EXPERIMENTAL RESEARCH

Minimally invasive percutaneous transpedicular screw fixation: increased accuracy and reduced radiation exposure by means of a novel electromagnetic navigation system

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Abstract

Background Minimally invasive percutaneous pedicle screw instrumentation methods may increase the need for intraoperative fluoroscopy, resulting in excessive radiation exposure for the patient, surgeon, and support staff. Electromagnetic field (EMF)-based navigation may aid more accurate placement of percutaneous pedicle screws while reducing fluoroscopic exposure. We compared the accuracy, time of insertion, and radiation exposure of EMF with traditional fluoroscopic percutaneous pedicle screw placement.

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R. von Jako (⊠) GE Healthcare, 301 Ballardvale St, Wilmington, MA 01887, USA e-mail: drvonjako@comcast.net *Methods* Minimally invasive pedicle screw placement in T8 to S1 pedicles of eight fresh-frozen human cadaveric torsos was guided with EMF or standard fluoroscopy. Setup, insertion, and fluoroscopic times and radiation exposure and accuracy (measured with post-procedural computed tomography) were analyzed in each group.

Results Sixty-two pedicle screws were placed under fluoroscopic guidance and 60 under EMF guidance. Ideal trajectories were achieved more frequently with EMF over all segments (62.7% vs. 40%; p=0.01). Greatest EMF accuracy was achieved in the lumbar spine, with significant improvements in both ideal trajectory and reduction of pedicle breaches over fluoroscopically guided placement (64.9% vs. 40%, p=0.03, and 16.2% vs. 42.5%, p=0.01, respectively). Fluoroscopy time was reduced 77% with the use of EMF (22 s vs. 5 s per level; p < 0.0001) over all spinal segments. Radiation exposure at the hand and body was reduced 60% (p=0.058) and 32% (p=0.073), respectively. Time for insertion did not vary between the two techniques. Conclusions Minimally invasive pedicle screw placement with the aid of EMF image guidance reduces fluoroscopy time and increases placement accuracy when compared with traditional fluoroscopic guidance while adding no additional time to the procedure.

Keywords Minimally invasive · Electromagnetic field navigation · Pedicle screw · Fluoroscopy · Accuracy

Introduction

Pedicle screw fixation provides superior biomechanical strength when compared with wiring or hook-based constructs for creation of a stable environment for spinal fusion

[5, 12, 22, 31, 36]. Standard methods of pedicle screw instrumentation require significant exposure of the posterior bony elements of the spine to provide landmarks from which to guide the placement of instrumentation. Such exposure is associated with significant amounts of blood loss [17], as well as paraspinal muscular injury, which has been associated with postoperative back pain [18, 19]. The accuracy of placement of pedicle screws has been shown to be improved with the use of frameless stereotaxic image guidance in most [2, 3, 21, 23] but not all [13] studies. Adoption of image-guided surgical techniques has been limited to date amid concerns of increased operative time and complexity of the technology [2]. Recently, developments in percutaneous pedicle screw fixation offer a less traumatic approach resulting in less damage to the surrounding musculature, decreased blood loss, and decreased recovery time [15, 16, 20]. These characteristics may eventually translate into improved long-term results, with decreased muscle denervation, atrophy, and pain [30]. Accurate minimally invasive pedicle screw placement is complicated, however, by the obscuration of normal anatomical landmarks. Errors in placement are therefore a primary concern, with one study reporting almost 10% of patients needing revision surgery [30]. Additionally, the technique depends heavily on fluoroscopic guidance, which can result in significant levels of radiation exposure to both the surgeon and assistant [28]. An efficient image-guided system that allows accurate pedicle screw placement and a reduction in the amount of fluoroscopic time would therefore be of value.

