Introduction

Pedicle screw fixation has been shown to be superior to other methods of instrumentation of the spine for spinal fusion and correction of spine deformity. In a meta-analysis of the literature by Yahiro of 5,756 patients reported in 101 articles, the success of fusions with pedicle screws was 94.8%, attesting to the clinical usefulness of this technique.

Pedicle screw fixation is not without complications, one of which is pedicle perforation, with rates ranging as high as 40%. Perforations can further lead to complications such as dural tear, nerve root injuries, paraplegia, or vascular injury.

Much of the variation in the literature depends on the method used to determine the perforation. 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. 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. Screw perforations 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 perforation postoperatively. However, the number of malpositioned screws are underestimated. In an article by Learch, et al. using cadaver specimens of the lumbar spine, only 63% of the screw positions were correctly identified on radiograph as compared to 87% with CT scan.

The reported perforation rates are higher in the thoracic spine. Belmont, et al. reported a perforation rate of 43% in the thoracic spine determined by CT scan. Fourteen percent of the 279 screws studied had penetrated medially into the spinal canal, and 29% were malpositioned through the lateral vertebral body cortex.

The rates are highest (approaching 40%) when a spine deformity such as scoliosis is present. In a study by Belmont, et al. in 2002 subsequent to the series they reported in 2001, the rate of screw perforation was 27% when there was no coronal deformity and 41% when there was a coronal deformity. Liljenqvist, et al. reported 8.3% medial penetration in a series of 120 thoracic pedicle screws in patients with idiopathic scoliosis as determined by postoperative CT scans. In this same series, 14.2% were lateral to the vertebral body, and one screw needed to be removed because of impingement of the aorta.
Perforations less than 2 mm on CT scan are thought not to be associated with clinical sequelae, and other authors report no problems with perforations as large as 4 mm. Gertzbein and Robbins reported an incidence of medial cortical penetration up to 8 mm with two minor neurological injuries. They hypothesize a 4-mm safe zone, which includes 2 mm of epidural space and 2 mm of subarachnoid space. Belmont, et al. considered screw penetration of the medial pedicle wall less than or equal to 2 mm to be acceptable.

When inserting screws in the pedicle, surgeons rely on various methods to ensure accurate placement. The gold standard is mechanical probing, often with or without fluoroscopy. The “freehand technique” is based on 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 to imaging techniques.

A fluoroscopic technique may provide more consistent results but carries some risks associated with radiation dose, especially to young patients and to the surgeon. Weinstein, et al. 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 definitive endpoint. Of the screws demonstrating perforations, 92% were medial, potentially injuring the spinal cord or a nerve root.

Three dimensional image-guided surgery (IGS) can result in better screw accuracy. In a randomized study, Laine, et al. 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 high cost as well as the added length of surgery and the time needed to reregister the system for each vertebral level being instrumented.

Surgeons have also used various electrophysiological monitoring techniques such as EMG and somatosensory evoked potentials (SEP) for assessing nerve root function and pedicle screw placement. Clements, et al. report thresholds above 10 mA as being associated with no postoperative nerve root radiculopathies. However, these techniques have major limitations. First, the use of a muscle relaxant (anesthesia) limits neuromuscular reaction. When a nerve is compressed, its stimulation threshold can be higher than normal, leading to a false-negative finding. Asghar, et al. recently suggested that thoracic screw stimulation, even with needle electrodes, is unreliable. In a study of 742 thoracic screws, 41 (6%) had a medial breach greater than 2 mm confirmed by CT scan. Only 18% of the medial breaches triggered an EMG threshold of less than 6 mA. The remainder of the medial breaches (61%) triggered at greater than 6 mA and, of those, 21% triggered at greater than 10 mA.

Despite all of the above mentioned techniques, there is still a need for an efficient, simple, and cost effective device which will help the surgeon to more safely drill a pilot hole for placement of a pedicle screw.

**Methodology**
PediGuard™ is a wireless electronic handheld pedicle screw pilot hole preparation instrument designed to continuously monitor the electrical conductivity of the tissue at its tip throughout the drilling process. It provides audible and visual feedback in response to local tissue conductivity changes. This feedback allows to discriminate between different types of tissue in contact with the tip detecting possible vertebral cortex perforations. PediGuard™ has received FDA 510(K) clearance for commercial distribution in the US.

