

RANDOMIZED TRIAL

Reduction in Radiation (Fluoroscopy) While Maintaining Safe Placement of Pedicle Screws During Lumbar Spine Fusion

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Study Design. Prospective, randomized, controlled study.**Objective.** To report the results of using the PediGuard (SpineGuard, Inc., San Francisco, CA), a local electrical conductivity measurement device, to reduce radiation exposure while drilling the pilot hole for pedicle screw placement.**Summary of Background Data.** Reports of pedicle screw placement in the lumbar spine have shown medial pedicle perforations with nerve root impingement in addition to lateral pedicle and vertebral body perforations that can impinge the nerve root within the psoas. Routine use of fluoroscopy (fluoro) is thought to reduce the risk of perforations but is associated with increased radiation. A new pedicle-drilling device (PediGuard) which uses electrical conductivity differentiation at the tip for assessing bone versus soft tissue, has been developed to improve the safe positioning of pedicle screws. This device not only warns of an impending medial breach but also is the only device available to, in real time, nonradiographically detect a lateral breach.**Methods.** Eighteen patients with a diagnosis of lumbar degenerative spine who had a posterior spinal fusion were enrolled. The average age of the patients was 55 ± 12 years. Postoperative computed tomographic scans were reviewed by an independent reviewer. Screws were considered “in” (<2 mm of breach) or “out” (≥ 2 mm of breach). In a randomized fashion, the surgeon placed a pilot hole either with a standard technique (manual probe) or the PediGuard, and used fluoro for each drilling as a guidance assist as

necessary. Electromyographic testing was not done by the surgeon. A total of 78 screws (39 via standard probe and 39 with PediGuard assist) were analyzed.

Results. There was no significant difference in breach rate of 2 mm or more by either of the 2 methods ($P = 1.000$), with 1 screw out in each group. Fluoro shots averaged 5.2 (range, 0–15) per screw in the PediGuard group versus 7.5 (range, 2–17) in the standard group ($P < 0.001$). This represents an average decrease of 2.3 (30%) fluoro shots per screw with the PediGuard. There were 202 total fluoro shots used in the PediGuard group versus 293 in the standard group.**Conclusion.** In this prospective, randomized trial of a pedicle drilling device that uses electrical conductivity differentiation at the tip for assessing bone versus soft tissue, the number of fluoro shots was reduced by 30% compared with a standard drilling probe while maintaining a 97.5% accurate, safe screw placement.**Key words:** radiation, fluoroscopy, pedicle screws, lumbar spine.
Spine 2012;37:E1305–E1309

Pedicle screw fixation has been shown to be superior to other methods of instrumentation for spinal fusion and correction of spine deformity.^{1–7} In a meta-analysis of the literature by Yahiro⁸ of 5756 patients reported in 101 articles, the success of fusions with pedicle screws was 94.8%, attesting to the clinical usefulness of pedicle screw instrumentation. However, 1 of the complications of pedicle screw placement is perforation of the pedicle and vertebral body wall.

Perforation rates range from 2.5% to 40%.^{9–12} A meta-analysis by Kosmopoulos and Schizas¹³ reported on 10,250 pedicle screws in patients having an accuracy of 89.8% (median, 86.6%) without the assistance of navigation. Many of the differences in the literature depend on the study methodology (computed tomographic [CT] scan vs. plain radiograph) used to determine the perforation.

Perforations can further lead to complications such as dural tear,¹² nerve root injuries,¹² paraplegia,^{12,14–16} or vascular injury.¹⁷ Nerve root injury, spinal cord injury, and vascular injury occurred in 1% of the patients. Radicular pain occurred in 1.5% of the patients, and dural tears occurred in 0.5%. In a meta-analysis⁸ of the literature of 5756 patients

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Acknowledgment date: September 8, 2011. Revision date: May 10, 2012. Acceptance date: June 22, 2012.

The device(s)/drug(s) submitted is/are FDA-approved or approved by a corresponding national agency for this indication.

SpineGuard, Inc. funds were received in support of this work.

One or more of the author(s) has/have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this manuscript: for example, honoraria, gifts, consultancies, royalties, stocks, stock options, decision-making position.

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DOI: 10.1097/BRS.0b013e3182666ad6

reported in 101 articles, there were 65 dural tears (1.1%) and 99 neural injuries (1.7%).

