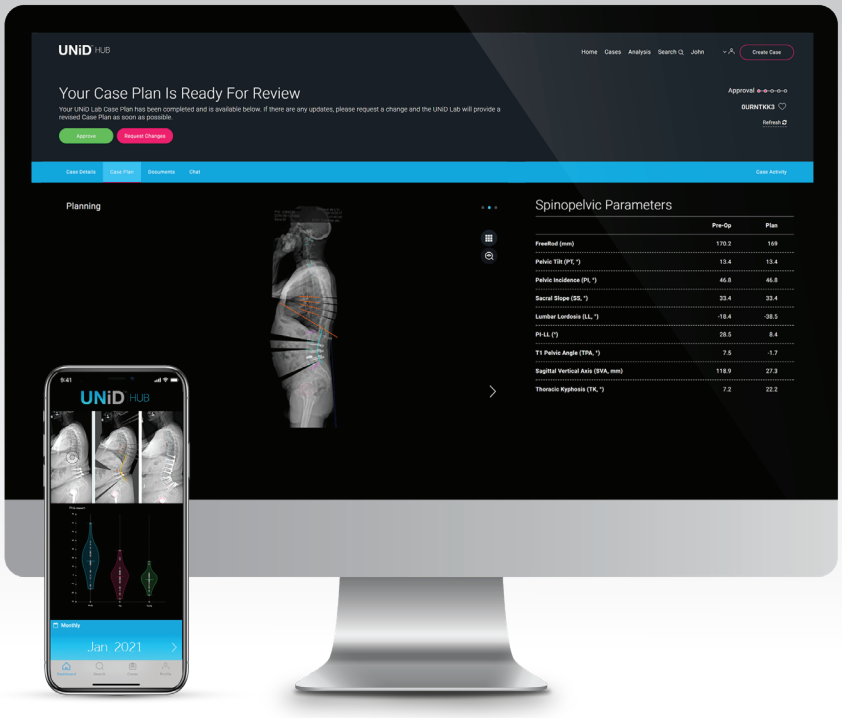
CLINICAL BRIEF

UNiD™ ASI

Adaptive Spine Intelligence



UNiD™ ASI images shown are for demonstration purposes only and no individual or patient health information is shown.

Medtronic

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INTRODUCTION TO UNiD™ ASI

UNiD™ Adaptive Spine Intelligence combines service, software, and patient-specific implants providing surgeons with a revolutionary approach to achieving better outcomes.

This clinical brief provides an overview of the clinical rationale, components, and clinical applications of UNiD™ Adaptive Spine Intelligence.

Clinical Issues, Results, and Solutions

This brief explores the clinical issues and related results or solutions with regard to sagittal alignment, surgical precision, O.R. efficiency, and the incidence of rod fracture.

UNiD™ Adaptive Spine Intelligence

Fundamental components of UNiD™ ASI systems-based platform are detailed: LAB, TEK, HUB, and the Iterative Virtuous Cycle.

UNiD™ LAB engineers provide spinopelvic parameters and surgical simulations based on surgeon input and preferences. UNiD™ TEK patient-specific implants are approved by the surgeon via the UNiD™ HUB. Clinical judgment and experience are required to properly use the software.

ENABLES SURGEONS

- Plan + Execute: Patient-specific **sagittal alignment**
- Reduce risk of rod breakage[1]
- Correct deformities with less rod flattening[2]

ENABLES HOSPITALS

- Provide **personalized** spinal solutions
- Reconfirm community leadership in treatment options
- Reduce the risk of revision surgeries due to adjacent segment disease[3, 4] and rod fracture[1]

CLINICAL BENEFITS OF SAGITTAL ALIGNMENT

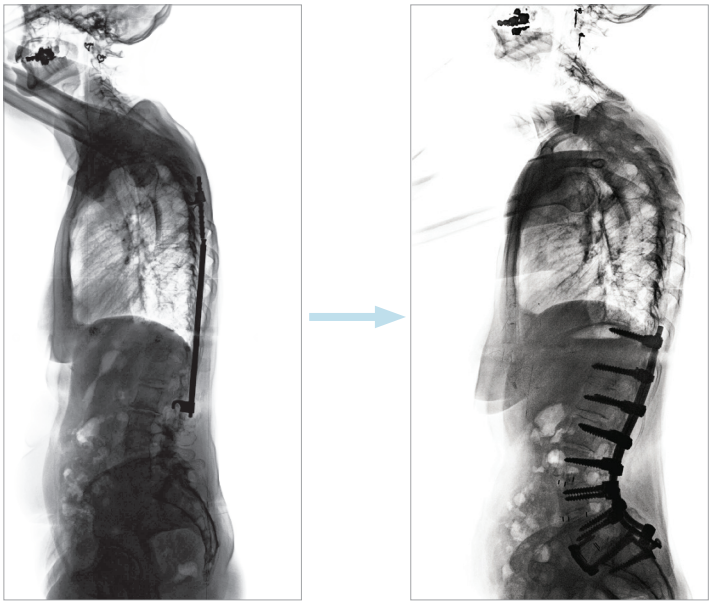
Sagittal alignment is the most dominant radiographic predictor of patient outcomes.[5,6]

Achieving harmonious alignment of key spinopelvic parameters, such as the sagittal vertical axis (SVA), pelvic incidence/lumbar lordosis mismatch (PI-LL), and pelvic tilt (PT), is a key goal of spinal deformity surgery.[5, 6]

Patients possessing postoperative spinopelvic parameters within normative ranges exhibit improved patient outcomes scores.[5, 6]

One of the risks of not achieving optimal alignment is revision spinal surgery.[7]

Clinical Transition to Patient-Specific Planning and Alignment



Harrington Rod

Patient-Specific Alignment

Key Clinical Issues

Sagittal re-alignment and clinical outcomes are directly linked.[5]

62% of patients remained sagittally malaligned after surgery.[3]

10x greater risk of developing adjacent segment disease when postoperative **ΔPI-LL ≥10°** for 1 to 3 level degenerative constructs.[4]

