22.9 minutes or 2.7 ± 0.4 hours. Our learning curve year 2000, operative time was 186.1 ± 27.2 minutes or 3.1 ± 0.45 hours. Subsequent years showed faster times than the initial year with the fastest time achieved in 2004, 127.3 ± 7.5 minutes or 2.1 ± 0.1 hours (Fig. 4).

Serial Imaging Group

The resulting 43 patients had times ranging from 125 to 312 minutes, with an average of 200.7 ± 47 minutes or 3.3 ± 0.8 hours. When excluding initial years from the analysis, operative times improved with a greater decrease in time with the serial x-ray procedure. Although a decreasing operative time trend was established, it does not seem that a plateau was established. Time continued to decrease at the most recent year that either procedure was being performed (Fig. 4). 83 83 83 85 85 87 89 91

DISCUSSION

This retrospective review evaluating operative times 95 for image navigation spine surgery is the first experience 97 described in the literature to our knowledge. As cohorts, our study clearly demonstrated an overall time benefit to 99 using fluoroscopy-based image guidance versus conventional standard serial radiographic imaging. Previously described and predicted image guidance operative time 101 incremental increases were not shown in our study compared with standard intraoperative imaging. In fact, 103 our study demonstrated an average of a 40 minutes decrease per case when analyzing all procedures and a 22 105 minutes decrease when including only the last 20 cases in each procedure group. Despite these faster times, the 107 operative duration for both procedures trended down 109 over time with the serial x-ray group having a greater decrease. It would be difficult to attribute this effect to a single factor, given the many variables (ie, learning curve, 111 OR-related inefficiencies, improved instrumentation, etc.). Despite such decreases no established duration 113 plateau was reached for either procedural group, given continued time decrease at the most recent year each 115 procedure was performed. Whether image guidance's 2004 trending time decrease represents a new time or is a 117 result of inadequate power will warrant further study.

- However, despite a potential new developing time decrease for image guidance, the current average 22
 minute less for the last 20 cases is not significantly less
- (P = 0.0503) than serial radiography. Perhaps the only 5 conclusion that can legitimately be made is that there is 1 little or no difference in the time required for the 2
- 7 techniques. Plain radiography is still used by many surgeons to
- 9 assist in localizing the skin incision and/or proper anatomic level for certain procedures.³ However, limita11 tions include a significant amount of time that can elapse
- while films are obtained, processed, and potentially repeated with resulting static images only. We postulate such time factors to be large contributors to overall
- 15 operative time in our initial years of serial radiographic imaging. Serial imaging with C-arm fluoroscopy ad-
- 17 dresses many radiographic serial imaging concerns. The availability of immediate successive image updates allows
- 19 dynamic visualization and thus facilitates procedure accuracy⁴⁻⁷; however, single plane images, excessive
- 21 radiation exposure (patient, staff, and surgeon), surgical field crowding, and lead shielding requirements can
 23 render this an unfavorable protocol.^{2,8} Thus, with such
- 23 render this an unfavorable protocol.^{2,8} Thus, with such shortcomings of serial radiography, fluoroscopy disad-
- vantages and currently equivalent and improving operative times with IGS, we will continue to further expect itswide spread acceptance.
- Our study demonstrated that with further operative use of each technique improved operative times were obtained for both methods. For the serial radiography
- 31 group, time improved to an average of 2.4 hours for the last 2 years of its use. Image guidance also demonstrated a
- 33 continued improvement in time since its first year of use in 2000. Image Guidance 2004 (2.1 h) surpassed previous
- 35 time averages for its 2001 to 2003 years, and any at best serial imaging times. However, given the few cases for image guidance 2004, it will require greater numbers and
- 37 image guidance 2004, it will require greater numbers and follow-up to confirm such new lower operative times.39 Although we have hypothesized and demonstrated time-
- savings with fluoroscopic image guidance techniques, we 41 have also identified several limitations with our study.
- Our operative dates have spanned over a 9-year period. In 43 the last 4 years we have experienced cases with the use of
- IGS. Surgeon innate speed and experience may have 45 improved throughout this time period placing the latter
- cases at an automatic time advantage. Although this maybe a possibility, it's also possible that speed and a procedural learning curve had been established before this
- 49 study time span. In an attempt to eliminate the experience factor we identified a 2-year span of overlap for the use of
- 51 both procedures. It's evident from this time period (2001 to 2002) that serial imaging provided faster times.
- 53 However, this period also marked the experienced use of one technique and the learning curve of another.
- Because both cohorts experienced an initial imaging modality learning curve, these times cannot be equally
 compared in their overlap time period. Subsequent
- statistical analysis of the last arbitrary 20 and 15 cases 59 demonstrates that, although not statistically significant,

