DSG TECHNOLOGY

Summaries of PediGuard® Clinical & Experimental Studies

SpineGuard®
Making spine surgery safer

GP1CF/121E

Content

	Pedicle screw placement	Breach detection	Ionizing radiation exposure	Training	MIS approach	Open approach	Takeaways
Publication							
Defino 2020	●		●			●	Screw placement accuracy: 97.3% Fluoroscopic shots reduction: 54.5%
Allaoui 2018	●	●				●	Screw placement accuracy in upper thoracic: 92.5%
Suess 2016	●	●				●	Screw placement accuracy: 97.6%
Dixon 2016	●	●				●	3 time less cortical breaches in the cervical spine
Williams 2014		●				●	Pedicle breach anticipation: 100% Breach anticipation overall: 87%
Guillen 2014		●		●	●		Overall sensitivity in detecting medial wall breach (with only 20mn didactic training with PediGuard): 95.8%
Bai 2013	●		●			●	Screw placement accuracy: 97.8% Fluoroscopic shots reduction: 24.5% Average surgical time reduction per screw: 15.4%
Chaput 2012	●		●			●	Screw placement accuracy: 97.5% Fluoroscopic shots reduction: 30%
Ovadia 2011	●					●	3 time less intraoperative neuro-monitoring alarms related to pedicle screw insertion
Bolger 2007		●				●	Breach detection: 98%

Content

	Pedicle screw placement	Breach detection	Ionizing radiation exposure	Training	MIS approach	Open approach	Takeaways
Oral communication/poster							
Koller 2014	●					●	Screw placement accuracy in C2: 98%
Heimen 2014	●		●			●	Significant decrease of the X-ray exposure with PediGuard
Lubansu 2011			●		●	●	Surgeon radiation dose reduction to the thyroïd: 51%
Chang 2009	●					●	Screw placement accuracy: 98.9%
Lubansu 2008			●			●	Fluoroscopic time reduction: 65%
Bocquet 2006	●					●	Screw placement accuracy: 94.2%

Publication: **Coluna/Columna** / Author: **Defino H**

Title	Does the Use of Dynamic Surgical Guidance Assist With Accurate Pedicle Screw Placement With Osteoporosis Or Osteopenia?
Country	Sãn Paulo, Brazil
Objective	To determine the effectiveness of DSG technology in accurate placement of pedicle screws in patients with poor bone quality.
PediGuard used	**Curved or Straight PediGuard device**
Type of the study	Prospective, randomized study

General and Demographic Data

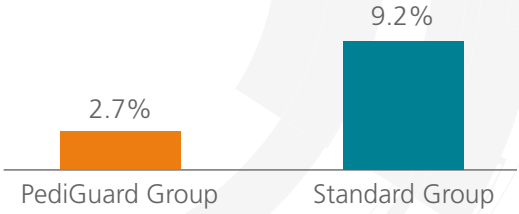
Patients (n=)	108 patients (97 had osteoporosis and 11 had osteopenia) Total of 657 pedicle screws (conventional technique: 357 screws vs. PediGuard device: 300 screws)

Key Data

97.3% of the pedicle screws were accurately placed when using the PediGuard probe.

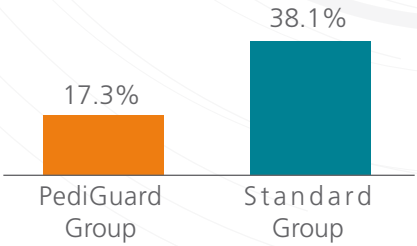
Number of misplaced screw was significantly lower when the PediGuard device was used ($p = 0.001$).

Misplaced Pedicle Screws



The number of fluoroscopy shots per screw was also significantly lower when the PediGuard device was used:

Fluoroscopic shots per screw



The fluoroscopic shot rate was 52/300 = 17.3% shots per screw when using the PediGuard device vs 136/357 = 38.1% shots per screw when using traditional methods ($p < 0.0001$).

There is a 54.5% decrease in fluoroscopic shots when the PediGuard is used.

Details

Inclusion criteria

- Primary surgery with pedicle screw fixation anywhere from T9-L5
- Older than 18 years old
- Osteopenia or osteoporosis
- Open Surgery
- Written informed consent

Exclusion criteria

- Pedicle screw insertion by image guided technique
- Previous surgery of fused spinal level
- Pregnant
- Congenital deformity of the spine
- Normal BMD

Patient's data

Female Age	No. of patients	Male Age	No. of patients
50-65	21	50-65	15
66-80	39	66-80	24
81-87	6	81-87	3

97 patients had osteoporosis and 11 patients had osteopenia.

Surgical data

Subjects were undergoing lumbar or thoracic pedicle screw fixation for fusion. They have been diagnosed with osteopenia or osteoporosis according to a Dexa evaluation.

Complete reference

Defino Helton, Williams John, Fernando da Silva Herrero Carlos, Betz Randal, Powell David, George Keri, Gaughan John. "Does The Use Of Dynamic Surgical Guidance Assist With Accurate Pedicle Screw Placement In Patients With Osteoporosis Or Osteopenia?" Coluna/Columna. 2020;19(3):189-93

Publication: **World Neurosurgery** / Author: **Allaoui M**

Title	Contribution of Dynamic Surgical Guidance to the Accurate Placement of Pedicle Screws in Deformity Surgery: A Retrospective Case Series.
Country	France
Objective	To assess the contribution of the Dynamic Surgical Guidance (DSG) probe in the accurate placement of thoracic and lumbar pedicle screws (PSs) in patients with spinal deformity.
PediGuard used	**Curved PediGuard probe (open approach)**
Type of the study	Retrospective study

General and Demographic Data

Patients (n=)	98 patients

Key Data

Of the pedicle screws used, **95.4% in the DSG group** and 92.2% in the Free Hand (FH) group were correctly placed (P = 0.0136).

