



Scientific & Clinical Evidence

Updated July 2022

PediGuard® probes have assisted spine surgeons in accurately placing about 500,000^a pedicle screws worldwide

With mounting clinical evidence confirming its efficacy, PediGuard devices, that integrate the DSG® Technology, are becoming a compelling answer to the clinical needs associated with safe and accurate pedicle screw placement.

Screw Placement Accuracy & Breach Detection

97% screw placement accuracy¹⁻⁸

98% breach detection⁹

100% pedicle breach anticipation¹⁰

92.5% Complex deformity, accuracy upper thoracic¹¹

3 times fewer pedicle perforations than with free-hand technique⁴

Surgical Education

58% breach rate reduction when used by residents⁸³

Radiation Safety & Surgical Efficiency

73% reduction of X-Ray times in MIS¹⁴

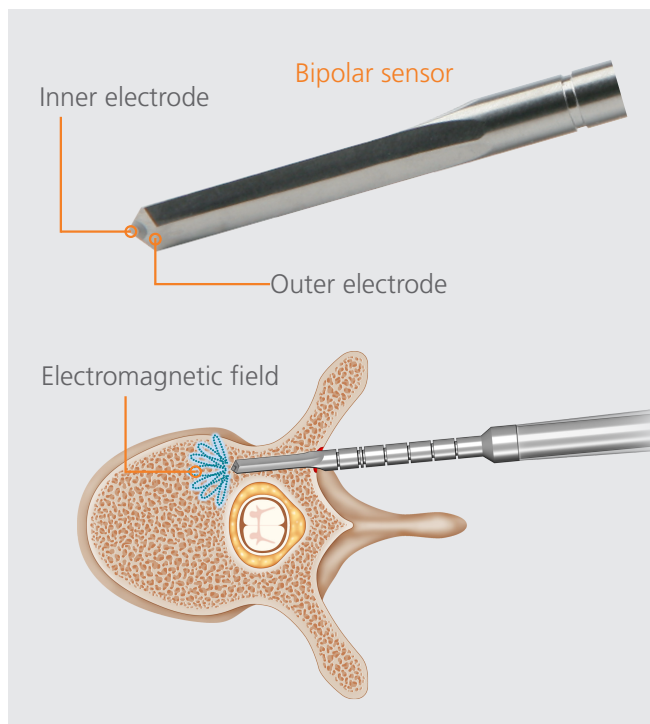
30% reduction of X-Ray shots in open^{4,5}

15% surgical time savings during screw placement⁴

New Applications & Techniques

91% cervical spine lateral mass and pedicle screw placement accuracy^{15,16}

New Technique Sacro-iliac fusion¹⁷



The bipolar sensor of PediGuard emits an electrical current which flows locally through the bone from the inner electrode to the outer electrode, creating a circular electromagnetic detection field at the very tip of the instrument. The real time, local changes in electrical conductivity of the bone as measured by the sensor are translated into audio feedback that varies in pitch and cadence to inform the surgeon about the nature of the bone at the tip while advancing through the pedicle down the vertebral body.

The result is that PediGuard can alert the surgeon about a possible perforation of the cortex, and furthermore may help the surgeon anticipate a breach by detecting the approaching cortical wall.

The mission of SpineGuard is to help the surgeon make spine surgery safer – for the patient, for him/her and the OR staff.

Learn more about the DSG family of products at:
www.spineguard.com

^aEstimation based on 5.5 screws per construct on average

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Pedicle Screw Challenges

Pedicle screw-based stabilization is the gold standard for treating spinal instabilities and deformities. Technological advancements such as screws in the thoracic spine, Cortical Bone Trajectory and Minimally Invasive Surgery are compounding the importance of pedicle screw placement.

Accuracy of Pedicle Screw Placement remains a Critical Issue in Spine Surgery

"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." (NICE 2015)¹⁸

Up to 20% of pedicle screws have been reported as misplaced when using conventional techniques (non-assisted techniques) and around **~5%** when using navigation or robotic-assisted^{19,20,21,22}.

Consequences of Misplaced Pedicle Screws are not to be Underestimated

Neurological Complications and Revision Surgery



3.7%

of the patients on average experience **neurological symptoms** after a spine surgery (from 0% to 11%).



4.4%

of the patients on average have a **revision surgery** to correct a misplaced screw (range 1% to 11%)^a.

2nd

cause of reoperation within 30 days of spine surgery inpatients is due to neurological complications after posterior lumbar instrumentation and/or in trauma patients^b.

Revision surgery for a misplaced screw is more common in trauma-cervical patients (15%) and deformity patients (10.7% for major deformity and 6.3% for spondylolisthesis)⁶⁴.

Vascular Complications

Vascular injuries are rare but life threatening. Many case reports have been published³⁹⁻⁶⁰.

Lawsuits

Spine surgeons are at a **higher risk of lawsuits** than doctors from other specialties. Nerve injury is the cause of **41% of the claims** according to a recent medicolegal study in spine surgery⁶⁵.

Cost Implications

\$17,650

to

additional cost for a revision surgery to correct a misplaced screw^{c-d}.

\$27,768

Examples of liability issues related to misplaced screws:

- Teenage girl left paralyzed (Ireland, €4,8m)⁶⁶,
- Permanent nerve damage with drop foot (USA, \$800,000)⁶²,
- New neurological symptoms (USA, \$1,272m)⁶⁸.

Conclusion

- Revision surgery to correct misplaced screw happens on average in **4.4%** of the patients.
- Neurological complications occur in up to **11%** of the patients.
- Vascular complications and loss of stability should not be underestimated.
- Liability issues are rare but the settlement amount can be very high.
- Navigation improves pedicle screw placement but increases significantly radiation exposure for patients.

