

Patient-Specific Spine Analytics

March 2nd 2023

The webinar will begin shortly...

Outline

- Introduction
- Presentation: Patient-Specific Spine Analytics
- Let's meet at AAOS 2023
- Q&A session



Host:

- Kristoffer Iversen, Technical Sales Executive, AnyBody Technology



Presenters:

- Dr. Isador Lieberman, Chief Medical Officer, Agada Medical
- Kobi Blank, VP R&D, Agada Medical
- Samuel Shannon, Ph.D, Sr. Algorithm Engineer, Agada Medical
- Pavel Galibarov, Ph.D, Sr. Consultant, AnyBody Technology



Control Panel

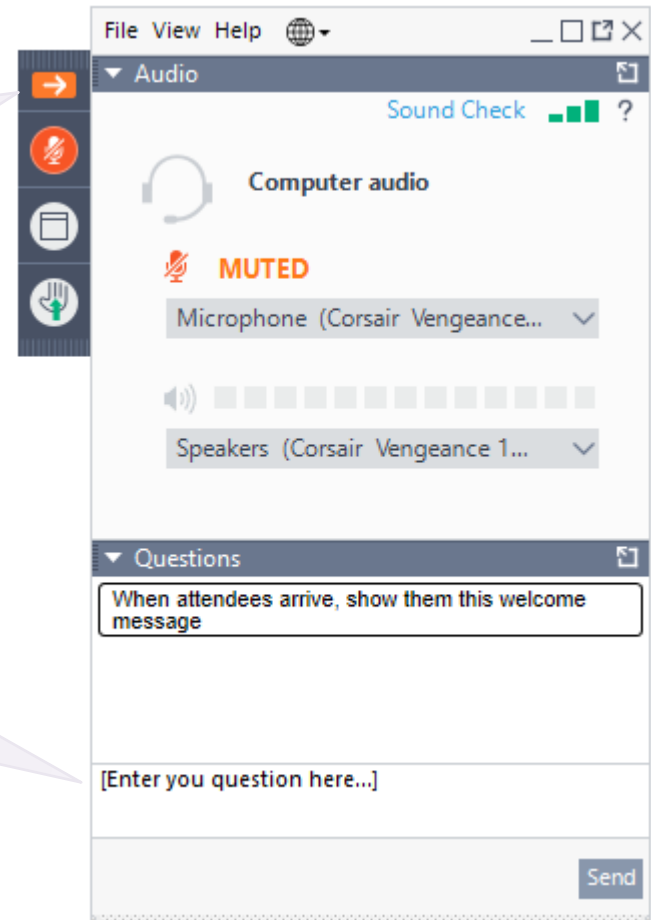
The Control Panel appears on the right side of your screen.

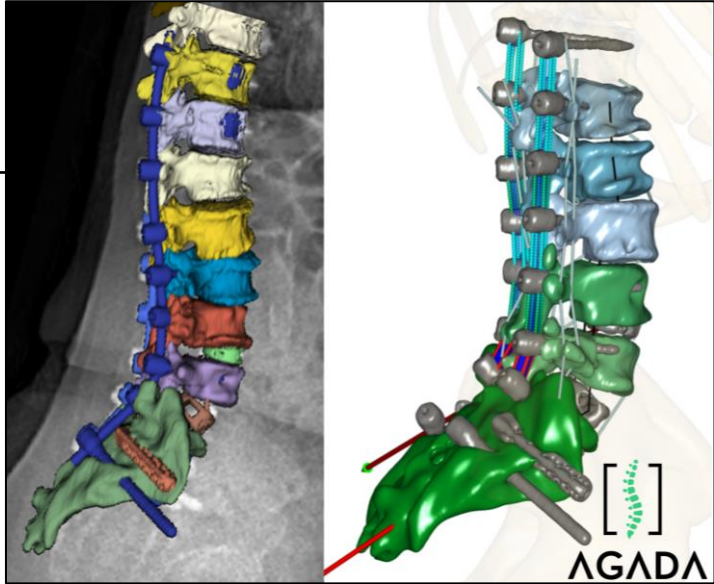
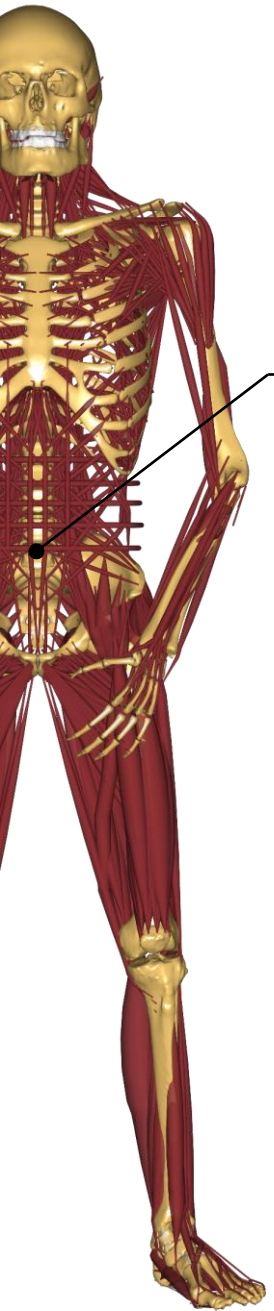
Submit questions and comments via the Questions panel.

Questions will be addressed at the end of the presentation. If your question is not addressed, we will do so by email.

Expand/Collapse the Control Panel

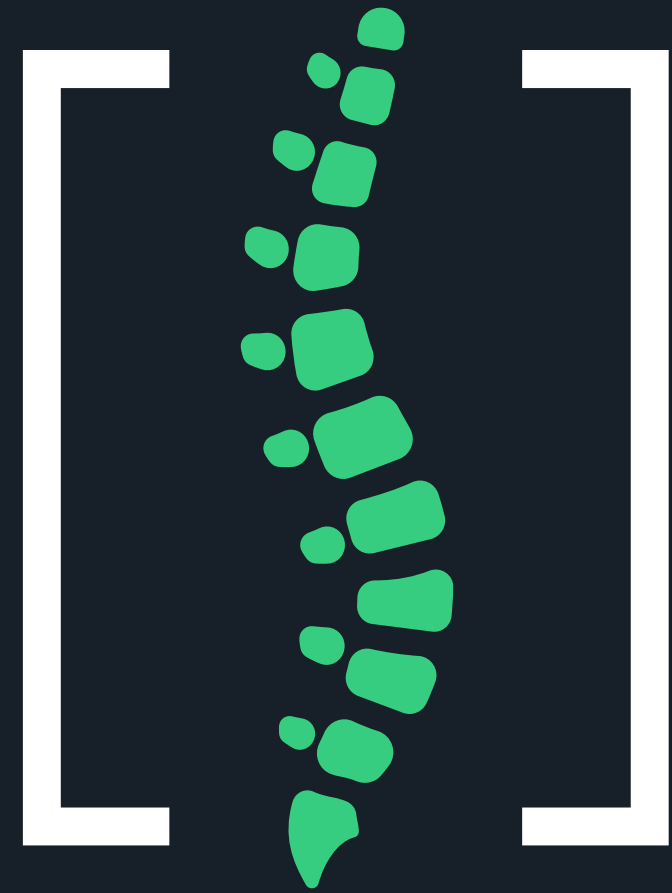
Ask a question during the presentation





Patient-Specific Spine Analytics

March 2nd 2023



AGADA

Defining the Future of
Spine Surgery



WHO WE ARE



Dr. Isador Lieberman

**Founder, President, Chairman of The Board,
Chief Medical Officer**

Orthopedic & Spine Surgeon, Former President of the Texas Back Institute. Leadership & clinical roles at the University of Toronto and the Cleveland Clinic. 40+ U.S. patents for spinal surgery instruments and implants. Author of industry-defining medical literature. Consultant to companies like Kyphon, SIBone, J&J DePuy Synthes and Mazor Robotics.