The difference in screw placement accuracy was greater at the **thoracic level** (**DSG group, 92.5%**; vs. FH group, 87.0%; P = 0.0310) than at the **lumbar level** (**DSG group, 98.0%**; vs. FH group, 95.4%; P = 0.0385).

Severe (>4 mm) lateral breaches occurred in 24 cases (4.0%) in the FH group but in only 5 (0.6%) in the DSG group (P < 0.0001).

No severe medial breach was observed in either group.

Despite having more patients with severe deformities in the DSG group, **pedicle screw insertion was significantly more accurate with DSG**. This technique also reduced the severe unacceptable lateral misplacement rate (>4 mm) and, consequently, the incidence of intraoperative screw revisions even in patients with severe deformities.

Details

Inclusion criteria

All pedicle screw-based posterior instrumentation and intraoperative O-arm imaging used to check the position of the pedicle screws.

Exclusion criteria

Patients who underwent surgery with navigation were excluded.
Patients aged <15 years were also excluded.

Patient's data

	DSG Group	FH Group
No. patients	57	47
Age (range), year	54.6 ± 16.6 (18-79)	58.6 ± 15.7 (16-82)
No. males	9	8
No. females	48	39
Diagnosis		
Degenerative lumbar scoliosis	20 (35.1)	15 (31.9)
Thoracolumbar scoliosis	15 (26.3)	5 (10.6)
Scoliosis with severe kyphosis	17 (29.8)	17 (36.2)
Spondylolisthesis	5 (8.8%)	10 (21.3)

Surgical data

3 senior spine surgeons with 15 years of operative experience in spine deformity surgery contributed to the present study. Two of them operated simultaneously on both sides of the spine. The surgeons were not designated to either the right or left side.
Each surgeon placed approximately 1/3 of the screws with the assistance of the other attending surgeon to check the pedicle trajectory.
The DSG probe was used to navigate the pedicle hole in 57 procedures (DSG group) and the PSs were implanted using only the FH technique in 47 (control or FH group).

Safety Assessment

All 98 patients had complete preoperative, intraoperative, and postoperative CT scans available

Complete reference

Allaoui Mohamed, Zairi Fahed, "Contribution of Dynamic Surgical Guidance to the Accurate Placement of Pedicle Screws in Deformity Surgery: A Retrospective Case Series." World Neurosurg. 2018 Dec;120:e466-e471.

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Publication: **Advances in Medicine** / Author: **Suess O**

Title	Control of Pedicle Screw Placement with an Electrical Conductivity Measurement Device: Initial Evaluation in the Thoracic and Lumbar Spine
Country	Germany
Objective	To report the author's experience with the PediGuard device in severe degenerative disease and spinal tumor surgery
PediGuard used	**Classic PediGuard device**
Type of the study	Retrospective study

General and Demographic Data

Patients (n=)	15 patients

Key Data

The signal remained constant, while the PediGuard device was advanced forward through the pedicle into the vertebral body in 72/84 (85.7%) pedicle sites. In the other 12/84 (14.3%) sites, sound and LED signals warned for variation in the measured conductivity as a sign for possible pedicle wall penetration. In these cases, the PediGuard probe was slightly moved backwards and redirected in another trajectory through the pedicle until no further warning signal occurred.

The screw placement was graded as "correct" for 78 of 84 (92.8%) screws and "suboptimal" for 4 of 84 screws (4.8%). Hence, **97.6% of the screws were satisfactorily placed**, whereas 2 of 84 (2.4%) screws had to be graded "misplaced".

The PediGuard device safely allowed detection of changes in the electromagnetic field around the instrument tip as a warning signal for tissue with different consistency to bone. With careful handling, it even allows **detection of cortical breaches before full penetration has occurred**, giving the surgeon the chance to **redirect the trajectory**. Further advantages of this technique include **easy handling without a time-consuming setup** and **no additional X-ray exposure**.

Details	
Inclusion criteria	Patients undergoing dorsal transpedicular stabilization operations on the thoracic and lumbar spine.
Exclusion criteria	Patients with cardiac pacemakers and severe osteoporosis were excluded from participation.
Patient's data	There were 6 male and 9 female patients with a mean age of 61 years (41–83 y). In 8/15 patients a degenerative disease with DDD, spinal canal stenosis, and spondylolisthesis was the indication for dorsal instrumentation with a screw/rod system. In the other 7/15 cases a metastatic tumor of the spine (3x adenocarcinoma of the lung, 2x mamma carcinoma, 1x prostate carcinoma, and 1x hypopharynx carcinoma) was operated on. There were 7 single-level and 8 multilevel procedures.
Surgical data	Polyaxial screws with a diameter of 5.5 mm (thoracic) or 6.5 mm (lumbar) and a length of 30–50 mm were placed into the vertebral bodies according to the trajectory given by the PediGuard device. The placement of the pedicle screws on postoperative CT was evaluated by an independent radiologist. The position of the pedicle screw was rated as "correct" when no screwthread penetration through the mediocaudal pedicle wall could be seen on the postoperative CT. The position was "suboptimal" (but acceptable) when the screwthread penetrated the pedicle wall less than 2 mm. The position was rated "misplaced" when the pedicle wall was penetrated 2 mm or more by the screwthread.
Safety Assessment	There was no clinical sign of radiculopathy immediately after surgery or on the 6 and 12-month follow-up examinations. No revision surgery was necessary. There were no mechanical failures of the PediGuard device during these 15 operations.
Complete reference	Suess Olaf, Schomacher Markus. "Control of Pedicle Screw Placement with an Electrical Conductivity Measurement Device: Initial Evaluation in the Thoracic and Lumbar Spine". Advances in Medicine. 2016: 4296294.

