

CHANGING THE WAY SURGERY IS DONE

ExcelsiusGPS®

Value Dossier

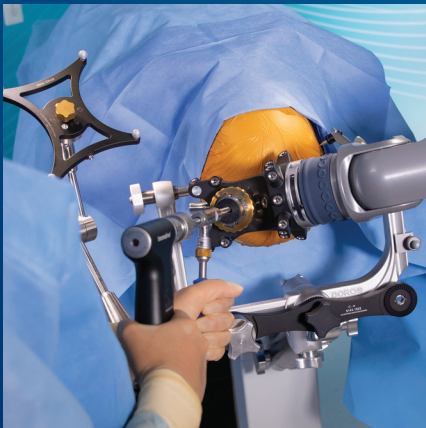


ExcelsiusGPS® is a comprehensive robotic navigation platform that is designed for accuracy and reduced radiation during spine and functional neurosurgical procedures.

ExcelsiusGPS[®]

ExcelsiusGPS[®] is designed to help improve clinical outcomes for patients and enhance surgeon and staff experiences throughout the continuum of care.

CHANGING THE WAY SURGERY IS DONE



DRIVE HOSPITAL
EFFICIENCIES



IMPROVE
PATIENT CARE



ENHANCE SURGICAL
EXPERIENCE

“

From my experience, ExcelsiusGPS[®] has offered many advantages to spine surgery. These include pre-planning screws and surgical workflow, efficiency of screw placement, less time spent in the OR, and enhancing your ability to do MIS, which may help avoid large open cases that may require more ICU resources.

Dr. Themistocles S. Protopsaltis
NYU Langone Health, New York

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Drive Hospital Efficiencies & Improve Patient Care

PRE-PLANNING FEATURES

ExcelsiusGPS® empowers surgeons to optimize their surgical plan for every patient.

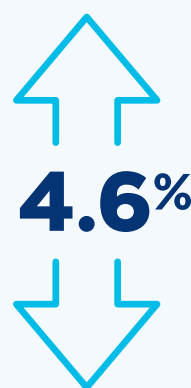
The preoperative imaging workflow allows for **pre-planning of trajectories** for navigated pedicle screws as well as navigated placement of interbody spacers, which may reduce intraoperative time spent in the OR by streamlining the surgeon's surgical workflow.

In a study of 151 consecutive patients who had undergone instrumented spinal fusion surgery, the surgeon preoperatively planned and subsequently placed larger pedicle screws for the group that underwent robot-assisted surgery.¹¹



INCREASE IN PEDICLE SCREW WIDTH

on average
(7 + 0.7 vs. 6.5 + 0.3mm; p < 0.001)



INCREASE IN PEDICLE SCREW LENGTH

on average
(47.8 + 6.4 vs. 45.7 + 4.3mm; p < 0.001)

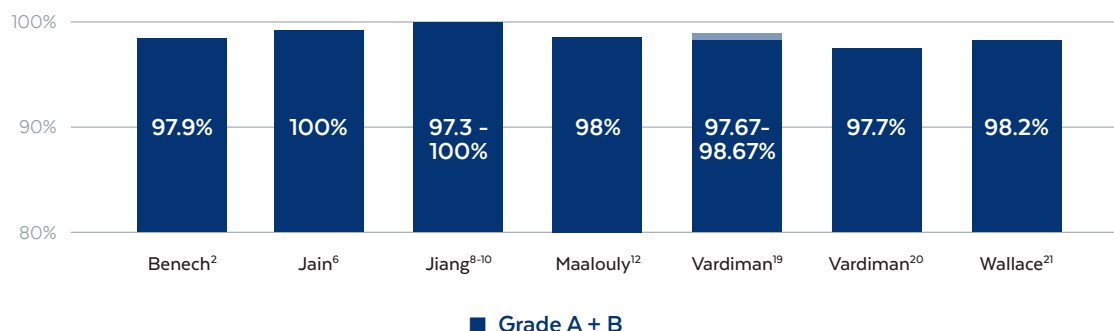
In addition, these larger pedicle screws being placed resulted in **12.6% higher stimulation thresholds**.