PediGuard™ features bipolar electrodes that avoid any shunting effect and keep the measured electrical conductivity independent of the insertion depth. When in the same medium, the electrical conductivity remains constant while the instrument is advanced into the vertebral pedicle. Variation occurs when the instrument passes through a boundary between two different media, for example, bone vs. blood. As shown in Fig. 1, PediGuard™ consists of an awl instrument with a hollow handle that accepts a built-in electronic printed circuit board. The electronic components allow performing measurements, with translation to audible signal and colored LEDs (Light Emitting Diodes) to be used as feedback to the surgeon.

**Surgical Techniques using PediGuard™**

**Determination of the size and style of the probe.**
First, the surgeon determines in which area of the spine the pedicles will be drilled. In the lower lumbar spine, generally a 4.0-mm diameter tip would be most advantageous. If one needs to go to L1 and L2 and, on radiograph, the pedicles look extremely small, one may wish to use 3.2-mm tip. If one is instrumenting most of the thoracic spine, the 3.2-mm or the 2.5-mm probe will be most advantageous.

There are two different styles of tip. The four-edge probe is much duller and is best used where there is soft cancellous bone within the pedicle. This would in most cases occur with degenerative spine in older patients. Where the cancellous bone is harder, it is recommended that one use the tri tip. Because the tri tip provides better control...
without having to push, it is widely preferred by surgeons.

The PediGuard™ is used in an anticipatory function during drilling of the vertebral pedicle. Due to 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 slow, then one is probably near or up against cortical bone. One can then gently rotate 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. 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 one 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.

In difficult pedicle screw placements, this anticipatory function can also be used for placing a drill hole going from the outside in, especially in the thoracic spine. In this scenario, one may wish to slide down the lateral side of the transverse process and upper lateral wall of the pedicle. One can then assure that cortical bone has been reached by the slow rate and low pitched sound. Then, one can drill through the lateral cortex of the pedicle and enter the cancellous bone of the pedicle and then on to the vertebral body, assuring that the tip is contained within bone.

If one does perforate outside of the pedicle wall, either medially or laterally, the device will detect this with a high rate, high pitched sound. This is the clear advantage of the PediGuard™; this would probably not be able to be determined with a standard probe. When this happens, the PediGuard™ device should be removed. One can still use bone wax or FloSeal or any other anticoagulant to try to decrease the bleeding out of the pedicle hole. One should then take a ball tip probe and palpate the walls of the pedicle to confirm the location of the breach. Sometimes, palpat ing the breach may be difficult, as the PediGuard™ is so accurate that only the very tip of the probe may perforate into the soft tissue before a large hole is made. Either way, if one can determine the location of the breach, one can redirect the PediGuard™ and create a new pedicle drill hole. One just reinserts the PediGuard™ device and puts it up firmly against cancellous bone and then begins drilling again. If the breach location is known (medial, lateral, superior, inferior), the surgeon can direct away from that. Otherwise, he or she should just continue to listen to the sound carefully and advance as appropriate. There are times when the surgeon cannot advance past the medial and lateral wall without perforation due to the starting hole entry point. It may be necessary on occasion to move the starting hole more laterally, even to the point of an outside-in technique, in order to pass through the pedicle morphology at that level.

Results

Results of Human Trials

Clinical studies have demonstrated the safety and efficacy of the PediGuard™ device. Bolger et al. reported a clinical study of 28 patients with 147 screws to determine cortical perforations detected by 1) the PediGuard™ alone; 2) the physician; and 3) both the PediGuard™ and the physician. A wide variety of instruments was used to check whether perforations had occurred. A total of 23 (16%) vertebral cortex perforations out of the 147 manual pedicle drillings were confirmed. Of these 23 perforations, 22 (95.7%) were detected by the PediGuard™ during the procedure. The one false negative (4.3%) occurred in a patient with leg
twitches while using the device, but only the audible and visual warnings were recorded in the study. One additional patient (1/147, or 0.6%) had a false positive, where there was a beep but no perforation confirmed. The PediGuard™ detects very small breaches which may be smaller than the ball tip feeler used to confirm a breach. A total of 12 vertebral cortex perforations (52.2%) were detected by the PediGuard™ but not by the physician. Five of the 28 patients had a CT postoperatively. When using this more definitive method of assessment, PediGuard™ had correctly identified all of the CT scan-confirmed pedicle screw breaches.