Many surgeons employ a manual technique of preparing the pedicle hole with a pedicle probe. The “free hand technique” is based on the knowledge of spinal anatomy. This technique results in the least radiation exposure to the patient and surgeon but is less accurate in placing contained pedicle screws as compared with imaging techniques.¹⁸ A fluoroscopic technique may provide more consistent results but carries some risks associated with radiation dose, especially to young patients^{19,20} and cumulatively to the surgeon.²⁰ A cadaver study by Rampersaud *et al*²¹ demonstrated that fluoroscopically assisted thoracolumbar pedicle screw placement exposes the spine surgeon to significantly greater (10–12 times) radiation levels than other nonspinal musculoskeletal procedures that involve the use of a fluoroscope.

A possible means to address the issue of increased radiation to improve pedicle screw accuracy may be the use of a local electrical conductivity measurement device. The PediGuard probe (SpineGuard, Inc., San Francisco, CA) is a 510 (k) approved device for pedicle screw insertion that provides the surgeon with additional feedback in the form of an audible tone when a breach has occurred or is about to occur. The PediGuard, which is shaped like an awl and has impedance measurement capability at the tip, is used in a back and forth motion to drill down through the pedicle cancellous bone. The electrical impedance changes as the instrument passes through cancellous and cortical bones as well as soft tissue.²² The use of this drilling device provides the surgeon additional opportunity to prepare a contained pilot hole without additional radiation exposure.

The purpose of this prospective, randomized, controlled study is to report the results of using the PediGuard to reduce radiation exposure while preparing the pilot hole for pedicle screw placement.

MATERIALS AND METHODS

The study was designed to analyze the potential for reduced fluoroscopy (fluoro) shots while maintaining the same accuracy. We did not plan to try to improve accuracy, because it is already excellent with fluoro techniques as used by the surgeon (C.C.). Therefore, the primary outcome was to reduce the number of fluoro shots while maintaining accurate screw placement.

Eighteen patients (6 male, 12 female) with a diagnosis of lumbar degenerative spine having a posterior spinal fusion (all by the principal investigator C.C.) were enrolled in the study. The average age of the patients was 55 ± 12 years. The surgeon (C.C.) had been in practice for 7 years at a tertiary referral center for complex spine surgery at the time of this study. He underwent cadaveric training with the PediGuard device and performed several training cases with the device before the study.

The first pedicle screw was randomly selected for insertion after the use of a standard pedicle probe or after the PediGuard device based on a randomized chart. Every subsequent pedicle screw insertion was randomized by an alternating

technique using either a standard probe or the PediGuard. The first pedicle was probed at either the most distal or the most proximal vertebra to be instrumented. Then, the opposite pedicle at the same level was drilled using the technique not used initially. At each subsequent level, the technique used on each side was reversed. For example, if at L3 the PediGuard was used on the left and surgeon's procedure on the right, then at L2 the PediGuard would be used on the right and surgeon's procedure on the left. This process was continued until all levels were instrumented. This randomization of the screw insertion *versus* randomizing patients was thought to eliminate most of the bias that arises from patient differences such as sex, pedicle size, bone density, patient's body mass index, and so on. The surgeon (C.C.) used fluoro for each drilling as a guidance assist as necessary.

Both groups had 2 screws placed in thoracic, 33 in lumbar, and 4 in sacral vertebrae. Once the pilot hole was placed, the surgeon inserted the titanium screws in his standard fashion. Electromyography (EMG) testing was not done by the surgeon. A total of 78 screws (39 *via* standard probe and 39 with PediGuard assist) were analyzed.

Surgical Technique for Use of the PediGuard

When the electrical impedance at the tip of the PediGuard changes, the surgeon is alerted to this change *via* audible and visual means. Because of the shape of the electromagnetic field at the tip of the device, the pitch and cadence of the sound emitted slightly changes before the nature of the bone or tissue changes. When first entering the cancellous bone, keeping firm pressure is necessary to get a sense of the rate and pitch of the sound for that particular pedicle. As one advances, if the rate and pitch decrease, then one is near or up against the cortical bone. One can then gently reangle the tip, keeping firm pressure to look for the original sound of the cancellous bone. Once the sound of the original cancellous bone is heard, then one should advance the PediGuard in that direction. This reangling of the tip to avoid cortical perforation by use of sound is called “anticipation.” It is extremely important to not decrease pressure of the tip on the bone, or blood will intervene, and then a very high pitch and rate of sound will result. In addition, if one angles the tip too far in any 1 direction, then blood will seep in and surround the electrode tips, and a high pitched, high cadence sound will be heard as a consequence of the tip measuring blood.