Mr. Kobi Blank

VP Research & Development

Kobi is a graduate of the MSM-Polytechnic University NY. He holds a B.Sc. in Mechanical Engineering, TAU. He has over 20 years' experience in medical devices, imaging systems, active implants, and manufacturing technologies (TopSpin Medical, SuperDimension, Medtronic, Sync-Rx, Philips). He has been a consultant to multiple medical device companies in the Cardiology and Orthopedics space.



Mr. Samuel Shannon

Senior Algorithm Engineer

Samuel holds a PhD. in computational mechanics. He specializes in algorithm development, including finite element analysis, machine learning & signal processing. He has over 12 years experience in the medical device industry.



THE PROBLEM

Nearly **1/3**
of Spinal
Surgeries

FAIL



\$10B

Total Addressable Market

Spinal Deformity

100k surgeries yearly

20%-36% **FAIL**

Cost of revision surgery: \$130k

Total revision burden: **\$2.6B**



\$5.6B

Yearly Revision Burden (US)

Spinal Degeneration

500k surgeries yearly

12%-40% **FAIL**

Cost of revision surgery: \$30k

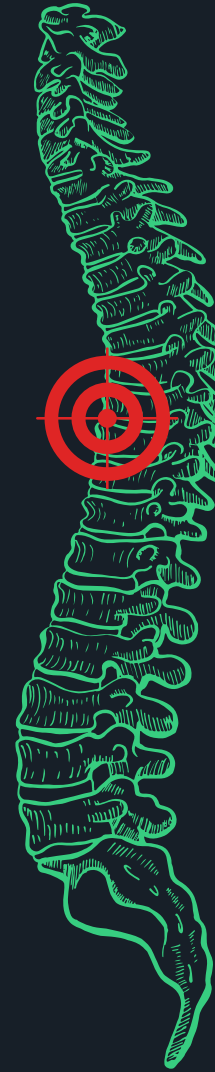
Total revision burden: **\$3B**





THE NEED

Quantify the Forces & Predict the Clinical Outcomes



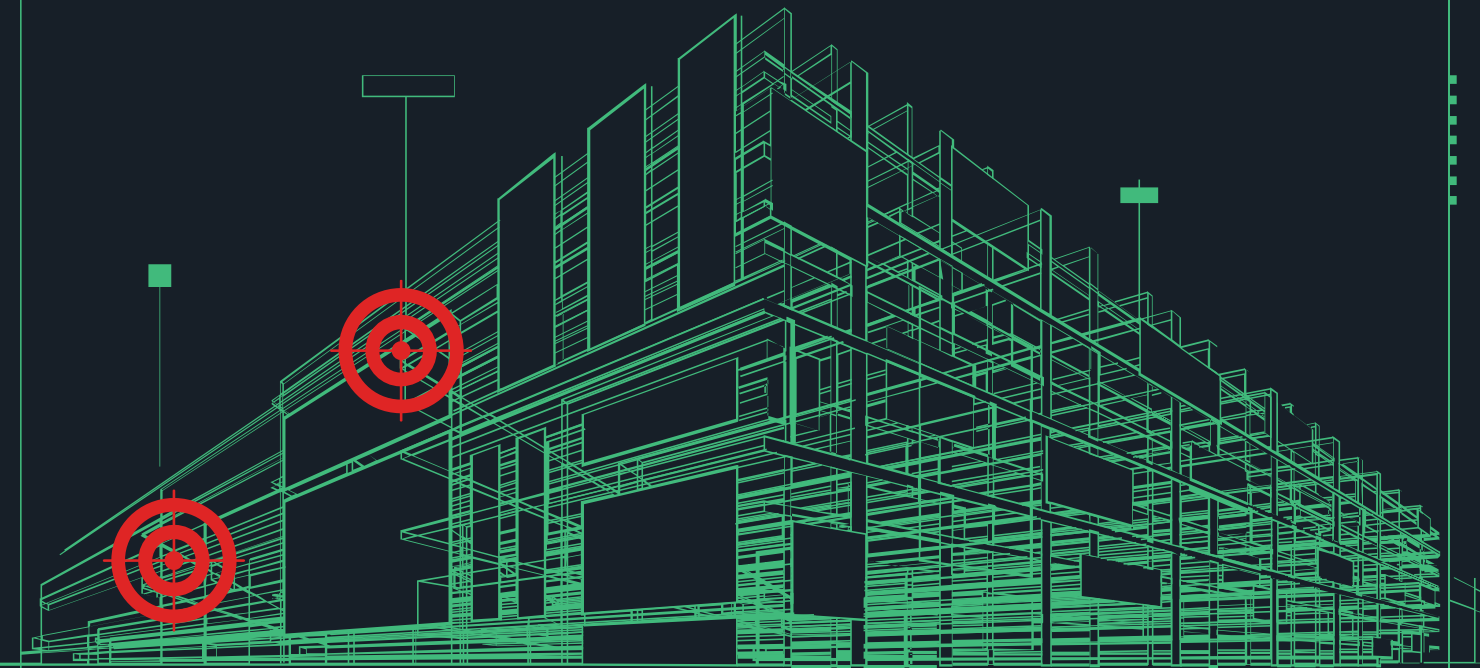
ART

To date, surgeons do not have the tools to analyze the forces on the spine, or to predict the outcome of surgery

Apply the Science to the Art

SCIENCE

Structural engineers must consider how a structure will support the forces acting on it

