PediGuard – A New Standard of Care in Pedicle Screw Placement

a report by
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Introduction

Since being first introduced in the late 1950s by Roy Camille, pedicle screw fixation has been a widely used technique for the stabilisation of the spine with conditions such as trauma and deformity and for the degenerative spine. Due to the inability to visualise the pedicle during pedicle drilling and actual screw placement, one of the main problems facing the surgeon is perforation of the vertebral wall. Such a perforation can lead to potential problems such as dysesthesia, paraparesis or paraplegia.

Techniques such as mechanical probing, electromyography (EMG), somatosensory evoked potentials (SSEPs), spinal cord monitoring and image guidance have aided in both the optimal placement of pedicle screws and avoidance of potential complications. However, these techniques have drawbacks in so far as probing is inconsistent and dependant on the individual surgeon and the use of EMG, SSEP and spinal cord monitoring are complex, requiring extra trained personnel for the duration of the surgery.

Post-operative solutions for the detection of accurate pedicle screw placement, including computerised tomography (CT) scanning, fluoroscopy and X-ray, along with feedback from the patients with regards to radicular pain, are all performed after the screw placement and will therefore not avoid permanent neurological deficits. Image guidance is expensive and requires training with a vast learning curve; however, it has become the gold standard in relation to pedicle screw surgery.

Image-guided Navigation

The use of image guidance for the placement of pedicle screws has been very beneficial for surgeons. Pre-operative CT scanning is loaded onto the system and a three-dimensional (3-D) image is generated, specific to the individual patient. Pre-operative planning allows the surgeon to measure all dimensions of the pedicle and choose the best trajectory for optimal placement of the screw avoiding both vital structures and breaches of the vertebral wall. This is particularly beneficial in patients with complex spine conditions and deformity. With the reconstructed 3-D model of the patient, the surgeon is able to define the individual anatomy and be confident with both the screw trajectory and placement.

The computer matches the pre-operative scans by a process of registration. Registration is necessary to orientate both the 3-D generated model and the pre-operative CT scans. This is achieved by clamping a registration arc onto one of the exposed spinous process, which through light-emitting diodes (LEDs) communicate back to the system. Registration points are then selected around this arc and, once established, registration is maintained by tracking the patient with the use of intra-red sensors.

Image guidance also has drawbacks. The system is expensive and user training is required. Pre-operative CT scanning is needed and time is required for loading the examination and for the pre-operative trajectory planning by the surgeon. In order to achieve the best advantage from the system there is a rather extensive learning curve, which can lead to over-reliance on the technology for the completion of the surgery. Over and above this, the registration is more accurate over a small area of the spine; if performing a multi-level procedure, re-registration may be required to avoid losing accuracy.

The other major drawback in the use of image guidance navigation is that it is only specific to certain spinal conditions, where there is a stable area of the spine for registration purposes. In conditions such as spondylolisthesis, a stress fracture of the *pars interarticularis* causes detachment of the stabilising elements posterior to the motion segment. This in turn causes a biomechanical misbalance resulting in a sheering and eventual failure of the annulus, which results in displacement of the vertebral body. Due to this occurrence, there is no stable anatomy to which the reference arc can be attached for accurate registration. Image guidance therefore cannot be used accurately in such conditions.

Electrical Impedance in Spine Surgery

In biological tissues, electrical impedance depends on tissue structure and blood content. The basic idea is that by assessing electrical impedance one could discriminate cortical bone from cancellous bone and both from soft tissue.

Electrical impedance (the opposite to electrical conductivity) measurements have previously been used in spine surgery, but have been met with criticism for the effective detection of vertebral breaches. One such criticism is the use of a standard instrument for the initial pilot hole prior to the use of the impedance probe. However, the pilot hole is often filled with blood and there is therefore no way to ascertain whether there is a vertebral breach from the impedance monitoring probe. Another criticism of impedance measuring in spinal surgery includes the use of monopolar probes. The active and return electrodes are some distance apart and considering that current will flow in the path of least resistance, which may be out of the pedicle hole, there is no reliable method to determine whether a breach has occurred.

