Conclusions

The pedicle screw is one of the spine surgeon's most commonly used tools, but its widespread prevalence doesn't make its proper placement any less challenging. The practice remains technically demanding, with a very small margin for error.
In order to assist the surgeons to accurately position the pedicle screws, intraoperative-based utilization of X-ray imaging tools and technologies have been successfully introduced. However these technologies expose the patient and the Operating Room team to the health risks associated with increased radiation exposure.

Recently introduced MySpine technology supports spine surgeons during the critical steps of pedicle screw placement by offering the potential for improved accuracy, as well as reduced radiation exposure.

MySpine® PATIENT MATCHED TECHNOLOGY IN SPINE SURGERY

Unique Anatomies
Patient-Matched
Solutions

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MySpine® PATIENT MATCHED TECHNOLOGY IN SPINE SURGERY
Medacta International

MYSPINE:

A new technology to reduce radiation exposure while maintaining high accuracy

MySpine®
PATIENT MATCHED TECHNOLOGY
IN SPINE SURGERY

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International

The tools and instruments used in spine surgery are continuously changing and improving. It has been shown and is accepted that the use of a navigation system is an extremely valuable tool in determining the **appropriate placement of pedicle screws**.

Everyone is exposed to natural radiation from food, water, radon gas, cosmic rays, and other naturally occurring radioactive materials resulting in an annual effective dose of approximately 3 mSv [e]. With the use of any ionizing radiation, such as x-ray, there are risks to the patient and to the staff in the operating room. Additional radiation from medical imaging augments the already present **risks of radiation-induced adverse consequences**, such as cancer, birth defects, and other deleterious occurrences.

PATIENT WISE

- **+91%** of breast cancer reported in women exposed to multiple diagnostic x rays [h] vs. normal population
- **+8%** risk of mortality among patients frequently exposed to radiographic exams [j] vs. normal population

SURGEON WISE

- **+190%** risk of breast cancer reported in orthopedic surgeons vs. normal population [k]
- **+100%** risk of all cancer reported in orthopedic surgeons vs. normal population [k]

There are measures that are taken to reduce the risk of radiation exposure, lead shields to cover the torso and neck, protective gloves and eye shields, and maintaining a safe distance from the radiation source. Even with appropriate measures taken, **the surgeon and the staff are still at risk of exposure from scatter radiation**. The newest imaging modalities such as the O-Arm™, have provided benefits, by utilizing intraoperative acquisition of 2D and 3D images of the spine and potentially allowing better placement of pedicle screws. However, these technologies are not without additional risks to the patient and operating room staff.

The effective dose limit for a non-occupationally exposed individual is 1 mSv per year above the background radiation dose of 3 mSv [e]. During a single O-Arm™ image acquisition, **the patient is exposed to an effective dose up to 81 mSv, a value over the documented annual dose limit [b]**. This can be over 50 times the regulated dose limit for a non-radiation worker.

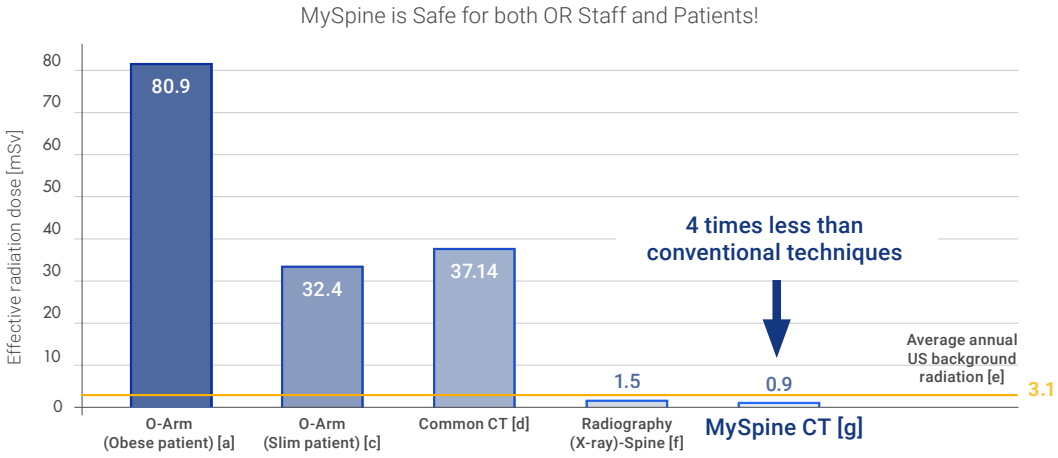
Though the risks of intraoperative radiation exposure to surgeons and staff are well documented within the peer reviewed literature, the perceived benefit in the accuracy of screw placement has made the use of intraoperative fluoroscopy and other sources of ionizing radiation in the operating room a fundamental requirement. The development of technologies to increase **surgical accuracy**, **reducing operative times**, and **improving outcomes** are the collaborative goals with industry and healthcare professionals. New instruments to aid in screw placement, imaging tools, and robotics have all been introduced in the last years with the goal of improving screw placement. Some of the most valuable tools, new imaging modalities and robotics, require a large capital investment for the facilities and therefore these options may not be available to all users.

MySpine Patient-Matched Technology by Medacta

MySpine technology utilizes a **low dose CT scan** of the patient's spine to create **patient specific instruments** designed and manufactured with the express intent of increasing accuracy when placing pedicle screws, thus reducing the need for the use of intra-operative fluoroscopy to confirm the appropriate placement of screws. The risks of exposure to high doses of radiation to both the patient and the surgical team can potentially be reduced through the utilization of this technology.

A patient who has been identified as needing a posterior, thoracolumbar fusion, is sent to a scanning facility and a low dose CT scan of their spine is performed. The data from this scan is transmitted securely to the manufacturer. The patient's anatomy is reconstructed and a **surgical plan is reviewed and approved by the surgeon**, determining the appropriate screw diameter, length and trajectory within the pedicle. 3D printed surgical guides are then created and provided for intraoperative use during the posterior fusion.

The figure below shows a comparison of radiation doses to the patient from different modalities in comparison to the MySpine technology.



Comparison of conventional and competitors technique irradiation vs. MySpine

The accuracy of MySpine technology is proven in a clinical study of pedicle screw placement utilizing post implantation CT scans. [l]

A total of **198 screws** were implanted, out of these **99.5%** were inserted in the safe zone. This result is comparable (or even better) to the values of robotic (97.8%) and navigated assisted techniques (95.6%) and greater than the traditional freehand approach (80%).