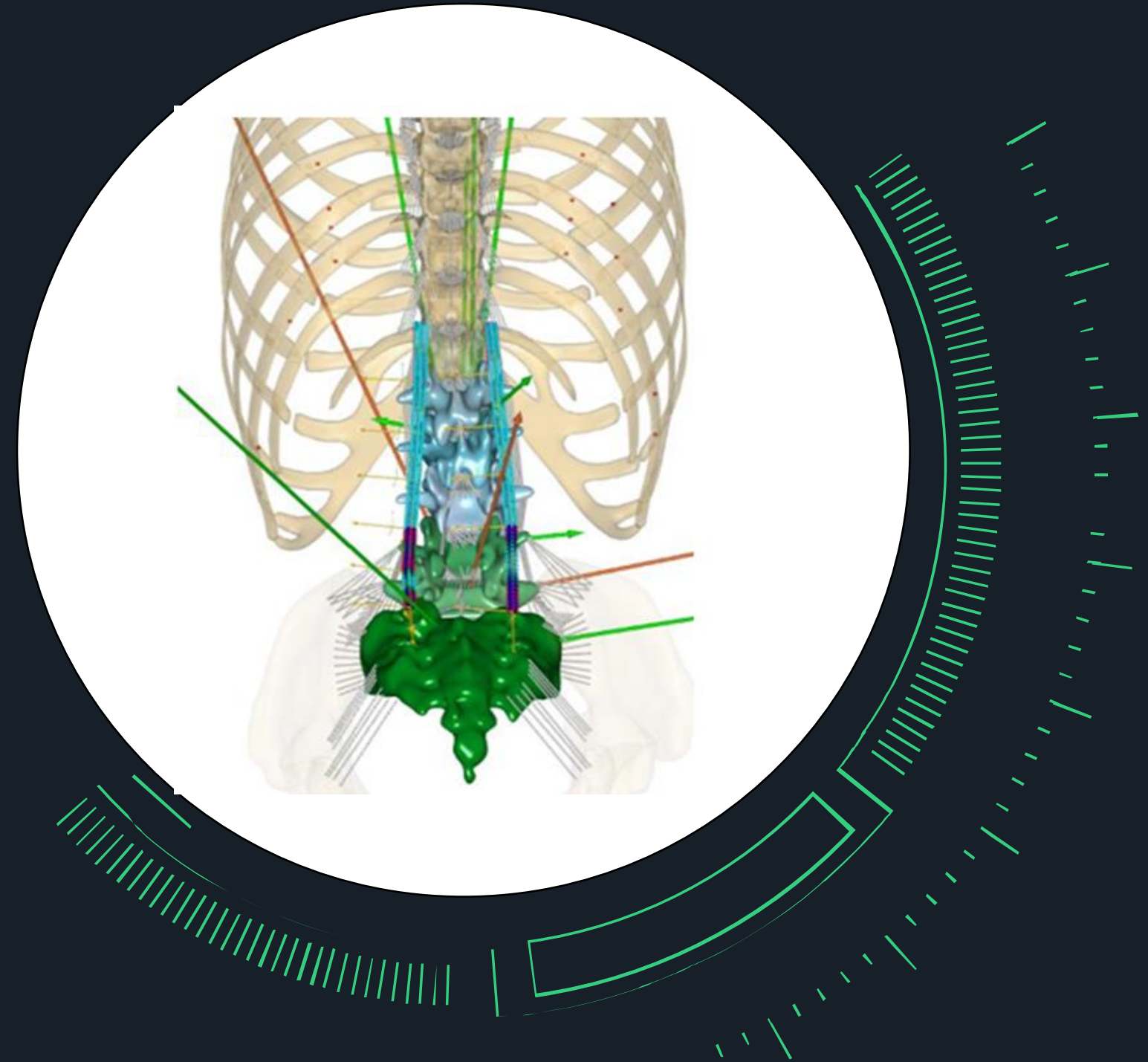




THE SOLUTION

THE SPINE ORACLE™

By calculating the forces acting on the patient's spine, THE SPINE ORACLE™ transforms the art of surgery from descriptive analytics to the science of surgery with prescriptive AI providing surgeons with the most appropriate least invasive surgical strategy and ensure an optimal outcome.



