

The PediGuard for placing pedicle screws in spinal surgery

Medtech innovation briefing

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Summary

The PediGuard is a battery-powered, single-use tool for drilling pilot holes in spinal pedicles into which pedicle screws can be inserted during spinal surgery. Small comparative trials in different populations of adults and children show that the PediGuard can reduce exposure to fluoroscopy, has high sensitivity and specificity for detecting pedicle perforations, and can significantly reduce the number of malpositioned screws. The PediGuard costs £500 per unit compared with the standard pedicle awl, which costs about £300.

<p>Product summary and likely place in therapy</p> <ul style="list-style-type: none"> • The PediGuard is a single-use device that is designed to drill through the vertebral pedicle to create a pilot hole for placing pedicle screws. • The PediGuard would be used in place of a standard pedicle awl in secondary and tertiary care during spinal surgery in which pedicle screws are placed. This would include spinal decompression or correction surgery where fusion and instrumentation are needed. 	<p>Effectiveness and safety</p> <ul style="list-style-type: none"> • Evidence for the PediGuard comes from 4 controlled studies of variable design and quality, involving a total of 405 patients. None of the studies was done in the UK. • Two randomised controlled trials (n=42 people with 694 pedicle screws and n=18 with 78 pedicle screws) comparing the PediGuard with the standard method for drilling pilot holes demonstrated a statistically significant reduction in the number of fluoroscopy exposures needed when using the PediGuard. • Accuracy of pedicle screw placement was significantly improved in the first study (p=0.001) and non-inferior in the second study (p>0.05). • A multicentre, non-randomised controlled trial (n=97,571 pedicle screws inserted) showed that the PediGuard detected 22 of 23 pedicle perforations compared with 10 of 23 using other methods of detection. Overall, the PediGuard had a 94% positive predictive value and 100% negative predictive value, yielding 99% specificity and 98% sensitivity. • A retrospective controlled study (n=248) compared the PediGuard with a standard method for drilling pilot holes to insert pedicle screws in children and young people with scoliosis. There was a statistically significant reduction in the number of clinically relevant malpositioned screws when the PediGuard was used.
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Technical factors	Cost and resource use
<ul style="list-style-type: none">• The PediGuard responds to the electrical conductivity of the tissue into which it is drilling in real time.• The PediGuard gives an alarm (through audio and visual feedback to the user) if the hole is being drilled into the wrong area of the pedicle, preventing potential spinal damage from malpositioned pedicle screws.	<ul style="list-style-type: none">• The PediGuard has an NHS acquisition cost of £500 per unit excluding VAT (compared with standard pedicle awls, which cost around £300, or cannulated pedicle awls, which cost around £750 excluding VAT).• No evidence on cost and resource use was available.

Introduction

The human spine is made up of 33 vertebrae, which provide physical strength while allowing the spine to be flexible. A number of conditions can damage or change the structure of the spine and surrounding tissue, including:

- Spinal deformity, the most common form of which is scoliosis. In the UK, spinal scoliosis affects 3–4 of every 1000 children and young people, and 7 out of 10 adults aged 65 years or older (NHS Choices 2013a).
- Spinal fractures, which happen most frequently in people with osteoporosis and as a result of trauma. Approximately 120,000 cases of vertebral fractures happen each year in the UK (van Staa et al. 2001).
- Age-related degenerative diseases of the spine, including osteoarthritis (spondylosis), spinal stenosis and degenerative spondylolisthesis. In the UK approximately 8.5 million people have radiologic evidence of osteoarthritis of the spine (Arthritis Research UK 2004).

- Primary and secondary (metastatic) tumours of the spine. Primary spinal tumours are rare and make up less than 5% of bone neoplasms, but spinal metastases are more common and affect about 40% of people with terminal cancer (Tidy 2011). They can also lead to the development of metastatic spinal cord compression. According to NICE's guideline on [metastatic spinal cord compression](#) there are about 4000 cases in England and Wales each year.

All of the conditions above can cause pain and restrict movement. The treatment recommendations will depend on the condition but in severe cases, spinal surgery may be offered (NHS Choices 2013b, 2013c). There are 3 broad types of spinal surgery:

- decompression of the neural elements without spinal fusion
- decompression of the neural elements with spinal fusion
- correction of deformity with spinal fusion.

The last 2 types of surgery involve spinal fusion. Spinal fusion is a procedure in which 2 or more vertebrae are joined together using a bone graft to stabilise and strengthen the spine (NHS Choices 2013d, 2013e). Spinal instrumentation, which involves the use of metal implants to hold the spine in place, may be used in spinal fusion (Awasthi and Thomas 2004).

The standard method for performing spinal instrumentation may involve drilling pilot holes using a sharp surgical tool such as a pedicle awl, and inserting metallic screws into the pilot holes in the vertebrae. This procedure can also be performed percutaneously, although this is a relatively new method and there is little evidence as to its clinical effectiveness. The metallic screws are often referred to as pedicle screws because they are inserted through a small canal of bone called the spinal pedicle; they can act as a foundation for spinal implants. A pedicle probe can be used to measure the depth and trajectory of the pilot hole (Awasthi and Thomas 2004).