PEDICLE SCREW PLACEMENT ACCURACY AND CONSISTENCY

ExcelsiusGPS® robot-assisted navigation has demonstrated high levels of accuracy in pedicle screw placement.^{2, 3, 8, 10, 19}

Multiple clinical studies in a surgical setting report **96%-100% screw placement accuracy** or successful placement by surgeons around the world with varying experience levels.^{2-6, 8-10, 12, 19-21}

Significant Pedicle Screw Placement Accuracy Achieved with ExcelsiusGPS® Using Gertzbein-Robbins Classifications



In a multicenter study, it was determined that the accuracy of screws placed with robotic assistance was minimally affected by different patient-related or screw-related variables for **preoperatively planned trajectories**.¹⁷ Variables considered were obesity, length of construct, gender, age, surgeon, screw length and diameter, and vertebral levels.

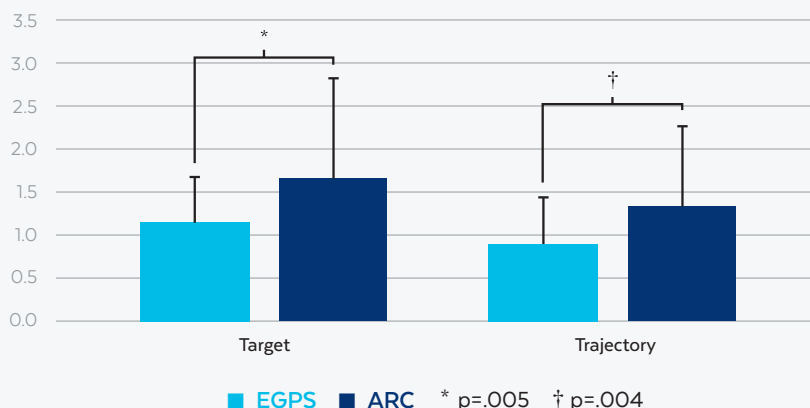
In a single-surgeon clinical study focused on ExcelsiusGPS® robot-assisted single position lateral surgery, the surgeon placed 98% of the pedicle screws successfully. There were no complications due to screw placement and no revisions due to malpositioned screws.⁵



CRANIAL SPOTLIGHT

In a cadaveric white paper study, data suggest that ExcelsiusGPS® Cranial Solutions reduced deep brain stimulation (DBS) target and trajectory errors by **31%** and **33%**, respectively, as compared to the ARC technique.¹⁴

Lead Accuracy

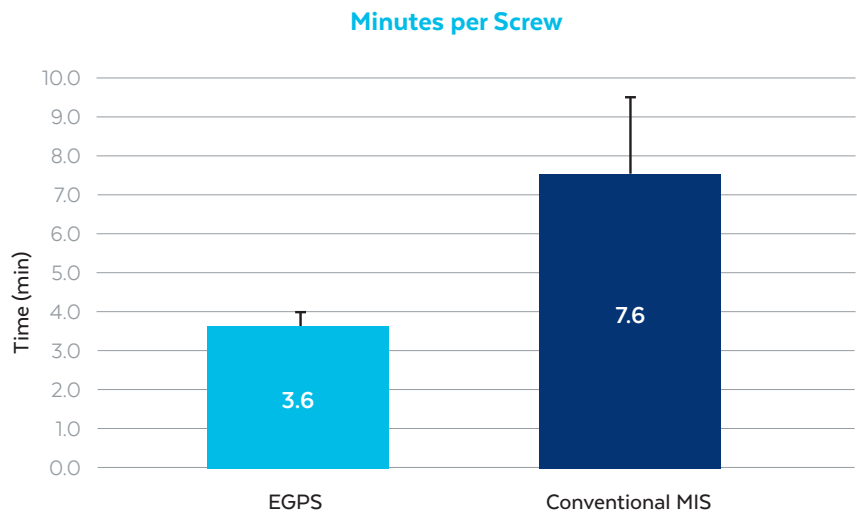


SUBSTANTIAL TIME REDUCTION

ExcelsiusGPS® has been shown to reduce screw placement time and overall procedure time in cadaveric studies.^{15, 18}