Each subject had a full neurological examination at discharge or their first outpatient follow-up visit. All patients had a CT scan of all screws placed. These scans were reviewed by an independent reviewer (AS). Perforations 2 mm or less on CT scan are thought not to be associated with clinical sequelae,²³ and other authors report perforations as large as 4 mm being associated with no problems.²⁴ Gertzbein and Robbins²⁵ hypothesize a 4 mm safe zone, which includes 2 mm of epidural space and 2 mm of subarachnoid space. Belmont *et al*⁹ considered screw penetration of the medial pedicle wall less than or equal to 2 mm to be acceptable. We considered screw perforation of less than 2 mm to be acceptable in this study. Screws were considered “in” (<2 mm of

breach [considered clinically insignificant]), or “out” (≥ 2 mm of breach [possibly clinically significant]).

Data Analysis

Breach rates were compared (PediGuard *vs.* manual) using Fisher exact test. The number of fluoro shots was analyzed using a repeated-measures analysis of variance on normalized ranks comparing the PediGuard and manual methods of placement. All analyses were carried out using SAS V9.1.3 software (SAS Institute, Cary, NC).

RESULTS

A total of 78 screws (39 *via* standard probe and 39 with PediGuard assist) in 18 patients were analyzed. There was no significant difference in breach rate 2 mm or more by either of the 2 methods ($P = 1.000$), with 1 screw out in each group. Both were medial breaches, 1 right L4 *via* PediGuard and 1 right L5 *via* standard technique on the same patient (no. 4) (Figure 1A, B), for a screw accuracy of 97.5% in each group.

The primary outcome of the study design was to assess the number of fluoro shots to insert a safe pedicle screw. Fluoro shots averaged 5.2 (range, 0–15) per screw in the PediGuard group *versus* 7.5 (range, 2–17) in the standard group ($P < 0.0001$) (Table 1). This represents an average decrease of 2.3 (30%) fluoro shots per screw with the PediGuard. There were 202 total fluoro shots used in the PediGuard group *versus* 293 in the standard group.

DISCUSSION

The major clinical significance of this study is the opportunity to reduce radiation exposure to the surgeon while maintaining safe pedicle screw placement for the patient. No patient in either group had a new radiculopathy or new neurological deficit. Because patients were prospectively evaluated neurologically and follow-up was 100%, this study provides high-level evidence that the PediGuard can provide safe pedicle screw placement similar to placement with standard techniques that are more heavily dependent on fluoroscopic imaging.

One advantage of this study is that postoperative CT scans for assessment of screw breach were obtained in all cases. The use of all titanium screws improved the accuracy of the review for screw breach. Titanium screws were used solely by this surgeon. Although there is some artifact from titanium screws on CT scans, the ability of the independent reviewer (A.S.) to scroll up and down the spine enabled him to reliably assess if a screw was in or out by the criteria used. Because the reviewer was blinded to the technique used for each screw, any error should have been equal in both groups.

Studies using a postoperative CT scan reviewed by independent or blinded reviewers show higher rates of perforation than those determined by radiograph. Laine *et al*²⁴ reviewed 30 low back operations. In this series of 152 pedicle screws, 32 screw perforations (21%) were detected by CT scan, whereas only 3 were detected by plain radiographs. Screws perforated less than 4 mm caused no neurological problems. In only 10 of the 30 patients were all the screws located within the pedicle. Many surgeons rely on plain radiographs to assess screw

