There exists a dynamic in which decreased technical demand means increased radiation exposure, while conversely, decreased use of imaging may lead to greater inadequacy of posterior fixation and increased health care resources for correcting associated complications.[5]

**IS THERE A SURGICAL MODALITY THAT CAN OPTIMIZE SCREW PLACEMENT ACCURACY IN AN EFFICIENT MANNER, WHILE SIMULTANEOUSLY DIMINISHING THE NEED FOR EXTENSIVE INTRAOPERATIVE IMAGING?**

**FURTHERMORE, CAN THIS BE DONE WITH LOW ASSOCIATED COST, IN A SCALABLE FASHION, AND WITH NO LEARNING CURVE?**

**COUPLED WITH EXCEPTIONAL ACCURACY RATES AND POTENTIALLY MINIMAL TO NO USE OF INTRAOPERATIVE IMAGING, THE MYSPINE TECHNOLOGY IS THE COMPREHENSIVE SOLUTION FOR ADDRESSING THE DEMANDS OF COMPLEX SPINAL DEFORMITY.**[13,14,15]

POSTERIOR VIEW (BACK)

LATERAL VIEW (SIDE)

## A SCALABLE SOLUTION

Advances in navigation and the introduction of robotic assisted technologies have led to improved accuracy rates. However, subsequent increases in radiation exposure, costs, technical demand, and scalability concerns have ensued. In more traditional degenerative pathology cases these gaps are less readily apparent.

However, complex deformity surgery amplifies the need for a solution that retains accuracy rates of navigation and robotic assisted systems, while addressing these additional concerns.

Patient specific placement guides have been introduced previously with good success. However, a primary limitation of these technologies is the capital equipment and resources required for production.[13,14,15]

Furthermore, the time necessary to perform 3D reconstructions can be significant, especially in complex cases, which can limit the ability for a surgeon or institution to develop templates in large volumes.
The MySpine technology offers a scalable solution in procuring patient matched guides without the overhead cost, resources, or time demands of previous proof-of-concept techniques.

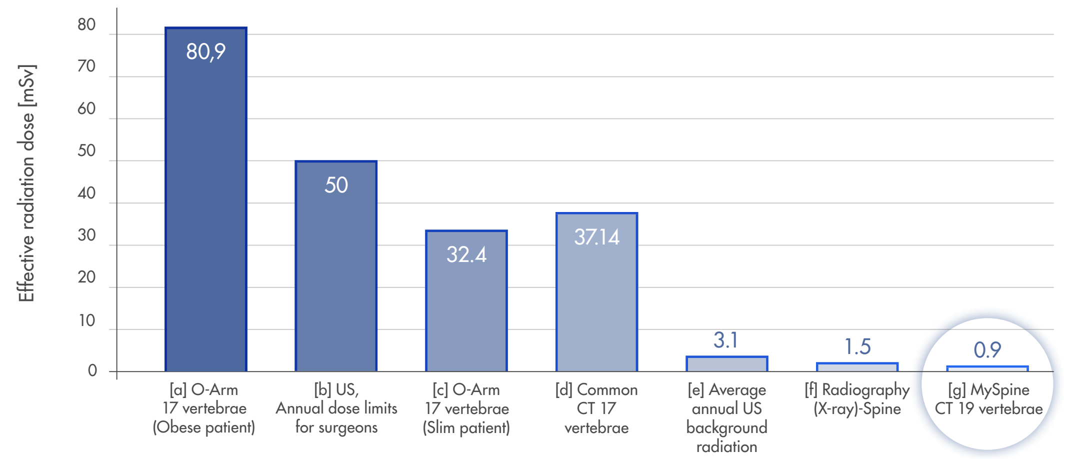
## MYSPINE VS. THE LITERATURE

| SCREW PLACEMENT ACCURACY IN SCOLIOTIC PATIENTS | BREACH DISTANCE | |
|---|---|---|
| | ≤2MM* | >2MM |
| PATIENT MATCHED GUIDE (MYSPINE) | 96.1%[6] | 3.9% |
| FREE-HAND | 70.8 to 94.7%[7-11] | 5.3 to 29.2% |
| NAVIGATION ASSISTED | 88.6 to 98.9%[7-11] | 1.1 to 11.4% |
| ROBOTIC ASSISTED | 92.8%[12] | 7.2% |

*Gertzbein Classification A/B; Considered Clinically Satisfactory[13]

## REDUCED X-RAY DOSE

MySpine is Safe for both OR Staff and Patients!