The main risk associated with placing pedicle screws is pedicle perforation, which occurs when the screw exits the vertebrae. This can result in dural tears, vascular injury, nerve injury or, rarely, spinal cord injury. The rate of pedicle perforations reported in the literature varies greatly. A systematic review and meta-analysis calculated a perforation risk of 6–15%, depending on the insertion method used (Shin et al. 2012). Evidence suggests that the risk of severe complications resulting from pedicle screw perforations ranges from 0.8% to 1.4% (Amato et al. 2010; Oh et al. 2014).

A reliable method to ensure safe drilling through the vertebral pedicle and into the vertebral body may reduce the rate of pedicle perforations and therefore improve patient outcomes and reduce costs.

Technology overview

This briefing describes the regulated use of the technology for the indication specified, in the setting described, and with any other specific equipment referred to. It is the responsibility of healthcare professionals to check the regulatory status of any intended use of the technology in other indications and settings.

About the technology

CE marking

Table 1 lists all the versions of the PediGuard available from the manufacturer, SpineGuard, with their associated CE mark status and device class.

Table 1 PediGuard products

Type and description	Intended for	Year CE mark awarded and class	Variations
Classic: features a straight shaft with a tapered tip	Drilling pilot holes that follow a straight passage through a pedicle	2012, Ia	Tri Tip 2.5XS
		2003, Ia	Tri Tip 2.5
			Tri Tip 3.2
			Tri Tip 4.0
Curved: features a curved shaft and a tapered tip	Drilling pilot holes that follow the natural curvature of a pedicle	2012, Ia	CurvXS
		2010, Ia	Curv

Cannulated: features a straight shaft that can be cannulated and a detachable handle	Percutaneous insertion of pedicle screws	2011, 1a	Starter Stylet – Bevel
		2011, 1a	Starter Stylet – Trocar

Description

The PediGuard is a single-use surgical tool for drilling pilot holes in order to place pedicle screws. It can be used to drill multiple pilot holes in a single patient, as long as the device is wiped with a saline-impregnated cloth between uses. The manufacturer states that battery life for the PediGuard allows for more than 5 hours of drilling time.

There are 3 types of PediGuard available: straight and curved for open surgeries and cannulated for minimally invasive approaches (table 1). Each has several tip length and diameter options to provide flexibility. The smaller sizes (Tri Tip 2.5XS and CurvXS) are designed to be used in small pedicles, such as in cervical vertebrae or in those of children and young people.

The PediGuard is similar in appearance to a pedicle awl; it has a stainless steel shaft with a pointed tip capable of boring through bone. The tip houses an electromagnetic bipolar sensor that responds to the electrical conductivity of the surrounding tissue. The handle contains a battery, speaker and LED; these provide audio and visual feedback in response to tissue conductivity. The feedback signals are as follows:

- Low-pitch, low-frequency sound: in cortical (hard) bone, such as that of the pedicle cortex.
- Medium-pitch, medium-frequency sound: in cancellous (spongy) bone, such as that of the inner portion of the vertebral pedicle and body.
- High-pitch, high-frequency sound: in soft tissues and blood.

The LED flashes at a speed corresponding to the frequency of the audio feedback.

Intended use

The PediGuard is intended for use during spinal surgery where the drilling of pilot holes is needed to place pedicle screws. The manufacturer states that the PediGuard should not be used on people with pacemakers or any other active implantable medical device, or in patients with severely osteoporotic vertebrae.

Setting and intended user

This tool is intended for use in secondary and tertiary care settings. Specifically, it would be used in operating theatres by appropriately qualified orthopaedic surgeons or neurosurgeons. Spinal surgery, particularly involving complex instrumentation, is increasingly done in tertiary centres.

Current NHS options

According to NICE's guideline on [metastatic spinal cord compression](#) patients with spinal metastases should be offered spinal surgery if:

- there is imaging evidence of structural spinal failure
- they have mechanical pain resistant to conventional analgesia.

In most cases in the UK, a surgeon drills pilot holes and places pedicle screws manually. Fluoroscopy (or, less often, intraoperative CT imaging) is commonly used to aid the placement of pedicle screws by providing real-time anatomical information, as well as information on screw trajectory and position (Patel et al. 2011). Fluoroscopy is quantified by the number of 'shots' used. Every fluoroscopy shot exposes the patient to radiation. Neuromonitoring can also be used to help drill pilot holes, in order to test the integrity of the pedicle wall without exposing the patient to ionising radiation (Mattei et al. 2009). Some tertiary care facilities may use spinal cord monitoring, which is a type of neuromonitoring, for complex cases, such as deformity, fracture and metastatic spinal cord compression cases, as well as significant proportion of degenerative spinal cases.

NICE is not aware of other CE-marked devices that have a similar function to the PediGuard.

Costs and use of the technology

Information on the cost of using the technology was provided by the manufacturer. The PediGuard has a NHS acquisition cost of £500 per single-use unit, excluding VAT.

The manufacturer provides a free half-day training course. Surgeons can also be trained by other surgeons who have used the device.