**Human
Modeling SW**



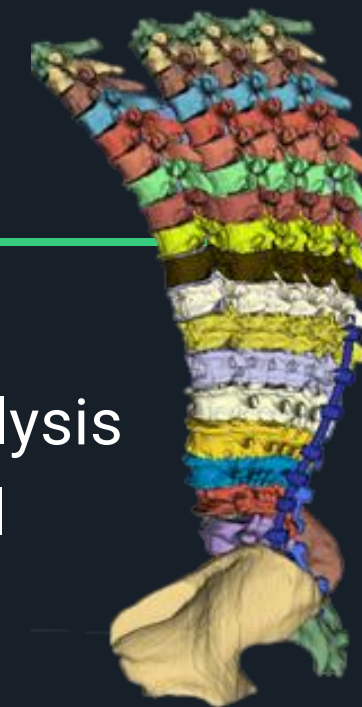
**Biomechanical
Simulation SW**



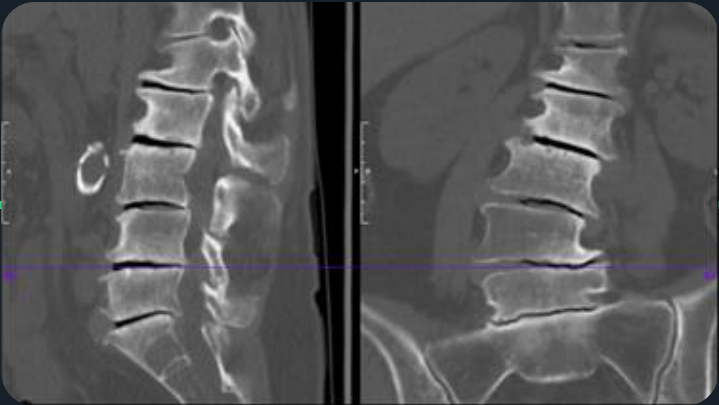
**Artificial
intelligence**



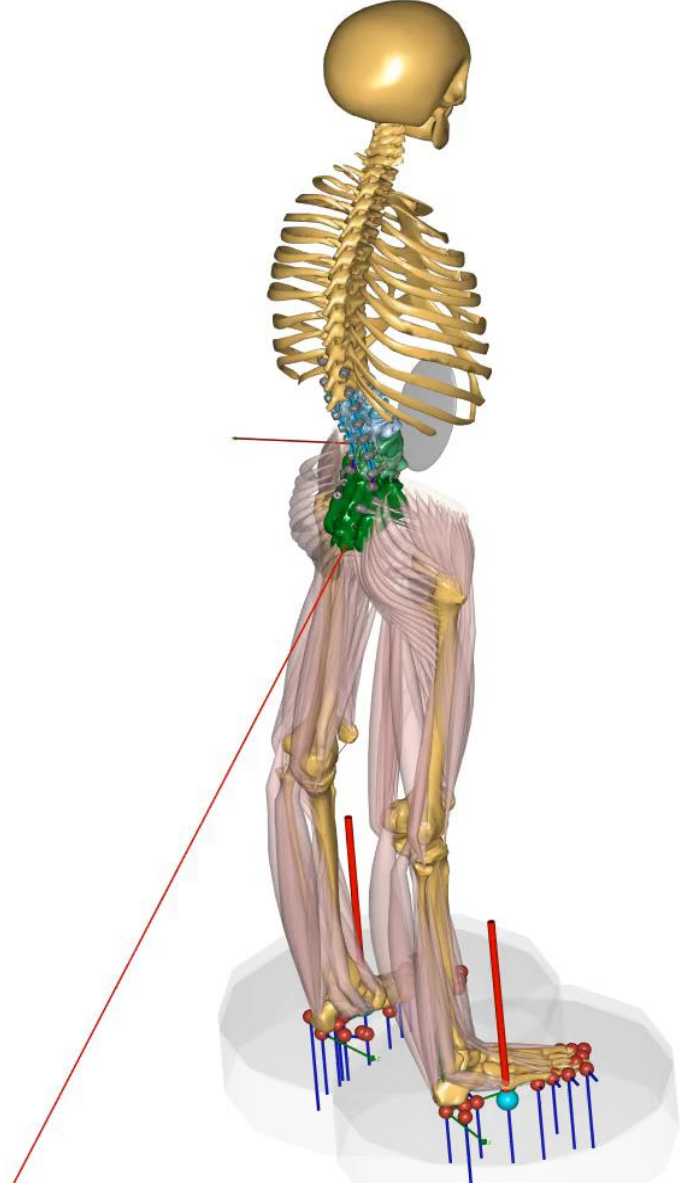
AGADA
THE SPINE ORACLE™



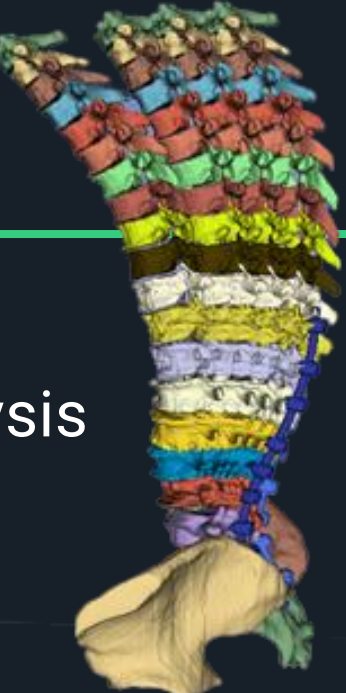
Imaging studies & anthropometric data



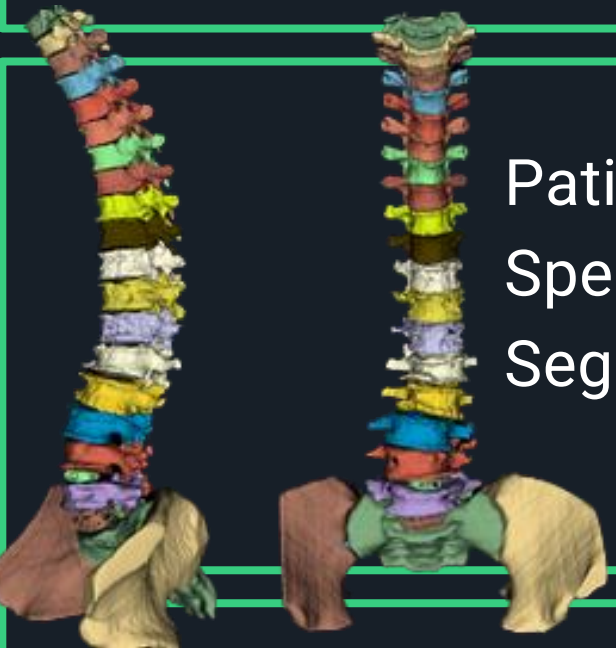
Dynamic force analysis pretreatment native state



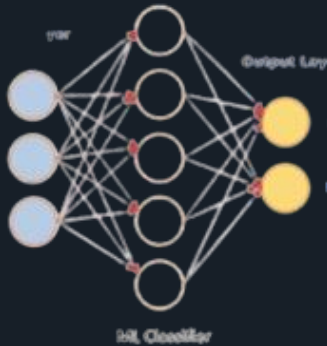
Dynamic force analysis comparing surgical strategies



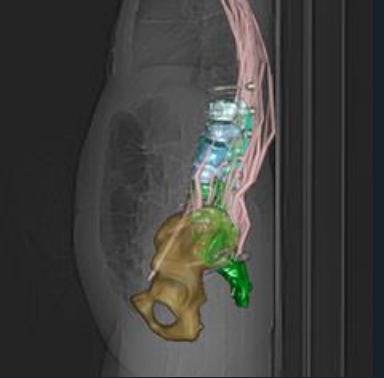
Patient Specific Segmentation



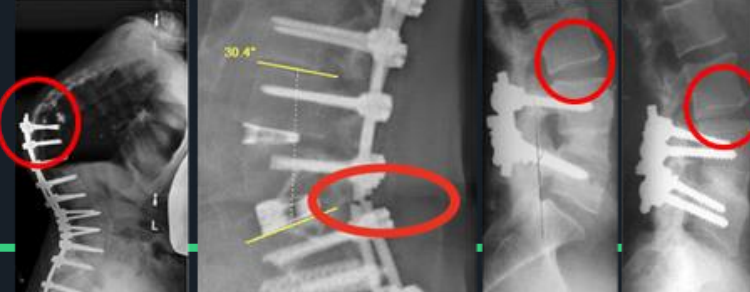
Artificial Intelligence
Machine learning
Predictive analytics
Big Data Analysis



Patient Specific Digital twin



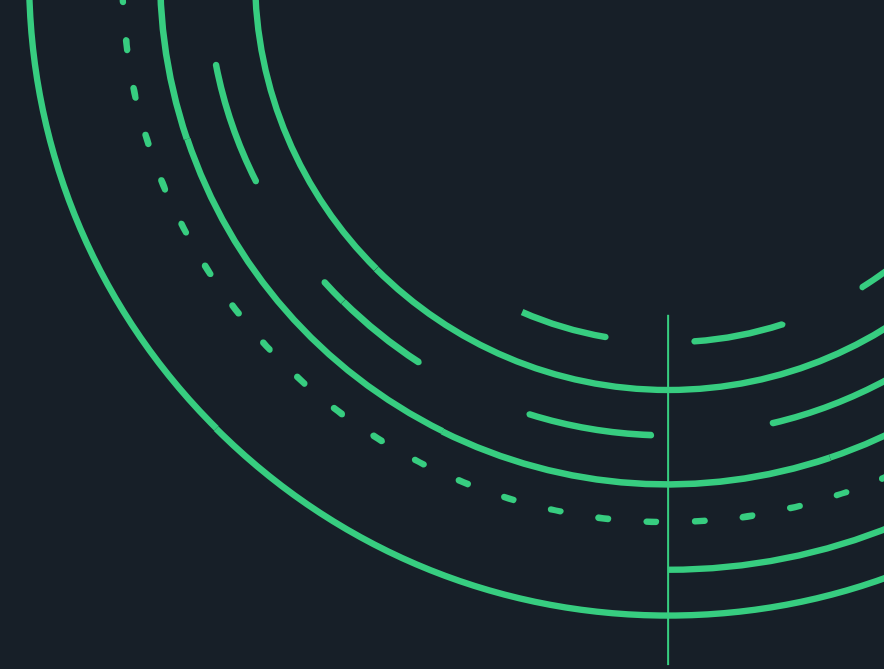
Optimized surgical solution to prevent poor outcome