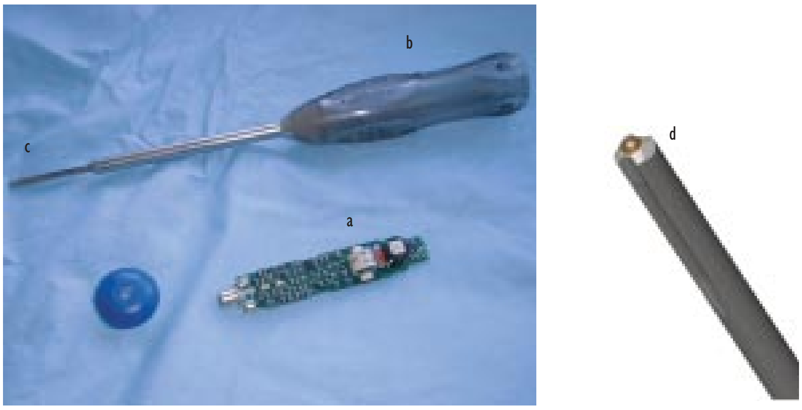
Electrical Conductivity Measuring Device

Taking into consideration these limitations and criticism of impedance measurement in spinal surgery, an electrical conductivity measuring device (PediGuard™, SpineVision, France) was designed as a freehand drilling bipolar instrument that measures electrical conductivity at the tip with four major advantages over other methods.

Firstly (and crucially) the PediGuard drills the first pilot hole. Secondly, the measurement is translated into a visible and an audio signal updated five times per second, to inform the surgeon in realtime when a change occurs at the tip. Thirdly, the PediGuard is less expensive when compared with the technology already in use. Finally, the PediGuard has a very short learning curve as the device acts like instruments already in use for pedicle screw surgery.

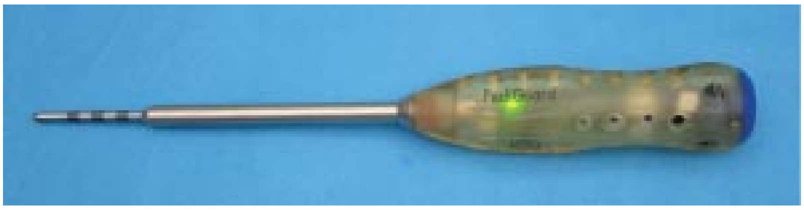
A feature of the device includes bipolar electrodes that avoid any shunting effects and keep the measured electrical conductivity independent of the insertion depth. In the same medium the electrical conductivity remains constant while the instrument is advanced into the vertebral pedicle and variation occurs when the instrument passes through the boundary between two difference media. Considering that electrical conductivity varies significantly just prior to a breach, the device is able to detect iatrogenic breach in the vertebral pedicle wall prior to an actual breach, therefore allowing the surgeon to redirect through the pedicle, preventing an actual breach from occurring.

Figure 1a: PediGuard Dissembled



The disposable circuit board (a) is placed into the hollow handle (b). The tip (c) is a standard drilling tool for pedicle preparation with the electromagnetic field sensor at the tip (d)

Figure 1b: Assembled PediGuard with the LED Activated



The device itself consists of a standard awl instrument with a hollow handle that accepts the built-in electronic printed circuit board (see *Figure 1a*) and the electromagnetic field sensor at the tip of the awl. Depending on surgeon's preference, the awl is available as either a reusable or disposable instrument. The circuit board is single-use only with a new board used for each patient. If using the disposable awl the circuit board is already assembled within the instrument.

Once assembled (see *Figure 1b*), the electronic components allow performing impedance measurement and translation to audible signal and coloured LEDs to be used as feedback to the surgeon. In addition to this, the device also features a neurostimulator that provides a constant voltage and a limited current at a fixed frequency, which can be used in conjunction with a standard EMG.

Animal Studies

Using standard operating techniques, 168 pedicle drillings were performed on 11 young porcine lumbar and thoracic spines whilst under general anaesthetic. All drillings were performed by a qualified veterinarian trained in the use of the PediGuard. Records were taken from both the veterinarian and the device.