Where manual pedicle screw placement is supplemented with fluoroscopic imaging, the NHS reference cost for fluoroscopic imaging is £262 for mobile or intraoperative contrast fluoroscopy procedures lasting more than 40 minutes (NHS reference cost 2012–13 code RA21Z [DOH 2013]). When the cost of the PediGuard is added to that of fluoroscopy, the average total cost per treatment is estimated to be £762.

The current manual technique involves standard, re-usable pedicle awls (£301.14 to £315.36, excluding VAT) or cannulated pedicle awls (£738.87 to £753.82, excluding VAT).

No other practical difficulties have been identified in using or adopting the technology.

Likely place in therapy

The PediGuard can be used in any spinal surgical procedures when drilling pilot holes is needed to place pedicle screws.

Specialist commentator comments

Two specialist commentators were concerned that severe osteoporotic bone changes were listed as a contraindication for the use of the PediGuard, and felt that this was a disadvantage of the technology. In addition, 1 of these commentators noted that the description 'severely osteoporotic' does not define a specific clinical population. The specialist stated that characterising osteoporotic bone is a surgical challenge. It was suggested that by the time a surgeon is able to recognise the true extent of a patient's bone deterioration, and so evaluate whether the PediGuard is an appropriate tool, the packaging may have already been opened.

One specialist commentator concluded that the device was simple and safe to use, with good sensitivity and specificity. However, he felt that the device was outdated, because

assistive technology and percutaneously inserting pedicle screws is becoming increasingly common in the NHS. Therefore, the PediGuard's true value is likely to lie in training and for use in complex cases. Two specialist commentators stated that further research may be warranted. In particular, they suggested that further information on the cost effectiveness of the device would be invaluable.

According to 1 specialist commentator, the number of spinal surgery procedures performed for metastatic disease is increasing.

Two specialist commentators commented on the published studies of the PediGuard. One noted that in the studies by Bai et al. (2013) and Chaput et al. (2012), a primary outcome was the number of fluoroscopy shots given to each patient. The commentator found this to be a poor outcome measure because the consequence of more exposures is not known. A second commentator noted that the study by Bai et al. (2013) stated that surgeons took between 65 and 225 seconds to insert one pedicle screw. This commentator reflected that, in their experience, the average time is approximately 5 minutes (300 seconds) per screw.

One specialist noted that all studies in this field are subject to performance bias as the risk of adverse events will vary in accordance with the complexity of the procedure and the experience of the surgeon. They emphasised the importance of patient-reported outcomes, such as pain, in the evaluation of a device like the PediGuard, noting that these may provide an accurate estimate of nerve injury rates.

One specialist commentator noted that none of the studies reported on the use of the cannulated PediGuard. The specialist stated that this is an important issue because future procedures that need the insertion of pedicle screws are likely to be performed percutaneously.

Equality considerations

NICE is committed to promoting equality and eliminating unlawful discrimination. We aim to comply fully with all legal obligations to:

- promote race and disability equality and equality of opportunity between men and women

- eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

The manufacturer states that the PediGuard should not be used on people with pacemakers or any other active implantable medical device, or on patients with severely osteoporotic vertebrae. Both of these groups of people may be considered to have a disability, which is a protected characteristic defined in the Equality Act 2010.

Evidence review

Clinical and technical evidence

Regulatory bodies

There were 3 incidents identified in the US Food and Drug Administration (FDA) database: Manufacturer and User Device Facility Experience (MAUDE). None of the incidents resulted in any patient harm. In the first, which occurred in March 2012, the tip of the device broke off during drilling and could not be retrieved from the patient's pedicle. In the other 2 cases the device malfunctioned before the procedure was started. These events were in July 2009 and August 2010.

A search of the Medicines and Healthcare Products Regulatory Agency (MHRA) website revealed no manufacturer Field Safety Notices or Medical Device Alerts for this device.

Clinical evidence

Five studies on the PediGuard were identified, of which 1 in vitro study was excluded from further consideration.

The evidence comprises 2 randomised controlled trials, 1 non-randomised controlled trial and a retrospective controlled study.

Randomised controlled trials

A study set in China by Bai et al. (2013) compared the PediGuard with a standard pedicle probe. The trial enrolled 42 people with adolescent idiopathic scoliosis, 20 of whom had the PediGuard and 22 of whom were considered a control group having a standard probe. In total, 694 screws were inserted: 362 in the PediGuard group and 332 in the control group. A statistically significant reduction in the number and duration of fluoroscopy shots was observed in the PediGuard group. The accuracy of screw placement also improved in the PediGuard group, with statistically significant improvement seen for screws inserted in the upper, middle and lower thoracic regions, but no statistical significance in the lower lumbar region. The time taken to place each screw showed a statistically significant reduction. A summary of these results is reported in tables 2 and 4.