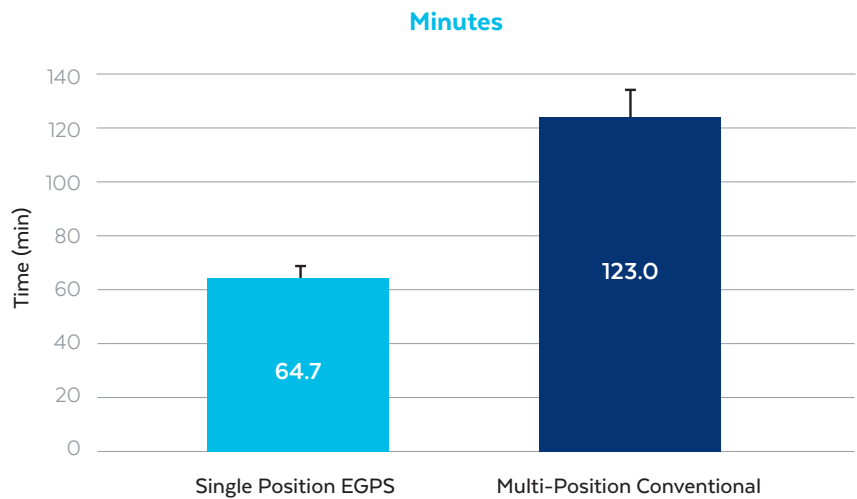
A **52% decrease in pedicle screw placement time** and a **9% decrease in overall procedure time** was demonstrated in a cadaveric study comparing ExcelsiusGPS® (EGPS) MIS procedures to conventional MIS.¹⁸

- **EGPS MIS:** average 3.6 ±0.4 minutes per screw
- **Conventional MIS:** average 7.6 ±2.0 minutes per screw



A **47.4% decrease in procedure time** for robot-assisted single position lateral compared to conventional multi-position lateral surgery was shown in a cadaveric white paper study, due to reduced screw placement time and elimination of patient repositioning.¹⁵

- **EGPS single position lateral:** average 64.7 ±4.1 minutes
- **Conventional multi-position lateral:** average 123.0 ±13.7 minutes



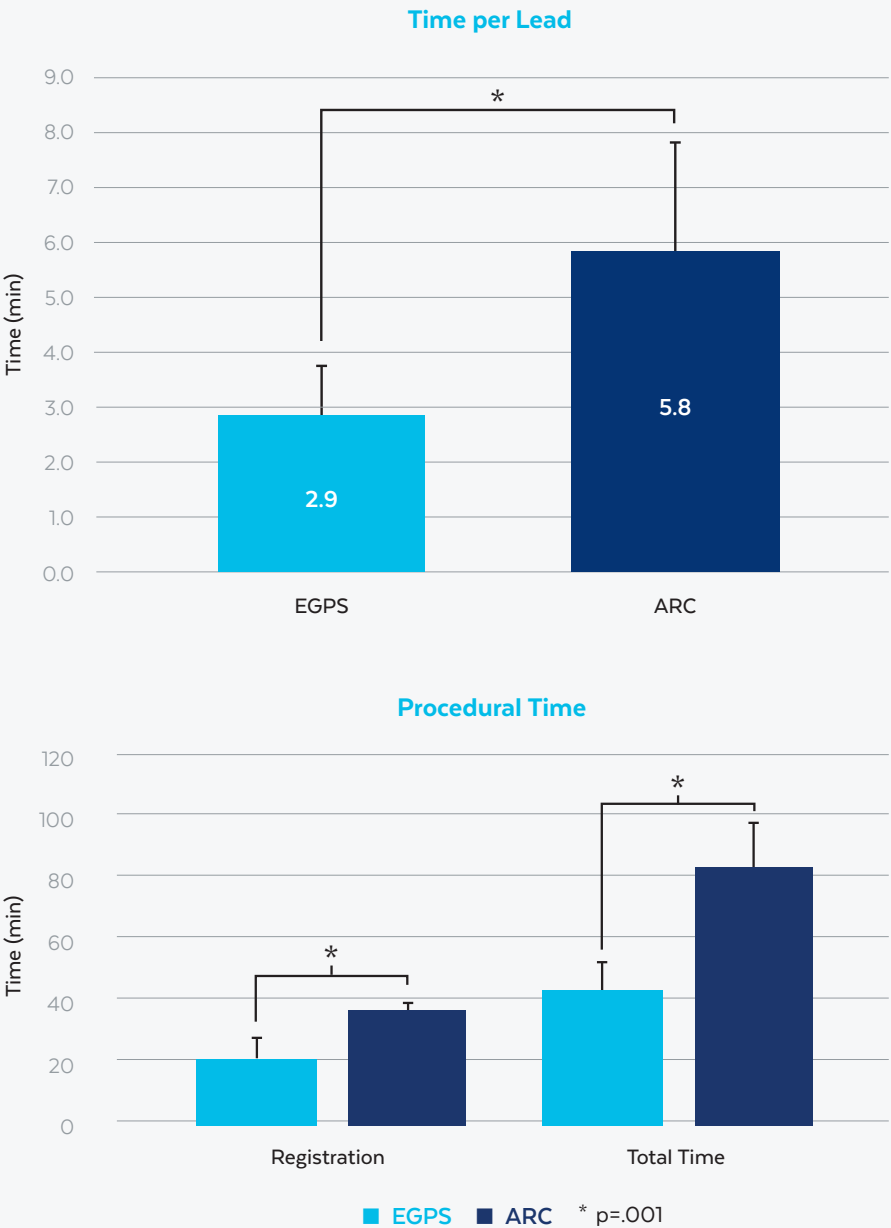
SUBSTANTIAL TIME REDUCTION (CONT'D)