^aBased on 11 studies²³⁻³⁵ including totally 3,617 patients and 18,494 pedicle screws.

^bBased on a large Japanese multi-center study³⁶.

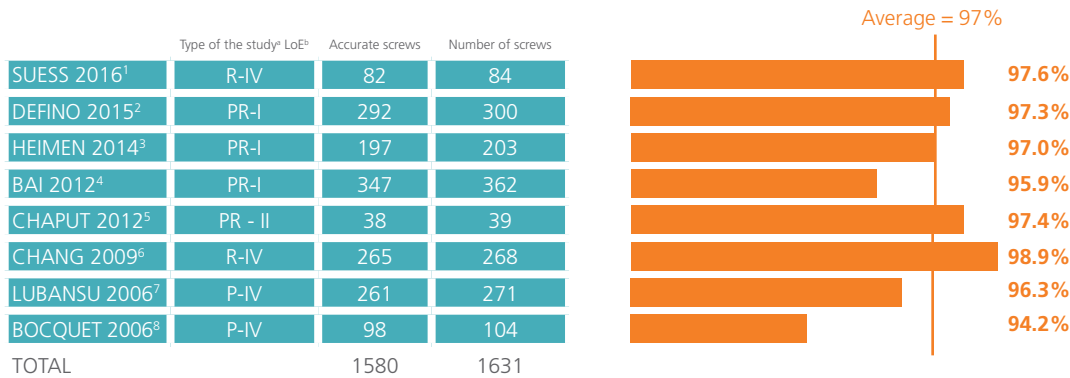
^cThose studies do not include indirect costs such as health care visits, diagnostic imaging, medication, injection, etc.

^dBased on four US economic studies⁶¹⁻⁶⁴.

Dynamic Surgical Guidance Solution

PediGuard devices are the only handheld devices that can anticipate¹⁰ and/or detect possible vertebral cortex perforation during pedicle preparation for screw placement. PediGuard probes can alert the surgeon prior to a breach by accurately analyzing the electrical conductivity of the surrounding tissues in real time.

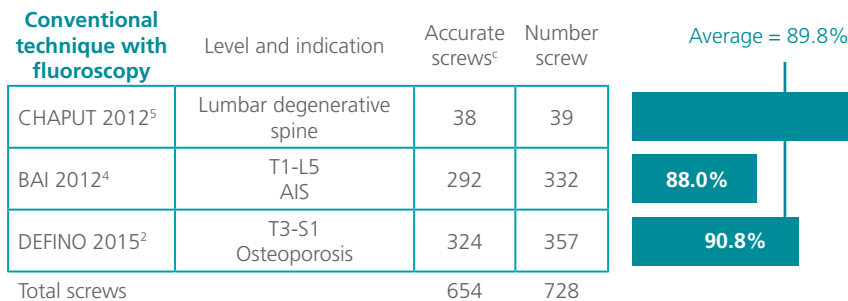
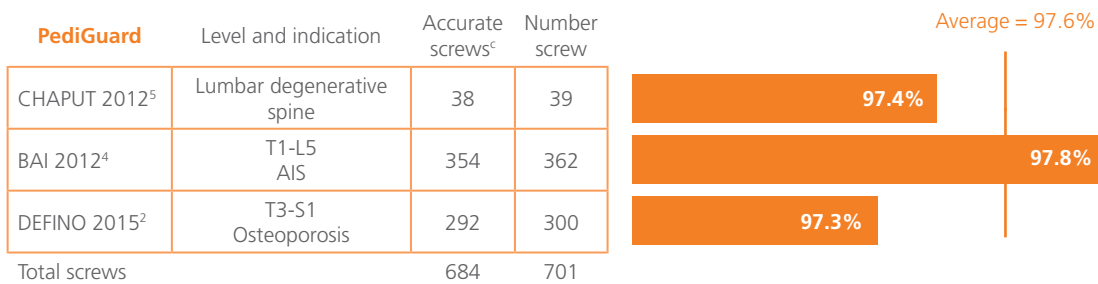
Strong Results in a Wide Number of Clinical Studies Worldwide



Very Accurate Technology

Those data suggest that accuracy of pedicle screw placement with the **PediGuard** device is drastically **improved** ranging from **94%**⁸ to **99%**⁶.

Accuracy Increased in Three Randomized Clinical Studies



There were no difference in Chaput's study because the surgeons relied on many fluoroscopic shots to provide a safe screw placement (7.5 fluoroscopic shots (range, 2-17) in the standard group versus 5.2 (range, 0-15) per screw in the PediGuard group, P < 0.0001)).

^aPR: Prospective Randomized, R: Retrospective, P: Prospective.

^bLoE: Level of Evidence.

^cScrews fully inside the pedicle or screw breaching 2mm or less.

Consistent and Reliable Breach Anticipation and Detection

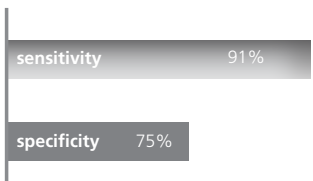
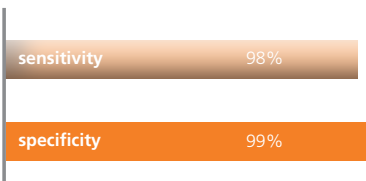
In an European multi-centre clinical trial with 11 senior surgeons in 9 centers, 521 pedicle drillings were performed on 97 patients. The PediGuard probe detected and therefore prevented **98%** of breaches (63/64)⁹.

3-Fold Reduction in Neurophysiological Alarms¹³

Screw placement in 248 scoliosis patients¹³ was retrospectively studied, and when a PediGuard probe was used:

- **3 times less** neuromonitoring alarms per screw were recorded,
- **Almost twice as many** screws were inserted per patient.