Chaput et al. (2012) conducted a USA-based study funded by the manufacturer of the PediGuard. The study compared pedicle screw placement using the PediGuard with a standard manual drilling method. A total of 78 screws were inserted in 18 people with a degenerative lumbar spine who were scheduled for posterior lumbar fusion. A single surgeon, who had prior PediGuard training on cadavers, used fluoroscopy guidance to place pedicle screws. Postoperative CT scans were used to assess pedicle perforation. The study demonstrated a 30% reduction in the number of fluoroscopy shots when using the PediGuard compared with standard manual drilling. There was no difference in the accuracy of pedicle screw placement using either technique, with each recording a single breach. A summary of these results is reported in tables 3 and 4.

Non-randomised controlled trials

Bolger et al. (2007) conducted a study to assess the PediGuard's ability to detect pedicle perforations. The study involved 9 centres and 11 surgeons in 5 European countries. It enrolled 97 people and involved the insertion of 571 pedicle screws. The study had 2 phases: phase 1 compared the diagnostic accuracy of the PediGuard with other detection methods (that were dependent upon the individual centre's protocol). Pedicle perforations were confirmed by postoperative CT. Phase 2 compared the diagnostic accuracy of the PediGuard with postoperative CT only. Overall, the study demonstrated that the PediGuard has a high level of diagnostic accuracy. A summary of these results is reported in table 5.

Retrospective controlled study

Ovadia et al. (2011) conducted a single-centre study based in Israel. The authors compared the accuracy of pedicle screw placement by a single surgeon in children with scoliosis, who were split into 2 groups: in the first group, 1270 screws were inserted using a standard manual drilling method. In the second group, 1400 screws were inserted using the PediGuard. Neuromonitoring was performed to assess screw placement. Using the PediGuard statistically significantly reduced the number of clinically relevant malpositioned pedicle screws, measured by the number of neuromonitoring alarms. A summary of these results is reported in table 6.

Table 2 Overview of the Bai et al. (2013) randomised controlled trial

Study component	Description
Objectives/ hypotheses	To compare the accuracy and time needed for pedicle screw placement between the PediGuard and the traditional free-hand pedicle finder in thoracic and lumbar spine.
Study design	Randomised controlled trial.
Setting	A centre in China, no recruitment period specified. Patients followed-up at 1 week for post-operative CT.
Inclusion/ exclusion criteria	<p>Inclusion:</p> <ul style="list-style-type: none"> • AIS diagnosis, Lenke type 1-V1 • Spinal curve between 40–80° <p>Exclusion:</p> <ul style="list-style-type: none"> • Non-AIS patients • Spinal curve >80° • Body weight >80 kg

<p>Primary outcomes</p>	<p>Primary:</p> <ul style="list-style-type: none"> • Time needed to place a pedicle screw • Number of intraoperative fluoroscopy shots needed • Position of pedicle screw using CT imaging (1 week post-operation): <ul style="list-style-type: none"> – grade 0 (no apparent violation of the pedicle) – grade 1 (<2 mm perforation of the pedicle, with 1 screw thread out of the pedicle) – grade 2 (between 2 mm and 4 mm of perforation of the pedicle, with half of the diameter of the screw outside of the pedicle) – grade 3 (>4 mm or complete perforation of the pedicle) • Rate of pedicle perforation (based upon graded system) <p>Secondary:</p> <ul style="list-style-type: none"> • Inter-observer and intra-observer variability (50 CT scans evaluated at an 8-week interval by 2 independent assessors)
<p>Statistical methods</p>	<p>Descriptive statistics were used to present data in the form of mean and ranges. T-test was used to compare time needed for pedicle screw placement and number of fluoroscopy shots. Pearson χ-squared test was used to compare rates of pedicle perforation. Kappa agreement was used to assess inter- and intra-observer reliability.</p> <p>Significance level was not stated.</p>
<p>Participants</p>	<p>A total of 42 patients: Lenke type I=18; Lenke type II=8; Lenke type III=6; Lenke type IV=2; Lenke type V=4; and Lenke type VI=4.</p> <p>Mean age=15±6.52 SD years (range, 10–18 years; median, 16 years).</p> <p>Mean Cobb angle=55.3±7 SD (range, 45–78°), mean number of segments instrumented was 9±3 (range, 6–14).</p> <p>ECD group: 20 patients; mean age=16.2±4.5 SD (range, 11–18 years); 4 male and 16 female; 362 pedicle screws placed.</p> <p>NPF group: 22 patients; mean age=15.5±5.6 SD (range, 10–18 years); 5 male and 17 female; 332 pedicle screws placed.</p>

<p>Results</p>	<p>Average screw placement time reduced significantly in the ECD group (204±33 SD [range, 65–255 seconds]) compared with the NPF group (241± 61 SD [range, 72–367 seconds]), p=0.009.</p> <p>The average number of fluoroscopy shots per case was significantly reduced in the ECD group (1.20±0.52 SD) compared with the NPF group (1.59±0.67 SD), p=0.040.</p> <p>Screw perforation rates were significantly reduced in the ECD group (15/362=4.1%) compared with the NPF group (47/332=14.2%), p=0.001.</p> <p>The number of screws successfully placed inside the pedicle (Grade 0) for the ECD group was 347/362 (95.9%) compared with 285/332 (85.8%) for the NPF group.</p> <p>The number of screws fully inside the pedicle + screw perforating <2 mm (Grade 0+Grade 1) for the ECD group was 354/362(97.8%) compared with 292/332 (88%) for the NPF group.</p> <p>Inter- (k=0.85) and intra-observer (k=0.83) variability showed a good rate of agreement.</p>
<p>Conclusions</p>	<p>Using the PediGuard increases pedicle screw accuracy and reduces placement time and radiation in posterior AIS.</p>
<p>Abbreviations: AIS, adolescent idiopathic scoliosis; CT, computed tomography; SD, standard deviation; ECD, electronic conductivity device (PediGuard); NPF, normal pedicle finder.</p>	

