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**Department of Health and Ageing**



Australia and New Zealand Horizon Scanning Network

**ANZHSN**

AN INITIATIVE OF THE NATIONAL, STATE AND  
TERRITORY GOVERNMENTS OF AUSTRALIA  
AND THE GOVERNMENT OF NEW ZEALAND

# **Horizon scanning technology Prioritising summary**

## **PediGuard® pedicle screw placement**

**August 2008**



**ASERNIP/S**

**Australian  
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Register  
of New  
Interventional  
Procedures -  
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Enquiries about the content of the report should be directed to:

HealthPACT Secretariat  
Department of Health and Ageing  
MDP 106  
GPO Box 9848  
Canberra ACT 2606  
AUSTRALIA

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This Horizon scanning prioritising summary was prepared by Mr. Irving Lee from the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical.

# PRIORITISING SUMMARY

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**REGISTER ID** S000079

**NAME OF TECHNOLOGY** PEDI GUARD®

**PURPOSE AND TARGET GROUP** PATIENTS UNDERGOING SPINAL FUSION WITH PEDICLE SCREW INSTRUMENTATION

## STAGE OF DEVELOPMENT (IN AUSTRALIA)

- |   |   |
|---|---|
| <input checked="" type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established  |
| <input type="checkbox"/> Experimental             | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational          | <input type="checkbox"/> Should be taken out of use   |
| <input type="checkbox"/> Nearly established       |   |

## AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- Yes  
 No  
 Not applicable

## INTERNATIONAL UTILISATION

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
United States		✓	

## IMPACT SUMMARY

SpineVision® (Paris, France) developed PediGuard® with the aim of ensuring accurate pedicle screw placement during spinal fusion procedures. The technology is currently not available in Australia, but is expected to be adopted rapidly if proven effective. It is the first device of its kind approved by the United States Food and Drug Administration for real-time detection of pedicle screw misplacement or perforation.

## BACKGROUND

Spinal fusion is a commonly performed surgical procedure for a variety of indications, ranging from pain due to movement of a painful vertebrae/facet joints to spinal deformation (scoliosis etc.). Pedicle screws are commonly utilised as a means of instrumentation for spinal fusion. Meta-analysis of published literature has shown that the success of spine fusion with the use of pedicle screws is 94.8% (Yahiro 1994), and it is,

therefore, widely practised for single- and multi-level spinal fusion. However, spinal fusion with pedicle screws is not without complications. The incidence of pedicle misplacement ranges from 10% to 55% (Davane and Myers 1992, Esses et al 1993, Vaccaro et al 1995). Screw misplacements that result in perforation or breach of the pedicle can contribute to failed spinal fusion and cause various complications<sup>1</sup>, such as dural tear, nerve root and vascular injuries and paraplegia (Yalçın et al 1995; Donovan et al 1996; Papin et al 1999; Suk et al 2001; An and Jenis 2005).

At the time of writing, the gold standard method of ensuring accurate pedicle screw placement is mechanical probing, with or without fluoroscopy. However, this ‘freehand technique’, which requires intimate knowledge of spinal anatomy, is less accurate than imaging techniques for placing pedicle screws (Laine et al 1997). Fluoroscopically guided techniques achieve more consistent results, but they expose the patient and surgeon to radiation. Although advanced three-dimensional image-guided techniques have demonstrated commendable results, they are associated with high costs and increased surgical time (Betz et al 2007).

The PediGuard® (SpineVision®, Paris, France) is a wireless electronic hand-held drill that prepares pilot holes for pedicle screw placement (Betz et al 2007). The tip of the device continually monitors the electrical conductivity of tissue throughout the drilling process using bipolar electrodes that maintain constant electrical conductivity when in the same medium. Variation in conductivity occurs when the tip passes through a boundary between two different media, such as blood and bone (Betz et al 2007). As the device penetrates the vertebra it provides audio and visual feedback, which enables the surgeon to discriminate between the different types of tissue in contact with the tip and thereby detect possible vertebral cortex perforations.