Comparison of PediGuard to EMG shows an Improvement in Sensitivity and Specificity Rates

	EMG ^{69,70} (based on 2 systematic reviews and meta-analysis)	PediGuard
Overall sensitivity and specificity of the probe <i>Sensitivity: Probability of breach detection given that there is a breach</i> <i>Specificity: Probability of NO breach detection given that there is NO breach</i>	(threshold 5-15 mA) 	(Bolger 2007 ⁹) 
Pedicle breach anticipation	No	100% (Williams ¹⁰)
Medial detection	Yes	100% (Williams ¹⁰)
Lateral or anterior breach detection	No	Yes (Williams ¹⁰ , Guillen ⁸³)
Detection in case of chronically compressed nerve root	Unlikely	Independent of the nerve condition
Misplaced screw	Up to 22%	3% on average ¹⁻⁷

Updated Guidelines for Intra-Operative Monitoring (IOM), 2014

The **American Association of Neurological Surgeons** have updated their **guidelines** regarding **IOM** during lumbar fusion for degenerative spine disease⁷¹:

- There is no evidence to date **that IOM can prevent injury to the nerve roots.**
- There is limited evidence that a **threshold below 5 mA** from direct stimulation of the screw can **indicate a medial pedicle breach by the screw.**
- Unfortunately, once a nerve root injury has taken place, changing the direction of the screw **does not** alter the outcome.

Additionally, Reviews of national databases^{72,73} demonstrated that the use of EMG and neuromonitoring for spine fusions does not decrease the risk of neurological injuries.

The Dynamic Surgical Guidance technology provides valuable feedback without interrupting the surgical procedure.

Safe Placement in Patients with Poor Bone Quality

Clinical Study part #1²

In a randomized clinical study including 108 patients², 97 patients had osteoporosis and 11 patients had osteopenia:

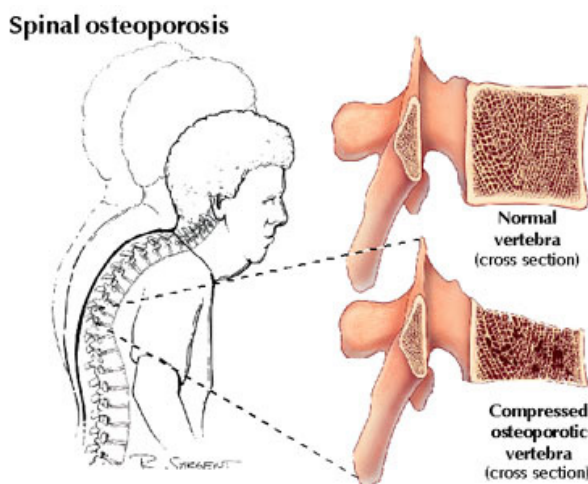
- **97.3%** of the screws accurately placed with the PediGuard probe instead of **90.8%** without the PediGuard probe,
- **54%** less fluoroscopic shots with the PediGuard.

Even in patients with osteoporosis or osteopenia, the PediGuard probe demonstrates at least **3 times** less pedicle breaches (>2mm).

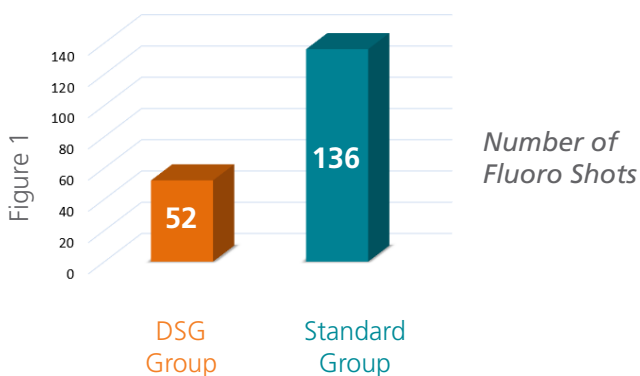
Clinical Study part #2²

Operative levels were from T3 to S1. Pedicle preparation was using either DSG or the free-hand technique. A total of 657 pedicle screws were placed.

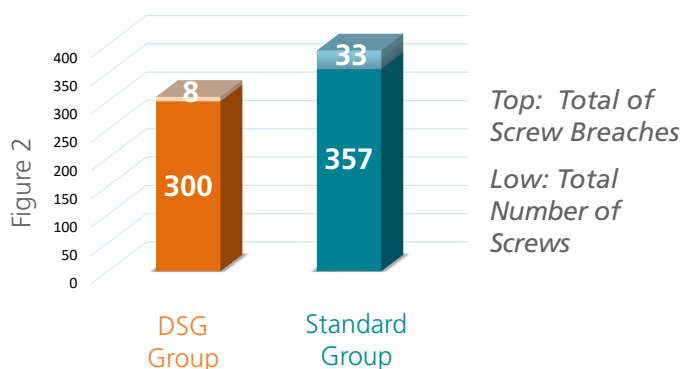
- Reduction of radiation was decreased by **74%** (P<0.0001) (Fig. 1).
- This combination of pedicle preservation and reduction of pedicle breaches during preparation led to a higher screw placement accuracy rate in the DSG assisted group. There was a **11%** breach rate in the Standard Technique group and a **2.6%** breach rate in the DSG assisted group (P<0.0001) (Fig. 2).



Reduction of Radiation (Fluoroscopy)



Screw Placement Accuracy



The use of Dynamic Surgical Guidance showed statistical significant differences in radiation exposure, screw placement accuracy and intra-operative pedicle preparation breaches.

These studies demonstrate that DSG has the potential for safely and effectively treating patients with demineralized bone.