Computer-aided fluoroscopic techniques [6, 9, 27, 29, 34] are among the various methodologies devised to increase the accuracy of screw placement; however, widespread adoption has been slow because of the increased set-up and operative times and lack of perceived benefit [3]. Electromagnetic field (EMF) navigation-based systems eliminate cumbersome optical array receivers as well as line-of-sight issues that can interfere with the normal flow of the operative procedure [10, 25]. The trade-off for this flexibility is the limited size of the EMF field (18-in. radial from center of EMF transmitter; Fig. 1). In addition, large ferromagnetic instruments can create distortion within the EMF field. Studies have confirmed that the accuracy of pedicle screw placement is similar using either optical or EMF-based navigation systems [6, 9, 27, 29, 35].

Although the results of stereotaxic guidance for pedicle screw placement in open procedures have been promising, a relative paucity of laboratory and clinical data exist regarding its use in a minimally invasive approach [1, 7, 8, 14]. To date, no laboratory work has been done to compare the radiation exposure to the user using dosimeter measurements. This study aims to compare the accuracy, time of insertion, and radiation from EMF-guided placement of minimally invasive



Fig. 1 Drawing showing that an 18-in. field is one of the limiting factors in the use of electromagnetic guidance

pedicle screws with the traditional fluoroscopically guided approach.

Materials and methods

The spines of eight fresh-frozen human cadavers with intact spines from at least T8 to the sacrum were prescreened for osseous vertebral pathological conditions, including evidence of tumor infiltration, traumatic disruption, or past surgical intervention. Intact cadaver torsos were placed in the prone position on radiolucent tables.

A GE OEC 9900 Elite fluoroscope with an integrated navigation system (GE Healthcare, Salt Lake City, UT; not commercially available) was used for fluoroscopic imaging (Fig. 2). To eliminate bias and confirm that the navigation system works with multiple screw constructs, two minimally invasive percutaneous pedicle screw systems that had been modified for use in an EMF environment were used: the Paramount (Integra Spine, Burlington, MA, USA) and the Pathfinder (Zimmer Spine, Austin, TX, USA) systems. Titanium screw extenders for each system were created to avoid interference within the EMF field that would be expected from the normal stainless steel extenders. A special bone biopsy needle known as the Nav Access Needle [33], which provides stable attachment of an EMF receiver, was used for Kirschner wire (K-wire) placement. A bone pin or spinous process clamp was used to attach the EMF dynamic reference transmitter to the spinous process



Fig. 2 Photograph showing the GE OEC 9900 Elite fluoroscopic display

of the level adjacent to the targeted vertebrae as previously described (Fig. 3) [11, 35]. The typical montage for transmitter placement was on the spinous processes of T11, L2, and L5, as the system allows for accurate navigation of up to three vertebrae from each transmitter location. For two cadavers, T8 was also used for placement of the EMF transmitter.

Four attending spinal surgeons (AA, LTK, MPC, and KSY) with experience in minimally invasive spine surgery



Fig. 3 Photograph showing the bone pin inserted into spinous process

and percutaneous pedicle screw instrumentation worked in pairs on each cadaver.

Procedure

Each cadaver was assigned to implantation with either the Pathfinder or the Paramount percutaneous pedicle screw system. Screw placement with EMF navigation (Nav) and standard fluoroscopic imaging (Fluoro) was compared between alternating segments rather than alternating technique from side to side. A comparison by level, in which one technique is performed bilaterally, was thought to reduce a potential bias for a reduction in time and improved accuracy based on knowledge gained from placement of the first screw when placing the contralateral screw. A comparison by level is also more consistent with the manner in which surgery is performed with sequential placement of screws bilaterally before moving to the next level.

The S1 level was allocated to either the Nav or Fluoro group on an alternate basis to ensure the numbers for this level were evenly randomized. All other levels starting at L5 and moving upward were randomly allocated based on a coin flip.

After placement of the EMF transmitter, anteroposterior (AP) and lateral fluoroscopic views of the vertebrae were saved on the Nav system. Transpedicular K-wires were then placed percutaneously using either the image guidance Nav Access needle or a standard Jamshidi needle with the aid of live AP and lateral fluoroscopic imaging (Figs. 4 and 5).