Following pedicle drilling and pedicle screw placement the pigs were sacrificed and the pedicles

Table 1: Statistical Analysis of the Device

	Animal Studies	Clinical Studies
Positive Predictive Value (PPV)	100%	94%
Negative Predictive Value (NPV)	96%	99.8%
Specificity	100%	99%
Sensitivity	97%	98%

were anatomically assessed for signs of breaches. These breaches were compared with the recordings taken during pedicle preparation and screw placement.

Using this protocol, there were 93 breaches detected on autopsy. The device correctly detected 90 (96%) of these breaches compared with 56 (60%) detected by the veterinarian. There were no pedicle breaches detected by the veterinarian and not by the device ($p<0.001$).

There were no breaches indicated by the device that were not identified on autopsy, but there were breaches that were undetected by the device. Negative predictive value (NPV) (the probability of no breach if no detection occurs) was 96%, with a positive predictive value (PPV) (the probability of breach if detection occurred) of 100% ($p<0.001$). Combining these results yields 97% sensitivity of the device with a specificity of 100% (see *Table 1*).

However, two breaches that led to minor effraction of the inter-vertebral discs, which went undetected by the auditory alert of the device, were detected on visual muscle contraction.

Clinical Studies

Eleven European senior surgeons were given an electrical conductivity measuring device (PediGuard, SpineVision) to be used in conjunction with their normal methods of pedicle preparation. Data were collected two-fold. The comparison was initially made between the PediGuard ability to detect a breach and the surgeon's own detection of a breach, as measured by independent post-operative CT scanning. However, since the surgeons were not blinded to the information from the instrument, a second set of data were collected looking at the accuracy of the device in detecting a breach in isolation. A total of 521 pedicle perforations were carried out on 97 patients.

Outcome Measures

A comparison was made between the PediGuard and the other detection possibilities (surgeon's tactile feeling, mechanical probing, fluoroscopy, CT scans, EMG, SSEP and surgical navigation – depending on their availability peri- and/or post-operatively). Thus, the detections of vertebral cortex fractures indicated by the measurement of electrical conductivity and by any other available possibility were registered and compared.

Results

Of 521 pedicle drillings 64 breaches were confirmed (12.3%). The PediGuard detected 63 (98.4%) of these breaches ($p<0.001$). There was one false-negative result, where the device did not alert to a breach occurring and four false-positives, where the device alerted to a breach but the breach could not be confirmed. On the first group of patients (N=28) it was registered whether the surgeon had detected the breach per-operatively by himself/herself. In 52% of cases, the PediGuard detected a breach that had not been detected by the surgeon. Overall, the PPV is 94% with a NPV of 99.8%. Combining these results yields a sensitivity of 98% and a specificity of 99% (see *Table 1*).

Conclusions

As these studies have shown, this electrical conductivity measurement device has a sensitivity of more than 98% and specificity of more than 99% in the detection of breaches. Over and above this, the PediGuard detected between 36% to 52% more breaches than the actual surgeon performing the surgeries.

The PediGuard is a hand-held wireless tool that is used not only as a navigational device but also as a perforation tool. The tool is therefore giving realtime feedback to the surgeon, without the surgeon having to change instruments and retaining momentum during pedicle preparation. As the device is integrated with the standard drilling tools used for pedicle screw surgery, the learning curve is minimal.

There is no need for pre-operative CT scanning or pre-operative planning, which is time-saving for the surgical team. Reducing the required amount of X-ray exposure is both beneficial to the patient and theatre staff.

Due to the fact that this tool does not require computer registration or vertebral tracking, it can be used in all aspects of spinal fixation, inclusive of fractures and spondylolisthesis cases, regardless of the degree of pars fracture and dislocation. The PediGuard can be used on the whole spine, including in thoracic pedicles.

PediGuard has become a standard of care (SOC) when the author has performed pedicle screw fixation and it has been used successfully on 10s of patients. This technology opens up new possibilities for spine surgery. ■