Scoliosis Patients

A Large Number of Patients Treated for Scoliosis Emerge from Surgery with Screws of Concern

Screws at risk impinging anatomic structures such as the **aorta, esophagus, trachea or lung** and screws causing **neurologic deficits or injuries** are reported in two recent large studies^{65,74}.

Risk of Vascular Complications

In patients with deformity, revision surgery to remove a screw at **risk for the aorta** is recommended in **4.7%** (7/148²⁶ and 6/127⁷⁴) of the patients.

Instability

Misplaced screws without clinical symptoms can lead to **screw loosening** (1.4%: 3/208 patients⁷⁶; 3.5%, 3/86 patients⁷⁷).

Cerebrospinal Fluid (CSF) Leaks

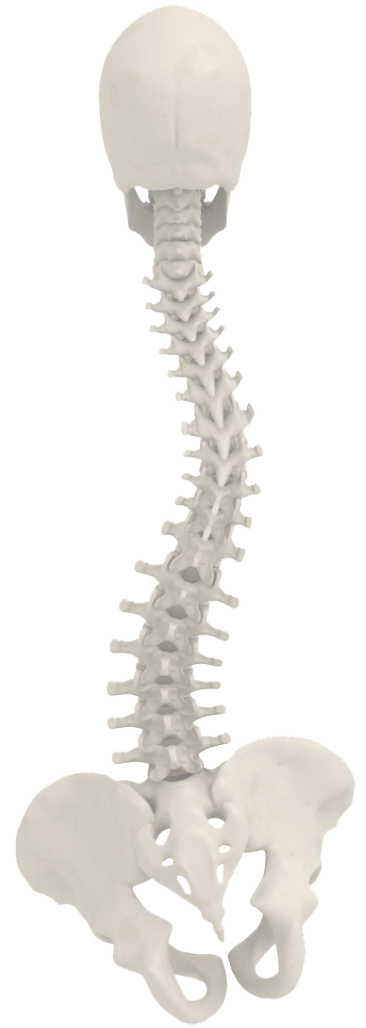
- **CSF leakage** without clinical symptoms from screw holes in 3.5% (3/86) patients⁷⁷.
- **Dural leak** causing **positional headaches** in 0.9% (3/322) patients⁷⁸.

Revision Surgery

Pedicle screw misplacement is the **first cause of reoperation** within 30 days of spine surgery in **1.7% AIS^a** patients in a US multi center study⁷⁹.

Radiation Exposure on Young Patients

- The **radiation exposure** is greater during **scoliosis surgery**⁸⁰.
- **Young people** are very **sensitive** to radiation exposure during their childhood¹¹⁹.
- **Girls** are at a **higher risk** of cancer development⁸¹.



How the DSG Technology can Help

A randomized clinical trial⁴ assessed the accuracy and time for pedicle screw placement with the DSG Technology and the Free-Hand technique for posterior scoliosis surgery.

- There were totally **3 times less pedicle perforations** in the DSG group (4.1%) than in the Free-Hand group (14.2%) (15 versus 47 (P<0.001)).
- The average **screw insertion time** was **decreased by 15%** in the DSG group.

A retrospective study¹¹ in patients with severe deformities showed a greater screw placement accuracy in the DSG Group compared with the Free-Hand technique, especially in the thoracic region (**92.5%** DSG Group vs 87% FH group).

A retrospective study¹¹⁷ in patients with severe syndromic and neuromuscular scoliosis, demonstrated a **10.2%** higher screw placement accuracy when using PediGuard and twice lower abandonment rate due to liquorrhea or perforation.

.... "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" (NICE 2015)¹⁸.

^aAIS: Adolescent Idiopathic Scoliosis

In the Cervical Spine

Poor placement and related complications of pedicle screws inserted in the cervical spine with the assistance of fluoroscopy are reported in the scientific literature⁸⁴⁻⁹⁰.

Prospective Clinical Study

Pedicle Screws Inserted with the PediGuard Probe

The prospective clinical study of Prof. Koller^{91,109} has been published in European Spine Journal.

- 137 patients included with **51%** of the patients presenting cervical deformities.
- 202 cervical pedicle screws inserted at C2 with 67 pedicles (33%) identified with sclerosis.
- 113 pedicle screws inserted from C3 to C7.

Preliminary Results for C2

- In 49 C2 pedicles (24%), post-op analysis of CT-scans showed **that the decision to stop pedicle tract preparation according to signals by PediGuard was the correct decision** (0% of nerve root injury).
- At follow-up of 1 year, **no** patient had **revision surgery** for Cervical Pedicle Screw (CPS) misplacement or a **neurovascular deficit**. There was **no vertebral artery injury**.
- 98% C2 were placed correctly.

In a published article¹⁶, Prof. Koller notes that the use of the PediGuard device, can speed up surgery for instrumented correction for Cervicothoracic Kyphosis.

Cadaveric Study

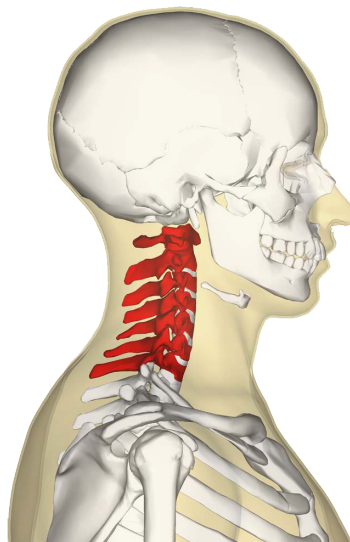
In a cadaveric study, the Dynamic Surgical Guidance probe¹⁵ was a safe tool to assist the surgeon with screw placement in the cervical spine. Additionally, the DSG Technology potentially avoids the cumulative risks associated with fluoroscopy and provides real-time feedback to the surgeon allowing correction at the time of breach.