THE SPINE ORACLE™

Case Demonstration

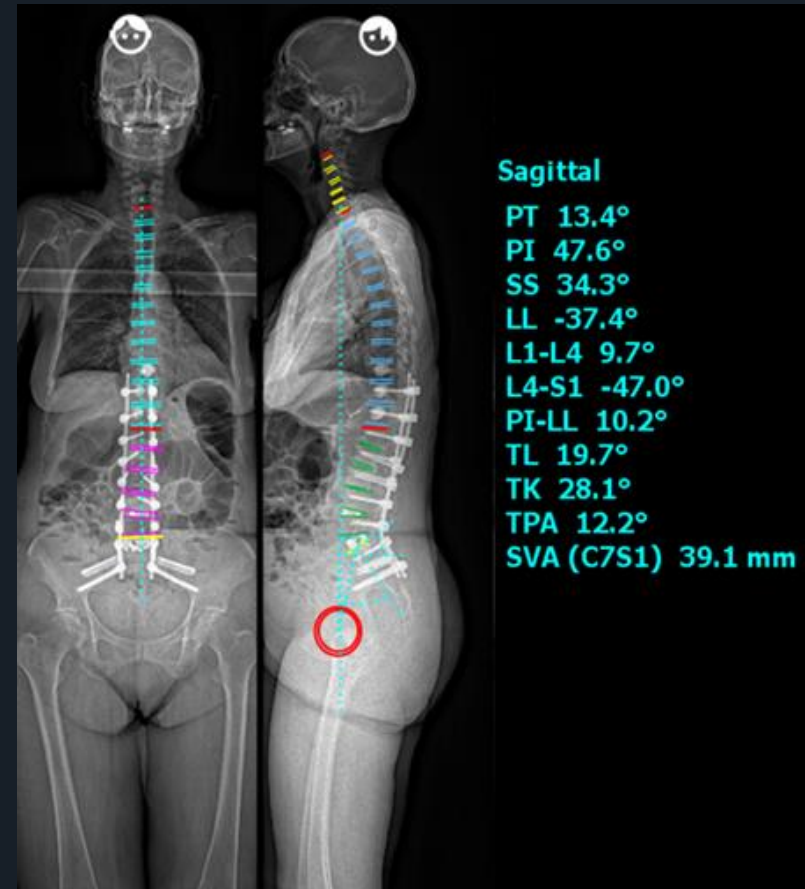
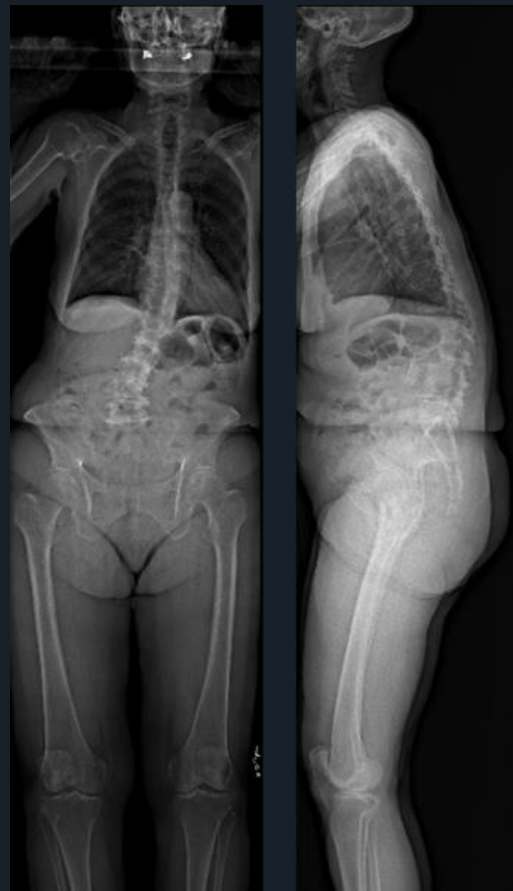


