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Independent assessment of a new pedicle probe and its ability to detect pedicle breach: a cadaveric study

Laboratory investigation

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Object. The authors undertook an independent, non–industry funded cadaveric study to evaluate the efficacy of a pedicle-probing device, which uses impedance measurement to warn of impending and actual pedicle screw breach.

Methods. A previously validated fresh-frozen cadaver model (saline-soaked spine) was used. Individuals at 3 levels of training (attending spine surgeon, orthopedic surgery resident, and medical student) used a cannulated pedicle-probing device to cannulate each of the levels between T-2 and S-1. Each pedicle was cannulated freehand using 2 approaches: 1) a standard trajectory through the middle of the pedicle, and 2) a medial trajectory aimed to breach the medial wall of the pedicle. A 16-slice helical CT scanner was used. The images were interpreted and analyzed by 2 orthopedic spine surgeons and a neuroradiologist.

Results. The sensitivity of the pedicle probe to detect impending breach or breach of 4 mm or less was 90.06%. The sensitivity in detecting medial wall breach was 95.8%. The positive predictive value was 87.1%. The device detected medial breach more often than lateral breach.

Conclusions. This study showed that this pedicle-probing device could reasonably be used to detect impending breach and actual breach of 4 mm or less. Medial breach was detected better than lateral breach. Use of the pedicle probe may improve patient safety.
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Key Words • **pedicle screw** • **PediGuard** • **pedicle breach** • **cadaveric study** • **technique**

Pedicle screw instrumentation is widely used in the lumbar spine as a means of stabilization to enhance arthrodesis, and it has recently gained acceptance for use in the thoracic spine. The use of pedicle screws for fixation is not without complications, however, with reported rates of breach ranging from 15% to 54%.[2,3,12,13] Perforations can further lead to complications such as dural tear, nerve root injury, spinal cord injury, vascular injury, or vertebral fractures.

The accuracy with which such instrumentation can be placed has been and continues to be the topic of much investigation. Much of the variation in perforation rates in the literature depends on the method used to determine the perforation. Studies using a postoperative CT scan show higher rates of perforation than those using radiographic assessment. Learch et al., using cadaver specimens of the lumbar spine, found that only 63% of screw positions were correctly identified on radiographs as compared with 87% on CT images.[9]

Abbreviation used in this paper: PPV = positive predictive value.

No test exists that gives surgeons 100% sensitivity and specificity with regard to impending breach, and electromyography-assisted pedicle screw placement warns of impingement on nerves but only after a breach has occurred. Therefore, the PediGuard dynamic surgical guidance device (SpineGuard) has been developed to aid surgeons in achieving safer pedicle screw placement.

This hand-held pedicle placement device uses audio alerts along with light-emitting diode (LED) warning lights to guide the surgeon. Electrical conductivity is measured at the tip of the probe, allowing relative differentiation of tissue conductivity, measured at 5 samples per second. The PediGuard device emits a different sound (frequency and pitch) to differentiate cancellous bone from cortical bone ("anticipation" of impending breach) and saline (indicating breach). Previous studies claim up to 98% specificity and 99% sensitivity with regard to the detection capabilities of this new pedicle-probing device. Other claims include up to a 30% reduction in the use of intraoperative fluoroscopy and a 15.4% reduction in screw placement time.[1]

The purpose of the present study was to impartially assess the value of this new pedicle-probing device in pedicle screw placement in the thoracic and lumbar spine by documenting correlations between CT findings and the results observed using the PediGuard alarm system (warnings of impending or actual breach) when individuals with various skill levels intentionally placed pins in a cadaver model and to add an unbiased product critique to the literature considering potential value fluctuations according to the skill level of the surgeon/operator. To date there are no studies that demonstrate the results of intentional attempts at breach with the purpose of recording the accuracy of this new pedicle-probing device.

Methods

A previously validated fresh-frozen cadaver model (saline-soaked spine) was used; 2 cadavers were used for this project. A cannulated T-handle PediGuard pedicle-probing device was inserted through each pedicle (bilaterally) of each vertebra from T-2 to S-1 without the assistance of fluoroscopy. One probe, with a measuring scale, was used for the entire study. Fully threaded Steinmann pins were inserted through the cannula of the probe to mark the exact point where the device was stopped. Then the Steinmann pins were advanced approximately 2 mm into the cortical bone to secure placement. A GE LightSpeed 16-slice helical CT scanner was used for imaging after pins were placed. Images were interpreted and analyzed by 2 spine surgeons and 1 neuroradiologist. Professional statistical services were used for analysis of results.