Fig. 4 Photograph showing how the K-wires are inserted through the Nav access needle with EMF receiver



Fig. 5 a NAV screen demonstrating target of the right pedicle at L5. b Lateral fluoroscopic capture showing the overlay of the planning trajectory and actual screw position

The percutaneous pedicle screw systems used similar tools, which required placement over the transpedicular K-wires. In the Nav group, these were all image guided and placed using the EMF cannulated T-handle, which allowed for real-time biplanar visualization of the trajectory and progression of the instrument through the pedicle. Standard fluoroscopic technique was used in the Fluoro group. The screw extenders and K-wires were removed, leaving the screws in place for subsequent computed tomography (CT) scan evaluation of screw placement accuracy.

Outcome measures

Intraoperative measured variables included set-up, insertion, and fluoroscopy times. Insertion time measurements included set-up and initial image capture time for both Nav and Fluoro groups. Radiation exposure was detected by hand and ring thermoluminescent dosimeter badges. Each screw was assessed for pedicle, vertebral, and critical breach on post-procedural CT reconstruction scans. The ideal screw trajectory, defined as convergence of the pedicle screws at the ventral aspect of the vertebral body and totally within the pedicle, was determined. A 4-point grading scale was used as follows: grade 0 (ideal)-accurate screw with no perforation through any cortex; grade 1 (minimally displaced)—safe screw with cortical perforation of <3 mm; grade 2 (moderately displaced)—displaced by \geq 3 mm but \leq 5 mm; and grade 3 (critical perforation)-displaced by >5 mm.

The accuracy of each technique over each spinal zone (thoracic, lumbar, and sacral) was statistically analyzed using a chi-square test with p=0.05 considered significant.

Results

In total, 122 pedicle screws were placed, 62 under fluoroscopic guidance and 60 under EMF guidance (Table 1). Seventy-eight of these were in the lumbar pedicle, 28 were in the thoracic spine, and 16 were in the sacral spine.

Accuracy of placement over all segments, as assessed by pedicle and vertebral body breaches, was slightly better in the EMF Nav group than in the conventional fluoroscopic C-arm group, but this difference was not statistically significant: Pedicle breaches were seen in 17% of EMF-placed screws and 29% of fluoroscopically placed screws (p=0.12), while vertebral body breaches were seen in 1.7% of the EMF-placed screws and 4.8% of the fluoroscopically placed screws (p=0.33) (Table 1). Accuracy of placement of lumbar pedicle screws was significantly improved with the use of EMF (16.2% pedicle breach vs. 42.5% with fluoroscopic; p=0.01), but there was no significant decrease in cortical breaches with the use of EMF in the thoracic or sacral regions.

Ideal screw trajectories were achieved more often with EMF guidance over all spinal segments (62.7% vs. 40%, p=0.01). This effect was most pronounced in the lumbar segments, where 64.9% of screws placed with EMF guidance achieved ideal trajectory vs. 40% placed with fluoroscopy (p=0.03). No grade 3 trajectories occurred with standard fluoroscopy or EMF navigation, and most trajectories in either group were grade 0 or 1 (Table 1). There was no significant difference between the two techniques over other segments.

Insertion times, including set-up time, between the two techniques did not significantly differ overall for the two
 Table 1
 Summary of pedicle

 screw placement data comparing electromagnetic navigation
 and fluoroscopy

	EM group	Fluoroscopy group	p value	
Number of pedicle screws placed	60	62		
Total insertion and setup time (s)	923	952	0.6911	
Average fluoroscopy time per level (s)	5	22	< 0.0001*	
Number of pedicle breaches (%)	10 (17)	18 (29)	0.12	
Number of lumbar pedicle breaches (%)	6 (16.2)	17 (42.5)	0.01	
Number of vertebral body breaches (%)	1 (1.7)	3 (4.8)	0.33	
Number of ideal (grade 0) trajectories (%)	37 (62.7)	25 (40)	0.01*	
Number of grade 1 trajectories (%)	18 (30.5)	35 (56)		
Number of grade 2 trajectories (%)	4 (6.8)	2 (3.2)		
Number of grade 3 trajectories (%)	0	0		
Ideal (grade 0) lumbar trajectories (%)	24 (64.9)	16 (40)	0.03*	
Radiation exposure in body (mrem)	13.8	20.2	0.073	
Radiation exposure in hand (mrem)	15.0	37.5	0.058	

groups (923 s with EMF vs. 952 s with Fluoro, p=0.6911), and this was also true for any spinal segment analyzed separately. Radiation time, however, was significantly reduced over all segments (5 s per level with EMF vs. 22 s per level with Fluoro, p<0.0001). Highly significant reductions in radiation time using EMF vs. Fluoro guidance were seen over all spinal segments upon individual blinded analysis by the radiologist (JAC).