- Fluoroscopy and other navigational assistance were not used for screw hole preparation or screw insertion.
- The breach rate for PediGuard activated was $6/68 = 9.0\%$.
- The breach rate for PediGuard non activated was $20/68 = 29.4\%$.

Scientific Publication

In a technical note¹¹⁸, Dr Kageyama et al. conclude that the DSG technology is useful for the **effective insertion** of a **C1 lateral mass screw** for the following reasons:

- (1) the frequency and pitch of its digital sound can be discerned;
- (2) it is easy to detect the cortical bone at the anterior margin of the atlas by the absence of sound from the DSG Technology;
- (3) the probe can be inserted slowly until the warning sound is heard, resulting in slight perforation of the anterior wall of the C1 lateral mass.



The PediGuard Probe for Residents

In a study, 2.1% of the patients (11/531) presented after a TLIF procedure⁷⁸ with worsening postoperative pain resulting from nerve root impingement by a pedicle screw. At least 50% of all pedicle screws had been placed by neurosurgical residents of varying experience. All implicated screws were removed and revised subsequently.

Experimental studies with the DSG Technology have demonstrated the added value of the PediGuard probe as a teaching tool for residents.

Reduction of the Learning Curve for Spine Surgery Residents

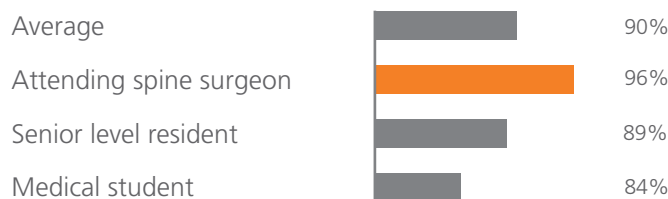
In a cadaveric study¹², 5 residents were randomized and assigned 3 specimens each to prepare bilateral pedicles from T8 to L5 (60 pedicles per resident) using either PediGuard devices or the Free-Hand technique.

PediGuard probes decreased:

- The **learning curve** for placing pedicle screws,
- The **breach rate by 58%** (19.7% in the non PediGuard vs 8.2% in the PediGuard group),
- **Surgery time by 21%** when placing pedicle screws.

Detection of Pedicle Breach with only 20 minutes of Didactic Training about the DSG Technology

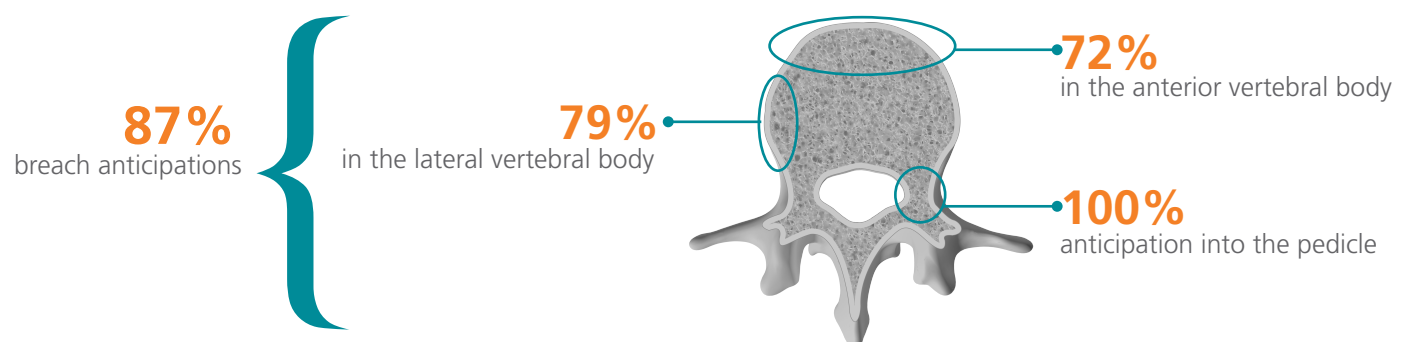
Individuals of 3 levels of training (attending spine surgeon, orthopedic surgery resident and medical student) used the Cannulated PediGuard device to cannulate each levels between T2 and S1⁸³.



Sensitivity of the Cannulated PediGuard probe to detect impending breach or breach of 4 mm or less.

Real Time Breach Detection and Anticipation

In a cadaver study in the U.S.¹⁰, the PediGuard probe warned the surgeons for an impending breach:



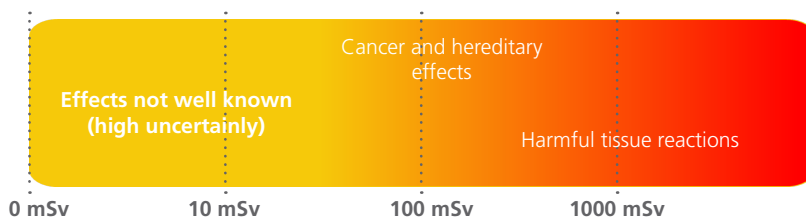
100% successful redirection without a breach after anticipation of an impending pedicle wall breach

Dangers of Radiation

Radiation exposure in spine surgery is excessive, protection is underutilized, and the long-term biological effects can be deadly. Fortunately, there is a growing concern among influential spine surgeons who are calling for the reduction of radiation vulnerability in the OR.

Surgeons' Greater Reliance on Fluoroscopy during Procedures exposes the Entire OR Team to Dangerous Radiation

- Surgeons are **highly exposed** especially in **MIS surgeries**⁹² and **scoliosis surgeries**⁹³.
- The **annual limit dose to the eye of 20 mSv/year**^{94,95} can be **exceeded** after:
 - **220 open TLIF** with 3.4 levels per case on average⁹⁶,
 - **112 MIS TLIF** with one level per case⁹⁷.