Individuals at 3 levels of training (attending spine surgeon, orthopedic surgery resident, and medical student) who had never used the device received 20 minutes of didactic training. The spine surgeon and resident physician were given 2 pedicles each to use for training.

The following 2 trajectories were used for each pedicle: 1) a standard direct anterior trajectory through the middle of the pedicle (Fig. 1), and 2) a medial trajectory intended to breach the medial wall of the pedicle (Fig. 2). Recordings of distance were made when the operator believed that the sound emitted suggested abutment against the cortical wall, impending breach, or actual breach. A threaded Steinmann pin was placed through the cannulated probing device to mark the point at which the surgeon felt breaches were made. This resulted in 2 pins per pedicle (Fig. 3).

Breach was confirmed by fine-cut CT scan, with the results interpreted by 3 attending physicians and averaged. For the purposes of our analysis, breach is defined as a pin with more than 25% of its diameter residing outside and medial, inferior, or superior to the pedicle[10] and/or a pin protruding more than 2 mm.[4,8]

Independent analyses of placement of Steinmann pins were performed by 2 fellowship-trained spine surgeons and a neuroradiologist. Analysis of the CT scan included recording the following data for each pin: 1) spinal level, noting laterality, and approach used; 2) whether the pedicle had been breached (yes/no); and 3) the extent of pin protrusion for any breached pedicles (i.e., pin diameter or millimeters). Our definition of breach required the pin to be protruding through the cortex by 2 mm or more than 25% of the pin diameter.

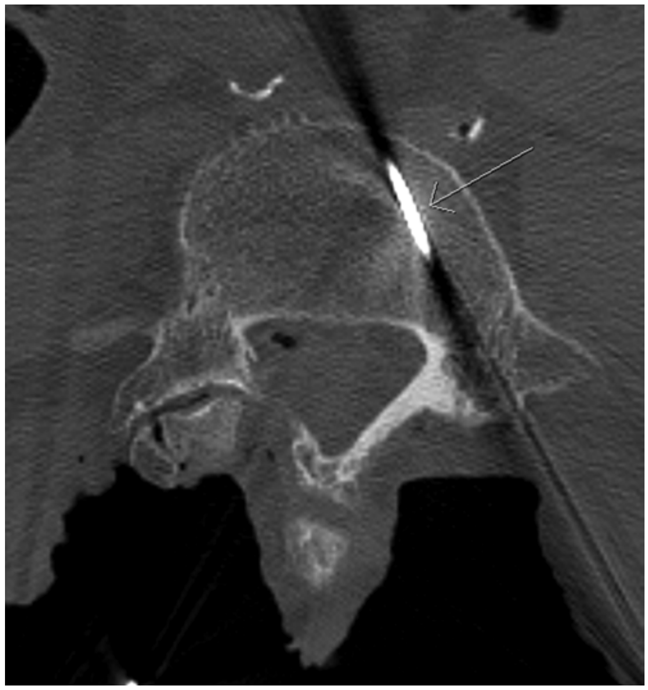

Fig. 1. Axial CT scan of a Steinmann pin placed using the standard direct anterior trajectory.

This interpretation will provide correlative information regarding surgeon interpretation of pedicle-probing alarms to cannulation outcome, specifically in the event of a breach or an impending breach. A total of 80 pedicles were cannulated and met our inclusion criteria, divided between operators at the 3 skill levels described. The specific division of performance of pedicle cannulation approaches follows: spine surgeon, 34 cannulations; resident orthopedic surgeon (PGY2), 24 cannulations; medical student, 22 cannulations.

Results

A true positive in our results analysis included Steinmann pins with impending breach within cortical bone and those that breached 4 mm or less. There were no regular false negatives. However, breaches greater than 4 mm with positive signal were counted as false negatives due to the fact that a breach of more than 4 mm would be unsafe for any patient.