Publication: **Eurospine J** / Author: **Dixon D**

Title	Accuracy of a dynamic surgical guidance probe for screw insertion in the cervical spine: a cadaveric study.
Country	U.S.A.
Objective	To report the cortical breach rate using the dynamic surgical guidance (DSG) probe versus traditional freehand technique for cervical lateral mass, cervical pedicle and cervical laminar screws.
PediGuard used	**PediGuard Straight, 2.5mm XS**
Type of the study	Cadaveric

General and Demographic Data

Specimen (n=)	9 male cadaver torsos

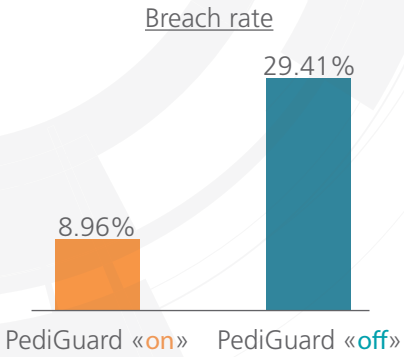
Key Data

Fluoroscopy and **other navigational assistance** were **not used** for screw hole preparation or screw insertion.

A total of 104 drillings were performed, 52 with DSG and 52 without DSG. There were 68 total pedicle drillings, 34 in each group. There were 18 drillings in the lamina and lateral mass. There was no significant difference between surgeons or between the left and right side. All breaches were in the pedicle, and none in the lamina or lateral mass.

The breach rate for PediGuard «on» was 6/68 = **8.96%**.

The breach rate for PediGuard «off» was 20/68 = **29.41%**.



The dynamic surgical guidance probe is a **safe tool** to assist the surgeon with screw placement in the **cervical spine**. Additionally, the **DSG** potentially **avoids** the **cumulative risks** associated with **fluoroscopy** and provides **real-time feedback** to the surgeon allowing correction at the time of breach.

Details

Surgical data	Bilateral C1 lateral mass, C2 pedicle screw and lamina, and C6–T1 pedicle screws were instrumented in these cadavers. Each investigator was assigned three specimens that were randomized by fixation point, side and order of technique for establishing a screw pilot hole. The technique for screw hole preparation utilized was either a DSG probe in the «on» mode or in the «off» mode using a freehand technique popularized by Lenke et al. Levels instrumented included C1 lateral mass, C2 pedicle screws and lamina screws, and C6-T1 pedicle screws. Fluoroscopy and other navigational assistance were not used for screw hole preparation or screw insertion. All specimens were CT imaged following insertion of all screws. A senior radiologist evaluated all scans and determined that a misplaced screw was a breach of ≥2 mm.
Complete reference	Dixon D, Darden B, Casamitjana J, Weissmann KA, Cristobal S, Powell D, Baluch D. Accuracy of a dynamic surgical guidance probe for screw insertion in the cervical spine: a cadaveric study. Eur Spine J. 2017 Apr;26(4):1149-1153. doi: 10.1007/s00586-016-4840-6. Epub 2016 Nov 14.

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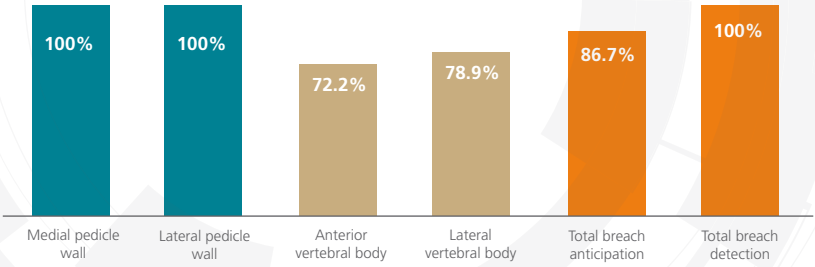
Publication: **Coluna/Columna 2014** / Author: **Williams J**

Title	Anticipation of vertebral pedicle breach through dynamic surgical guidance.
Country	USA (Las Vegas, Nevada)
Objective	To determine the effectiveness of the DSG technology to anticipate an impending breach and allow redirection during placement of a pilot pedicle hole.
PediGuard used	**Curved PediGuard probe (open approach)**
Type of the study	Cadaveric
Specimen	A cadaver model (saline prepared) was used for this study.

Key Data

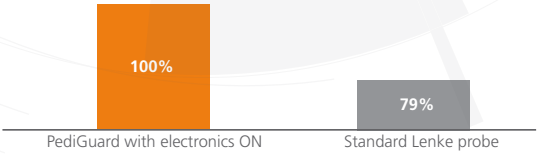
With the Curved PediGuard:

- **Successful** anticipation of impending breaches in 65/75 drillings (**87%**)



Rates of pedicle wall and vertebral body breach anticipation using the PediGuard probe with electronics ON

- **100%** detection of the breaches
- **Successful redirection** after the anticipation of an impending pedicle breach in **100%** of the drillings versus only **79%** with the standard Lenke probe



Anticipation rate with PediGuard and the Standard Lenke probe

Details	
Methodology	A. Part 1 of the study: Anticipation The surgeon used fluoroscopy to find the starting points over the pedicles in the thoracic and lumbar spine. The surgeon then commenced drilling with the PediGuard probe purposefully planning for a pedicle or vertebral body wall breach. The surgeon stopped probing when the sound changed, suggesting abutment against the cortical wall ("anticipation" of impending breach). A fluoroscopic image was then taken. The surgeon finished drilling with the pedicle probe in the same direction and performed a breach. B. Part 2 of the study: Redirection 3 probes were used in the study: 1) The PediGuard probe with electronics ON, which changes sound to differentiate cancellous bone from cortical bone from saline indicating breach 2) The PediGuard probe with electronics OFF 3) Standard Lenke probe Two operating surgeons purposely placed the tip of the probe on the medial or lateral pedicle cortex (simulating an impending pedicle wall breach) based on a randomization schedule. After the images were taken, the operating surgeon (blinded to x-rays) was instructed to redirect and continue drilling into the vertebral body.
Complete reference	Williams John, Samdani Amer, Defino Helton Luiz Aparecido, George Keri, Gaughan John, and Betz Randal. "Anticipation of vertebral pedicle breach through dynamic surgical guidance." Coluna/Columna 13.3 (2014): 210-213. Print.