UNiD™ Clinical Results

SVA IMPROVED
81% achieved normative SVA values

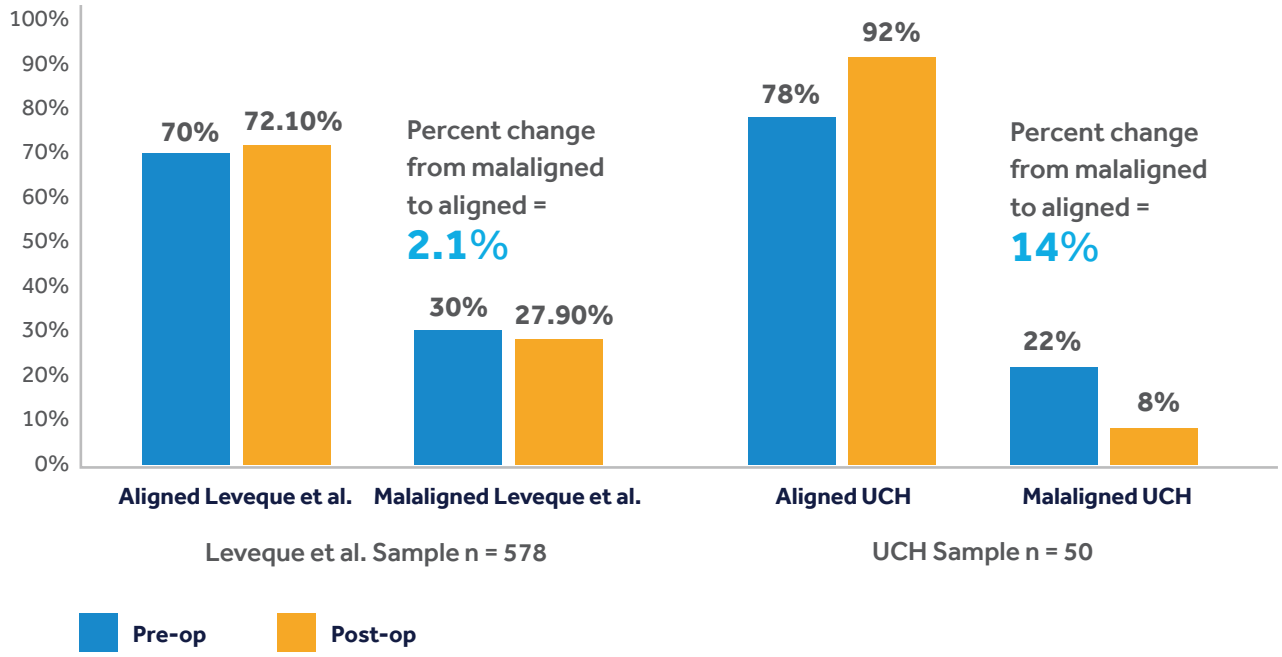
Significant improvement for all key parameters postoperatively[8]

PI-LL < 10
Achieved in all cases

All patients had postoperative **PI-LL** of less than 10°[8]

BETTER ALIGNMENT IN DEGEN PATIENTS

Kuris *et al* compared a series of 50 degenerative UNiD™ rod patients to 578 patients from Leveque *et al* on the percentage of patients whose alignment improved, worsened, or stayed the same.[10]



SAGITTAL ALIGNMENT IN AIS PATIENTS

In Solla *et al*, 17 hypokyphotic (<20 degrees) and 20 normal kyphosis AIS patients were treated with UNiD™ rods:[11]

- Mean TK increased by 21 degrees in the hypokyphotic group and 8 degrees in the normal group
- **Zero cases of proximal junctional kyphosis (PJK) at one-year follow-up**
- Concave rod angle was correlated with postoperative TK

Parameters	Overall cohort *n* = 37	H group *n* = 17	N group *n* = 20	*p* value (H vs. N)
Overall kyphosis before surgery	20 (1 to 46)	11 (1 to 19)	30 (20 to 46)	**<0.0001**
Planned overall kyphosis	37 (27 to 44)	37 (28 to 44)	37 (27 to 43)	0.51
Overall kyphosis at last follow-up	35 (25 to 56)	32 (25 to 39)	38 (27 to 56)	**0.001**
p value (overall kyphosis before surgery vs. at last follow-up)	**<0.001**	**<0.0001**	**0.002**	

RADIUS OF CURVATURE
LESS IS MORE (LORDOSIS)

In a study of 60 UNiD™ rod patients, Branche et al analyzed how the radius of curvature of patient-specific rods differed between patients and at different levels.[9]

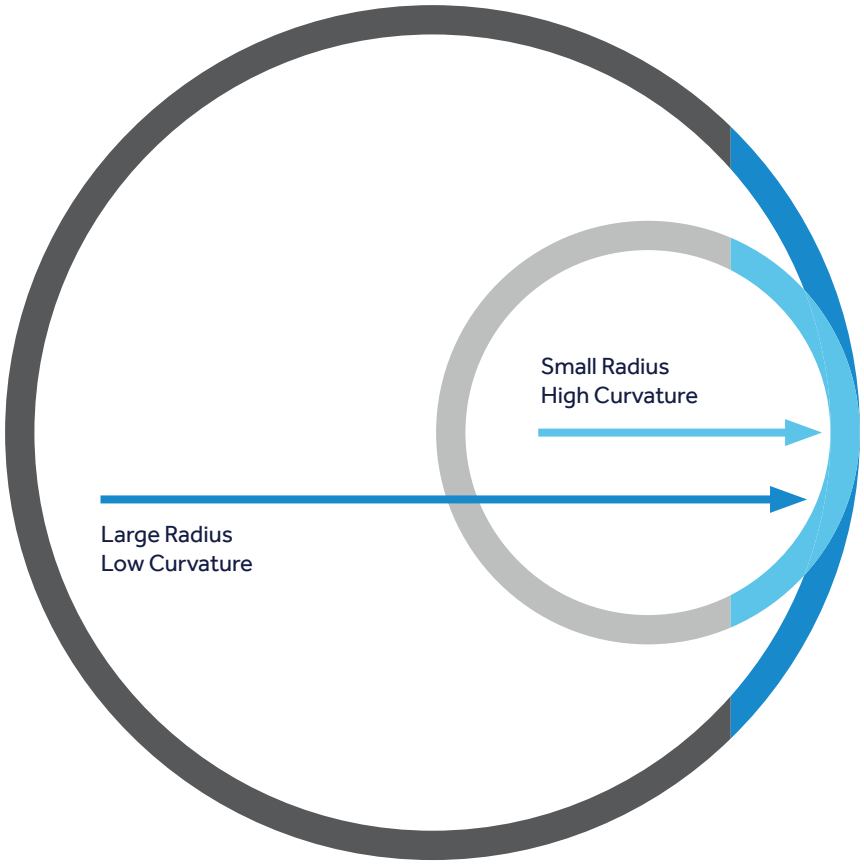
The rods were highly personalized, with standard deviations of 40-53% from the average curves.