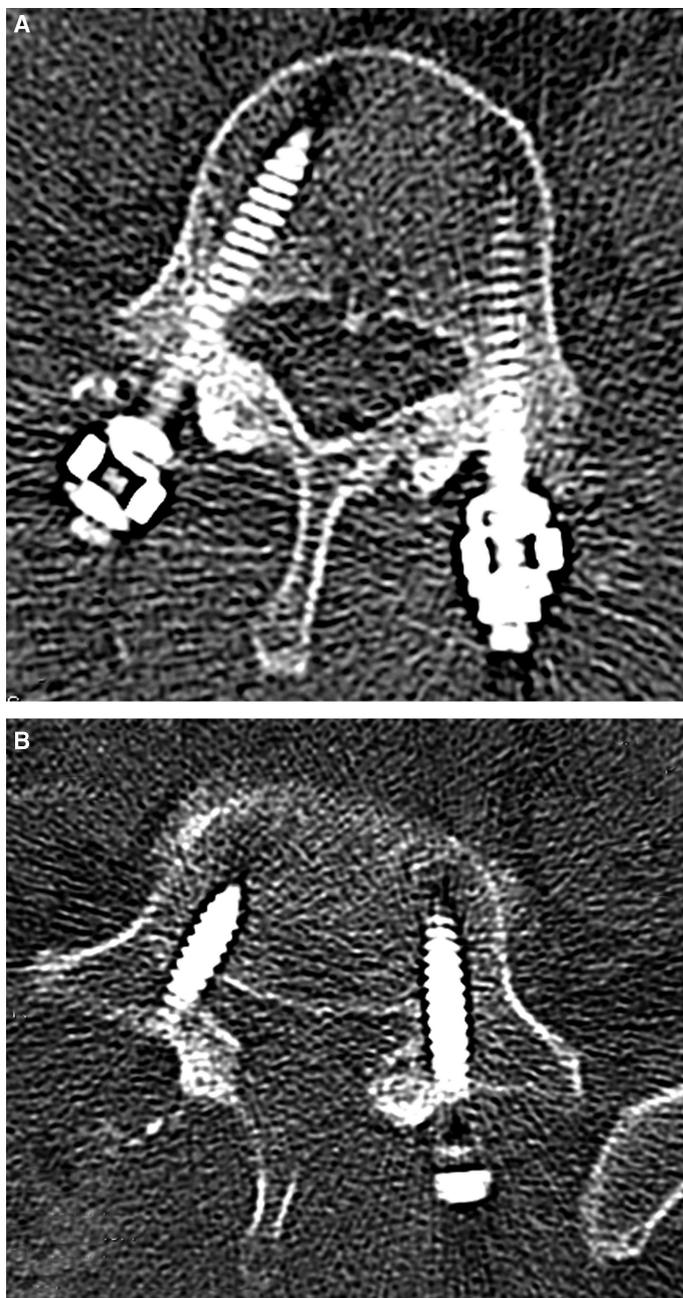


Figure 1. (A) Patient 4: L4 right breach 2 mm or more (insertion *via* PediGuard). (B) Patient 4: L5 right breach 2 mm or more (insertion *via* surgeon's standard fluoroscopic technique).

perforation postoperatively. However, the number of malpositioned screws is underestimated. In an article by Leach *et al*²⁶ using cadaver specimens of the lumbar spine, only 63% of the screw positions were correctly identified on radiograph as compared with 87% with CT scan.

Weinstein *et al*²⁷ wrote a classic article on the use of fluoroscopic guidance for screw placement in cadaver specimens in which any evidence of cortical perforation was considered to be a failure of screw placement. This occurred in 21% of the screws placed where direct visualization was the definite endpoint. Of the screws demonstrating perforations, 92% were medial, potentially injuring the spinal cord or a nerve root. Additional

TABLE 1. Results of Pedicle Screw Placement Using PediGuard or Standard Manual Probe

	In (or <2 mm Breach)	Out (or ≥2 mm Breach)	No. Fluoroscopy Shots	
			Mean	SD
Standard manual technique (n = 39)	38 (97.5%)	1 (2.5%)	7.5 (range, 2–17)	3.60
PediGuard technique (n = 39)	38 (97.5%)	1 (2.5%)	5.2 (range, 0–15)	3.30

variations exist—for example, using anatomical placement for the anteroposterior positioning and the use of fluoro for sagittal guidance.²⁸ The basic concept is that fluoro is used to guide each drill hole instead of just confirming screw placement. Use of fluoro, however, is inefficient, especially with the time involved in switching from anteroposterior to lateral views. In addition, it is ergonomically obstructive and may expose the surgeon and patient to potentially hazardous amounts of radiation.^{21,29} Fluoroscopic techniques have been reported to have relatively high false-negative rates (approximately 13%).³⁰

A study by Ul Haque *et al*²⁰ on radiation exposure with all screw constructs in adolescent idiopathic scoliosis showed that a nonclassified radiation worker (*i.e.*, the surgeon) inserting approximately 2800 screws under fluoroscopic guidance is projected to receive 13.49 mSv of whole-body ionizing radiation and 4.31 mSv of thyroid gland irradiation annually. The National Council on Radiation Protection's current recommendations set lifetime dose equivalent limits for classified workers (radiologists) at 10 mSv per year of life and at 3 mSv per year of life for nonclassified workers (spine surgeons). At the levels estimated, a surgeon beginning his/her career at 30 years of age would possibly exceed the lifetime limit for nonclassified workers in less than 10 years ($10 \times 13.49 \text{ mSv} = 135 \text{ mSv}$). Normally nonclassified workers would be able to work 45 years if they received 3 mSv or less per year ($45 \times 3 \text{ mSv} = 135 \text{ mSv}$).²⁰

The study by Rampersaud *et al*²¹ reported that surgeons may be exposed to 10 to 12 times greater radiographic radiation dose rates during fluoroscopically assisted pedicle screw insertion than during other nonspinal musculoskeletal procedures. This is primarily due to the increased energy required to fluoroscopically image the lumbar spine and the proximity of the surgeon's hands to the primary and backscatter sources of radiation that occur during this imaging. Currently, established guidelines recommend monitoring for personnel who are exposed to greater than 10% of the maximum permissible annual whole-body dose.^{21,22,29} Given a permissible whole-body dose of 5000 mrem per year, the levels of radiation exposure documented in this study would place many spine surgeons above this 10% limit.

