Accuracy of pedicle screw placement remains a critical issue in spine surgery. A number of patients emerge from surgery with misplaced screws. Now, there is an efficient solution to this problem...

**Challenges in pedicle screw placement**

**Pedicle screw misplacement**

Pedicle screws are the most common implants used in spinal surgery. Unfortunately, unacceptably high rates of pedicle screw misplacements in the vertebrae persist, which can lead to dramatic neurologic and vascular impairment.

Scientific literature reveals that about 20% of pedicle screws are misplaced using conventional techniques, causing a 2% to 11% overall complication rate for spinal fusion procedures.

“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.” (NICE11 2015)

**Cost implications**

Based on 3 economic studies conducted in the US the direct cost for a revision surgery to correct a misplaced screw ranges from $17,650 to $27,677. Those studies do not include indirect costs such as physician (office), diagnostic imaging, medication, injections, etc…

**Dangers of radiation**

Often, fluoroscopy is used to check the progress of the drilling prior to inserting the pedicle screws or to check their correct placement. It is an imaging technique commonly used to obtain real-time images of the patient’s anatomy and involves high levels of x-ray radiation. While a patient’s exposure to X-ray is often limited to one surgery, spine surgeons who perform several surgeries a year are exposed to x-ray radiation to a greater extent.

**Surgeons’ greater reliance on fluoroscopy during procedures exposes the OR team to dangerous 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.

- The average spine surgeon will receive the maximum allowable lifetime exposure of radiation for workers within 10 years of practice.
- Surgeons are highly exposed especially in MIS surgeries and scoliosis surgeries.

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**What the surgeons are saying about DSG™ Technology...**

“Anything we can do to help us get a safer screw insertion is certainly worthwhile, given that published rates of pedicle screw misplacements can be as high as 40 percent. PediGuard will probably become a standard tool in any spine surgery requiring instrumentation.”

Randal Betz, M.D.
Pediatric Orthopaedic Surgeon
Philadelphia

“We surgeons are constantly faced with difficult treatment planning for complex cervical deformities. By integrating the PediGuard device into surgery, we are able to provide our patients with greater construct stability, less neurological risk, and a better overall surgical outcome.”

Heiko Koller, M.D.
Werner Wicker Klinik
Bad Wildungen
Germany

“When not using PediGuard, we would regularly reach our facility mandated radiation level by October and not be permitted to operate for the rest of the year. With PediGuard, we have been able to keep our radiation exposure low.”

Mokbel Chedid, M.D.
Neurosurgeon Henry Ford Hospital
Detroit, Michigan
DSG™ (Dynamic Surgical Guidance) Technology

What the surgeons are saying about DSG™ Technology...

Maurice Bourlion, Ph.D. and Ciaran Bolger, M.D. invented the DSG™ Technology, which is based on the differential electrical conductivity in various tissue types. This principle is effectively utilized during insertion of screw implants in the spine via real-time feedback provided as audio and visual cues to the surgeon.

The PediGuard® Probes (commercialized in about 50 countries)

The PediGuard® Probes are the first devices that incorporate the DSG™ Technology. They are the world’s first and only stand-alone, handheld instruments capable of accurately detecting changes in tissue type, alerting surgeons of potential pedicular or vertebral breaches during pedicle screw site preparation. Real-time feedback, provided via audio and visual signals, gives surgeons additional information about the trajectory during pedicle preparation. More importantly, the use of PediGuard® requires no change in surgical technique.

The PediGuard® technology is available in a wide range of shapes and sizes for surgeon preference (more information on www.spineguard.com):
- PediGuard® Straight
- PediGuard® Curved
- PediGuard® Cannulated

Improving Accuracy of Screw Placement for Patients

The PediGuard® Probes enable spine surgeons to accurately prepare the vertebra for screw insertion. Data from several clinical studies published in peer-reviewed journals show that improved screw placement accuracy can be achieved when pedicles are prepared with the PediGuard® probe. On average, screws placed after drilling with the PediGuard® probes have an accuracy of more than 97.5%.