#### **CLINICAL NEED AND BURDEN OF DISEASE**

From 2004 to 2005, the National Hospital Morbidity Database reported that a total of 6202 spinal fusion procedures and 5876 internal spine fixation procedures were performed in Australia. Spinal fusion alone accounted for approximately 40% of spine procedures from 2004 to 2005 (Australian Institute of Health and Welfare 2008).

Perforation rates for pedicle screws vary considerably depending on the location (e.g. lumbar or thoracic), the technique used for screw placement and the method used to identify screw perforations. Postoperative computed tomography (CT) scans tend to identify a higher rate of perforation relative to radiographs (Laine et al 1997). In fact, plain radiographs have been shown to underestimate the number of malpositioned pedicle screws (Learch et al 2004). The rate of pedicle screw misplacement ranges from 10% to 55% (Davane and Myers 1992, Esses et al 1993, Vaccaro et al 1995), while pedicle perforation has been shown to occur in up to 40% of cases and is particularly common when spinal deformities, such as scoliosis, are present (Belmont et al 2002).

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<sup>1</sup> Research indicates that perforations of less than 2mm are unlikely to be associated with clinical complications; however some studies have reported no complications with perforations as large as 4mm (Schulze et al. 1998, Laine et al. 1997).

## **DIFFUSION**

The PediGuard was approved (510k) by the Food and Drug Administration (FDA) in February 2005 for commercial distribution in the United States. It was the first device cleared by the FDA for real-time detection of vertebral pedicle breach (MTB Europe 2005). By mid 2007, SpineVision reported that 250 surgeons had been trained to use the PediGuard (Sofinnova 2007).

Since PediGuard is the first device of its kind, it is likely to diffuse at a relatively fast pace if it is proven to be useful and more effective in preventing pedicle screw misplacement or perforation relative to existing techniques.

## **COMPARATORS**

Surgeons utilise various methods to ensure accurate placement of pedicle screws.

- Freehand technique
- Fluoroscopy
- Three-dimensional imaging techniques (e.g. computed tomography)
- Electrophysiological monitoring techniques (e.g. electromyography recording, somatosensory evoked potentials, compound muscle action potentials)

## **SAFETY AND EFFECTIVENESS ISSUES**

Two main articles were identified: a white paper published by SpineVision (Betz et al 2007) and a multicentre comparative study (Bolger et al 2007). Betz et al (2007) summarised the results presented at two annual meetings (Belgian Society of Neurosurgery and EuroSpine), as well as the results of an ongoing randomised controlled trial in the United States. The meeting abstracts contained within Betz et al (2007) were not included in this summary because of their lack of detail.

The randomised controlled trial compared the effectiveness of PediGuard (60 screws) and a control technique (62 screws) in 7 patients with the surgeon's standard manual or fluoroscopic procedure for identifying screw misplacement or perforations. Postoperative CT scans revealed that 79% of screws were placed correctly, i.e. a breach of less than 2 mm, and 21% of pedicle screw perforations exceeded 2 mm when the manual technique was utilised. In comparison, 86.7% of screws inserted with PediGuard aid were within 2 mm, while the remaining 13.3% had a breach greater than 2 mm (Table 1). The authors claimed that the 8% improvement achieved with PediGuard represented a significant trend, and that an analysis of perforation direction indicated a significant reduction in medial perforations with the use of PediGuard (Table 1). However, these results were not analysed statistically.

**Table 1: Direction of pedicle screw perforations for PediGuard and manual technique (perforations from the thoracic (T12) to sacral (S1) vertebrae degenerative cases; titanium screws) (Betz et al 2007)**

	<b>PediGuard (n=60)</b>	<b>Manual (n=62)</b>
Anterior	3 (5%)	4 (6.5%)
Lateral	3 (5%)	3 (5%)
Medial	1 (1.5%)	6 (9.5%)
Superior	1 (1.5%)	0 (0%)
Total	8 (13%)	13 (21%)

When PediGuard was compared to fluoroscopic-guided drilling in patients with deformity, CT assessment revealed that the number of perforations of greater than 2 mm was similar between both groups. However, the use of PediGuard required less time per screw (8% reduction: 229 seconds versus 211 seconds) and fewer radiation shots (29% reduction: 4.5 versus 3.2), compared to fluoroscopic-guided drilling (Betz et al 2007). It should be noted that for this randomised trial, the results were not statistically analysed and hence no details were provided on the statistical test conducted. The authors disclosed that approximately 320 screws are needed to determine statistical significance (Betz et al 2007). Therefore, any claimed “significant” reduction noted in this article should be taken in view of the fact that the power of the study is substantially limited at this point in time.