Comparison of conventional and competitors technique irradiation vs. MySpine

*[a] Lange et.al. Estimating the effective radiation dose imparted to patients by intraoperative cone-beam computed tomography in toracolumbar spinal surgery, Spine 2013 [b] US Nuclear Regulatory Commission's (USNRC) [c] Lange et.al. Estimating the effective radiation dose imparted to patients by intraoperative cone-beam computed tomography in toracolumbar spinal surgery, Spine 2013 [d] Biswas et.al. Radiation Exposure from Musculoskeletal Computerized Tomographic Scans, JBJS Am. 2009 [e] Health Physics Society Specialists in Radiation Safety, Lawrence Berkeley National Laboratory; Fact Sheet 2010 [f] Radiation Dose in X-Ray and CT Exams; 2013 Radiological Society of North America, Inc [g] MySpine, Charité University Hospital, Berlin, Germany*

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MySpine Deformity Leaflet
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Last update: October 2017

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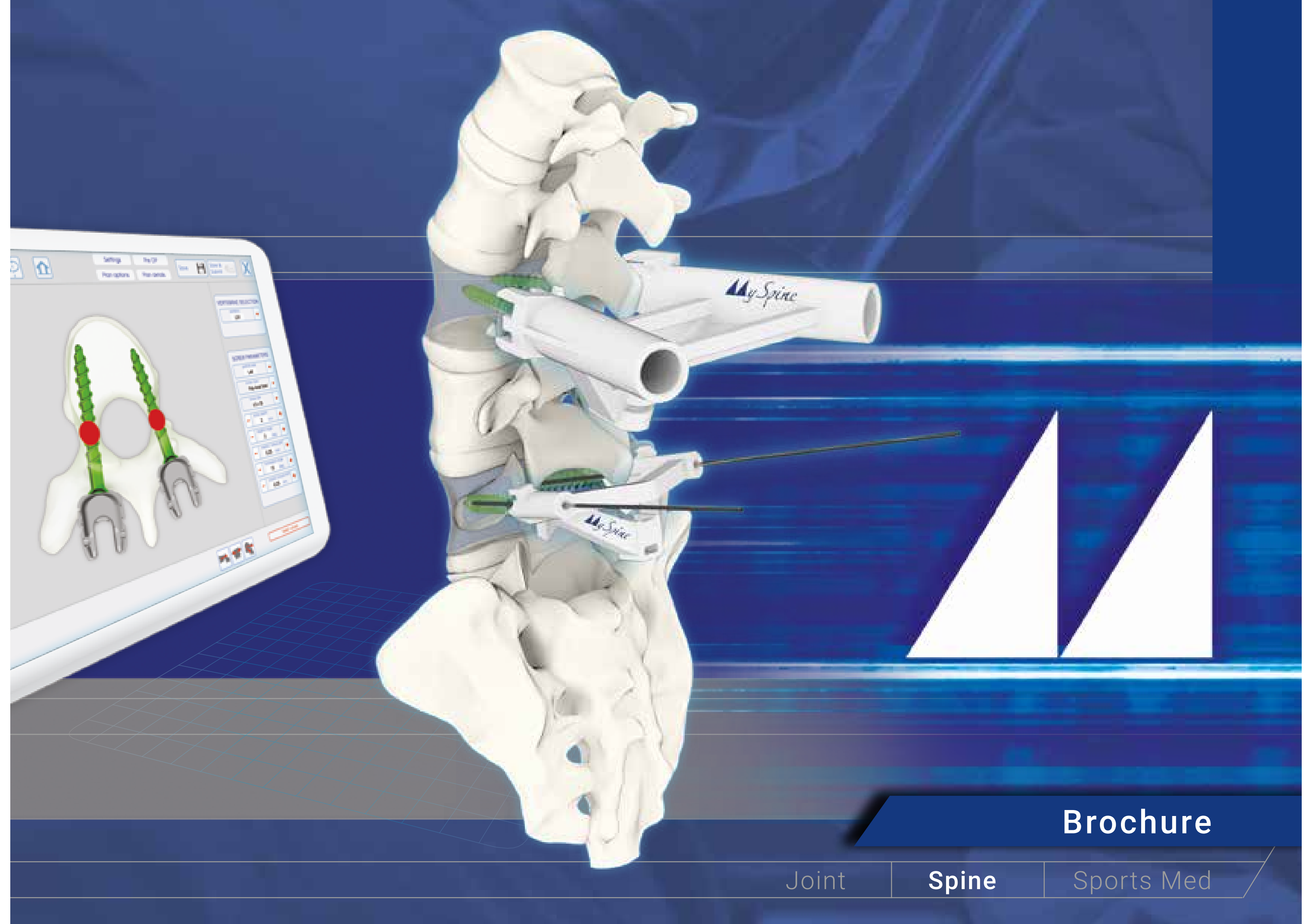
MySpine®