- Short-term to long-term consequences due to repetitive fluoroscopic procedures are:
 - **Back pain** due to heavy protections⁹⁸,
 - **Lens opacities**⁹⁹⁻¹⁰¹,
 - **Cancer** (breast, neck, brain)^{103,104,119}.
- Other limitations are observed:
 - Protective equipment is low or insufficient especially at the eyes and neck¹⁰⁵,
 - Lead aprons are subject to internal wear and their protection can be weakened without visible changes¹⁰⁶⁻¹⁰⁸,
 - Operator's legs, arms and head are usually not fully protected.



Randal Betz, MD
Pediatric Orthopaedic Surgeon
Lawrenceville, New Jersey

"I am very concerned not only for myself but my colleagues about the amount of radiation we are all receiving during spine surgery."



Helton Defino, MD
Orthopedic Surgeon
Ribeirao Preto, Brazil

"We are very concerned about repeated radiation especially now with new techniques since minimally invasive surgery was introduced in spinal surgery."



Larry T. Khoo, MD
Neurosurgeon, The Spine Clinic of Los Angeles, California

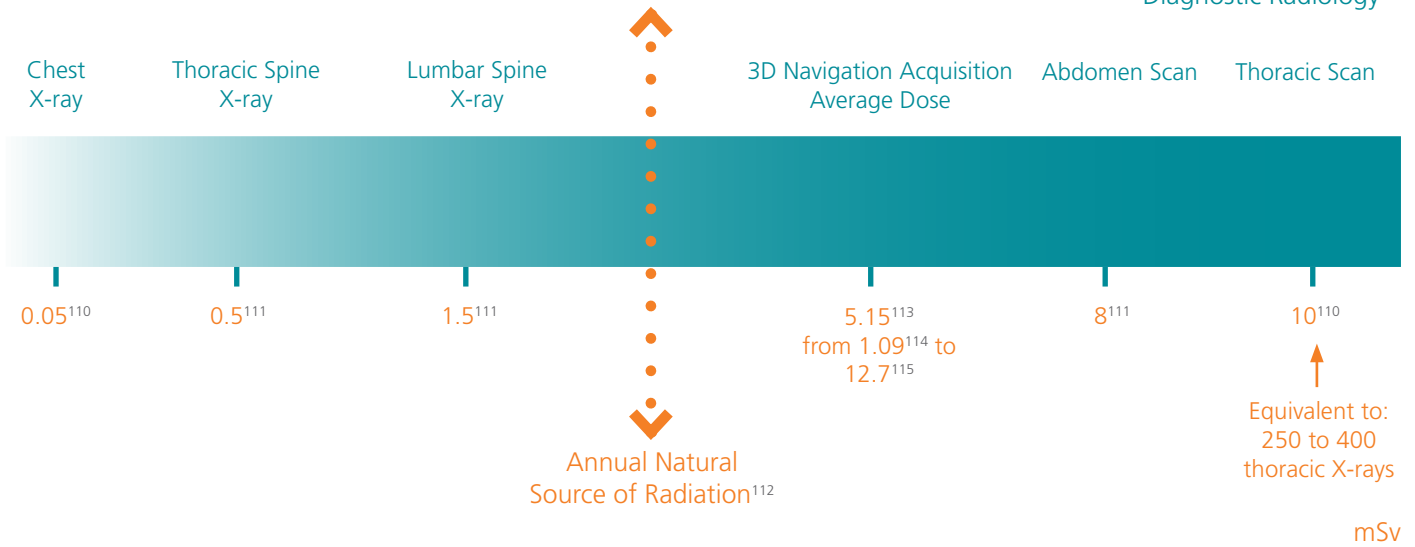
"Decreasing overall radiation exposure both shielded and unshielded is very important because even when we are shielded parts of us are still exposed. This rings true personally for me because one of my practice partners passed away

from what we believe was radiation thyroid malignancy. These are not just abstractions of fear but are real things that we can measure and knowing that radiation is a quantitative, a cumulative dose and anything that we can do to cut down 10 to 20% would have a tremendous impact on our safety and practice."



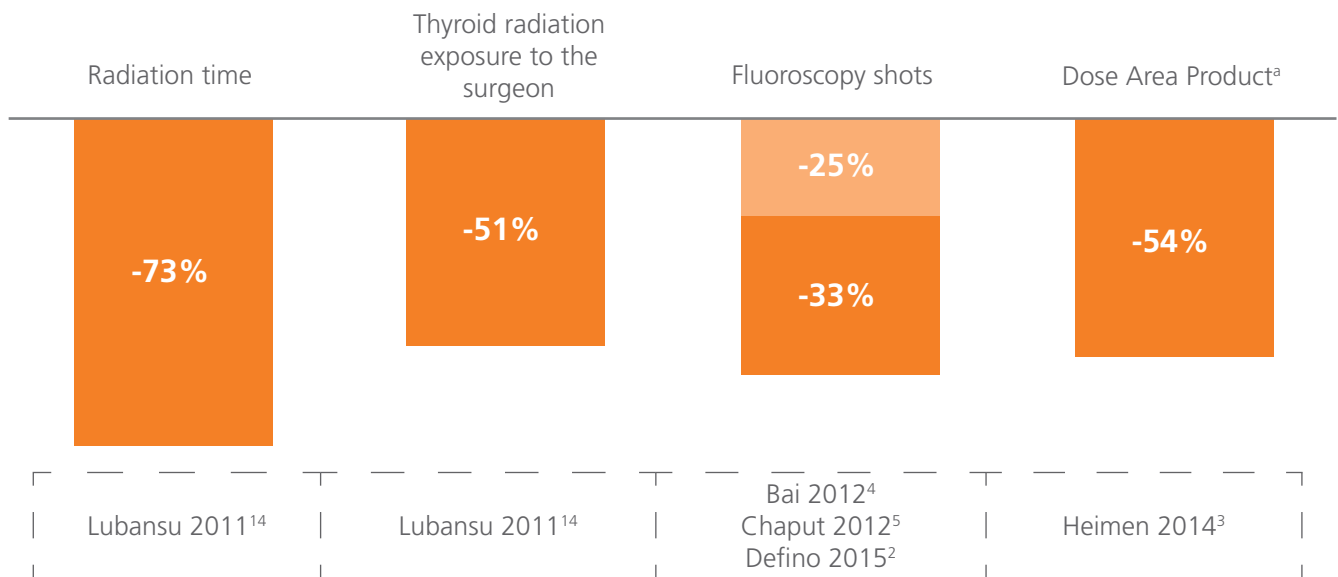
Ciaran Bolger, MD
Neurosurgeon, Beaumont Hospital
Dublin, Ireland