The multicentre clinical trial by Bolger et al (2007) compared PediGuard’s ability to detect perforations with the surgeon’s traditional method of pedicle preparation. No details were provided on the “traditional” method utilised by the 11 surgeons in the study. Data were collected in two stages: surgeons used the PediGuard as a pedicle awl but were asked to rely on their traditional methods to detect perforations. The output from PediGuard was noted at each drilling procedure and postoperative CT imaging was used to determine if a perforation had occurred. In the first arm<sup>2</sup> of this study, 147 pedicle screws were inserted and 23 (16%) perforations were noted during postoperative CT scanning. PediGuard successfully identified 96% (22/23) of these perforations intraoperatively, while the traditional method detected 43% (10/23) ( $P \leq 0.001$ ). The sensitivity and specificity of PediGuard was 96% and 99%; with corresponding positive and negative likelihood ratios of 96.0 and 0.04. Thus, PediGuard provided convincing diagnostic evidence in detecting pedicle breaches. Sensitivity, specificity and likelihood ratios were not reported for the traditional methods.

In the second arm<sup>3</sup> of the study, 374 pedicle drillings were undertaken in 69 patients. Postoperative CT scans confirmed that all 41 incidences of perforations were detected intraoperatively by PediGuard ( $P \leq 0.001$ ). The authors noted 100% sensitivity and 99% specificity for PediGuard, with corresponding positive and negative likelihood ratios of 99.0 and 0.01 (Bolger et al 2007).

<sup>2</sup> Surgeon’s method vs. PediGuard. Postoperative CT scans utilised to determine the actual rate of pedicle screw perforations.

<sup>3</sup> Surgeons limited to PediGuard only as sole guide of pedicle perforations; accuracy was assessed by comparing with post-operative CT scans.

Overall, PediGuard successfully detected 98% (63/64) of pedicle screw breaches. However the device was responsible for four false positive results. The overall positive predictive value is 94% with a negative predictive value of 99.8%. Combining all these results, the PediGuard achieved 98% sensitivity and 99% specificity (Bolger et al 2007). Once again, sensitivity, specificity and likelihood ratios were not reported for the traditional methods.

#### **COST IMPACT**

No cost-effectiveness studies on the PediGuard have been conducted. The cost of the device is approximately SG\$2000 (~AUD\$1553<sup>4</sup>) (Biotech Singapore 2007).

#### **ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS**

No issues were identified from the retrieved material.

#### **OTHER ISSUES**

The paper by Betz et al (2007) was commissioned by SpineVision and published on the company website.

#### **SUMMARY OF FINDINGS**

Limited evidence from one randomised controlled trial indicated that PediGuard and fluoroscopically guided techniques are equally effective in creating accurate drill holes for screw insertion and are substantially superior to manual techniques. The reduced exposure of patient's to radiation is a substantial advantage as well. However, this randomised trial is ongoing, and the results available thus far are not sufficient to conclusively determine the effectiveness of PediGuard. A non-randomised comparative study reported that PediGuard was easier to use and significantly more effective in detecting pedicle breaches, compared to traditional techniques, although it was unclear what these methods involved as they were not described.

#### **HEALTHPACT ACTION**

The PediGuard appears to be a promising device, not only due to its potential effectiveness, but also its ease of use. Due to the scarcity of evidence and the potentially low cost impact, PediGuard will be archived.

#### **NUMBER OF STUDIES INCLUDED**

Total number of studies	2
Level II evidence	1
Level III-2 evidence	1

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<sup>4</sup> Exchange rate as of 30 May 2008.

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**SEARCH CRITERIA TO BE USED**

PediGuard, pedicle screw placement, electric conduct\* AND pedicle screw.