For constructs above (cranial) and below (caudal) L4/L5, **the rods had two distinct curves to account for greater lordosis below L4/L5.**

	1 ROC	2 ROC	
Portion of rod	N/A	Cranial (UIV-L4/L5	Caudal (L4/L5-LIV)
Average curvature, mm	59	105	68
Standard deviation	23.7	55.9	28.5

Abbreviations:

LIV – lower instrumented vertebra
N/A – not available
ROC – radii of curvature
UIV – upper instrumented vertebra



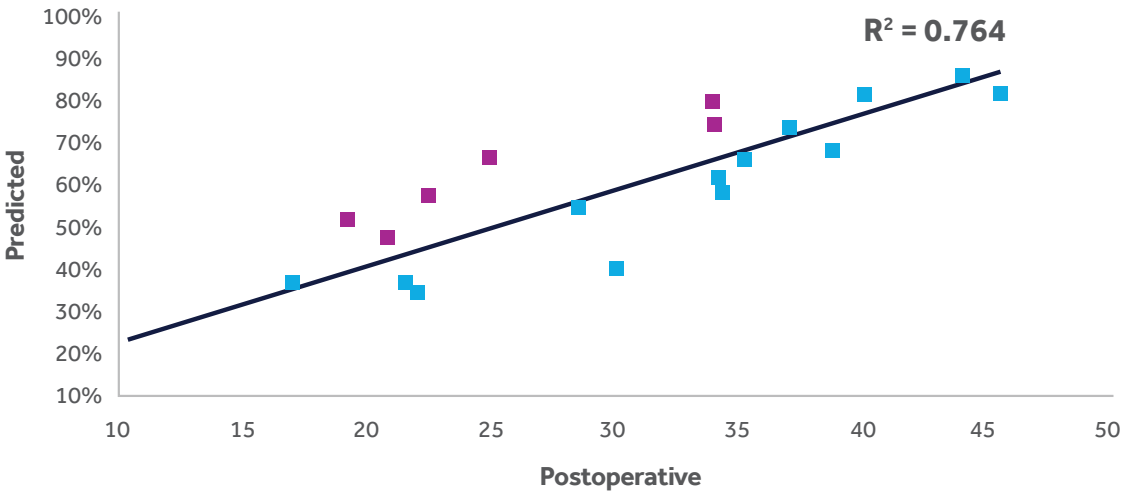
MACHINE LEARNING: PREDICTION OF THORACIC KYPHOSIS AND PELVIC TILT

Lee *et al* analyzed 20 adult deformity cases, instrumented from T10 or T11 to the pelvis, to determine the ability of UNiD™ Adaptive Spine Intelligence to predict postoperative pelvic tilt and thoracic kyphosis in un-instrumented regions of the spine.[12]

	Postoperative	Predicted	*P*
TK (T4-T12), deg	38.3 (9.5)	37.6 (10.2)	.847
Uninstrumented TK, deg	29.8 (9.6)	33.9 (9.8)	.188
Pelvic tilt, deg	22.7 (8.7)	23.4 (7.1)	.754

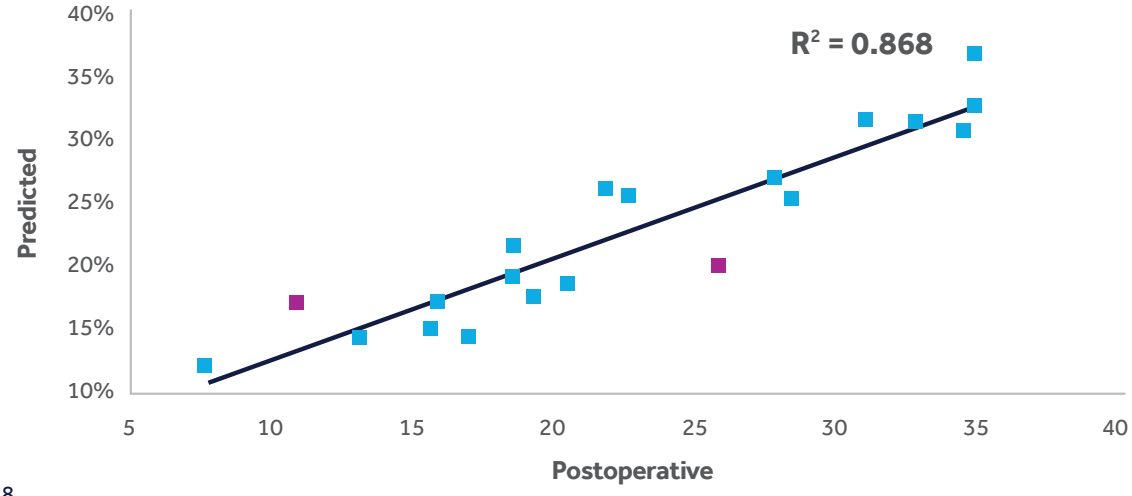
These findings suggest that surgeons could use this technology to consider the risk of proximal junctional kyphosis in adult deformity patients.

Un-Instrumented Thoracic Kyphosis, Including Outliers (>6 degrees)



The predicted versus the postoperative values for the thoracic kyphosis in the uninstrumented spine after surgery. Outliers are included.

Pelvic Tilt, Including Outliers (>4 degrees)

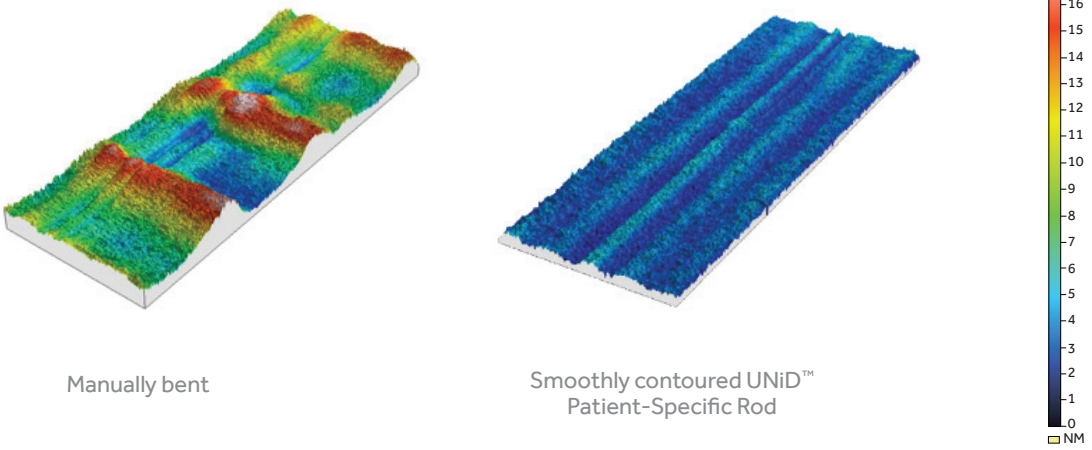


The predicted versus the postoperative values for the pelvic tilt after spine surgery. Outliers are included.

POTENTIAL FOR PRECISION AND EFFICIENCY

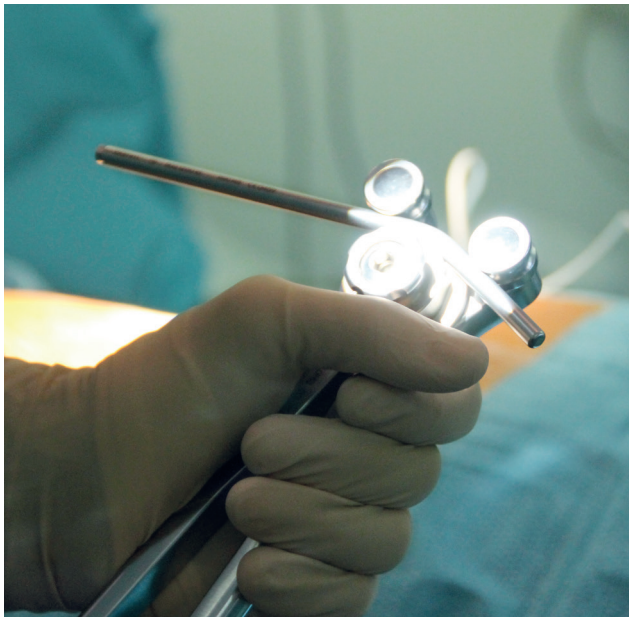
UNiD™ Adaptive Spine Intelligence gives surgeons the tools to more precisely achieve their surgical goals, increasing efficiency in both the preoperative planning phase as well as in the operating room.