CRANIAL SPOTLIGHT

In a cadaveric white paper study, data suggest that there was a **50% reduced time per lead insertion** for DBS targets and a **48% reduction in total procedure time** with ExcelsiusGPS® Cranial Solutions, as compared to the ARC technique.¹⁴

- **EGPS**: average 2.9 ±0.9 minutes lead
- **ARC**: average 5.8 ±2.0 minutes per lead



PERIOPERATIVE OUTCOMES

ExcelsiusGPS® enables accurate screw placement and allows surgeons to perform more minimally invasive procedures – which have historically reported reduced tissue damage, blood loss, and length of stay compared to conventional open procedures – allowing a quick path to recovery for the patient.^{4, 12, 19–21}

Shorter **length of stay** and reduced **blood loss** have been reported for patients undergoing robotic spine surgery compared to conventional fluoroscopic and freehand navigation procedures⁹



Low complication rates have been reported for robot-assisted lumbosacral pedicle screw placement^{2, 4–6, 16, 19–21}

Low surgical revision rates due to screw malpositioning have been reported for patients treated with ExcelsiusGPS^{®5–6, 8, 16}

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Insertion of the screws typically takes as long as an hour, but with the robot, we completed [a recent outpatient procedure] in under 10 minutes. Our patient was able to go home immediately after surgery, without the intense pain that normally follows this kind of spinal fusion, and avoided a costly, extended hospital stay.

Dr. Praveen Kadimcherla
Atlantic Spine Center, New Jersey

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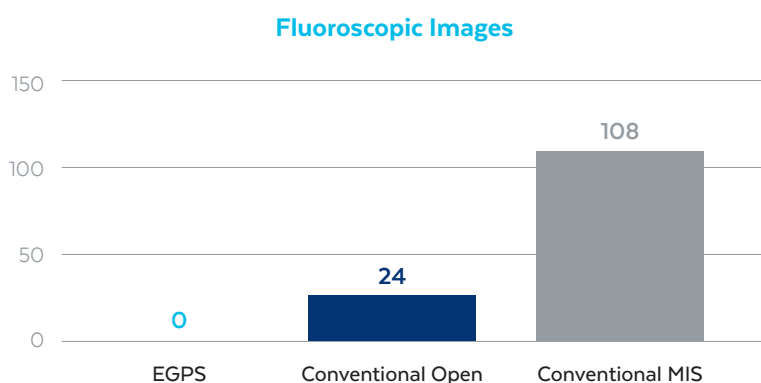
Enhance Surgical Experience

Clinical and cadaveric studies using ExcelsiusGPS® have shown improved accuracy of pedicle screw placement^{13, 18} compared to traditional open and percutaneous methods, lower radiation exposure^{11, 14-15, 18}, and shorter operating times.¹⁸

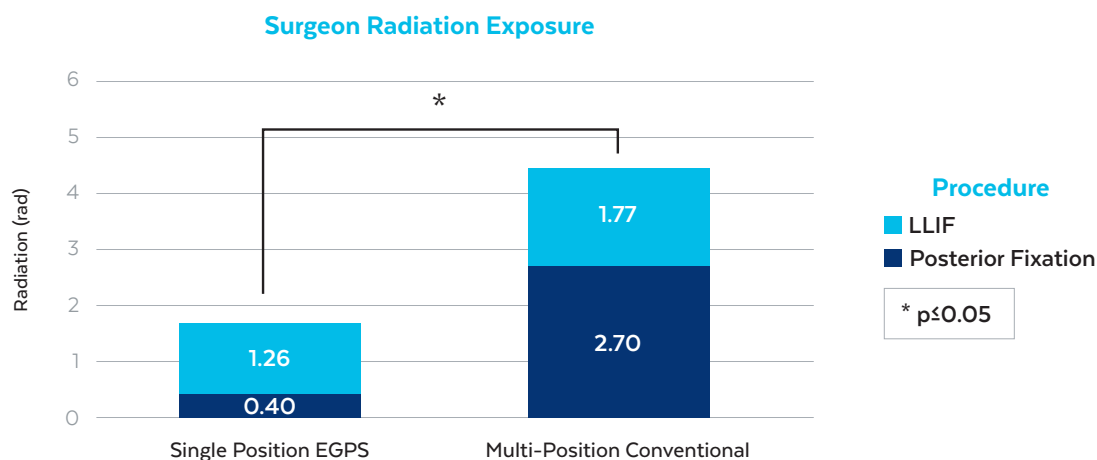
RADIATION EXPOSURE

ExcelsiusGPS® has been shown in cadaveric studies to reduce radiation exposure.¹⁸