Three-dimensional image-guidance systems allow the surgeon to visualize patient-specific imaging along surgically relevant planes both pre- and intraoperatively. Image-guided surgery utilizing preoperative CT scans or intraoperative fluoro have been promoted to give better accuracy of pedicle screw placement. In a randomized study, Laine *et al*¹⁸ showed a reduction in the perforation rate from 13.4% in a conventional group to 4.6% in a computer-assisted image-guided

group. However, this technique has not become popular because of the initial cost (\$200,000), the added surgical time, and the need to reregister the system for each vertebral level being instrumented.²⁹ This technique may require less radiation exposure than fluoro, but that is unproven.²⁹ Because 3-dimensional image guidance is not in widespread use, we did not compare it with the PediGuard.

EMG is another method similar to radiography to confirm safe position of the pilot probe (stimulation of the probe) or the screw (stimulation of the screw). Clements *et al*³¹ report thresholds above 10 mA as being associated with no postoperative nerve root radiculopathies.

Some surgeons like to use EMG stimulation of the probe for muscle contraction to assist in determining pedicle wall breaches before inserting the pedicle screw. The PediGuard may be used in conjunction with any standard EMG monitoring system to detect contraction of muscles. An EMG monitor is not provided with the PediGuard system. As is standard in the use of an EMG monitor, leads should be strategically placed on the patient's legs and attached to the monitor so that the monitor will register muscle contraction in the leg should the PediGuard stimulate a corresponding nerve in the spine.

Previous studies with the PediGuard have shown usefulness of the device to improve pedicle screw insertion safety. Bolger *et al*³² reported 147 manual pedicle drillings performed in 11 hospitals during 28 spinal surgeries between September 2002 and March 2003. A total of 23 vertebral cortex perforations of the 147 manual pedicle drillings (16%) were confirmed, 22 of which (95.7%) were detected by the PediGuard during the procedure.

A potential weakness of the study is that the use of fluoro can be user dependent and subjective in nature. The surgeon may have been unintentionally "biased" to use more fluoro when not using the probe and less likely when using it. It is the routine practice of the surgeon for this trial to keep fluoro to a minimum in all cases secondary to the risks of radiation exposure, the surgical team, the potential risk of bacterial contamination of the wound by the C-arm, and the ergonomic issues related to the use of the C-arm. Therefore, an effort was made to use the minimum amount of fluoro required for both methods of preparing the pedicle. It was also early in the surgeon's experience with the PediGuard, and as such this randomized series represents the "learning curve" of a surgeon with this device. It is possible that further reductions in fluoroscopy use could be safely achieved with more experience with the PediGuard device.

False positives for breach (when the surgeon relaxes steady pressure from the probe and allows blood to reach the tip) do

occur, as do difficulties in passing through sclerotic pedicles while generating consistent cortical pitches and frequencies. These are next to impossible to keep track of as far as data collection, as the surgeon moves the probe almost immediately in response to these sound changes. Recording these would add considerable time to the procedure and be unsafe for the patient. By using the screw randomization scheme instead of patient randomization, these difficulties should be equal in both groups.

CONCLUSION

In this prospective, randomized trial of a pedicle-drilling device that uses electrical conductivity differentiation at the tip for assessing bone *versus* soft tissue, the number of fluoro shots was reduced by 30% as compared with a standard drilling probe. A 97.5% safe screw placement was maintained on CT, and no neurological complications or new radicular symptoms occurred.

➤ Key Points

- ❑ A new pedicle-drilling device, which uses electrical conductivity differentiation at the tip for assessing bone *versus* soft tissue, was used to improve the safe positioning of pedicle screws.
- ❑ This device not only warns of impending medial breach but also is the only device available to, in real time, nonradiographically detect lateral breach.
- ❑ In a prospective, randomized trial using this device, the number of fluoro shots was reduced by 30% compared with a standard drilling probe.
- ❑ This reduction of radiation occurred while maintaining a 97.5% accurate, safe screw placement.

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