PATIENT MATCHED TECHNOLOGY
IN SPINE SURGERY

UNIQUE ANATOMIES PATIENT-MATCHED SOLUTIONS



Brochure

Joint | Spine | Sports Med

# PEDICLE SCREW PLACEMENT IN COMPLEX DEFORMITY:

A Review of Contemporary Techniques and Introduction of a Novel Comprehensive Solution

Medacta International



## AN INTRODUCTION FOR COMPLEX DEFORMITY

**MAJOR COMPLICATION**
in 3-column reconstructions ranges from
**25 TO 59%**

Complex deformity in the thoracolumbar spine is an exceptionally challenging pathology, often requiring extensive and intricate surgical reconstruction for sufficient symptomatic resolution.

However, despite continued advancement in surgical modalities, major complication occurrence in 3-column reconstructions still ranges from 25 to 59%.[1]

While the etiologies of complex deformity and subsequent complications are often multifactorial, the common denominator for clinical success largely stems from establishing adequate posterior stabilization via pedicle screw and rod fixation.

Length-of-construct, soft-tissue abnormalities, curve pattern/ magnitude, and extent of de-rotation all play major roles in the ability to achieve sufficient and accurate posterior stabilization.

**OPERATIVE TIMES**
in complex deformity can range up to
**9 TO 15 HOURS**

**PEDICLE SCREW PLACEMENT INACCURACIES**
in the thoracolumbar spine can range from
**14 TO 26%**

Consideration must also be given to use of operating room resources and radiation exposure in pursuit of successful placement.

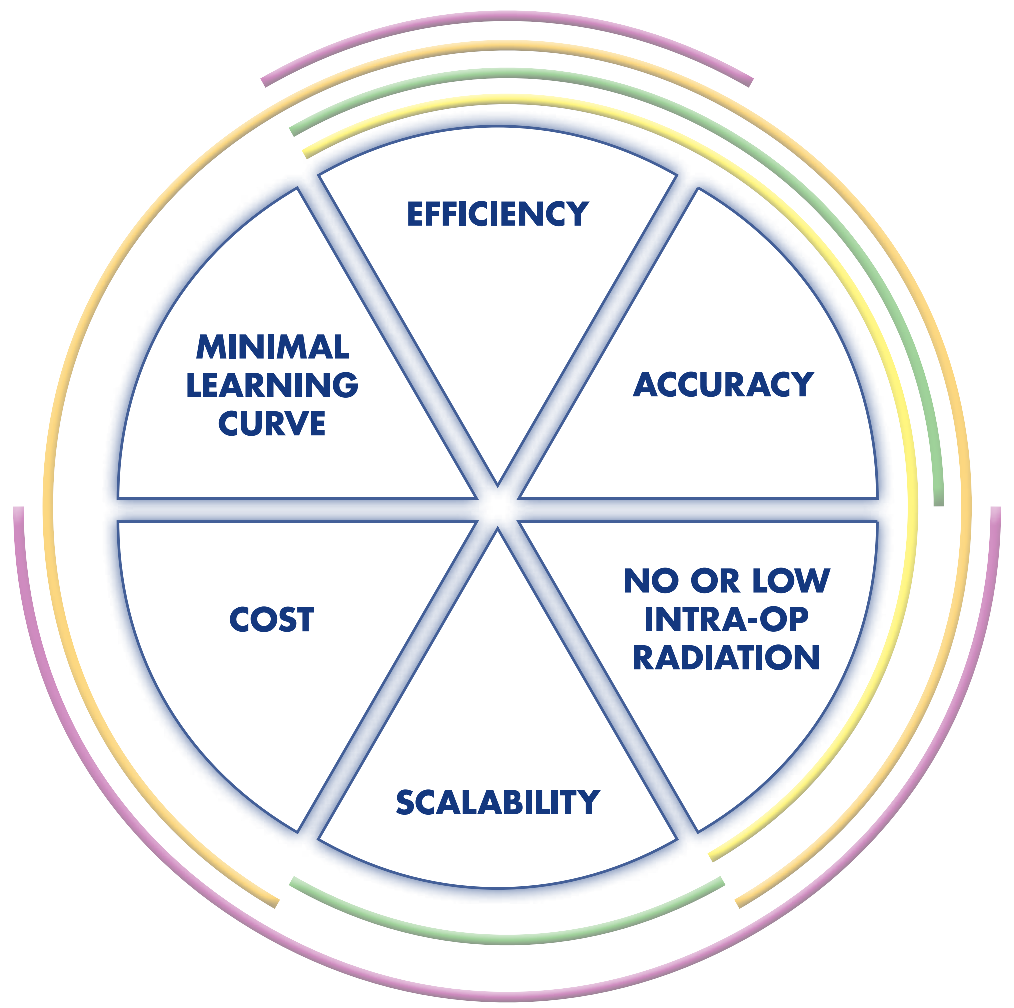
Operative times in complex deformity can range upwards of 9 to 15 hours[2], while pedicle screw placement inaccuracies in the thoracolumbar spine can range from 14 to 26%[3] depending on technique.