3-D Rod Surface Analysis*



Manually bent

Smoothly contoured UNiD™ Patient-Specific Rod



Strength

Yamada *et al* found that notch-free curved CoCr rods have greater durability than notched curved rods, while maintaining their stiffness.[13]

Each UNiD™ Rod is industrially produced in a lab for the highest level of control. The resulting rods are smoothly contoured, aligned with the case plan, and notch-free.

See back cover for the risks of UNiD™ rods.

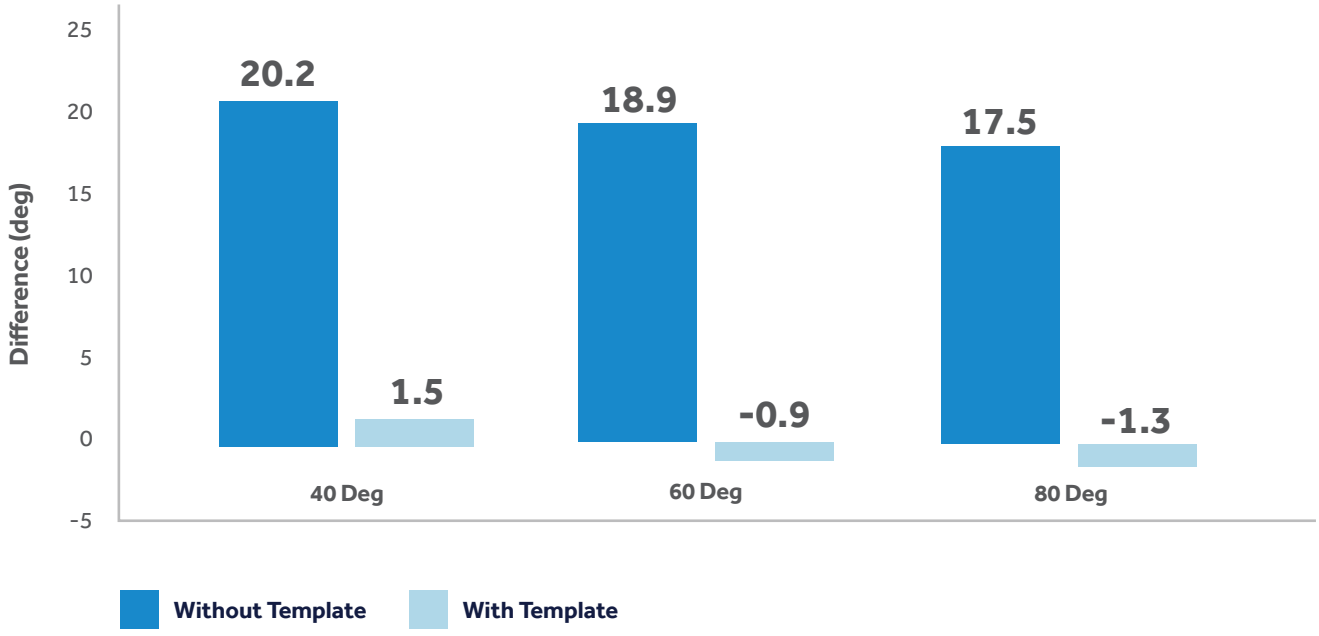
*3-D Optical Profilometer - Non-Contact Measurement and Analysis

ROD BENDING ACCURACY

In Sardi *et al*, ten experienced surgeons were asked to contour rods using a French Bender to 40, 60, and 80 degrees.[14]

Without a template, surgeons overbent by a mean of 17.5 to 20.2 degrees for each desired angle, but with a template, they came within an average of two degrees of their target angle.

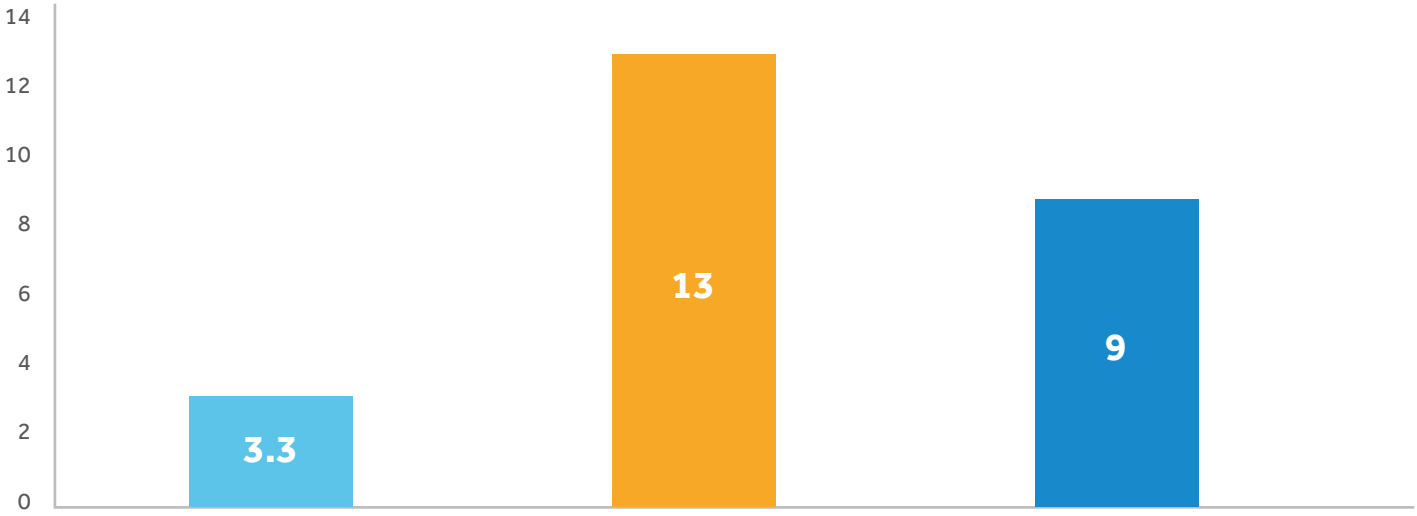
Average Diffference from Target Angle



LESS ROD FLATTENING

Three studies assessed the difference in rod contour after implantation,[2, 15, 16] as well as the Cobb Angle (CA) correction they were able to achieve. Change in rod contour (flattening) was assessed by modeling the difference in concave rod deflection between the preoperative and implanted rods.