Table 3 Overview of the Chaput et al. (2012) randomised controlled trial

<p>Study component</p>	<p>Description</p>
<p>Objectives/ hypotheses</p>	<p>To report the results of using the PediGuard to reduce radiation exposure while preparing the pilot hole for pedicle screw placement.</p>
<p>Study design</p>	<p>Randomised controlled trial.</p>

Setting	USA-based centre; no recruitment period specified. Patients were followed-up at discharge or their first outpatient follow-up visit.
Inclusion/exclusion criteria	Inclusion: people diagnosed with a degenerative lumbar spine having a posterior spinal fusion. No exclusion criteria were specified.
Primary outcomes	Primary: <ul style="list-style-type: none"> • Breach rate for either technique, as defined by ≥ 2 mm of screw encroaching into the epidural space. • The number of intraoperative fluoroscopy shots required with each technique.
Statistical methods	Descriptive statistics were used to present data in the form of mean, ranges, SD and percentages. Fisher's exact test was used to compare breach rates between the techniques. The ANOVA test was used to compare the number of fluoroscopy shots between the techniques. Significance level was not stated.
Participants	18 patients; mean age= 55 \pm 12 SD years. Two groups with a total of 78 screws inserted; PediGuard, n=39 screws inserted and standard, n=39 screws inserted.
Results	One breach was recorded in each group. There was no significant difference in breach rate between the 2 groups (97.5% for each group), p=1.000. The total number of fluoroscopy shots in the PediGuard group was 202, compared with 293 used in the standard group (30% reduction). A significant difference was demonstrated in the mean number of fluoroscopy shots: PediGuard=5.2 (range, 0–15 and 3.30 SD) compared with standard=7.5 (range, 2–17 and 3.60 SD), p<0.0001.
Conclusions	The use of the PediGuard reduced the number of fluoroscopy shots by 30% compared with a standard drilling probe and this reduction of radiation occurred while maintaining a 97.5% accurate, safe screw placement.

Abbreviations: ANOVA, analysis of variance; n, number; SD, standard deviation.

Table 4 Summary of the randomised controlled trials

	PediGuard	Standard manual insertion	Analysis
Bai et al. (2013)			
Design			
Randomised	n=362	n=332	
Efficacy	n=362	n=332	
Primary outcome: number of pedicle breaches	15/362 (4.1%)	47/332 (14.2%)	p=0.001
Selected secondary outcomes			
Time needed to insert a pedicle screw	Mean 204±33 SD (range, 65–255) seconds	Mean 241± 61 SD (range, 72–367) seconds	p=0.009
Number of fluoroscopy shots needed per screw	Mean 1.20±0.52 SD	Mean 1.59±0.67 SD	p=0.040
Safety	n=42	n=42	
Patients reporting serious adverse events	Not reported	Not reported	
Neurovascular involvement	0	0	
Revision surgery	0	0	
Chaput et al. (2012)			
Design			
Randomised	n=39	n=39	
Efficacy	n=39	n=39	

Primary outcome: number of fluoroscopy shots needed using each technique	Median 5.2±3.30 SD (range, 0–15)	Median 7.5±3.60 SD (range, 2–17)	p<0.0001
Selected secondary outcomes			
Successful pedicle screw insertion (or <2mm breach)	38/39	38/39	p=1.000
Unsuccessful pedicle screw insertion, ≥2mm breach	1/39	1/39	
Safety	n=18	n=18	
Patients reporting serious adverse events	Not reported	Not reported	
Neurological deficit following surgery	0	0	
Radiculopathy following surgery	0	0	
Abbreviations: SD, standard deviation.			

Table 5 Overview of the Bolger et al. (2007) study

Study component	Description
Objectives/ hypotheses	To assess the diagnostic accuracy of the PediGuard in detecting pedicle perforation in comparison with other standard methods.
Study design	Multicentre, prospective, biphasic study.
Setting	Five European centres. Recruitment was between September 2002 and September 2004. No follow-up period was reported.
Inclusion/ exclusion criteria	No inclusion or exclusion criteria were reported.