Image-guided navigation has been suggested as a means to reduce operative time and screw placement inaccuracies.

However, routine use of imaging can result in the accumulation of large absorbed radiation doses over the careers of surgeons and their surgical staff[4].

# UNIQUE ANATOMIES PATIENT-MATCHED SOLUTIONS

## COMPREHENSIVE COMPONENTS OF PEDICLE SCREW PLACEMENT TECHNIQUES




**EFFICIENCY**
Can placement be achieved quickly and with diminished soft-tissue disruption?

**ACCURACY**
Can placement be achieved accurately?

**NO OR LOW INTRA-OP RADIATION**
Is intra-op floroscopy and CT imaging marginalized or eliminated?

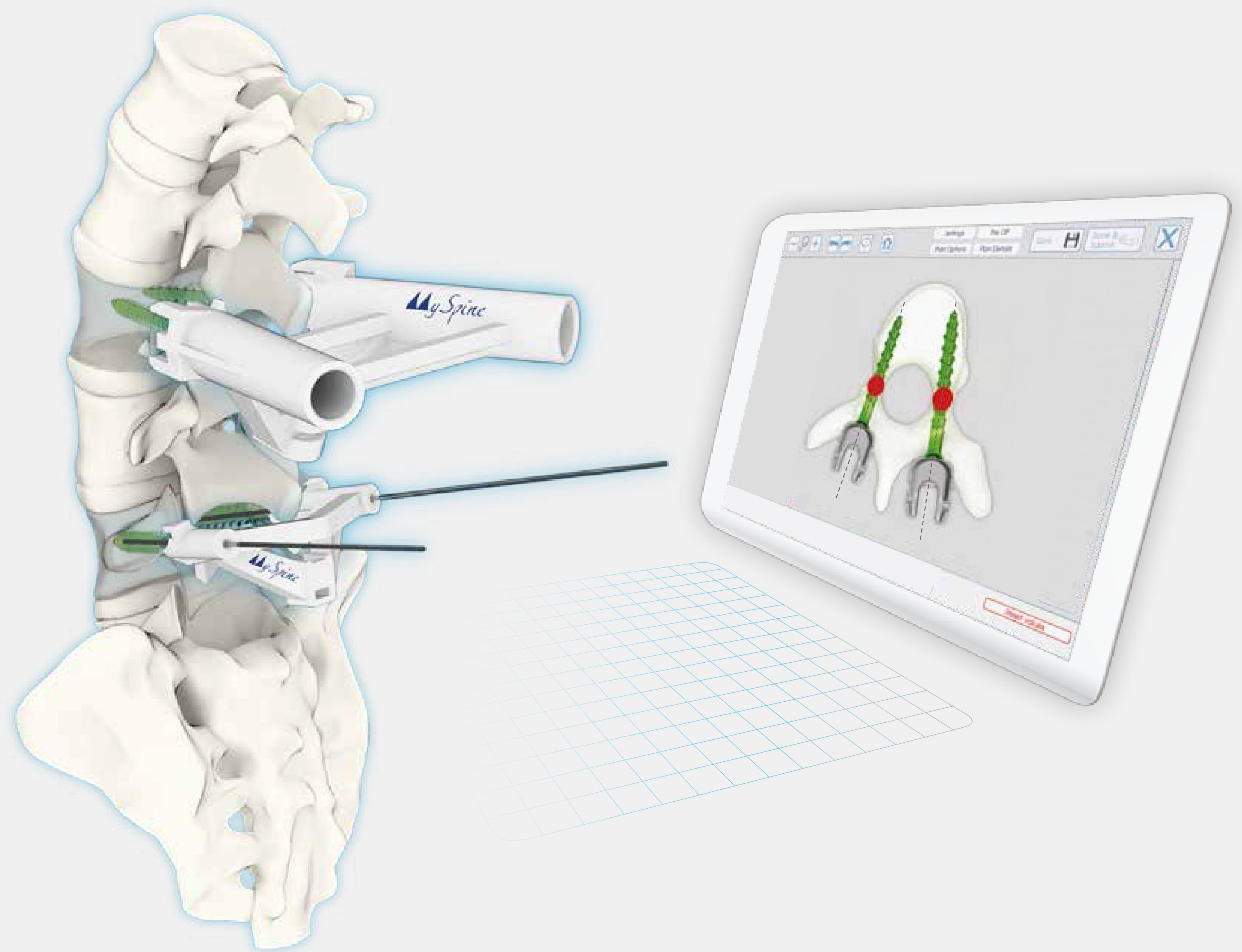
**SCALABILITY**
Can the technology accommodate high surgical volumes without the need for additional resources or capital equipment?