Mean Concave Rod Deflection (mm) in AIS Patients

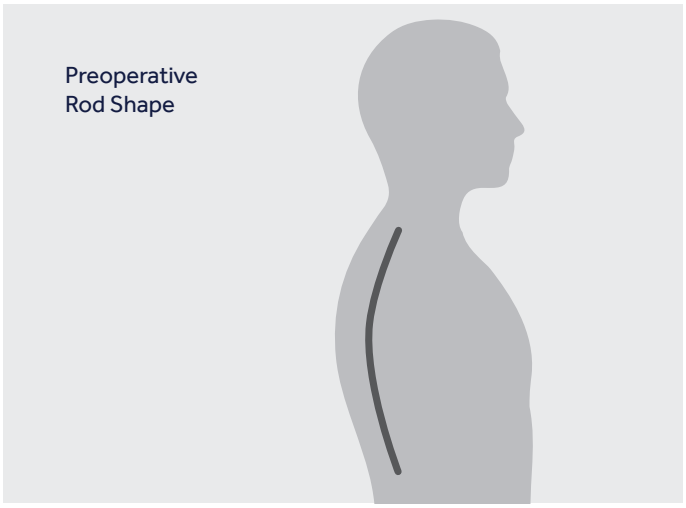


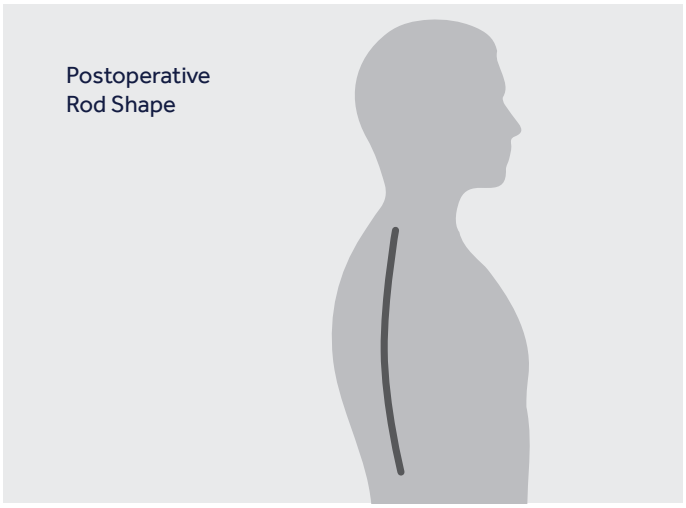
Aminian et al
- Mean CA Correction: 38.3°
- 10 Ti Rod Constructs
- 3 CoCr Rod Constructs
- 9 Hybrid (Ti/CoCr) Constructs
- **All 6.0 mm UNiD™ Rods**

Cidambi et al
- 5.5 mm Rods
- Mean CA Correction: 40°
- 27 Ultrahigh Strength Steel Constructs

Sia et al
- 5.5 mm Rods
- Mean CA Correction: 40.6°
- 11 CoCr Constructs
- 10 Ti Constructs

Flattening of a Concave Rod after Implantation





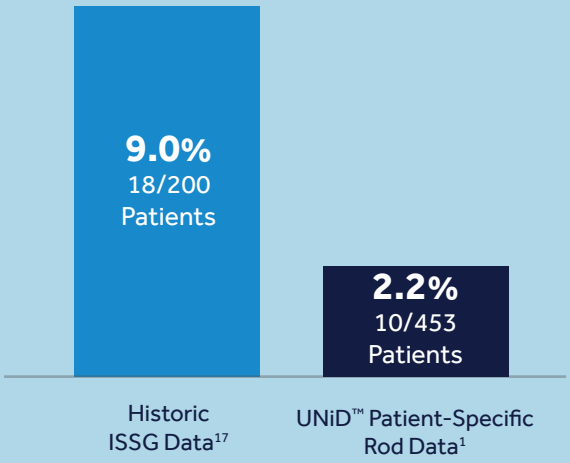
REDUCED INCIDENCE OF ROD FRACTURE

Evaluation of postoperative data indicates a reduction in the rod fracture rate:

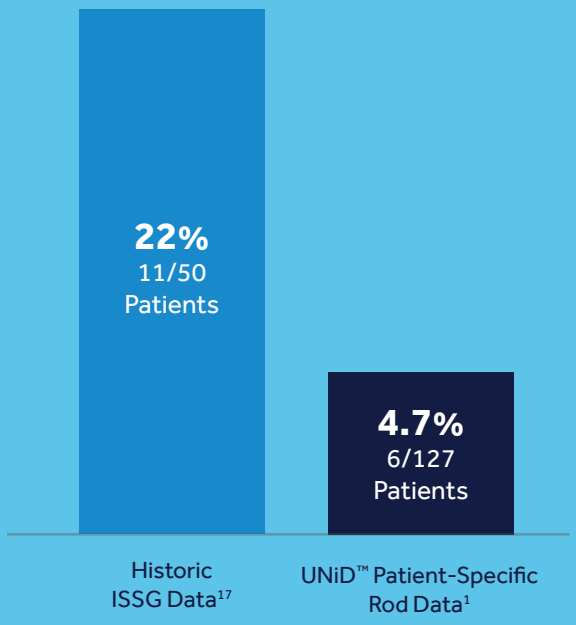
In adult deformity cases (> 5 levels) at least one year after surgery, UNiD Rods had a fracture rate of 10/453 patients, or 2.2%. In a subset of International Spine Study Group (ISSG) data with the same parameters, 18/200 (9.0%) of adult deformity patients experienced rod fractures.[1, 17]

When patients from the same two studies underwent a pedicle subtraction osteotomy (PSO) in the procedure, the rate is **reduced by 79%**, an improvement over the 22.0% rod fracture rate associated with procedures involving a PSO.[1, 17]

Rod Fracture Rates in Adult Deformity Cases



Rod Fracture Rate in Cases involving a PSO

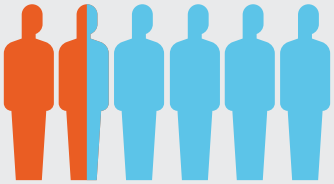


Risks associated with these spinal implants include loosening, disassembly, bending, and/or breakage of components. A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results.

COSTS TO THE HEALTHCARE SYSTEM

Healthcare providers are increasingly concerned about the cost of complications, readmissions, and reoperations associated with adjacent segment disease and implant failure, such as spinal rod fracture.

In a study[18] of **484 consecutive adult spinal deformity patients** with an average **follow-up of 4.8 years**:



27%
of patients underwent a revision surgery

Costs associated with revision averaged
$67,262

In revision patients, total costs increased by
70%

In a study[19] of consecutive adult scoliosis patients, **126 primary patients** were compared to **124 revision patients**. In this study, revision patients had:

29%
more complications

26%
longer O.R. times

31%
greater blood loss

UNiD™
ADAPTIVE SPINE INTELLIGENCE

Plan. Execute. Analyze.

The surgeon-centric platform provides a **planning** service staffed by biomedical engineers, precise intraoperative **execution** with personalized solutions, and insightful **analytics** of surgical results with the ultimate goal of improving clinical outcomes.