<p>Primary outcomes</p>	<p>Primary:</p> <ul style="list-style-type: none"> • The ability of the device to detect pedicle breaches against other available methods of detection. <p>Phase 1:</p> <ul style="list-style-type: none"> • Pedicle screws placed using PediGuard in addition to the surgeon's usual method of guidance (for example: tactile feel, mechanical probing, fluoroscopy, CT scans, EMG, SEEP, computer assisted navigation; depending on their availability in each centre). • Post-operative CT was to assess accuracy. <p>Phase 2:</p> <ul style="list-style-type: none"> • Pedicle screws placed using the PediGuard only. • Post-operative CT was to assess accuracy.
<p>Statistical methods</p>	<p>Data were presented as actual values and percentages. Significance level was not stated.</p>
<p>Participants</p>	<p>97 patients in 9 centres. 521 pedicle screws were placed in total; phase 1=147 and phase 2=374. No further patient characteristics were reported.</p>

<p>Results</p>	<p>Phase 1 (147 pedicle screws inserted):</p> <ul style="list-style-type: none"> • 23/147 (16%) confirmed breaches on postoperative CT scanning. • 10/23 (43%) breaches detected by the surgeon's own method. • 22/23 (96%) breaches detected by the PediGuard. • 1 false-negative result using the PediGuard (99% negative predictive value). • 1 false-positive result using the PediGuard (96% positive predictive value). • 96% specificity. • 99% sensitivity. <p>Phase 2 (374 pedicle screws inserted):</p> <ul style="list-style-type: none"> • 41/374 (11%) confirmed breaches on postoperative CT scanning. • 41/41 (100%) breaches detected by the PediGuard. • 3 false-positive results using the PediGuard (93% positive predictive value). • 0 false-negative results using the PediGuard. • 100% specificity. • 99% sensitivity. • 41 (11%) confirmed breaches on postoperative CT scanning.
<p>Conclusions</p>	<p>This device offers a simple, safe and sensitive method of detecting pedicle breach during routine drilling of the pedicle.</p>
<p>Abbreviations; CT, computed tomography; EMG, electromyography; SEEP, somatosensory evoked potentials.</p>	

Table 6 Overview of the Ovadia et al. (2011) retrospective, controlled clinical study

Study component	Description
Objectives/ hypotheses	To evaluate the contribution of an ECD (PediGuard) to the safety of thoracic and lumbar pedicle screw placement in a large group of people with scoliosis, of diverse aetiologies.
Study design	Retrospective, controlled clinical study.
Setting	Single centre based in Israel. This study recruited patients between 2003 and 2009. No follow-up period was reported.
Inclusion/ exclusion criteria	Inclusion: <ul style="list-style-type: none"> • Scoliosis diagnosis • Received spinal deformity correction surgery No exclusion criteria were reported.
Primary outcomes	The number of clinically relevant malpositioned pedicle screws, measured by intra-operative neuromonitoring.
Statistical methods	Descriptive statistics were used to present data in the form of mean and SD. Fisher's exact test was used to compare the rate of abnormal neuromonitoring events within each group. The statistical comparison used the number of screws as the unit of analysis. Significance level was not stated.

<p>Participants</p>	<p>A total of 248 people with scoliosis were studied in the following groups:</p> <p>Group 1: pedicle screws inserted with standard manual hand drilling n=150.</p> <p>97 women (64.7%) and 53 men (35.3%); mean age 13.68±3.8 SD years.</p> <p>23 congenital scoliosis (15.6%); 80 idiopathic scoliosis (53.1%); 47 other(31.3%); preoperative Cobb angle, 73.3±21.3°SD; postoperative Cobb angle, 29.2±13.2°SD; Cobb angle correction, 60.2%.</p> <p>Group 2: pedicle screws inserted with the use of ECD (PediGuard) n=98.</p> <p>73 women (74.5%) and 25 men (25.5%); mean age, 14.35±2.9 SD years.</p> <p>10 congenital scoliosis (10.2%); 61 idiopathic scoliosis (62.2%); 27 other (27.6%); preoperative Cobb angle, 69.8±16.2°SD; postoperative Cobb angle, 24±9.7°SD; Cobb angle correction, 65.6%.</p> <p>The 2 study groups were matched by age, sex, scoliosis aetiology, Cobb angle, and surgical criteria.</p>
<p>Results</p>	<p>Group 1 had a total of 1270 pedicle screws, mean number of screws/procedure=8.5.</p> <p>Group 2 had a total of 1400 pedicle screws, mean number of screws/procedure=14.</p> <p>A significant reduction in number of neuromonitoring alarms was demonstrated using the PediGuard.</p> <p>Group 2: 3 procedures (3%) compared with Group 1: 10 procedures (6.6%) where the PediGuard was not used (p=0.048).</p> <p>Nine of the 13 monitoring alarms (69%) were associated with implantation adjacent to the apex of the spinal curve.</p>
<p>Conclusions</p>	<p>The use of an ECD significantly reduced the incidence of clinically relevant malpositioned screws in a variety of scoliosis patients, thereby increasing the safety of pedicle screw implantation.</p>
<p>Abbreviations: ECD, electronic conductivity device; SD, standard deviation.</p>	

Recent and ongoing studies

One ongoing clinical trial has been identified relating to the PediGuard:

- [NCT00549627](#): Evaluation of the PediGuard for Pedicle Screw Insertion. Patient recruitment was suspended in February 2009.

The manufacturer has stated that it will be starting a prospective randomised trial using the cannulated PediGuard in 2015. Also, the manufacturer indicated that a prospective, randomized trial set in Brazil completed in early 2015. This study investigated the use of the PediGuard in people with diminished bone mineral density.

