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 studies12,13,14 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 practice16.
- Surgeons are highly exposed especially in MIS surgeries and scoliosis surgeries.
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® probes are 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 vertebrae 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 fluoroscopy22,23 in standard open procedures, a 73% reduction in radiation time in (MIS)24 minimally invasive procedures, and a 15% surgical time saving25 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 over 40,000 procedures globally.
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.
DSG™ Technology enabled Threaded Drill system

(First surgery performed in September 2015)

The DSG™ Threaded Drill system includes a DSG™ cannulated threaded drill, 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 Threaded Drill system protrudes from the tip of the DSG™ threaded drill. 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 threaded drill engage with bone.

The inherent design of the DSG™ Threaded Drills makes it an optimal choice for use in MIS/percutaneous procedures. Additionally, the DSG™ Threaded Drills 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.