**COST**
Is there a high associated cost to the practice or institution?

**NO LEARNING CURVE**
Can the technology be readily adopted into the practice?

## MYSPINE PATIENT MATCHED SOLUTION...

- **LOW-DOSE CT UPLOADED REMOTELY TO MEDACTA WEB PLATFORM**
  SCALABILITY
  The only production input is a standard low-dose pre-op CT
- **SEGMENTATION, 3D PLANNING & VALIDATION REPORT**
  COST, SCALABILITY, MINIMAL LEARNING CURVE
  No internal resources required at hospital. Outsourcing accommodates high-volume. No need for software training
- **GUIDE DESIGN ACCORDING TO SURGEON APPROVED PLAN**
  ACCURACY
  Validation report ensures visual familiarization and affirmation of placement according to surgeon/patient needs
- **3D PRINTING OF GUIDES**
  COST, SCALABILITY
  No on-site capital equipment needed
- **SURGICAL INTRODUCTION**
  EFFICIENCY
  Introduced into patient via standard access and anatomical landmarks




Delivery of patient-matched instrumentation within 3 weeks of CT upload.

- **ONLINE CASE MANAGEMENT**
  MySpine cases are managed by proprietary encrypted software for no additional cost. The surgeon can access the case database at anytime with internet access.
  Online interactive 3D planning tool for reliable pedicle targeting and screw trajectory identification.
  The information on the website is always kept up-to-date.
- **COMPLETE IN-HOUSE TECHNOLOGY**
  The MySpine process is kept completely in-house from the 3D anatomical reconstruction to the manufacturing of the guides, allowing a direct contact between the surgeon and the MySpine team.
- **3 WEEKS LEAD TIME**
  The shortest delivery time in today's market for this technology.
- **A PERSONAL MYSPINE ENGINEER**
  Each surgeon is assigned a personal MySpine engineer to assist with any questions regarding the case planning process.

## REVIEW PEDICLE SCREW PLACEMENT TECHNIQUES

| TECHNIQUE | PROS | CONS |
|---|---|---|
| PATIENT MATCHED GUIDE/ TEMPLATE ASSISTED | ■ No required intra-op imaging<br>■ Optimized procedural time<br>■ Surgical workflow maintained<br>■ Improved accuracy (vs. free-hand)<br>■ Minimal learning curve<br>■ Patient specific | ■ 3 week lead time and pre-op scanning per protocol |
| OPEN FREE-HAND PLACEMENT | ■ Can diminish intra-op radiation exposure (vs. navigation)<br>■ Facilitates faster procedural time (vs. navigation/assisted)<br>■ Streamlined work-flow | ■ Inaccuracies (especially in patients with altered morphology)<br>■ Learning curve<br>■ Often require intra-op fluoroscopy for confirmation<br>■ Potential surgeon fatigue |
| 2D/3D NAVIGATION ASSISTED | ■ Improved accuracy (vs. free-hand)<br>■ Real-time internal anatomical visualization | ■ Pronounced radiation usage<br>■ Learning curve/training limitations<br>■ Intra-op software/device troubleshooting concerns<br>■ Often requires preoperative CT via specific protocol<br>■ Less favorable work-flow (vs. free-hand)<br>■ Longer procedural time<br>■ Availability/cost |
| ROBOTIC ASSISTED | ■ Improved accuracy (vs. free-hand)<br>■ Real-time internal anatomical visualization<br>■ Marginal surgeon demand<br>■ Decreased radiation exposure (vs. navigation) | ■ Increased radiation exposure (vs. free-hand)<br>■ Capital equipment - availability/cost<br>■ Longer procedure time (vs. free-hand)<br>■ Intra-op software/device troubleshooting concerns<br>■ Learning curve/training limitations<br>■ May require re-calibration and registration intraoperatively depending on length of construct |