Preoperative CT

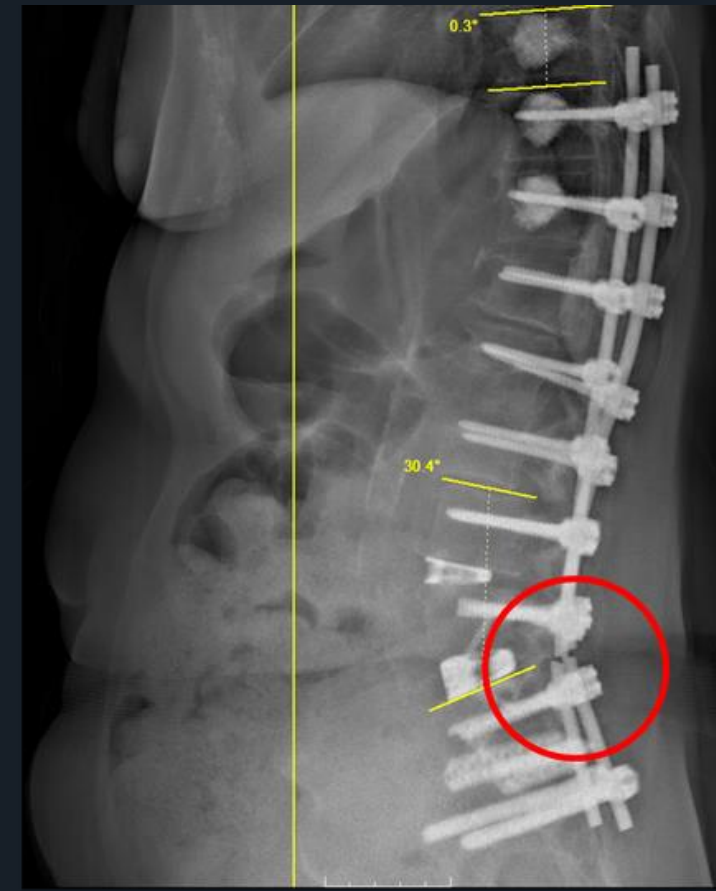
Preoperative Plan

Follow Up Result

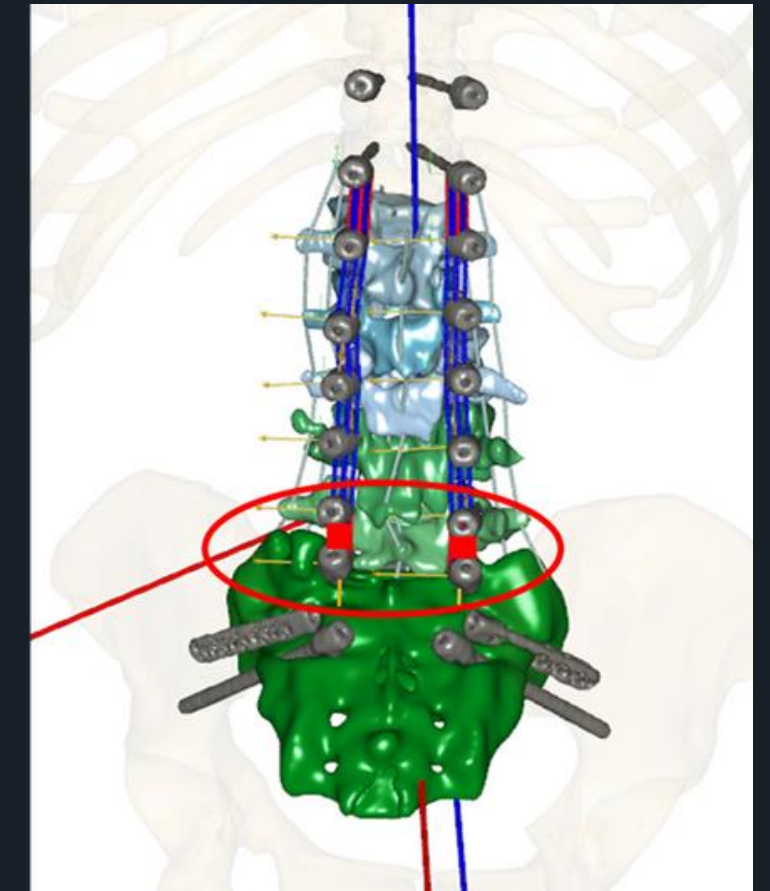
THE SPINE ORACLE™



Current planning software based on geometric alignment failed to predict the rod fracture



Rod fracture at 6 months



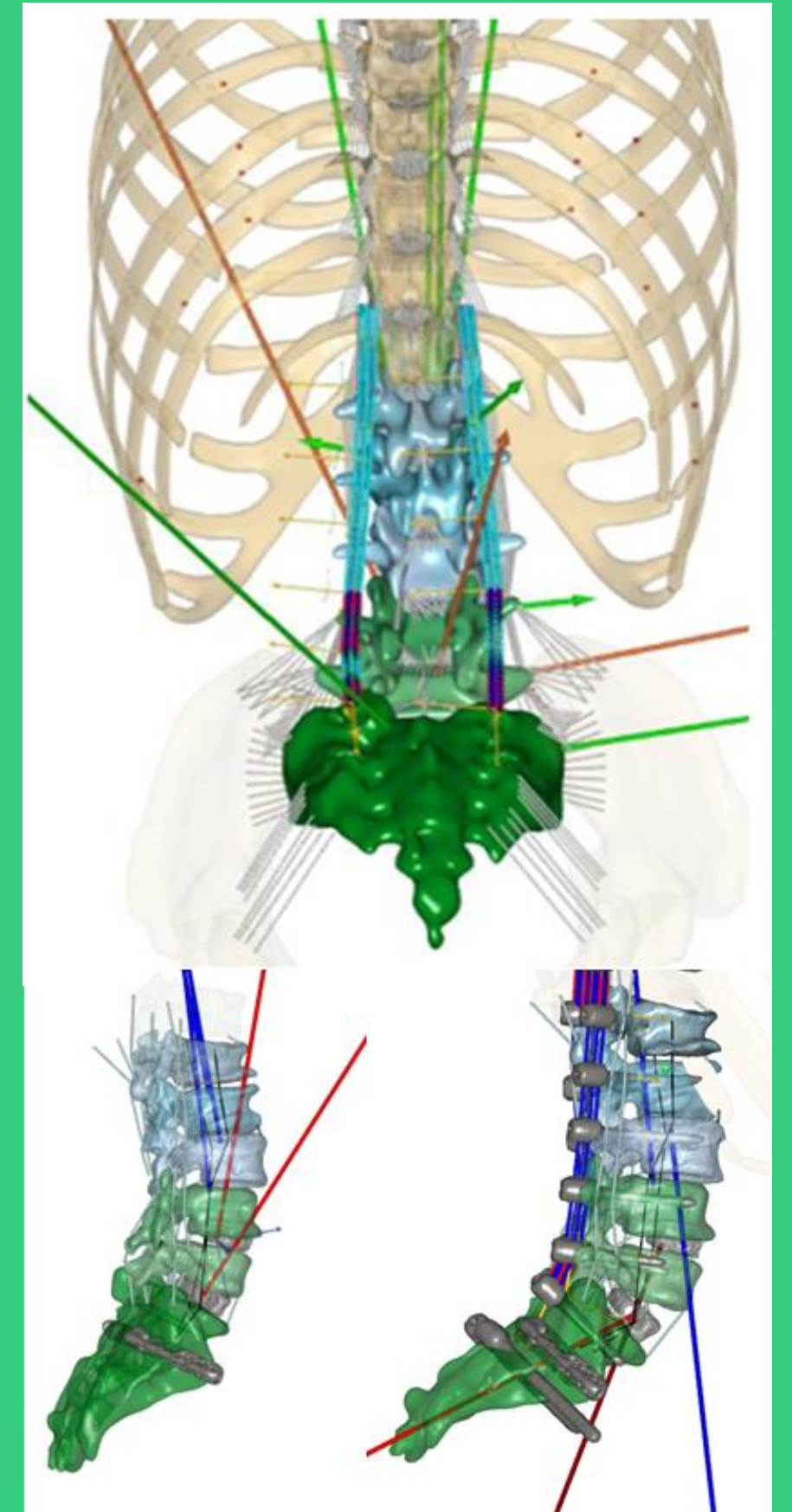
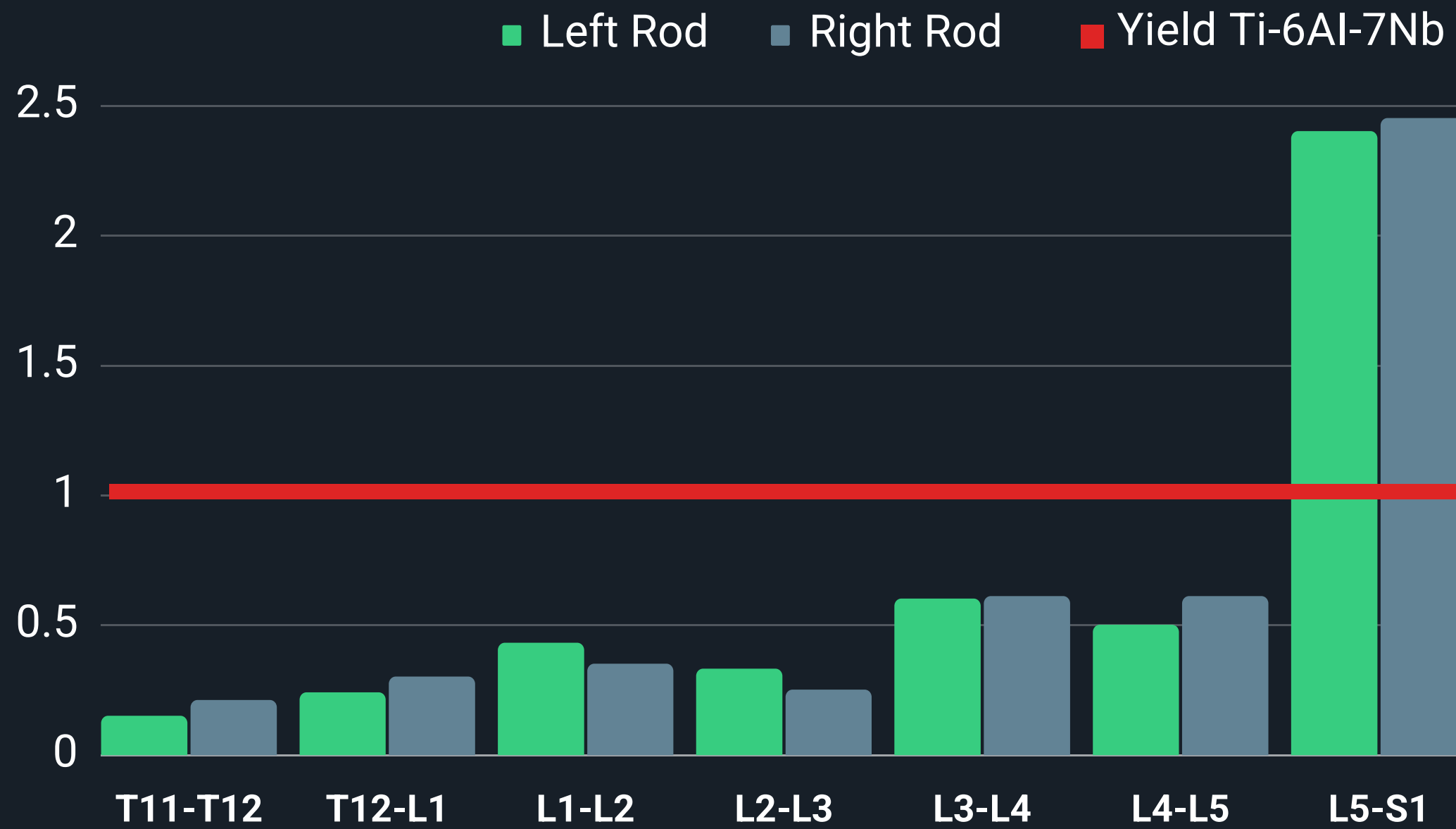
Retrospective analysis predicted the rod fracture