During the second phase of this study, Bolger et al. reported on an additional 374 pedicle drillings performed on 69 patients. Postoperative CT imaging showed 41 confirmed breaches (41/374, or 11%). The PediGuard™ had correctly detected 100% of the breaches. Pearson’s correlation coefficient was 374.000 (P < 0.001). There were three false positives where there was an increase in the frequency of the beats; however, no break was detected in the pedicle cortex on postoperative CT scan. This so-called false positive can occur, as only the tip of the PediGuard™ goes through the cortex and a true hole is not made. The PediGuard™ drill hole can be redirected such that the final position of the screw on CT scan is then in a correct position. There were no false negatives.

At the Belgian Society of Neurosurgery in 2006, Lubansu et al. reported on a series of 40 patients with spondylolisthesis in 7, fractures in 7, and degenerative lesions in 26. They studied 188 pedicle screws inserted using the hand-held PediGuard™ device. All patients were analyzed postoperatively by CT scan. Five screws out of 188 (2.7%) were shown to be misplaced. The authors concluded that the PediGuard™ improved their screw placement accuracy to a “good position rate” of 97.3%.

In 2006, Bocquet reported on a series of 104 screws placed in 15 patients from T12 to S1. All patients had a postoperative CT scan, the results of which were interpreted by a radiologist. Bocquet reported that 98 of the 104 screws (94.2%) were well placed. He cites in his paper that with previous techniques analyzed by the same CT scan controlled studies, his misplaced screw rate was approximately 20%.

US Clinical Trial

In 2006, a study group was assembled to investigate the effectiveness of the PediGuard™ device for placement of the pedicle screw pilot drill hole, reducing pedicle screw breaches during thoracic and lumbar pedicle screw fixation of the spine.

The first hypothesis is that the PediGuard™ would be more accurate for pedicle screw placement as compared to other standard manual techniques of pedicle screw insertion. It is felt that at least 90% of the screws placed with PediGuard™ would be positioned correctly (< 2 mm of breach by CT scan), in contrast to only 80% of screws using manual placement. The second hypothesis is that the PediGuard™ will not be inferior to fluoroscopic techniques for pedicle screw insertion. Both techniques will achieve a 90% accuracy in the placement of screws; however, the radiation dose will be less in the PediGuard™ group.

The study design includes a randomized process of pedicle screw insertion in which the surgeon alternates between the pedicle drill hole being placed using PediGuard™ versus his or her other standard technique, either manual or fluoroscopic. The randomization occurs with the first hole drilled. Then, the insertion technique (PediGuard™ versus surgeon’s standard technique) alternates with each additional screw going left to right and proximal. Once the pedicle drill hole is placed, all other aspects of the pedicle screw insertion, including tapping, screw insertion, and electrical stimulation, are the same for both techniques. As part of standard of care, a postoperative CT scan is performed on every patient. The CT scans are reviewed by a team of five surgeons very familiar with pedicle screw insertion.

Study of CT analysis. Because of the wide variability when reading CT scans for millimeters of breach, a pilot study was performed to determine the accuracy of this CT assessment. In this study, four experienced spine surgeons read postoperative CT scans of 4 patients with degenerative disease and titanium screws placed at T12 and below. Measurements of three surgeons were compared to the fourth surgeon, who was considered the ‘control.’ Of the 118 measurements, 43 (36.4%) were found to deviate by greater than or equal to 1 mm. The average deviation from control was 0.417 ± 1.52 (range, -3 to +5), indicating a very large bias in the measurements (Figure 2). Based on this preliminary study, a consensus meeting of 5 surgeons was called to read all the postoperative CT scans to derive a millimeter of breach and also a direction (medial, lateral, superior, inferior, anterior). Utilizing this consensus data, a group of 7 patients had titanium screws between T12 and S1 for degenerative surgical procedures, with 52 screws placed by a manual technique and 60 with
Figure 2. Measurements of millimeters of breach by 3 surgeons showing amount of deviation when compared to a fourth surgeon (control).

the current PediGuard™. With the manual technique, 79% of screws were within 2 mm and 21% of pedicle screw breaches were out by greater than 2 mm. Using the PediGuard™, there was a trend toward significant improvement, with 86.7% being within 2 mm and 13.3% being out greater than 2 mm. This 8% improvement with PediGuard™ appears to be a significant clinical trend (Table 1).