Title	Independent assessment of a new pedicle probe and its ability to detect pedicle breach: a cadaveric study.
Country	USA (Loma Linda, California)
Objective	To impartially evaluate the efficacy of the PediGuard device to warn of an impending and actual pedicle screw breach.
PediGuard used	**Cannulated PediGuard device (MIS approach)**
Type of the study	Independent, non-industry funded cadaveric study

General and Demographic Data

Specimen (n=)	2 cadavers (saline prepared) were used for this study from T2 to S1 without the assistance of fluoroscopy.

Key Data

Participants	Attending spine surgeon	Senior-level resident	Medical student	Overall
Sensitivity	96%	89%	84%	90.06%

Sensitivity of the PediGuard probe to detect an impending or actual breach of 4 mm or less

Overall **sensitivity** in detecting **medial** wall **breach** (for all participants with only 20mn didactic training with PediGuard) **95.8%**.

The overall sensitivity of 90.06% is significantly lower than most previously reported studies on PediGuard probe's accuracy. The authors believe this may be due to the following:

1) The 3 operators had varying surgical experience.
2) All operators had no prior experience with PediGuard.
3) Cannulation was performed **without any** fluoroscopic assistance.

This study showed that the PediGuard device could reasonably be used to **detect impending breach** and breach of less than or equal to 4 mm.

Details	
Surgical data	Once the authors believed they had breached or were at impending breach they would lightly tap their pin into the pedicle, which could have superficially lengthened their actual value where breach was recorded.
Accuracy Assessment	Breach was confirmed by fine-cut CT scan, with the results interpreted by 3 attending physicians and averaged. For the purposes of our analysis, breach is defined as a pin with more than 25% of its diameter residing outside and medial, inferior, or superior to the pedicle and/or a pin protruding more than 2 mm.
Complete reference	Guillen Phillip T., Knopper Ryan G., Kroger Jared, Wycliffe Nathaniel D., Danisa Olumide A., and Cheng Wayne K.. "Independent assessment of a new pedicle probe and its ability to detect pedicle breach: a cadaveric study." Journal of Neurosurgery: Spine 21.5 (2014): 821-825. Web. 29 Aug. 2014.

Publication: **Journal of Spinal Disorders and Techniques 2013** Author: **Bai Y**

Title	Comparison of the Pedicle Screws Placement Between Electronic Conductivity Device and Normal Pedicle Finder in Posterior Surgery of Scoliosis
Country	Singapore
Objective	To compare the accuracy and time of pedicle screw placement between the PediGuard device and the conventional free-hand technique in the thoracic and lumbar spine.
PediGuard used	**Classic PediGuard probe (open approach)**
Type of the study	Prospective, randomized, controlled study

General and Demographic Data

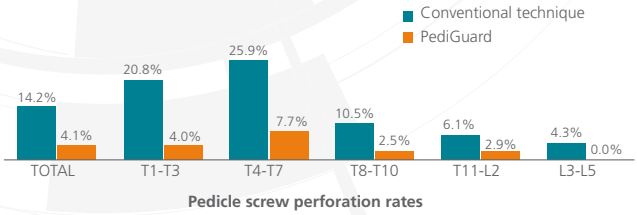
Patients (n=)	42 patients aged 10-18 years • Conventional technique: 22 patients • PediGuard: 20 patients

Key Data

	Conventional	PediGuard
Screws inserted	332	362
Screws fully inside the pedicle, Grade 0	285 (**85.8%**)	347 (**95.9%**)
In (or < 2 mm breach), Grade 0 + Grade 1	292 (**88.0%**)	354 (**97.8%**)
Avg. time / screw	241 ± 61	204 ± 33
Avg. number of fluoroscopic shot per case	1.59 ± 0.67	1.20 ± 0.52

Post-op CT scan and 2 independent reviewers

- Average time reduction: **15.4%** (p=0.009)
- Reduction of the average number of fluoroscopic shot: **24.5%** (p=0.040)



Pedicle screw perforation rates

The PediGuard device **increased** pedicle screw **accuracy**, especially in T1–T10, and **reduced insertion time** and **radiation** in adolescent idiopathic scoliosis.

Details

Inclusion criteria

Adolescent Idiopathic Scoliosis (AIS) patients with scoliosis curve between 40 and 80.

Exclusion criteria

Non-AIS deformities, more severe deformities, or a body weight of more than 80 kg were excluded because in these conditions, it would significantly alter the pedicle diameter, which could influence the pedicle screw placement accuracy and time.

Patient's data

	Conventional	PediGuard
No. patients	22	20
Age (range), year	15.5 ± 5.6 (10-18)	16.2 ± 4.5 (11-18)
No. males	5	4
No. females	17	16

The average major curve Cobb angle was 55.3 ± 7 degrees (range, 45–78 degrees).

Surgical data

All patients underwent posterior spinal fusion with pedicle screw only constructs. The average number of segments instrumented was 9 ± 3 (range, 6–14).

Safety assessment

None of these patients had any clinical evidence of neurovascular involvement and revision surgery.

Complete reference

Bai Yu-Shu, Yun-Fei Niu, Zi-Qiang Chen, Xiao-Dong Zhu, Liu Ka Po Gabriel, Hee Kit Wong, and Ming Li. "Comparison of the Pedicle Screws Placement Between Electronic Conductivity Device and Normal Pedicle Finder in Posterior Surgery of Scoliosis." Journal of Spinal Disorders and Techniques 26.6 (2013): 316-320. Print.