Costs and resource consequences

Approximately 11,350 finished consultant episodes were reported in the Hospital Episodes Statistics 2012–13 (HSCIC 2013) for spinal surgery involving fusion or instrumentation (V36–V46, V66). According to the manufacturer, since its introduction the PediGuard has been used in 35,000 procedures worldwide and is currently being used at 3 NHS centres.

Use of the PediGuard would not require any changes in the way that current services are organised or delivered. No other additional facilities or technologies are needed alongside the technology.

No published evidence on resource consequences of the PediGuard was identified in the systematic review of evidence.

Strengths and limitations of the evidence

Of the 2 randomised controlled trials, only Chaput et al. (2012) reported their randomisation method. This was done by alternating between the 2 methods of drilling pedicle pilot holes. The use of an inpatient randomisation scheme ensures that all confounding factors are equally distributed in both groups. It is unclear how the randomisation methods may have influenced the outcomes of Bai et al. (2013). Additionally, although Ovadia et al. (2011) was a retrospective controlled trial, the 2 study groups were matched by a number of factors including: age, sex, scoliosis aetiology, Cobb angle and surgical criteria. Matching ensures that the 2 groups are as homogenous as is practicable. This limits the impact of confounding factors on the results and, therefore, reduces selection bias.

None of the included studies reported a sample size calculation. Consequently it is unclear if the studies were adequately powered to detect any differences in the primary and secondary outcomes.

The operators could not be blinded to the intervention and control groups in either of the randomised controlled trials. Although this may introduce performance bias, this limitation is common in studies involving medical devices.

In surgical procedures, another source of potential performance bias is the surgeon's training to use the device, and the duration of the learning curve associated with the procedure. Only Chaput et al. (2012) stated that cadaveric training was undertaken by the sole user in this study who also had previous experience with using the PediGuard in previous clinical cases. In addition, Ovadia et al. (2011) reported that the surgeon involved with the study was an experienced senior spine specialist. None of the other studies reported whether the investigators had undergone prior training with the device, nor did they report the investigators' level of prior experience.

Although 3 studies reported the PediGuard's effect on pedicle perforations, there was variability in the grading system each used. Bai et al. (2013) used a 4-grade system, while Chaput et al. (2012) used a 2-grade system to assess pedicle perforations. However, in both studies the same definition of perforation was used, with up to 2 mm of screw perforating the vertebral cortex considered as acceptable. Bolger et al. (2007) did not report on their definition of pedicle perforation or how it was measured. Furthermore, the authors state that 'other methods of detection' were used as a comparison to the PediGuard. It may be difficult to directly compare outcomes from phase 1 of the study by Bolger et al. (2007) if many unspecified methods of detection were used.

The number of fluoroscopy shots, as recorded by both Bai et al. (2013) and Chaput et al. (2012), is an objective measurement but it is not a direct measure of radiation exposure. A more appropriate outcome measure may have been the effective dose (measured in Sieverts).

Although 3 types of the PediGuard exist, each of which is available in various sizes, none of the studies states which PediGuard tool was used and the reasons for its selection.

The study by Chaput et al. (2013) was funded by the manufacturer and the lead author of Bolger et al. (2007) is listed by SpineGuard as an original co-inventor of the PediGuard. This has the potential for introducing bias in the reporting of outcomes.

Relevance to NICE guidance programmes

NICE has issued the following guidance:

- [Direct C1 lateral mass screw for cervical spine stabilisation](#) (2005) NICE interventional procedures guidance 146
- [Balloon kyphoplasty for vertebral compression fractures](#) (2006) NICE interventional procedures guidance 166
- [Lateral \(including extreme, extra and direct lateral\) interbody fusion in the lumbar spine](#) (2009) NICE interventional procedures guidance 321
- [Non rigid stabilisation techniques for the treatment of low back pain](#) (2010) NICE interventional procedures guidance 366
- [Transaxial interbody lumbosacral fusion](#) (2011) NICE interventional procedures guidance 387
- [The MAGEC system for spinal lengthening in children with scoliosis](#) (2014) NICE medical technologies guidance 18

NICE guidance related to pedicle screw placement in spinal surgery is in development and is expected to be published as follows:

- [Complex fractures: Assessment and management of complex fractures](#) NICE guideline (publication expected February 2016)
- [Spinal injury assessment: assessment and imaging, and early management for spinal injury \(spinal column or spinal cord injury\)](#) NICE guideline (publication expected February 2016)
- [Low back pain and sciatica: management of non-specific low back pain and sciatica](#) NICE guideline (publication expected November 2016).