An analysis of the direction of the breach shows a very significant reduction in medial breaches (Table 1). With the standard manual technique, 6 of 62 screws (9.5%) were out medially versus only 1 of 60 screws (1.5%) with the PediGuard™. Lateral and anterior breaches were similar. This finding of a six-fold reduction in medial breaches becomes more significant when considering that all screws in this study were tested with EMG monitoring and recorded above 10 mA.

A power analysis suggests that we need approximately 320 screws in each group to determine statistical significance. Continuation of this study is underway.

A study by Ul Haque, Shufflebarger et al. on radiation exposure with all screw constructs in adolescent idiopathic scoliosis showed that a nonclassified radiation worker (i.e. the surgeon) inserting approximately 2,800 screws under fluoroscopic guidance received in one year the ten-year equivalent of allowable radiation for a nonclassified worker.

<table>
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<tr>
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<th>PediGuard™ (N=60)</th>
<th>Manual (N=62)</th>
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<tbody>
<tr>
<td>Anterior</td>
<td>3 (5%)</td>
<td>4 (6.5%)</td>
</tr>
<tr>
<td>Lateral</td>
<td>3 (5%)</td>
<td>3 (5%)</td>
</tr>
<tr>
<td>Medial</td>
<td>1 (1.5%)</td>
<td>6 (9.5%)</td>
</tr>
<tr>
<td>Superior</td>
<td>1 (1.5%)</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>8 (13%)</td>
<td>13 (21%)</td>
</tr>
</tbody>
</table>

Table 1. Breaches T12 to S1, Titanium Screws, Degenerative Cases.

In the US clinical trial of PediGuard™, we analyzed deformity cases with titanium screws between T11 and S1 and compared screws inserted following drilling with fluoroscopic drilling alone versus PediGuard™. CT assessment of screws demonstrated breaches greater than 2 mm to be equal in both groups (Table 2).

<table>
<thead>
<tr>
<th></th>
<th>In</th>
<th>Out &gt; 2 mm</th>
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<tbody>
<tr>
<td>PediGuard™</td>
<td>81.4</td>
<td>18.5</td>
</tr>
<tr>
<td>Fluoroscopy</td>
<td>80.7</td>
<td>19.2</td>
</tr>
</tbody>
</table>

Table 2. Percentage of Breaches: Deformity Cases T11-S1, Titanium.
Table 3. Average Time per Screw and Radiation Exposure.

<table>
<thead>
<tr>
<th></th>
<th>PediGuard™</th>
<th>Fluoroscopy</th>
<th>Reduction obtained with PediGuard™</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average Time per Screw (seconds)</td>
<td>211</td>
<td>229</td>
<td>-8%</td>
</tr>
<tr>
<td>Average Number of Fluoro Shots (Radiation Exposure)</td>
<td>3.2</td>
<td>4.5</td>
<td>-29%</td>
</tr>
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This data is encouraging because while the perforation rate greater than 2 mm is equal by both techniques, the average time per screw is reduced by approximately 10%, and the average radiation exposure is reduced by approximately 30% with PediGuard™ (Table 3).

One cannot compare the breach rates between the cohorts used for the PediGuard™ vs manual and the fluoro vs the PediGuard™ groups. These were different patients.

Conclusions

1. Screw perforation rate continues to be a significant problem for surgeons in both the thoracic and lumbar spine. In the lumbar spine (both deformed and not deformed), approximately 20% of screw holes show greater than 2 mm of breach based on CT scan analysis using standard insertion techniques.

2. Preliminary analysis of patients having had surgery for degenerative conditions with titanium screws between T12 and S1 shows a significant clinical trend in reduction of breach (by 8%) using the PediGuard™ device and a six-fold reduction in medial breaches as compared to the freehand technique.

3. In patients with deformity having titanium screws in the lumbar spine, performance between PediGuard™ and a fluoroscopic technique for creating a drill hole for pedicle screw insertion appears to be equal. However, data suggest that the average time per screw is reduced by approximately 10% and also the number of fluoro shots per screw are significantly reduced with the PediGuard™, reducing the average radiation exposure by approximately 30%.

References


* Rx Only! See package insert for labeling limitations, intended uses, relevant warnings, precautions, side effects and contraindications.