Publication: ***Spine 2012 /*** Author: ***Chaput C***

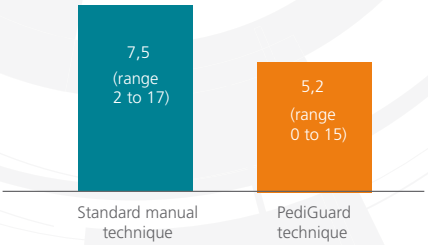
Title	Reduction in Radiation (Fluoroscopy) While Maintaining Safe Placement of Pedicle Screws During Lumbar Spine Fusion.
Place of the study	USA (Temple, Texas)
Objective	To analyze the potential for reduced fluoroscopy shots while maintaining accurate screw placement.
PediGuard Version	**Classic PediGuard device (open approach)**
Type of the study	Prospective, randomized, controlled study

General and Demographic Data

Patients (n=)	18 patients aged 55 ± 12 years

Key Data

Pedicle screw placement rates	In (or < 2 mm breach)	Out (or ≥ 2mm breach)
Standard manual technique (39 pedicle screws)	38 (97.5%)	1 (2.5%)
PediGuard technique (39 pedicle screws)	38 (97.5%)	1 (2.5%)



Number of fluoroscopy shots per screw

In this study, the **number of fluoroscopic shots** was **reduced by 30%** compared with a standard drilling probe while maintaining a **97.5% accurate, safe screw placement**.

Details	
Inclusion criteria	Patients with a diagnosis of lumbar degenerative spine having a posterior spinal fusion.
Randomization	The first pedicle screw was randomly selected for insertion after the use of a standard pedicle probe or after the PediGuard device based on a randomized chart. Every subsequent pedicle screw insertion was randomized by an alternating technique using either a standard probe or the PediGuard device.
Surgical data	The first pedicle was probed at either the most distal or the most proximal vertebra to be instrumented. Then, the opposite pedicle at the same level was drilled using the technique not used initially. At each subsequent level, the technique used on each side was reversed. For example, if at L3 the PediGuard device was used on the left and surgeon's procedure on the right, then at L2 the PediGuard device would be used on the right and surgeon's procedure on the left. This process was continued until all levels were instrumented. This randomization of the screw insertion versus randomizing patients was thought to eliminate most of the bias that arises from patient differences such as sex, pedicle size, bone density, patient's body mass index, and so on. The surgeon used fluoroscopy for each drilling as a guidance assist as necessary.
Safety assessment	No patient in either group had a new radiculopathy or new neurological deficit.
Complete reference	Chaput Christopher D., George Keri, Samdani Amer F., Williams John I., Gaughan John, and Betz Randal R.. "Reduction in Radiation (Fluoroscopy) While Maintaining Safe Placement of Pedicle Screws During Lumbar Spine Fusion." Spine 37.21 (2012): E1305-E1309. Print.

Publication: **Spine 2011** / Author: **Ovadia D**

Title	The Contribution of an Electronic Conductivity Device to the Safety of Pedicle Screw Insertion in Scoliosis Surgery.
Country	Israel (Tel Aviv)
Objective	To evaluate the contribution of the PediGuard device to the safety of thoracic and lumbar pedicle screw placement in a large group of pediatric patients with scoliosis.
PediGuard used	**Classic PediGuard probe (open approach)**
Type of the study	Retrospective, comparative, controlled clinical study
Duration	From 2003 to 2009

General and Demographic Data

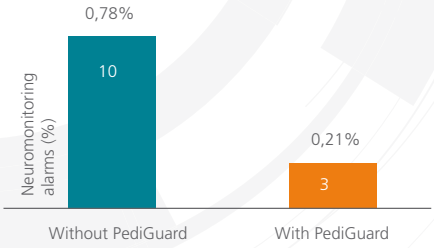
Patients (n=)	248 pediatric scoliosis patients aged 14.06 ± 3.38 years: • PediGuard: 150 patients • Without PediGuard: 98 patients

Key Data

Clinically relevant misplacement of pedicle screws was established by intraoperative neurophysiological monitoring alarms concomitant with screw insertion.

In the PediGuard group:

- Fewer intraoperative monitoring alarms related to pedicle screw insertion
- Higher number of implanted pedicle screws per patient (average of 14.3 with PediGuard vs. 8.5 without PediGuard)



Statistically significant
(P = 0.048)

According to the authors, the **routine use** of the **PediGuard** device significantly **increases** the **safety** of **scoliosis surgery** and significantly **reduces** the incidence of **clinically relevant misplaced pedicle screws**.

Details

Inclusion criteria

Patients with scoliosis of various etiologies (idiopathic, congenital, neuromuscular, syndromic).

Patient's data

	Age (SD)	Congenital (%)	Idiopathic (%)	Others (%)	Cobb angle (SD)	
					Pre-op	Post-op
Group without PediGuard	13.7 (3.8)	23 (15.6)	80 (53.1)	47 (31.3)	73.3° (21.3°)	29.2° (13.2°)
Group with PediGuard	14.4 (2.9)	10 (10.2)	61 (62.2)	27 (27.6)	68.9° (16.2°)	24° (9.7°)

- In the group without PediGuard, the authors initially used hybrid instrumentation for fixation and gradually transferred to all pedicle screw construct. Average number of screws per patient was 8.5
- In the group with PediGuard, pedicle screws alone were used. Average number of screws per patient was 14.3

Surgical data

Both groups were operated on by a single senior spine surgeon and continuously monitored with intraoperative multimodal evoked potentials (SSEPs, MEPs) and electromyography (EMG) by a single neurophysiologist. All pedicle screws were implanted using the free-hand technique.
The default surgical approach was to implant pedicle screws in all spinal levels on the concave side of the scoliotic curve, and in every other spinal level on the convex side. Whenever the pedicle width was found by the surgeon to be extremely narrow or deformed, thus endanger a safe screw implantation, that particular segment was skipped.