VISUAL ANALYSIS

QUANTIFIED ANALYSIS

Rod Stress Analysis





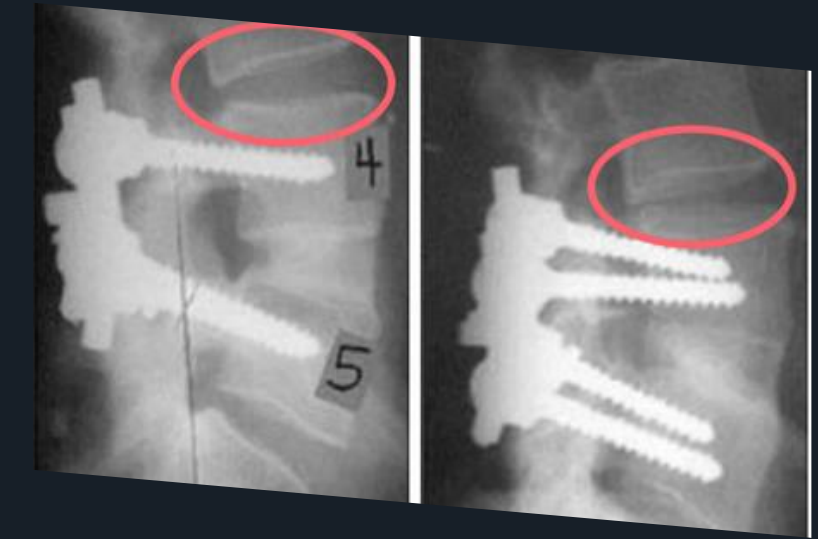
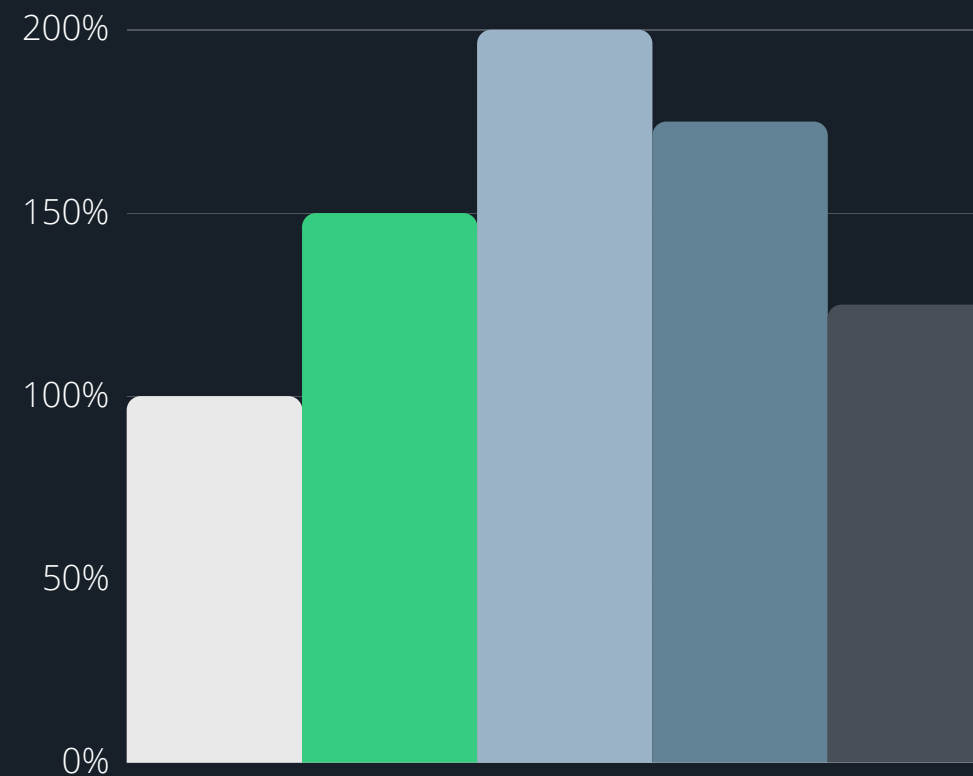
PROXIMAL JUNCTIONAL FAILURE
ADJACENT LEVEL DEGENERATION