UNiD™ LAB

Engineering Services

UNiD™ LAB is our team of biomedical engineers who provide a suite of services that allow the surgeon to analyze, plan, understand, and improve their patients' outcomes. More specifically, the UNiD™ LAB works collaboratively with the surgeon through the proprietary UNiD™ HUB software to provide a detailed analysis of the patient's spinopelvic parameters, simulate surgical strategies and technologies using proprietary data and algorithms, and collect postoperative outcomes.

- Spinopelvic parameter measurements
- Normative alignment value comparison
- Proprietary predictive planning models
- Case strategy based on latest scientific literature and surgeon preferences
- Postoperative data collection

UNiD™ HUB

Interactive Portal

UNiD™ HUB is our software interface. This HIPAA compliant interactive platform, accessible via desktop or a mobile device, provides A.I. and analytics and facilitates surgical plan simulations, clinical and surgical workflows, outcome reports, and communication with the UNiD™ LAB. (For more detail, see page 13).

UNiD™ TEK

Personalized Implants

UNiD™ TEK is a suite of technologies enhanced by the UNiD™ HUB platform and UNiD™ LAB Service.

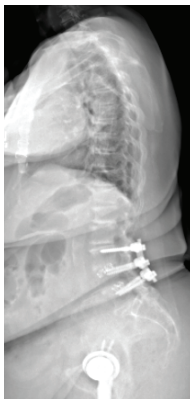
Each TEK implant aligns with the surgical case plan, providing intraoperative plan confirmation. UNiD™ Rods, part of our UNiD™ TEK product portfolio, are patient-specific rods. UNiD™ Rods are industrially bent for each patient according to the surgical plan to provide optimal sagittal alignment.

- Match surgical plan
- Intra-op confirmation
- Industrially bent
- No notch technology

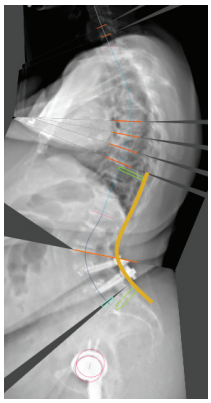
PLAN
PRE-OP PLANNING SERVICES

1 Imaging Analysis

The UNiD™ cycle begins for each patient with the rapid identification of spinopelvic parameters using calibrated x-rays. Integration with PACS and communication via the UNiD™ HUB support the goal of improved patient workflows.



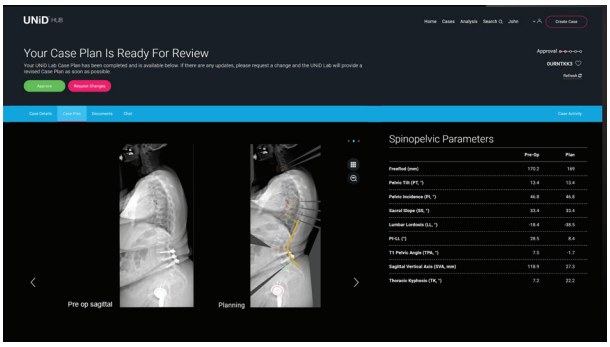
Pre-Op



Plan

2 Case Simulation

The UNiD™ LAB engineer uses proprietary software platform – the UNID™ HUB – to simulate multiple surgical strategies based on a combination of the surgeon's input and preferences, as well as scientific literature. Each simulation is processed through proprietary predictive models allowing the surgeon to visualize the postoperative compensatory mechanisms most likely to occur.



EXECUTE
INTRA-OP SERVICES

3 Personalized Implants

UNiD™ TEK is a suite of technologies enhanced by the UNiD™ HUB platform and UNiD™ LAB Services. UNiD™ Rods are manufactured following surgical planning performed by a surgeon for a given patient. The UNiD™ Rod implants are fabricated with advanced in-house manufacturing technology. UNiD™ Rods are FDA cleared in the U.S. for compatibility with the CD Horizon™ Solera™ Spinal System.

4 Case Support

UNiD™ Rods are aligned with the preoperative surgical plan, helping to guide the surgery and provide intraoperative confirmation.

Risks associated with these spinal implants include loosening, disassembly, bending, and/or breakage of components.

ANALYZE
POST-OP SERVICES

5 Data Collection

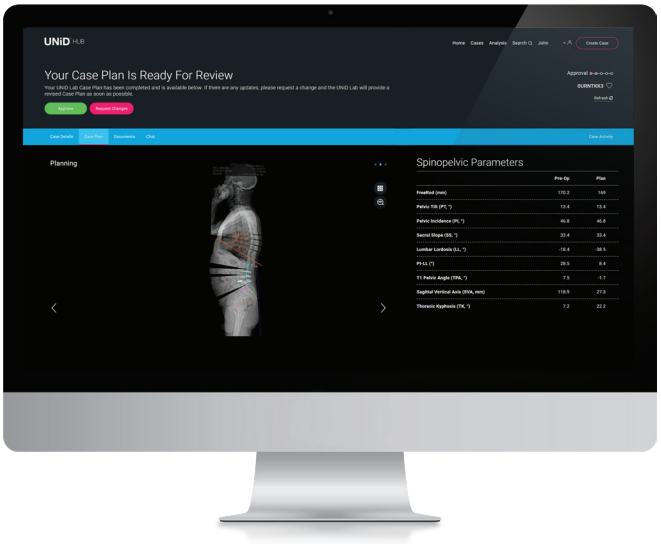
This process combines data collection, advanced analytics, and visualization within the UNiD™ HUB. Surgical cases are organized and easily accessed. Multiple output options are available for use in presentations, reports, and clinical studies.

6 Machine Learning

Data scientists use machine learning to identify correlations and tendencies within the aggregated set of de-identified data. The growing pool of UNiD™ data increases the power of this cognitive insight.

7 Predictive Modeling

Proprietary predictive planning models also use machine learning to estimate compensatory mechanisms and to provide decision making support in surgical strategy. The entire UNiD™ ASI system is strengthened as surgical outcomes are assessed and integrated into the predictive models.



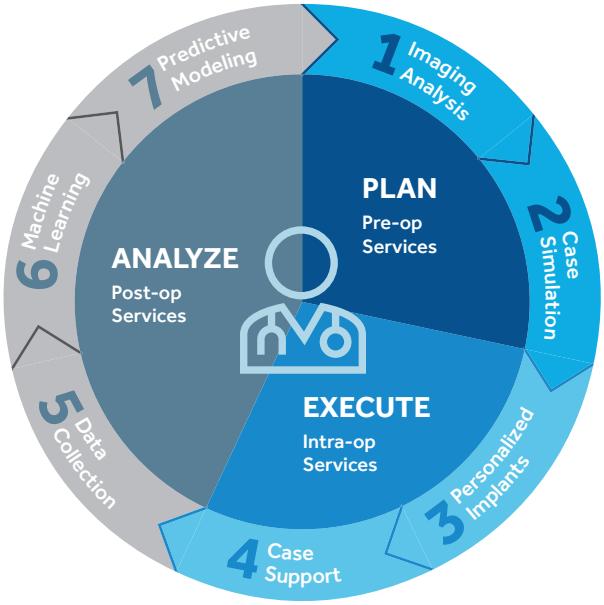
UNiD™ LAB engineers provide spinopelvic parameters and surgical simulations based on surgeon input and preferences. UNiD™ TEK patient-specific implants are approved by the surgeon via the UNiD™ HUB. Clinical judgment and experience are required to properly use the software.