The PediGuard® probes minimize the need for x-rays and do not require additional equipment during use. Therefore, it can significantly reduce the amount of radiation exposure for the surgeon, the hospital staff and the patient. Clinical studies have documented a 25% to 30% reduction in fluoroscopy time, a 73% reduction in radiation time in (MIS) minimally invasive procedures, and a 15% surgical time saving when the PediGuard probes were used to prepare pedicles.

Moreover, the real-time feedback from these devices provides residents and fellows greater confidence in preparing pedicles and placing screws; and also allows the surgeon trainer to make any necessary adjustments to the trajectory in real-time.

Since their introduction, products with the DSG™ Technology have helped in improving accuracy of placing pedicle screws in the spine in close to 40,000 procedures globally.

“Because of the off-set axis of PediGuard Curved, it alerts me if there is a breach and where that breach is.”

Ciaran Bolger, M.D.
Head of Department for Clinical Neuroscience, Royal College of Surgeons in Ireland, Director of Research & Development, National Neurosurgical Unit, Beaumont Hospital, Ireland, Current President of the EuroSpine Society

“Cannulated PediGuard gives me security during pedicle drilling while decreasing the number of X-ray shots and without using additional expensive equipment. There are no new steps to add to the procedure and the device is compatible with any pedicle screw system available on the market. For all of these reasons: security, OR team protection, universality and compatibility, the Cannulated PediGuard is a clear solution to the challenges in MIS.”

Charles Court, M.D.
PUPH, Hôpital Bicêtre Paris, France

“The new miniaturized sensor of the XS Curved PediGuard allows us to access the smallest and most difficult pedicles encountered in our deformity cases. Like for the precedent design, the new curve gives us precious directional information as well as the ability to redirect. In a teaching context, it is very reassuring to receive the instant auditory feedback when the resident or any other trainee is creating the trajectory for the screw within the pedicle.”

Sergey Neckrysh, M.D.
Chief of Spine Surgery, Assistant Professor Department of Neurosurgery, University of Illinois Chicago

“Because of the PediGuard’s real-time auditory feedback and the added visual feedback via the instrument’s display screen, there’s a much greater level of confidence in pedicle screw placement.”

Ali Mazidi, M.D.
Spine Surgery Fellow, Oakland University William Beaumont Health System Rochester, Minnesota

“DSG™ user for over eight years, I have benefitted using this device for pedicle screw insertion. After training and a brief learning curve, you add a third sense—the auditory—as an additional help for pedicle preparation. With time, the sound frequency and tone becomes a preeminent part of your technique. For a University Hospital, PediGuard is an invaluable teaching tool: you can assist your residents and ensure safe control of their actions.”

André Kaelin, M.D.
Clinique des Grangettes, Geneva Switzerland


**DSG™ Technology enabled Pedicle Screw System**

(in development, first surgeries scheduled end of 2015)

The DSG™ Screw System (smart screw) takes the DSG™ Technology one step further. It potentially eliminates the need for preparing a pedicle prior to screw insertion. This may significantly minimize the surgical procedure time, and further reduce the chance of cortical wall breaches or pedicle compromise.

The DSG™ Screw system includes a cannulated pedicle screw, a DSG™ Pin with the proprietary DSG™ bipolar sensor embedded, and a DSG™ Handle assembly, which includes the electronics to read and translate the signal from the DSG™ sensor.

Screws* that incorporate the DSG™ Technology are of a specific design that allows non-skiving cortex coating, bone penetration without pilot hole and controlled redirection when needed as the screw is being advanced into the pedicle.

**K-wire less technique in MIS**

The DSG™ Screws are designed to enhance the ease of insertion of screws during percutaneous approaches. The DSG™ Screw system obviates the need for a k-wire (which is typically used in MIS / percutaneous surgical approaches to help guide instruments and implants during such procedures along a desired trajectory). This one-step insertion technique may drastically decrease the amount of radiation exposure, typically used during such procedures, not only for the patient but also for the surgeon and the OR staff. Therefore, it is anticipated that the time required for screw placement may also be reduced considerably.

**Cortical Bone Trajectory (CBT) technique**

The (CBT) technique is a new pedicle screw fixation method for lumbar spine surgery. CBT differs from traditional pedicle screw trajectory in the starting point and insertion direction. The new trajectory penetrates a region that is richer in cortical bone compared to when using the traditional trajectory and offers higher cortical bone contact.