FluoroNav was still faster; 151.4 versus 173.0 minutes (last 20 cases) and 149.4 versus 156.9 minutes (last 15 cases). Despite not being statistically significant, clinical significance may apply. What can be stated with absolute certainty, however, is that the use of image navigation did not cause an increase in operative time compared with standard intraoperative imaging techniques. 65

Another potential limitation of this study is the fact 67 that the pedicle screw instrumentation changed over time. Earlier cases were performed using TSRH pedicle screw 69 and rod instrumentation whereas latter cases used CD Horizon M8 instrumentation (both from Medtronic 71 Sofamor Danek, Memphis, TN). Whether one system 73 affords faster application is unknown. In such a retrospective analysis there are limitations in the attempt to control or eliminate all potential confounding variables. 75 We used stringent case eligibility criteria; however, the presence of unknown or unforeseen factors may alter 77 slightly each individual operative experience. Also, our study only reviewed fluoroscopy based IGS, excluding 79 any cases of computed tomography-based image guidance. Our data may not be extrapolated to this different 81 technique for there are additional steps and preoperative precise testing required.⁴ Finally, surgeon system famil-83 iarity and experience can dictate the overall time experience. We understand these potential and real 85 limitations. The results of improved time efficacy with fluoroscopy-based image guidance may be confirmed with 87 a prospective study in the future. 89

CONCLUSIONS

Our study demonstrated time-savings with the use of fluoroscopy-based image guidance versus serial radio-93 graphy. Although statistical significance was not found in all comparisons, it is clear that the use of this type of 95 image navigation spine surgery did not increase the time of the intraoperative experience. Conventional wisdom 97 has been that image guidance is a great idea, but it comes with the cost of increased operative time. This study 99 demonstrates that with modern spine image navigation techniques operative times are not longer, and in fact the 101 times are less. This technique can make the spine operation more efficient while eliminating the hazards of 103 radiation for the surgeon, patient, and OR staff. Given the additional benefits to image guidance, including safety 105 and accuracy of spinal implant placement, we predict IGS will become an increasingly accepted and practiced form 107 of spinal surgery.

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REFERENCES

- 111 1. Choi WW, et al. Computer-assisted fluoroscopic targeting system for pedicle screw insertion. *Neurosurgery*. 2000;47:872–878. 2. Holly LT. Foley KT. Intraoperative spinal navigation. *Spine*. 113
- 2. Holly LT, Foley KT. Intraoperative spinal navigation. *Spine*. 2003;28(15 Suppl):S54–S61.
- Odgers CJt, et al. Accuracy of pedicle screw placement with the assistance of lateral plain radiography. J Spinal Disord. 1996;9:334–338.
 Mirza SK et al. Accuracy of thoracic vertebral body screw placement 117
- 4. Mirza SK, et al. Accuracy of thoracic vertebral body screw placement using standard fluoroscopy, fluoroscopic image guidance, and

- computed tomographic image guidance: a cadaver study. *Spine*. 2003;28:402–413.
- Laine T, et al. Accuracy of pedicle screw insertion with and without computer assistance: a randomized controlled clinical study in 100 consecutive patients. *Eur Spine J.* 2000;9:235–240; discussion 241.
 Gertzbein SD. Robbins SE. Accuracy of pedicular screw placement in
 - 6. Gertzbein SD, Robbins SE. Accuracy of pedicular screw placement in vivo. *Spine*. 1990;15:11–14.
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- Kamimura M, Ebara S, Itoh H, et al. Accurate pedicle screw insertion under the control of a computer-assistance image guiding system: laboratory test and clinical study. J Orthop Sci. 1999;4:197–206.
- Carbone JJ, et al. Fluoroscopically assisted pedicle screw fixation for thoracic and thoracolumbar injuries: technique and short-term complications. *Spine*. 2003;28:91–97.