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results.

ITERATIVE
VIRTUOUS CYCLE

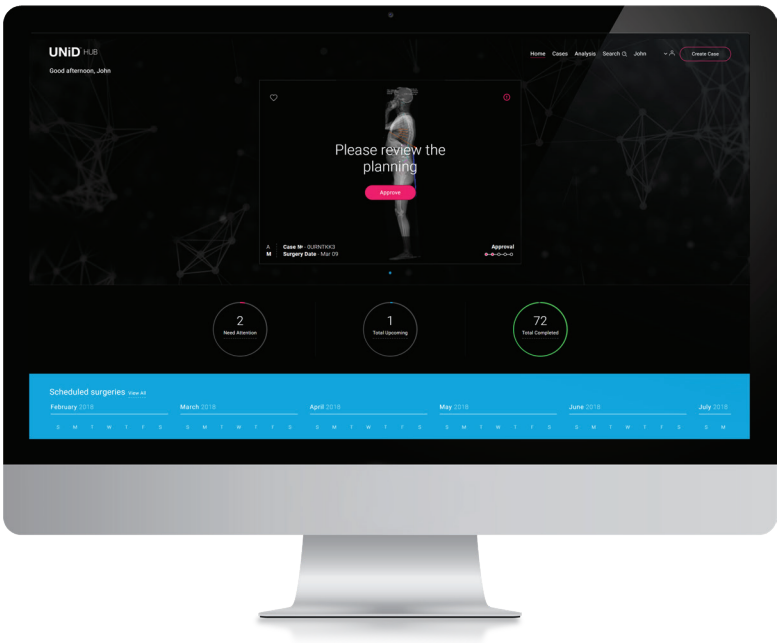
UNiD™ ASI leverages the aggregation of all UNiD™ procedures via a proprietary 7-step process that creates an **Iterative Virtuous Cycle**.

Through the power of data collection and machine learning, a unique capability is created, allowing for a continuous cycle of improvement.



UNID™ HUB
INTERACTIVE PORTAL

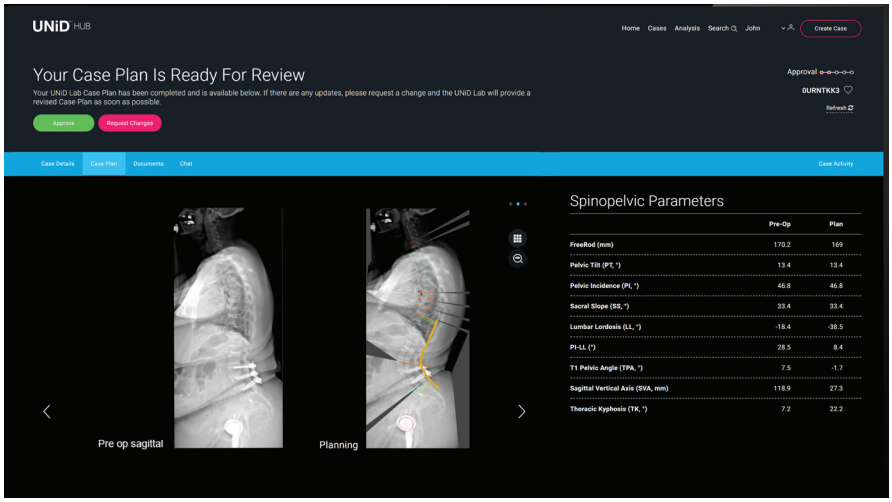
Facilitates communication with the planning service of the UNiD™ LAB and allows the surgeon to leverage the power of Adaptive Spine Intelligence.



Accessible via desktop or a mobile device, the HIPAA compliant UNiD™ HUB is a centralized location for review and approval of surgical plans as well as a valuable resource for organizing and analyzing surgical results.

PLAN

Simulation and Plan Approval



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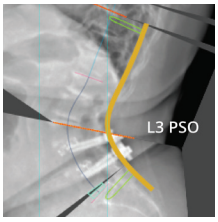
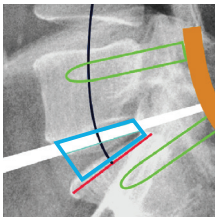
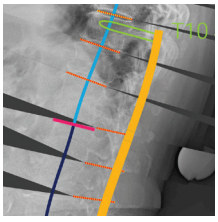


Osteotomies



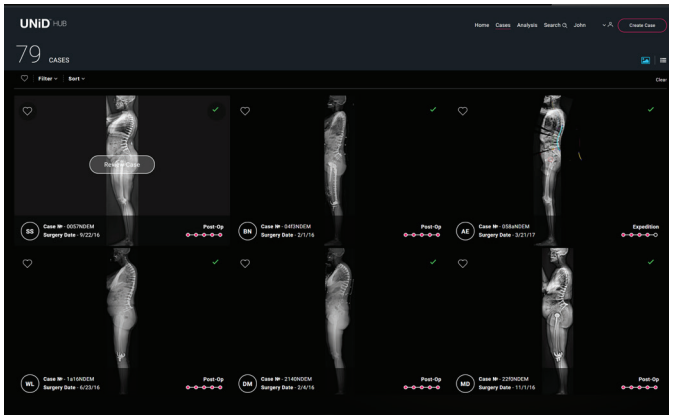
Cage Planning



Rod Planning

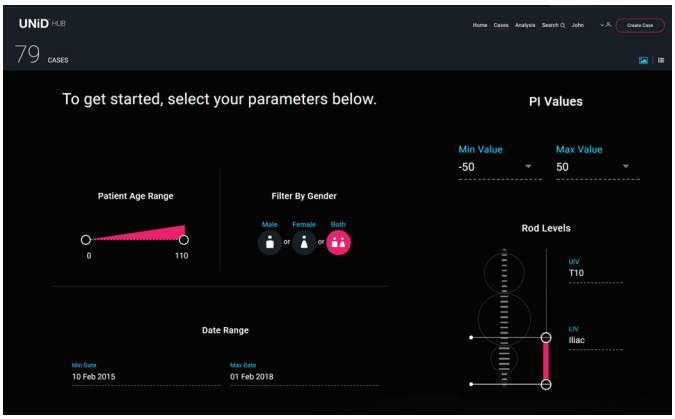
ANALYZE

Database of Surgeries



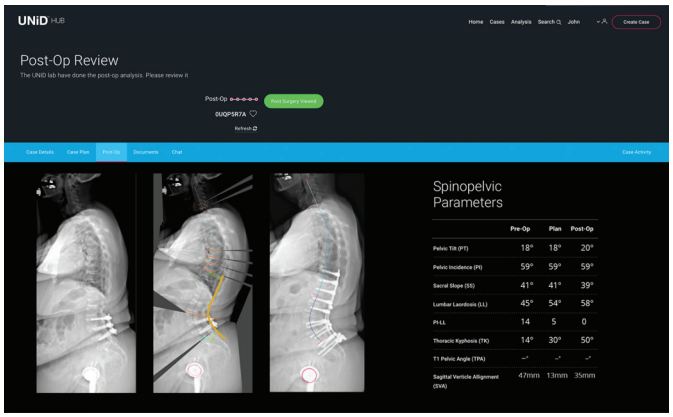
Parameters and images for all surgeries are well organized and easily accessible.