Total body and hand radiation doses seen by the operating surgeons were decreased with the use of EMF, although these results were just less than significant (13.8 vs. 20.2 mrem, p=0.073, and 15.0 vs. 37.5 mrem, p=0.058, for body and hand, respectively). Of note, all surgeons attempted to reduce radiation exposure by stepping away from the operative table during image acquisition for both the Nav and Fluoro groups, which is reflective of their experience using fluoroscopy.

Discussion

Although the literature has not confirmed that image guidance is superior to fluoroscopic guidance in traditional open procedures for placing pedicle screws, few studies have compared these techniques for placement of percutaneous pedicle screws. Fewer studies have analyzed radiation exposure using the two techniques, and none, to our knowledge, have analyzed recent EMF technology. Accuracy of pedicle screw placement in this study was measured by assessment of cortical breach in both the pedicle and vertebral body as well as by subjective assessment of ideal trajectory. We found that accuracy of placement of lumbar pedicle screws was significantly improved by both of these measures; however, the accuracy was not significantly improved for thoracic and sacral screws. Significant gains in pedicle screw placement accuracy with guidance in the lumbar spine have also been demonstrated in a recent, large meta-analysis [21].

Cortical breach has been the most commonly used measure in determining pedicle screw accuracy [21], but there is significant variability in the definition of these findings in the literature, making comparisons between series difficult. Kosmopoulous and Schizas [21] reported on the use of 35 different methods of assessment in their metaanalysis and noted that approximately 50% of studies making claims about the accuracy of placement did not clearly define how accuracy was assessed. Even when cortical breach is used as a parameter, considerable variation exists between studies. Some authors have reported only a cortical breach of >2 mm and others reported only on the direction of breach [21, 30]. The assessment of cortical breach is straightforward on postprocedural CT scans and should represent a minimum reporting requirement to serve as a basis for comparison between studies. The amount and direction of breach are secondary measures that may or may not have significance in relation to the potential of neural injury [32]; that is, medial cortical breaches have more significance than lateral pedicle cortex breaches.

Although the subgroup analysis indicated that accuracy with navigation was improved in the lumbar spine, increased accuracy of pedicle screw placement in the thoracic spine was not illustrated in this study. In fact, the results suggested a trend toward greater inaccuracy with the EMF navigation system. Similar results have been reported in another study [13], but this is not a universal finding [2, 3]. Kosmopoulos and Schizas [21] noted similar findings in the thoracic group in their metaanalysis. They reported a decreased median accuracy of thoracic pedicle screw placement in vivo with the use of navigation compared with fluoroscopy alone (94.3% accurate vs. 82.2%) and very similar results in cadaver studies (74.9% accurate with navigation and 74.5% without). Possible explanations for this finding are that the learning curve needed to master the navigation technology is steep, and the decreased diameter of the thoracic pedicle makes screw placement inaccuracies more prevalent.

The accuracy of screw placement is of great importance with placement of percutaneous pedicle screws, but operative and radiation exposure times must also be considered. Time for insertion with the EMF technique (and thus operative time) did not vary from that of the standard fluoroscopically guided technique in the current study, which is especially significant because the version of the navigation system in this study was new to all participating surgeons. Thus, shorter operative times would be expected with further familiarity with the navigation system and instrument refinement. Although increased speed has not been shown in other studies, this can be a reasonably expected byproduct of navigation because manipulation of a fluoroscope during surgery can be time consuming, especially in minimally invasive surgeries that require AP and lateral imaging for each level. Elimination of the required movement of the fluoroscope around the operative field should also reduce the potential for contamination of the operative field and concern for infection [4]. Additionally, simultaneous viewing of both AP and lateral projections facilitates percutaneous screw placement.