Ninety-eight pedicle tracts were created. Eighteen were used as practice and therefore eliminated, leaving 80 for analysis, as described in *Methods*. The results of the CT analysis are shown in Table 1. The sensitivity of the pedicle probe to detect impending breach or breach of 4 mm or less was 90.06% (Table 2). For the attending spine surgeon, the sensitivity of detecting impending or actual breach was 96%; for the senior-level resident, the sensitivity was 89%; and for the medical student, the sensitivity was 84%. The overall sensitivity in detecting medial wall breach (for all participants) was 95.8%. The positive predictive value (PPV) was 87.1% (Table 2). The device detected medial breach more often than lateral breach.

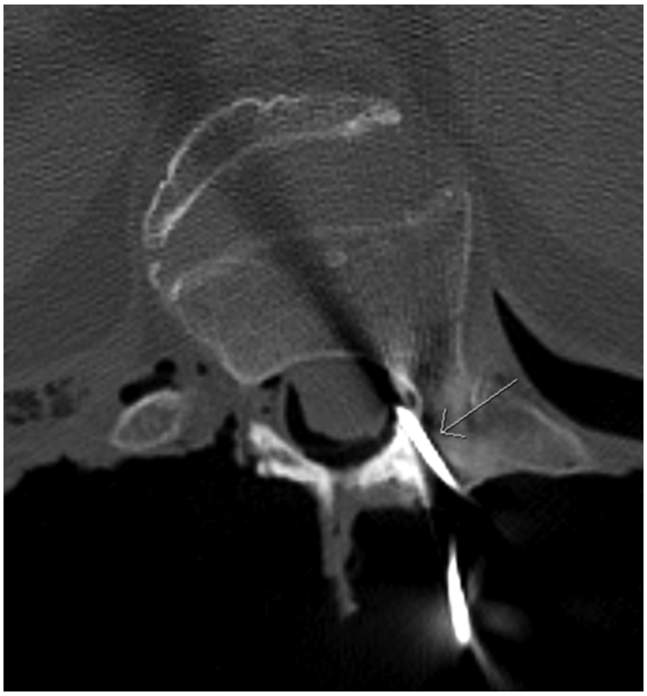

Fig. 2. Axial CT scan of a Steinmann pin placed using the medial trajectory.

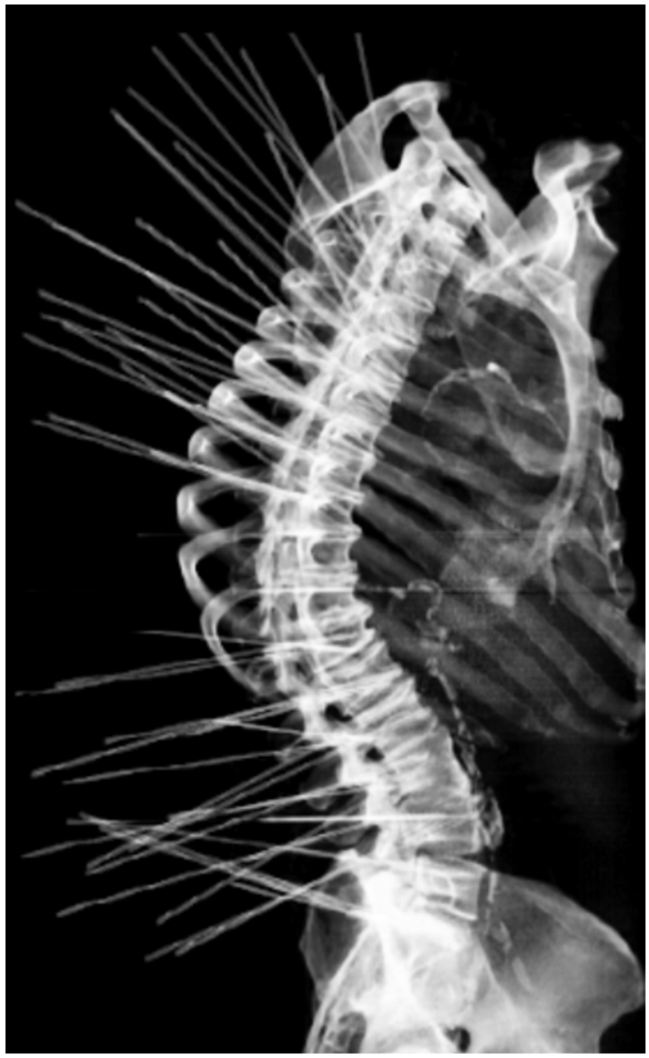

Fig. 3. Ghost 3D CT scan reconstruction of cadaver with all Steinmann pins in place.