"I am very concerned about repeated exposure to radiation over a lifetime of work. I think it is a significant problem and it's a problem that is becoming an increasing problem because with minimally invasive techniques we are using far more radiation than our predecessors were."



PediGuard Devices can significantly reduce Radiation

Studies show that the PediGuard probe can significantly reduce the radiation exposure to the surgeon and the OR team:



PediGuard family of products complies with the recommendations of the International Commission for Radiation Protection (ICRP) and the ALARA principle As Low as Reasonably Achievable¹¹⁶.

^aDose measured on the fluoroscopic system

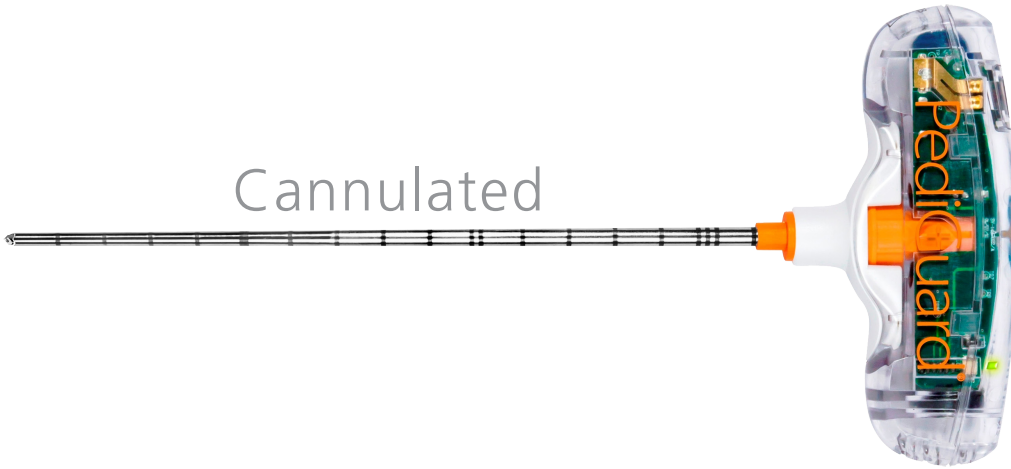
Straight



Curved



Cannulated



Threaded



Biomechanical studies with DSG

Perfect anchorage of screws in the pedicles is a crucial feature to achieve a good stabilization of the spinal construct. Two biomechanical studies demonstrated that the DSG Technology may help to reach this objective.

Study #1

Pilot hole done with the Threaded PediGuard

A biomechanical study¹²⁰ has the objective to experimentally evaluate the influence of the pilot hole tapping using the Threaded PediGuard and a screw with a different pitch from the Threaded PediGuard.

Three types of tapping were performed to do the pilot holes in polyurethane blocks:

1. Line-to-line tapping (tap with same pitch and external diameter of the screw),
2. Undertapping with congruent pitch (tap with the same pitch and 1mm smaller external diameter than the screw),
3. Undertapping with incongruent pitch (Threaded PediGuard with different pitch and/or different number of lead and 1mm smaller external diameter than the screw).

After screw insertion, pullout strength was evaluated.

Conclusion: The shape and pitch of the undertapping tool (Threaded PediGuard) has no influence on the pullout strength of the screw; [rather, it is the appropriate undertapping diameter that matters to optimize pull out strength].



Study #2

One-step screw direct insertion with DSG Screw

A biomechanical study¹²¹ has the objective to evaluate *in vitro* the direct pedicle screw insertion pullout strength.

A further development of Dynamic Surgical Guidance technique was the combination of DSG technology and a pedicle screw in just one device to develop a "A Dynamic Surgical Guidance Screw" (DSG Screw). The DSG Screw (SpineGuard/Zavation Dynamic Surgical Guidance Z-Direct Screw) is a pedicle screw system with a breach anticipation sensor located at the tip of the screw. The device provides a real-time surgical guidance and the ability to insert directly the screw into the pedicle without drilling a pilot hole neither tapping.

Screws directly inserted without a pilot hole and without tapping showed, statistically higher pullout strength than pedicle screws that were either tapped or screws that followed a pilot hole.

Conclusion: DSG Screw showed the highest pullout strength after its insertion without pilot hole and tapping.

DSG Technology in robotics applications

Using an electrical conductivity loop control system for automated breach prevention during robotic powered drilling of bone.