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Chaput CD, George K, Samdani AF et al. (2012) Reduction in Radiation (Fluoroscopy) While Maintaining Safe Placement of Pedicle Screws During Lumbar Spine Fusion. *Spine* 37: E1305–9

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NHS Choices (2013b) Scoliosis - Treatment in adults [accessed 10 December 2014]

NHS Choices (2013c) Scoliosis - Treatment in children [accessed 10 December 2014]

NHS Choices (2013d) Back Pain - Treatment [accessed 19 December 2014]

NHS Choice (2013e) Lumbar decompression surgery - How it's performed [accessed 16 January 2015]

Oh HS, Kim JS, Lee SH et al. (2013) Comparison between the accuracy of percutaneous and open pedicle screw fixations in lumbosacral fusion. *The Spinal Journal* 13(12): 1751–7

Ovadia D, Korn A, Fishkin M et al. (2011) The Contribution of an Electronic Conductivity Device to the Safety of Pedicle Screw Insertion in Scoliosis Surgery. *Spine* 36(20): E1314–21

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Ireland: A Questionnaire Study. The Open Biomedical Engineering Journal 5: 90–7

Shin BJ, James AR, Njoku IU et al. (2012) Pedicle screw navigation: a systematic review and meta-analysis of perforation risk for computer-navigated versus freehand insertion. Journal of Neurosurgery: Spine 17(2): 113–22

Ul Haque M, Shufflebarger H, O'Brien M et al. (2006) Radiation Exposure During Pedicle Screw Placement in Adolescent Idiopathic Scoliosis: Is Fluoroscopy Safe? Spine 31(21): 2516–20

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van Staa TP, Dennison EM, Leufkens HG et al. (2001) Epidemiology of fractures in England and Wales. Bone 29: 517–22

Search strategy and evidence selection

Search strategy

For the clinical evidence

Embase 1980 to 2014 Week 46, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to Present; searched 19 November 2014.

1. pediguard.mp.
2. Electric Conductivity/ or Electric Impedance/
3. Monitoring, Intraoperative/is, mt [Instrumentation, Methods]
4. 2 and 3
5. device.mp. or "Equipment and Supplies"/
6. tool.mp.

7. 5 or 6

8. 4 and 7

9. pedicle screw?.mp.

10. placement.mp.

11. insertion.mp.

12. probe.mp.

13. 10 or 11 or 12

14. 9 and 13

15. 1 or 8 or 14

16. Spinal Fusion/is [Instrumentation]

17. Spinal Diseases/su [Surgery]

18. Spinal Fractures/su [Surgery]

19. 16 or 17 or 18

20. 15 and 19

21. limit 20 to (English language and humans and yr="2003 - Current")

The Cochrane Database of Systematic Reviews (CDSR) and the Database of Abstracts of Reviews of Effect (DARE) were searched on 19th November 2014 using the following keywords:

- Pediguard OR
- Pedicle screw placement AND
- Spinal Surgery

For the economic evidence

Embase 1980 to 2014 Week 47, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to Present; Searched on 26 November 2014.

1. pediguard.mp.
2. Electric Conductivity/ or Electric Impedance/
3. Monitoring, Intraoperative/is, mt [Instrumentation, Methods]
4. 2 and 3
5. device.mp. or "Equipment and Supplies"/
6. tool.mp.
7. 5 or 6
8. 4 and 7
9. pedicle screw?.mp.
10. placement.mp.
11. insertion.mp.
12. probe.mp.
13. 10 or 11 or 12
14. 9 and 13
15. 1 or 8 or 14
16. Spinal Fusion/is [Instrumentation]
17. Spinal Diseases/su [Surgery]

18. Spinal Fractures/su [Surgery]

19. 16 or 17 or 18

20. cost*.mp.

21. economic*.mp.

22. 20 or 21

23. 15 and 19 and 22

24. limit 23 to English language

25. limit 24 to yr="2003 -Current"

26. limit 25 to humans

27. remove duplicates from 26

Cochrane Database of Systematic Reviews: Issue 11 of 12, November 2014; Cochrane Central Register of Controlled Trials: Issue 10 of 12, October 2014; Database of Abstracts of Reviews of Effect: Issue 4 of 4, October 2014; Health Technology Assessment Database: Issue 4 of 4, October 2014; NHS Economic Evaluation Database: Issue 4 of 4, October 2014.

1. Pediguard

2. Pedicle screw placement

3. 1 or 2

4. Spinal surgery

5. 3 and 4

6. cost*

7 economic*

8. 6 or 7

9. 5 and 8 (published 2003 to 2014)

Evidence selection

For the clinical evidence

- Total number of publications reviewed: 496
- Total number of publications considered relevant: 57
- Total number of publications selected for inclusion in this briefing: 4

For the economic evidence

- Total abstracts: 31
- Duplicates: 0
- Abstracts reviewed: 31
- Full papers reviewed: 3
- Studies for review: 0

Exclusion criteria: case studies, editorials, letters, reviews, conference proceedings/ abstracts, animal studies, non-English language studies, not using PediGuard.

About this briefing

Medtech innovation briefings summarise the published evidence and information available for individual medical technologies. The briefings provide information to aid local decision-making by clinicians, managers, and procurement professionals.

Medtech innovation briefings aim to present information and critically review the strengths and weaknesses of the relevant evidence, but contain no recommendations and **are not**

formal NICE guidance.

Development of this briefing

This briefing was developed for NICE by King's Technology Evaluation Centre (KiTEC). The [interim process and methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality assured and approved for publication.

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