Safety assessment

- Monitoring returned to normal following screw removal and reinsertion
- All 13 neuromonitoring alarms were resolved by the end of the procedure and none of the 248 study patients had any neurological sequels

Complete reference

Ovadia Dror, Akiva Korn, Michael Fishkin, David M. Steinberg, Shlomo Wientroub, and Elisha Ofiram. "The Contribution of an Electronic Conductivity Device to the Safety of Pedicle Screw Insertion in Scoliosis Surgery." Spine 36.20 (2011): E1314-E1321. Print.

Publication: **European Spine Journal 2007** / Author: **Bolger C**

Title	Electrical conductivity measurement: a new technique to detect iatrogenic initial pedicle perforation.
Place of the study	European multicentric study (9 centers)
Objective	To ascertain if the PediGuard device could detect the presence of pedicle cortical breaches and if the detection rate was superior to the surgeon's traditional methods of detecting breaches.
PediGuard version	**Classic PediGuard probe (open approach)**
Type of the study	Prospective, comparative study
Duration	From September 2002 to September 2004

General and Demographic Data

Patients (n=)	97 patients

Key Data

- 521 pedicle drillings on 97 patients performed by 11 surgeons
- Post-operative CT imaging confirmed 64 breaches (12.3%)
- The PediGuard device detected 63 of the 64 breaches (**98.4%**)
- The overall sensitivity anf specificity are **98%** and **99%** for detecting a pedicle breach respectively

	First arm of study (32 patients)	Second arm of study (69 patients)	Total (97 patients)
Detected by surgeon	10/23 (43.5%)	N/A	10/23 (**43.5%**)
Detected by the PediGuard device	22/23 (95.7%)	41/41 (100%)	63/64 (**98.4%**)
Detected on CT scanning	23 (15.6%)	41 (11.0%)	64 (12.3%)
Total drillings	147	374	521

Results of breaches detected by device and surgeon during pedicle preparation

This **first clinical study** performed with the **PediGuard** probe showed that it had a **sensitivity** of **98%** in the detection of breaches and detected **52% more breaches** than the actual surgeon performing the surgeries. Thus, the PediGuard device gave **real-time feedback** to the surgeon without the surgeon having to change instruments and therefore not losing momentum during pedicle preparation.

Details	
Inclusion criteria	Patients undergoing a single or multiple spinal fusion at any level (thoracic / lumbar).
Surgical data	Initially, the surgeon proceeded with his normal protocol for inserting pedicle screws using the device and his traditional methods to detect pedicle breaches. The surgeon's ability to detect a pedicle breach by his traditional methods was compared to those detected by the device. In the second module of the study, the surgeon was limited to using the electrical conductivity detection device as their sole guide to detect pedicle breaches. The accuracy of the tool was assessed for breach detection. Post-operative fine cut CT scanning was used to detect the pedicle breaches.
Safety assessment	There were no adverse events noted with the use of the PediGuard device.
Complete reference	Bolger Ciaran, Kelleher Michael O., McEvoy Linda, Brayda-Bruno Marco, Kaelin Andre, Lazennec Jean-Yves, Le Huec Jean-Charles, Logroscino Carlo, Mata P, Moreta P, Saillant G, and Zeller R. "Electrical conductivity measurement: a new technique to detect iatrogenic initial pedicle perforation." European Spine Journal 16.11 (2007):1919-1924. Print.

Oral Communication: **CSRS 2014** / Author: **Koller H**

Title	Analysis of Cervical Screw Placement Accuracy and Fixation in 137 Patients with Focus on Patients with Cervical Deformity using an Electrical Conductivity Device (ECD)
Country	Germany
Objective	To report the efficacy and accuracy of using the PediGuard device for insertion of cervical pedicle screw (CPS), especially in the treatment of cervical deformities (CD)
PediGuard used	**Classic PediGuard probe**
Type of the study	Prospective

General and Demographic Data

Patients (n=)	137 patients

Key Data

202CPS inserted in C2 and 113 CPS inserted in C3-C7.

Average number of fused levels per patient: 5.3±4.2.

Correct screw placement	170 (84%)
Acceptable screw placement	28 (14%)
Unacceptable screw placement	4 (2%)

Pedicle screw placement accuracy at C2

An impassable cortical pedicle isthmus was correctly identified by the PediGuard probe, allowing use of shorter screws without breaching. In patients with anomalous course of the vertebral artery and dysplastic anatomy, 'close to target screw placement' enabled safe insertion of the longest screws possible in the individual anatomy.

At follow-up of 1 year, **no patient** had **revision surgery** for CPS misplacement or a **neurovascular deficit**. There were **no vertebral artery injuries**.

The **PediGuard** probe was shown to be of **particular advantage** in patients with **cervical deformity** with **distortion** of **anatomical landmarks** and **morphology**.

Additional information

Inclusion criteria	Patients undergoing cervical pedicle screw placement for various indications
Patient's data	Average age: 59 years, range (10-87 years). Diagnoses included: • Previous cervical surgery, n=61 (45%) • Spinal cord injury, n=13 (9%) • Neuromuscular disease, n=4 (3%) • Ankylosing spondylitis, n=19 (14%) • Rheumatoid arthritis, n=32 (23%) • Cervical deformity in 51% of the patients Analysis of pre-op CT-scans revealed 67 (33%) C2 pedicles with sclerosis. Left/right diameter of the C2 pedicle was 5.6±1.7mm/5.4±1.6mm.
Surgical data	Total surgical time was 245±101minutes, blood loss was 637±319ml. PediGuard version: Classic 2.5mm.
Safety assessment	Pedicle screw assessment on post-op CT scan: • Type I – correct • Type II – acceptable (< ½ screw diameter out or <2mm) • Type III – unacceptable screw with potential for neurovascular injury At follow-up of 1 year, no patient had revision surgery for CPS misplacement or a neurovascular deficit. There were no vertebral artery injuries.
Complete reference	Koller H, Mayer M. Analysis of Cervical Screw Placement Accuracy and Fixation in 137 Patients with Focus on Patients with Cervical Deformity using an Electrical Conductivity Device (ECD). CSRS meeting 2014