Statistical Analysis

For sample size calculation, a hypothesized PPV was set to 0.882. A sample size of 65 was required to detect a statistically significant difference from a PPV of 0.75 with 80% power and a Type I error rate of 0.05 (2-tailed).

Discussion

Few studies have assessed the efficacy of the PediGuard device on cadavers. This is the first study to assess its accuracy with the intention of reaching impending breach and actual breach. In this study, no financial support was used. By using an attending physician, a resident physician, and a medical student, there was decreased bias due to an operator's prior surgical experience.

Our sensitivity of 90.06% is significantly lower than most previously reported studies on this pedicle probe's accuracy. We believe this may be due to the following: 1) The 3 operators had varying surgical experience. 2) All operators had no prior experience with this pedicle probe. 3) Cannulation was performed without any fluoroscopic assistance.

It should be noted that the ability to detect medial wall breach is consistent with previously reported funded studies.

Accuracy With Various Modalities

There are many proven techniques used to insert pedicle screws, including fluoroscopic or radiographic guidance, stereotactic guidance systems based on CT, and direct visualization with the use of a laminotomy to identify key landmarks. Percentages for malpositioned screw placement vary greatly in the literature. With the use of intraoperative imaging, pedicle wall breaches have been reported to range between 3.7% and 38.9%. Using bony landmarks alone, pedicle wall breaches have been reported in the range of 15.9% to 54.7%.[14] Higher accuracy, with perforation rates of between 4.3% and 14.3%, has been achieved using computer-assisted techniques,[7] although Kim et al. found a malposition rate of 6.2% using freehand technique.[6] These percentages vary based on the level of the spine and techniques used, and controversy continues to exist.

In 2012, the *European Spine Journal* published an analysis of all prospective in vivo clinical studies that assessed the results of pedicle screw placement techniques regardless of indication for surgery. Twenty-six prospective clinical studies were eventually included in the analysis. These studies included a total of 1105 patients in whom 6617 screws were inserted. In the studies using freehand technique, the percentage of the screws fully contained in the pedicle ranged from 69% to 94%; with the aid of fluoroscopy, the values ranged from 28% to 85%; using

TABLE 1: Results of CT analysis

Signal & CT Reviewer*	CT Assessment: Breach	No Breach
impending breach or breach signal		
Reviewer 1	63	9
Reviewer 2	64	10
Reviewer 3	64	9
no signal heard at initial breach		
Reviewer 1	8	
Reviewer 2	6	
Reviewer 3	7	

* Reviewers 1, 2, and 3 were the 2 attending orthopedic spine surgeons and 1 attending neuroradiologist who interpreted and analyzed the CT images.

TABLE 2: Sensitivity and PPV for PediGuard detection of impending and actual breach

Measure	Value
sensitivity	
Reviewer 1	88.7%
Reviewer 2	91.4%
Reviewer 3	90.1%
average	90.06%
PPV	
Reviewer 1	87.5%
Reviewer 2	86.4%
Reviewer 3	87.8%
average	87.1%

CT navigation, from 89% to 100%; and using fluoroscopy-based navigation, from 81% to 92%. Higher accuracy is seen with the use of navigation systems.[4]

The accuracy of these modalities also varies. The gold standard for detecting pedicle screw perforation is direct observation for breach. However, in clinical settings this is not possible. Grauer et al. describe 3D fluoroscopy as having a sensitivity and specificity of 70% for detecting pedicle wall violation and conventional CT as having a range of 70%–89% sensitivity and 85%–93% specificity for identifying correct placement of pedicle screws.[5] Lastly, Learch et al. concluded that 63% of screw positions were correctly identified on radiograph as compared with 87% with CT scan.[9]

Grauer et al. introduced a drilling probe called SafePath (Mekanika), which showed superior placement of lumbosacral screws when compared with use of a curette, but more violations in thoracic pedicle screw placement.[5]