“I am able to place longer screws, with higher confidence with DSG’s prospective detection method and that informs me typically before, not after I have created a breach in the cortical bone,” said Richard Hynes, M.D.

* As of July 2015, two co-development partnerships have been signed with NeuroFrance (NFI) and Zavation.

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*The smart screw technology is an opportunity to further use the Dynamic Surgical Guidance platform to improve our ability to place pedicle screws safely, especially in a MIS setting. The benefits of this technology are far-reaching. The smart screw has the potential to influence many aspects of pedicle screw placement-accuracy, decreased radiation exposure, and improved bone screw fixation to name a few."

John I. Williams, M.D.
Orthopedic Surgeon, Fort Wayne, Indiana

“Integrating the Dynamic Surgical Guidance technology with pedicle screws will greatly optimize the workflow and accuracy, and reduce radiation exposure for surgeons in both the traditional and MIS surgical settings. Not only will the smart screw allow for active real time guidance breach-avoidance through the pedicle, but it will also provide unprecedented feedback and confidence in the ultimate fixation of the screw itself.”

Larry T. Khoo, M.D.
Neurosurgeon
The Spine Clinic of Los Angeles Society for Minimally Invasive Spine Surgery (SMISS)

“The PediGuard has shown its accuracy in pedicle preparation. The partnership between SpineGuard and NeuroFrance is a great development for the spine surgeon community with the integration of two technologies into one device - a new screw with an original design combined with the DSG technology. This first dynamically guided screw will be the most innovative device of the year in Spine surgery, as it will further reduce complications and associated costs. We look forward to using it.”

Patrick Tropiano M.D.
Professor of Orthopaedic Surgery at Marseille La Timone University Hospital – France

“I was able to trial the DSG screw in the lab before its release. It worked like a charm. It is an awl (removable), tap and monitored screw, all in one. No guide pin that can be advanced inadvertently is needed. I knew immediately where the trajectory of the screw was going, even without fluoroscopy. Rather than use 5 steps to put a screw into the spine, only one step was needed. I could redirect it easily if needed. I even used it to perform a new technique that I had never done before, and finished putting the screw in perfectly on two separate tries within 90 seconds from the time of the skin incision using only 3 x-rays per screw. I believe that this novel technology will be a game changer for spine surgeons. I look forward to using it clinically as soon as it gets approved.”

Thomas Freeman, M.D.
Professor, college of medicine neurosurgery, USF Health Tampa, Florida

“DSG adds auditory cues combined with visual cues from fluoroscopy during the Cortical Bone Trajectory MIDLF approach. This results in remarkable improvement in accuracy and safety while placing the maximal length screw possible.”

Richard Hynes, M.D.
The B.A.C.K Center Melbourne, Florida
**DSG™ Technology enabled Tap System**

*(in development, first surgeries scheduled end of 2015)*

The DSG™ Tap system includes a DSG™ cannulated tap, a DSG™ Pin with the proprietary DSG™ bipolar sensor embedded, and a DSG™ Handle assembly, which includes the electronics to read and translate the signal from the sensor.

The DSG™ Pin used in the Tap system protrudes from the tip of the DSG™ tap. The DSG™ sensor, placed in front of a specifically designed awl type nose and progressive thread shape, allows for identifying tissue type and redirecting as necessary before the main threads of the tap engage with bone.

The DSG™ Tap potentially eliminates the need for drilling the pedicle with a probe. Combining the drilling and tapping into one step may reduce the surgical procedure time, and minimize cortical wall breaches or pedicle compromise.

The inherent design of the DSG™ Taps makes it an optimal choice for use in MIS/percutaneous procedures. Additionally, the DSG™ Taps allow the surgeon to take advantage of this unique technology without having to change the implant system they are familiar with.

**DSG™: A Game Changer**

With its expanded applications and inherent cost benefit to the healthcare system, devices with the DSG™ Technology can be expected to be standard of care in spinal stabilization in the near future.
Bibliography

11. NICE: Medtech innovation briefing. The PediGuard for placing pedicle screws in spinal surgery. Published: 25 March 2015

For more information on SpineGuard® and the DSG™ Technology, please visit our website at www.spineguard.com.