Oral communication: **DWG 2014** / Author: **Heimen K**

Title	Prospektive Untersuchung der Schraubenpositionierung bei Spondylodesen zwischen Bildwandler gesteuerter (Standard) und Schraubenplatzierung mittels induktivem Pfriem.
Country	Germany (Leipzig).
Objective	To compare the conventional placement of pedicle screws into the thoracic and lumbar spine to the inductive controlled placement focusing on the precision of the pedicle screw, the time needed for surgery and the amount of x-ray radiation.
PediGuard used	**Classic PediGuard device (open approach)**
Type of the study	Prospective and randomized
Duration	From 04/2012 to 06/2014

General and Demographic Data

Patients (n=)	68 patients with a minimum of 4 pedicle screws in the lumbar or thoracic spine.

Key Data

- In the standard group: 11 lateral pedicle perforations (**5.4%**)
- In the PediGuard group: 6 lateral pedicle perforations (**3%**)
- No medial pedicle perforation in both groups
- **Significant decrease of** the **X-ray exposure** in the PediGuard group

Details

Inclusion criteria	Patients undergoing posterior spinal fusion with at least 4 pedicle screws inserted in the lumbar and/or thoracic spine.
Patient's data	• Standard group: 34 patients, 204 pedicle screws • PediGuard group: 34 patients, 203 pedicle screws
Surgical data	Before surgery started, the patient was randomized to the PediGuard group or the standard group. The surgeries were done by three surgeons. During the operation, the time for the screw placement and the x-ray exposure of each screw were measured. The screw placement accuracy was evaluated by an independent blinded radiologist with postoperative CT scan.
Complete reference	Heimen Kathrin , Hallbauer Thomas, Zander J, Erli H. J. "Prospektive Untersuchung der Schraubenpositionierung bei Spondylodesen zwischen Bildwandler gesteuerter (Standard) und Schraubenplatzierung mittels induktivem Pfriem." DWG annual meeting. Congress Center Leizpig, Leizpig, Germany. 11-13 Dec. 2014. Oral presentation.

E-poster: **Eurospine 2011** / Author: **Lubansu A**

Title	Prospective Evaluation of a Free-Hand Electrical Conductivity Measuring Device to Reduce Radiation Exposure during Fluoroscopically Assisted Open or Minimally Invasive Pedicle Screw Arthrodesis.
Country	Belgium
Objective	To evaluate the efficiency of the PediGuard device to prevent misplacement of screws and reduce radiation exposure during open and MIS (minimally invasive surgery) PPSF (posterior pedicle screw fixation).
PediGuard used	**Classic PediGuard probe (open and MIS approach)**
Type of the study	Prospective, comparative study

General and Demographic Data

Patients (n=)	• Group A: Open PPSF helped with fluoroscopy alone, 15 patients • Group B: Open PPSF helped with fluoroscopy + PediGuard, 15 patients • Group C: MIS PPSF helped with fluoroscopy alone, 15 patients • Group D: MIS PPSF helped with fluoroscopy + PediGuard, 15 patients

Key Data

No misplaced screws observed in any groups.

- **In open surgery**, between group A and B, significant reduction was noted for the total fluoroscopy time (33%, $p<0.02$), the AP (71%, $p<0.05$) and lateral patient exposures (55%, $p<0.05$)

- **In MIS surgery**, between group C and D, the total fluoroscopy time, thyroid surgeon exposure and lateral patient exposure were significantly reduced (respectively 73% ($p<0.01$), 51% ($p<0.05$) and 61% ($p<0.05$))

	MIS surgeries	**Radiation dose patient (mSv)**		**Radiation dose surgeon (mSv)**	
	Fluoroscopy time (min)	Frontal radiation exposure	Lateral radiation exposure	Thyroid	Gonad
Group C (control)	6.63	10.81	44.92	0.31	0.48
Group D (with PediGuard)	1.79	8.50	17.72	0.15	0.18
% reduction	-73%	-21%	-61%	-51%	-61%
P	< 0.01	NS	<0.05	< 0.05	<0.05

The authors confirm that the **PediGuard** device is an **easy-to-use tool**, without hardware and ancillaries, which **optimizes** the **screw positioning** with a **reduced amount** of **radiation exposure** to the patients and the surgical staffs.

Details	
Patient's data	A. 9 men/6 women (mean age: 56 years (42-72)) B. 10 men/5 women (mean age: 48 years (30-69)) C. 8 men/7 women (mean age: 45 years (19-70)) D. 7 men/8 women (mean age: 51 years (34-65))
Surgical data	Radiation exposures were measured using dosimeters, placed on the patients and the surgeon. Radiation doses to thyroid, eyes and gonad of the surgeon were measured. Lateral and frontal (AP) dosimeters were placed on the patients. CT scans were performed postoperatively to assess the screw placement by an independent radiologist.
Complete reference	Lubansu Alphonse, Drogba Landry, Masudi Jospeh, and Dewitte Olivier. "Prospective Evaluation of a Free-Hand Electrical Conductivity Measuring Device to Reduce Radiation Exposure during Fluoroscopically Assisted Open or Minimally Invasive Pedicle Screw Arthrodesis." EuroSpine Annual Meeting. Milan, Italy. 19-21 Oct. 2011. E-poster presentation.