Intraoperative Neuromonitoring

To avoid neurological complications and detect perforations, surgeons have incorporated intraoperative neuromonitoring as an integral part of complex spine surgery. The reported neurological deficit rates vary greatly, ranging from 1% to 11%. Previously established threshold data for triggered electromyography and respective compound muscle action potentials, derived from a study of 4857 pedicle screws, are as follows: threshold > 8.0 mA, screw entirely in pedicle; threshold 4–8 mA, potential for pedicle wall defect; threshold < 4.0 mA, strong likelihood for pedicle wall defect and possible contact with nerve or dural tissue.[11]

Pedicle Breach Definition and Dangers: Why Use a 4-mm Cutoff?

While radiographic breaches are often asymptomatic, the possibility of nerve root irritation or neurological deficits makes the avoidance of pedicle screw malplacement of paramount importance. In our study we chose a 4-mm cutoff when measuring a true positive for detection of breach by the device. We chose this primarily because evidence exists arguing that a breach of 4 mm or less is not clinically relevant and because of the possibility of Steinmann pin migration when transporting the cadaver to the CT scanner. Once we believed we had breached or were at impending breach we would lightly tap our Steinmann pin into the pedicle, which could have superficially lengthened our actual value where breach was recorded. We were meticulous in recording cadence changes in millimeters and also meticulous when correlating our data, in millimeters, from when we heard the sound change indicating impending breach to where the tip of the Steinmann pin resided on CT scan (which we also measured in millimeters). We took this into account when calculating true positive values. Every 4-mm measurement with CT scan correlated with a signal of impending breach 3–4 mm prior to a signal change from the PediGuard device indicating impending breach prior to breach and placement of a Steinmann pin. Therefore, the surgeon would have known not to continue. There were times we included Steinmann pins that had breached up to 4 mm in our true positive calculations.

It has been shown that medial pedicle perforation by more than 4 mm may endanger the neural elements. Zeiller et al. defined a high-risk screw as one with medial pedicle wall penetration of greater than 2 mm (n = 3) or anterolateral body penetration of greater than 3 mm.[14] Laine et al. concluded that a breach of 4 mm or less causes no real damage.[8]

Advantages and Disadvantages of This Study

Advantages of this study included the fact that this was a nonfunded study; operators involved were of different levels of training, with almost no prior experience with this device; and no fluoroscopic assistance was used. In addition, this is the first study attempting to either stop at impending breach or just minimally breach, testing the accuracy of the device.

Disadvantages of this study included having a limited number of pedicles and 80 pedicles probed. In addition, there was a chance of K-wire migration during transport of the cadaver to the CT scanner. One spine surgeon measured 8 false negatives and the 2 other physicians measured 9. There were times when cancellous pitch was heard when in fact we had passed cortical bone and had breached. In addition, it seemed the sound became less reliable as time passed.

Lastly, determination of breach and detection of the change in cadence and frequency required subjective interpretation. Nevertheless, the change in pitch was recorded, and it was felt that after completing this experiment immediately after the instructional course on difference in cadence and pitch, the recording was accurate, consistent, and valuable.

Improper Use

We found that applying too much pressure on the T-handle during cannulation altered the frequency of the sound emitted, thereby significantly distorting or limiting the interpretation ability of the surgeon. Also, variation in hand placement during advancement of the cannulated T-handle will alter sound quality.

Conclusions

This was an independent, non–financially supported study that showed that the PediGuard device could reasonably be used to detect impending breach and breach of less than or equal to 4 mm. Medial breach was detected better than lateral breach.

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Disclosure

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper. Dr. Danisa is a consultant for NuVasive and receives royalties from Globus Medical. Dr. Cheng is a member of the Medical Board of Trustees for the Musculoskeletal Transplant Foundation and is on the Educational Committee.

Author contributions to the study and manuscript preparation include the following. Conception and design: Guillen, Cheng. Acquisition of data: Guillen, Knopper, Kroger, Cheng. Analysis and interpretation of data: Guillen, Knopper, Wycliffe, Cheng. Drafting the article: Guillen, Knopper, Cheng. Critically revising the article: all authors. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Danisa. Administrative/technical/material support: Wycliffe, Cheng. Study supervision: Cheng.

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