Multiple Search Options



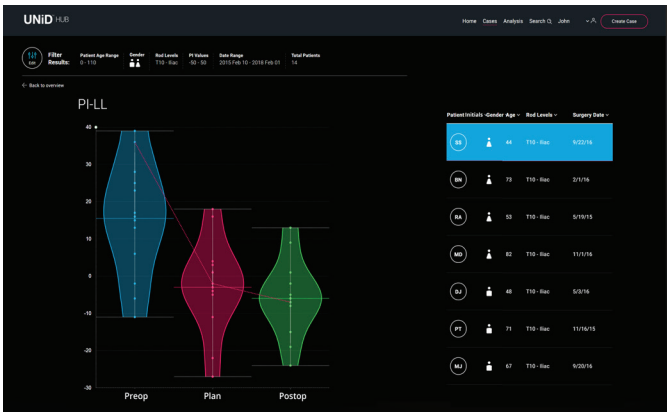
Ability to query along multiple parameters allows focus on a particular subset of cases.

Review Postoperative Results



Compare pre-op, plan, and post-op images and parameters for individual patients or use the Outcome Analysis Toolkit for a broader review of the database.

Outcome Analysis Toolkit



Advanced analytics and visualization of outcome data provides valuable insight and opportunity for improvement. Multiple output options are available for use in presentations, reports, and clinical studies.

REFERENCES

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IMPORTANT
PRODUCT INFORMATION

CD HORIZON™ SYSTEM INDICATIONS

The CD Horizon™ Spinal System with or without Sextant™ instrumentation is intended for posterior, non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (DDD - defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e. fracture or dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, or lordosis), tumor, pseudarthrosis, and/or failed previous fusion. Except for hooks, when used as an anterolateral thoracic/lumbar system, the CD Horizon™ Spinal System titanium, cobalt chrome, and stainless steel implants may also be used for the same indications as an adjunct to fusion.

With the exception of DDD, the CD Horizon™ Legacy™ 3.5mm rods and associated components may be used for the aforementioned indications in skeletally mature patients as an adjunct to fusion. The 3.5mm rods may be used for the specific pediatric indications noted below.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CD Horizon™ Spinal System titanium, cobalt chrome, and stainless steel implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e. scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the CD Horizon™ Spinal System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/ spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The CD Horizon™ PEEK rods are intended to provide posterior supplemental fixation when used with an interbody fusion cage for patients diagnosed with DDD. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level. This device is intended for 1-2 level use in the lumbosacral spine (L2 – S1) in skeletally mature patients. The device is intended for use with an interbody fusion cage at the instrumented level and is not intended for stand-alone use.

The CD Horizon™ Spire™ plate is a posterior, single-level, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fixation in the following conditions: DDD (as previously defined), spondylolisthesis, trauma, and/or tumor.

In order to achieve additional levels of fixation, the CD Horizon™ Spinal System rods may be connected to the Vertex™ Reconstruction System with the Vertex™ rod connector. Refer to the Vertex™ Reconstruction System package insert for a list of the Vertex™ indications of use.

RISKS

All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of potential adverse events includes:

- Early or late loosening of any or all of the components.
- Disassembly, bending, or breakage of any or all of the components.
- Post-operative change in spinal curvature, loss of correction, height, or reduction.
- Infection.

PASS LP SYSTEM DESCRIPTION

The internal fixation devices are composed of screws, hooks, rods, plates, cross links, connection and locking devices .The range of different sizes and shapes of the implants allows the surgeon to adapt to the pathology and morphology of each of his patients. The implants are manufactured in titanium alloy Ti-6Al-4V ELI conforming to ISO 5832-3 specifications and ASTM F136 specifications, with the exception of the rods intended for in situ bending which are manufactured in non-alloyed titanium (CP titanium) conforming to ISO 5832-2 specifications and ASTM F67 specifications and the CoCr rods which are manufactured in cobalt chrome alloy Co-Cr28Mo6 conforming to ISO 5832-12 specifications and ASTM F1537 specifications. The Patient Specific Rod has been designed and manufactured for one specific patient. The Patient Specific Rod should be used during surgery for this patient only and should not be reused (single use only). Refer to the surgical technique brochure for additional information. If this Patient Specific Rod does not perform as intended, use the standard PASS LP rod to complete the surgery. Under no circumstances are the implants reusable.

INDICATIONS

The PASS LP spinal systems include a pedicle system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine:

- Fractures.
- Dislocation.
- Failed previous fusion (pseudarthrosis).
- Spinal stenosis.
- Degenerative spondylolisthesis with objective evidence of neurological impairment.
- Spinal deformations such as scoliosis or kyphosis.
- Loss of stability due to tumors.

The PASS LP spinal systems are also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5–S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The PASS LP also include hooks and rods and sacral/iliac screws indicated for degenerative disc disease (ddd) defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudarthrosis and failed previous fusion.

Except for rod plates, when used for posterior non-cervical pedicle screw fixation in pediatric patients, the PASS LP spinal system implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The PASS LP spinal system is intended to be used with allograft and/or autograft. Pediatric pedicle screw fixation is limited to a posterior approach.

WARNING: The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.

RISKS

In addition to the risks associated with surgery of the spine without instrumentation, a number of possible undesirable effects may occur with instrumented surgery (including but not limited to):

- Detachment, deformation, mobilization, slipping, breakage of one or all of the components.
- Pain due to the surgery, the fracture, deformation and or migration of an implant.
- Fracture of the pedicle during insertion of a pedicular screw.
- Postoperative loss of correction and/or reduction of the spine, partial or total loss of the corrections achieved.

UNID™ SPINE ANALYZER INDICATIONS

The UNiD™ Spine Analyzer is intended for assisting healthcare professionals in viewing and measuring images as well as planning orthopedic surgeries. The device allows surgeons and service providers to perform generic as well as spine related measurements on images, and to plan surgical procedures. The device also includes tools for measuring anatomical components for placement of surgical implants. Clinical judgment and experience are required to properly use the software.

Please refer questions on the risks and benefits of UNiD™ ASI to unidsupport@medicrea.com.

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Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.

Consult instructions for use at this website www.medtronic.com/manuals.

Note: Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

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