Poster: **AANS 2009** / Author: **Chang V**

Title	Clinical application of a specialized hand held pedicle drilling tool for pedicle screw placement in thoraco-lumbar fusions.
Country	USA (Detroit, Michigan)
Objective	To report the author's experience with the PediGuard device for pedicle screw placement in thoracolumbar fusions.
PediGuard used	**Classic PediGuard probe (open approach)**
Type of the study	Retrospective review

General and Demographic Data

Patients (n=)	• 60 adult patients reviewed • 42 patients were evaluated with computed tomography (CT) scanning post-operatively to assess pedicle breach

Key Data

- 268 screws were placed and evaluated with CT scan:
  - 2 thoracic screws
  - 202 lumbar screws
  - 64 sacral screws

- Overall number of pedicle breaches noted on post-operative imaging were 2 lumbar and 1 sacral. All 3 breaches were medial

- 1.1% pedicle breach when using this device, or **98.9% accuracy rate**

- The PediGuard device can be a **useful** adjunct in free hand techniques with **increased accuracy**

Details

Inclusion criteria	Patients where the PediGuard device was used primarily for preparation of pedicle screw placement for instrumented arthrodesis in the thoraco-lumbar spine.
Safety assessment	None of the breaches were clinically significant and without the need for re-operation.
Complete reference	Chang Victor, Patra Sanjay, Chedid Mokbel. "Clinical application of a specialized hand held pedicle drilling tool for pedicle screw placement in thoraco-lumbar fusions." AANS Annual Meeting. San Diego Convention Center, San Diego, California. 2-6 May 2009. Poster presentation.

Oral Communication: **SFCR 2008** / Author: **Lubansu A**

Title	Prospective evaluation of the interest of a free-hand electrical conductivity measuring device to reduce radiation exposure during fluoroscopically assisted pedicle screw fixation.
Country	Belgium
Objective	To compare the radiation dose received by the patients and the surgeon during posterior pedicle screw fixation (PPSF) under fluoroscopic control with and without the help of the PediGuard device.
PediGuard used	**Classic PediGuard probe**
Type of the study	Prospective, randomized, monocentric clinical study

General and Demographic Data

Patients (n=)

30 patients were randomized by opening an envelope just before the procedure:

- Group A: 15 patients under fluoroscopy alone
- Group B: 15 patients under fluoroscopy + the PediGuard device

Patients were not informed in which group they were affected.

Key Data

All screws were optimally positioned.

- Fluoroscopy time **reduction** by **65%**
- Radiation **dose** to the patient reduced by **73%** and **80%** for lateral and frontal exposure respectively

	Fluoroscopy time (min)	Radiation exposure (mSv)			
		Patient frontal	Patient lateral	Surgeon eye	Surgeon gonad
Group A (control)	6.2	14.1	61.8	0.18	0.36
Group B (with PediGuard)	2.2	2.8	16.7	0.12	0.317
% reduction	**65%**	**80%**	**73%**	33%	12%
P	P<0.001	P<0.02	P<0.01	NS*	NS*

*NS= non significant difference of radiation dose to the surgeon because dosimeters are not sensitive enough to scattered beams

Fluoroscopy time and radiation exposure with and without the PediGuard device

This study demonstrates that the **PediGuard** probe, while optimizing the positioning of screws, **allows significant reduction** of the amount **of radiation** exposure to the **patient** and therefore to the **spinal surgeons**.

Additional information

Inclusion criteria	Inclusion criteria: • Patients who underwent posterior pedicle screw fixation (PPSF) • Patients between 18 and 80 years old • Patients able to understand the aim of the study • Patients who read and signed the informed consent Exclusion criteria: • Surgical site infection • Systemic infectious disease • Fever or leukocytosis • Osteoporosis, osteopenia or other metabolic bone disease • Suspected or known allergy to titanium • Pregnancy
Patient's data	• Group A (n=15, 10 men, 5 women, mean age: 50 yrs (21-71)) • Group B (n=15, 8 men, 7 women, mean age: 49 yrs (25-73))
Surgical data	Measurements of radiation exposure were realized by placing thermoluminescent dosimeters on both surgeon and patients. Radiation doses to the surgeon's thyroid, eyes and gonad were measured. Lateral and frontal dosimeters were placed on the patients. Fluoroscopy time was also recorded. The reading of the dosimeters was done independently by a certified body for nuclear control (class I).
Complete reference	Lubansu A, Pirotte B, Rynkowski M, Zemmouchi A, Dewitte O. "Prospective evaluation of the interest of a free-hand electrical conductivity measuring device to reduce radiation exposure during fluoroscopically assisted pedicle screw fixation." SFCR 2008.

Poster: **Eurospine & IMAST 2006** / Author: **Bocquet J-F**

Title	Pedicle screw placement in spinal surgery at lumbar level: interest of guidance by conductivity measurement in the placement of 104 pedicle screws.
Country	France
Objective	To evaluate the clinical interest of PediGuard, a new pedicle drilling system, in pedicle screw placement, compared to results obtained with other systems described in the literature.
PediGuard used	**Classic PediGuard probe (open approach)**
Type of the study	A prospective monocentric study

General and Demographic Data

Patients (n=)	104 screws were placed on 15 patients from T12 to S1.

Key Data

- 98 screws perfectly placed (**94.2%**)
- No complication reported

The results show that the **PediGuard** probe is a simple device able to assist the surgeon in screw placement by **accurate real time detection**.

No additional surgery time, **no additional examination**, **no preliminary steps** are needed.

The PediGuard device seems to significantly decrease the number of misplaced screws at lumbar level.

Details

Patient's data

Spine pathology	Number of screws	%
Scoliotic	52	50%
Degenerative	40	38.5%
Traumatic	8	7.6%
Malformative	4	3.8%
Total	**104**	**100%**

Surgical data

Placement was controlled by sagittal and lateral x-ray images and post-op CT-scan jointly interpreted by a radiologist and an orthopaedic surgeon blinded to surgery.

Complete reference

Bocquet Jean-François and Violas Philippe. "Pedicle screw placement in spinal surgery at lumbar level: interest of guidance by conductivity measurement in the placement of 104 pedicle screws." EuroSpine Annual Meeting. Istanbul, Turkey. 28-25 Oct. 2006. IMAST Annual Meeting. Athens, Greece. 12-15 Jul. 2006. Poster presentation.

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