An additional outcome measure in this study was total fluoroscopic time and total radiation exposure. The reduction in fluoroscopic time with EMF was highly significant, but the reduction in radiation exposure measured on the dosimeters was not statistically significant. This is likely due to each surgeon's habit of backing away from the fluoroscope with each exposure, which may provide some protection to the surgeon. Although it was not measured with dosimeters, the highly significant reduction in fluoroscopic time should reduce the exposure to the patient. Total fluoroscopic time and radiation exposure are directly related, and any reduction in exposure time should be of benefit for the patient and the operating room staff. This finding holds special implications for the spine surgeon, as radiation exposure in spinal surgery has been demonstrated to be 10-12 times that of other musculoskeletal surgeries and has the potential to exceed recommended yearly allowances [28]. Factors unique to spine surgery that may contribute to increased exposure include the increased penetrating beam energy requirements to image the spine adequately [24], proximity of the surgeon's hands to the field (which may be exacerbated by the need to maintain alignment of instrumentation), increased Compton scatter at the beam entry site, and the frequent necessity of having either the surgeon or assistant standing next to the beam generator [28]. Furthermore, poor technique in which the hands are directly irradiated can dramatically increase exposure to as high as 4,000 mrem/min (recommended yearly hand allowance is 50,000 mrem) [26]. While the consequences of chronic radiation exposure are, as yet, unknown, the increasing exposure beyond recommended limits is certainly cause for concern, especially as minimally invasive techniques requiring fluoroscopy increase in frequency.

Potential disadvantages of the EMF navigation system over traditional fluoroscopy could include system set-up and registration time and the chance of software failure. In addition, there is the need for additional incisions and time to place the spinous process tracking system and the possibility of displacement of the spinous process tracking system. Redo operations in patients in whom the spinous process has been removed previously would present a challenge. Inaccuracies could also be associated with shifting of the attached dynamic reference transmitter position during applications of pedicle screws. Resecuring the bumped transmitter with updated fluoroscopic images allows continued navigation. Minor inaccuracies (i.e., <3 mm) might be of less importance in targeting the L4 to S1 pedicles, as these are the more frequently instrumented pedicles. The 18-in. surgical field may present a potential limitation in the use of EMF navigation when tracking some elongated instruments used in percutaneous approaches.

Conclusions

The use of EMF navigation for the insertion of percutaneous pedicle screw instrumentation was found to increase accuracy in the lumbar spine. The increase in accuracy is similar to those reported in the literature for optical-based navigation techniques. A significant reduction in fluoroscopic time was also noted in the EMF navigation group. This is an important factor in minimally invasive surgery, which requires a more extensive use of fluoroscopy. The use of EMF navigation avoids the cumbersome line-of-sight issues of the opticalbased systems; thus, it may facilitate minimally invasive percutaneous procedures. Guidance should, therefore, be considered a valuable tool in the spine surgeon's armamentarium, especially when applying instrumention in revision or deformity spine surgery.

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Disclosure Ron Von Jako is an employee of GE Healthcare. Larry T. Khoo serves as a consultant for Zimmer Spine, GE, and Integra Life Sciences. Ali Araghi is a consultant, stockholder, and design surgeon with Integra Life Sciences, a consultant for Zimmer Spine, and an Advisory Board member for GE. Ken Yonemura has consulting agreements with Zimmer Spine and GE. Mick Perez-Cruet has consulting agreements with Zimmer Spine and GE.

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Comment

This article reports on electromagnetically controlled minimally invasive pedicle screw insertion in the TL spine including S1, on cadavers, and reports greater accuracy and less radiation exposure than with more "traditional" fluoroscopy-based screw insertion. This seems a promising step toward facilitating screw insertion with desired radiation reduction. The article points in the right direction, but does not resolve the ongoing controversy between advantages and disadvantages of "minimally" invasive vs. "open." Furthermore, electromagnetical guidance may facilitate both open and "minimally invasive" techniques.

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