In a cadaveric lab study, **no fluoroscopic images** were taken during robot-assisted navigated MIS placement of pedicle screws, compared to **108 fluoroscopic images** during conventional MIS techniques.¹⁸



An **85% decrease in radiation** was demonstrated in a cadaveric study during a single position lateral procedure with ExcelsiusGPS® compared to a conventional multi-position procedure.¹⁵



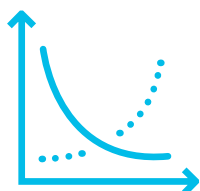
CRANIAL SPOTLIGHT

A simulated lab study demonstrated **97.5% less radiation** emitted for ExcelsiusGPS® Cranial Solutions registration than for the ARC technique.¹⁴

EASE OF USE & LEARNING CURVE

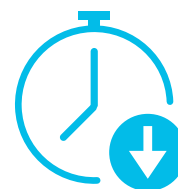
ExcelsiusGPS® is designed to be intuitive, with a minimal learning curve.

In a cadaveric study, surgeons with no experience with robot-assisted navigation surgeries achieved **low pedicle screw breach rates (2.5%)** compared to conventional fluoroscopy-guided techniques (40%).¹³



Fellows and experienced surgeons showed similar learning adaptation rates with robotic navigation techniques in a clinical setting; the study showed **increased accuracy** for residents after placing their first 30 screws.¹⁶

Surgeons may experience a linear relationship between number of cases and time. Profiling of an initial case series showed an average **reduction in operation duration of 4.6 minutes** with each additional case.⁹

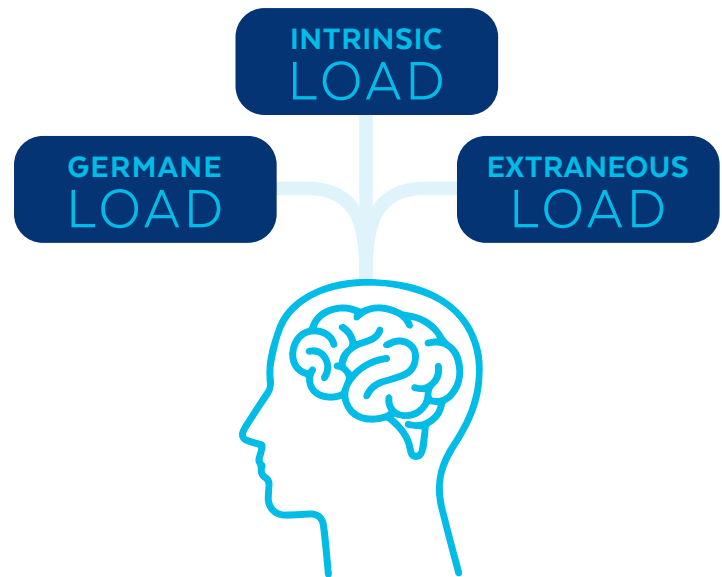


COGNITIVE LOAD & PHYSICAL STRAIN

Using ExcelsiusGPS® may help to reduce the cognitive load required by surgeons by reducing complexity and streamlining the entire surgery.

There are many moving parts in the OR during a surgery at any single point in time. Humans only have so much mental capacity before the brain becomes overloaded.

The goal is to reduce extraneous cognitive load to maximize germane load and better manage intrinsic load.



Additionally, using ExcelsiusGPS® may help reduce physical strain on surgeons and OR staff. Standing in the OR for 4 to 8+ hours a day for procedures that require extreme attention is physically demanding and exhausting. ExcelsiusGPS® can help lessen the load.

“

If you have too many elements of a procedure that are not part of that intrinsic activity, then you can very easily become mentally exhausted... ExcelsiusGPS® allows us to break down the procedure into a logical sequence of steps. Now we are able to eliminate all of the extraneous information that normally would come into our brains during a freehand technique through the use of live navigation and reliance on the preoperative plan already established.

Dr. Ian Madom

South County Health, Rhode Island

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