Studies^{122, 123, 124}

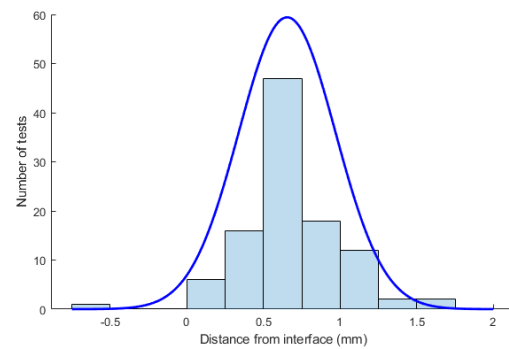
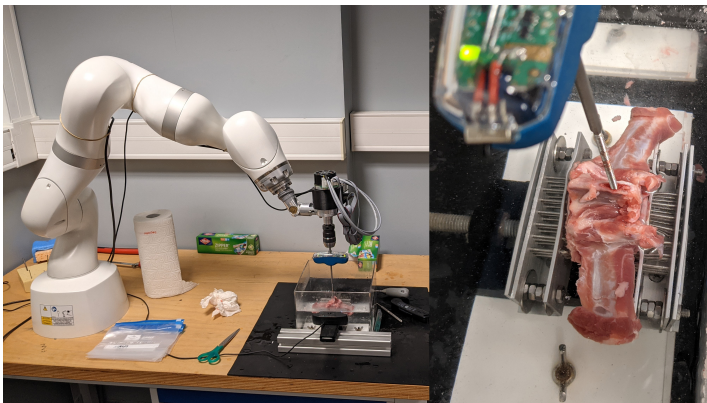
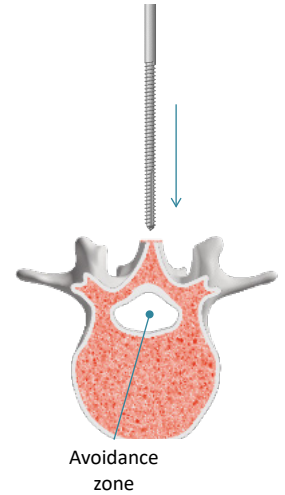
The objective of the study was to quantify the performance of tissue electrical conductivity measurement in real time to automatically detect and prevent bone breaches without utilization of imaging technologies in an ex-vivo animal model

Method

- A first series of 100 drill-through to collect data on measured electrical conductivity and penetration depth as a function of time
- An analysis work to optimize breach detection algorithms based on the collected data
- A second series of 104 drillings with real-time prospective application of the algorithms in order to automatically stop the robot with the instrument tip as close as possible to the bone/canal interface during the drilling

Success criteria

- PASS if tip is within +/- 2mm from the bone/canal interface (grade B)
- FAIL if tip is more than 2mm before (false positive) or more than 2mm after (false negative) the bone/canal interface.



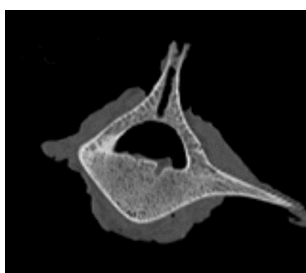
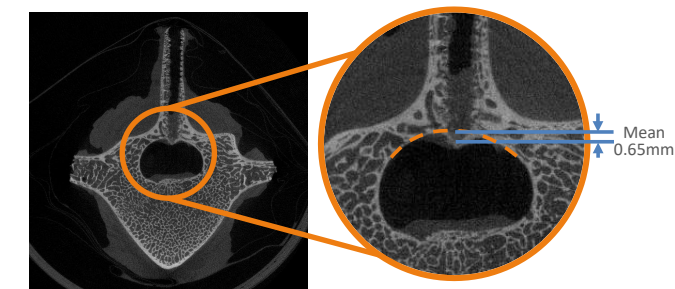
Conclusion:

These results demonstrate in an ex-vivo experiment the **robustness and efficacy of tissue electrical conductivity measured in real-time to detect bone boundaries and prevent breaches.**

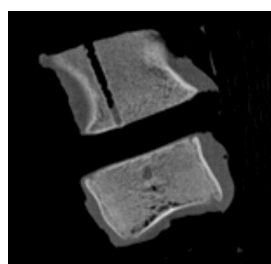
Beyond that, it opens appealing perspectives since the methodology articulating data collection, algorithm fine-tuning, and experimental verification is validated and can be repeated.

We are currently testing other algorithms of Artificial Intelligence learning, and evaluating what can be done from actual surgery data collected

In the context of the FAROS European project, we are evaluating how to combine DSG with other robot-generated or additional sensor-generated signals in order to produce even more advanced functions than breach detection and demonstrate the technical feasibility of automatic screw insertion without X-ray imaging.



Axial view



Sagittal view

This updated brochure presents 11 new publications (in blue) since the previous version of March 2019 and includes 25 papers on PediGuard (in orange) as follows:

- 14 published articles (2 in Spine, 1 in Journal of Spinal Disorders, 4 in European Spine Journal, 1 in Journal of Neurosurgery Spine, 1 in Coluna/Columna, 1 in Advances in Medicine, 1 in World Neurosurgery, 1 in Journal of clinical medicine, 2 in Brazilian Journal of Orthopaedics)^a.
- 10 oral presentations or posters in major congresses (Belgian Society of Neurosurgery 2006, IMAST 2006, AANS 2009, Eurospine 2011, SpineWeek 2012, CSRS-AP 2014, CNS 2014, Congresso Brasileiro de Coluna 2015, DWG Meeting 2014, SRS 2015).
- 1 publication by the NICE (National Institute for Health and Care Excellence, UK) 2015.

^aWe can also add 5 peer-reviewed publications on PediGuard that are not referenced in the brochure (1 in Spine, 3 in European Spine Journal, 1 in Coluna/Columna).

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