Additional Unmet Clinical Needs



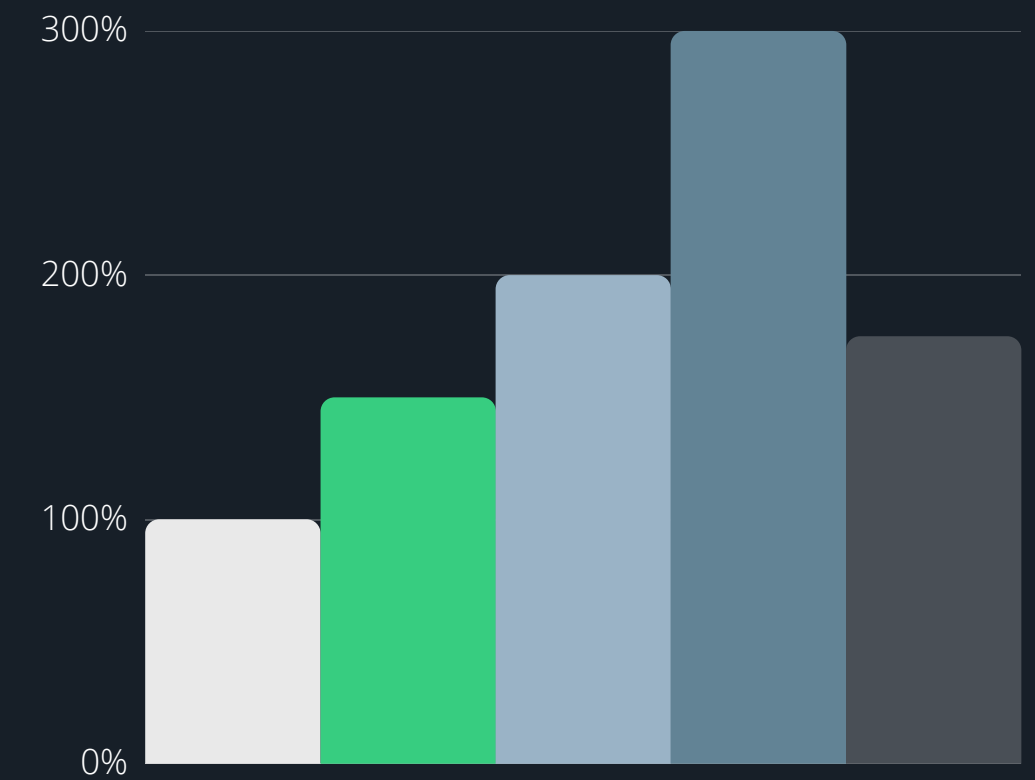
Prevalence of Proximal
junction failure (10%-30%)

UPPER VERTEBRA STRESS



Prevalence of Adjacent level
degeneration (20%-40%)

INTRA-DISCAL PRESSURE

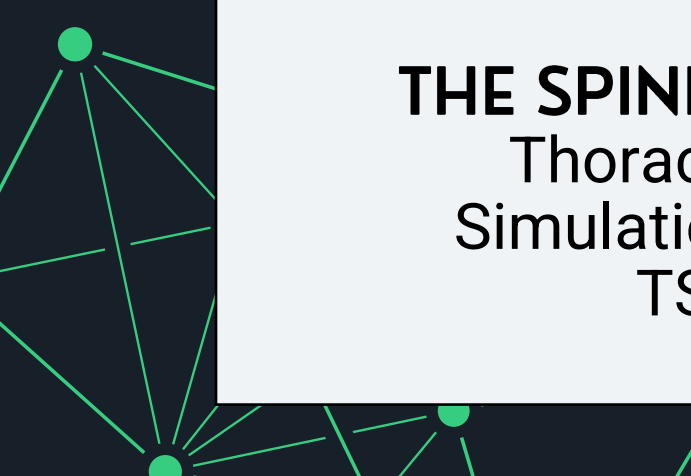




STATUS

Where We Are Today

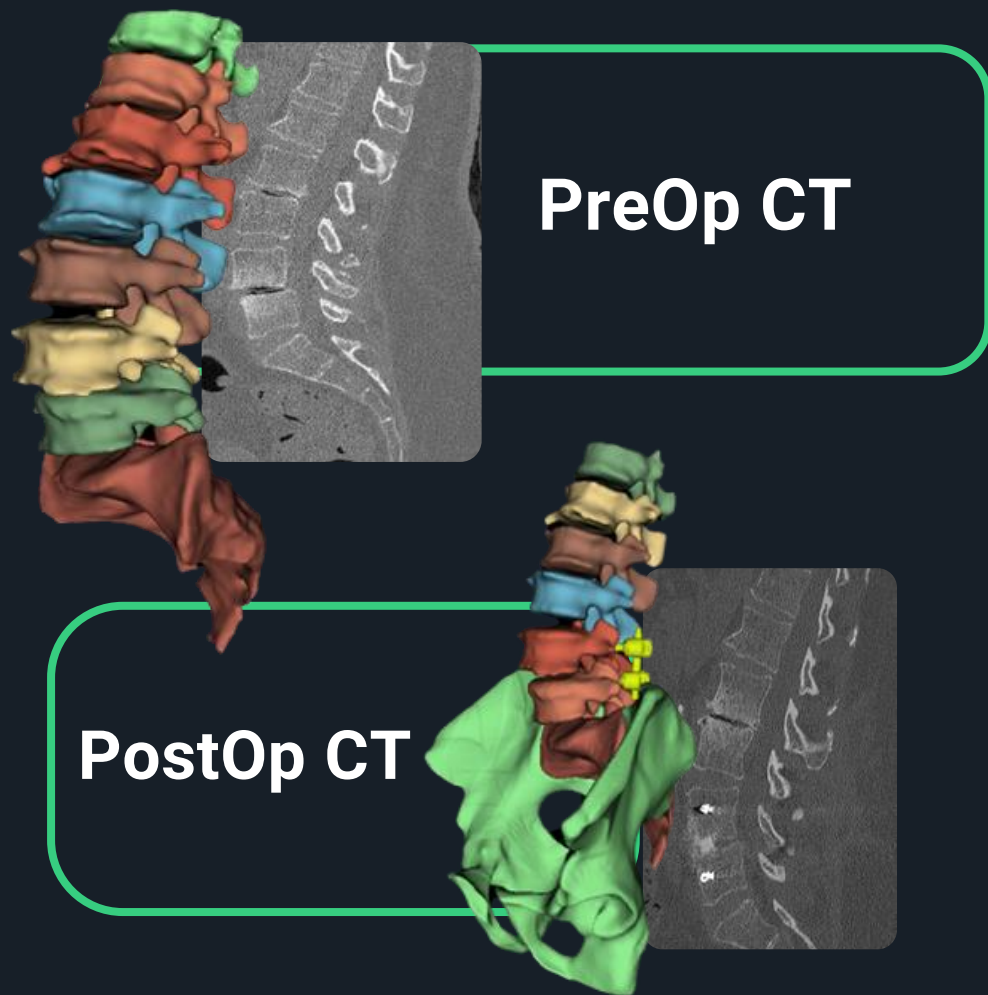
Technology	Function	Current Status
THE SPINE ORACLE™ Automatic Spine Segmentation Algorithm ASSA	Using patient CT scan a fully segmented spine model is created that includes the entire spine and pelvis.	Working prototype complete
THE SPINE ORACLE™ Lumbar Spine Simulation Module LSSM	The segmented spine model is morphed into the simulation module to analyze the forces at the treated level(s) and above and below a one or two-level lumbar fusion or total disc replacement. The module also analyzes the volumetric assessment of spinal stenosis.	Working prototype complete
THE SPINE ORACLE™ Thoracic Spine Simulation Module TSSM	The segmented spine model is morphed into the simulation module to analyze the forces at the upper instrumented level and adjacent level during deformity surgery to predict and prevent PJK and PJF.	Working prototype functional



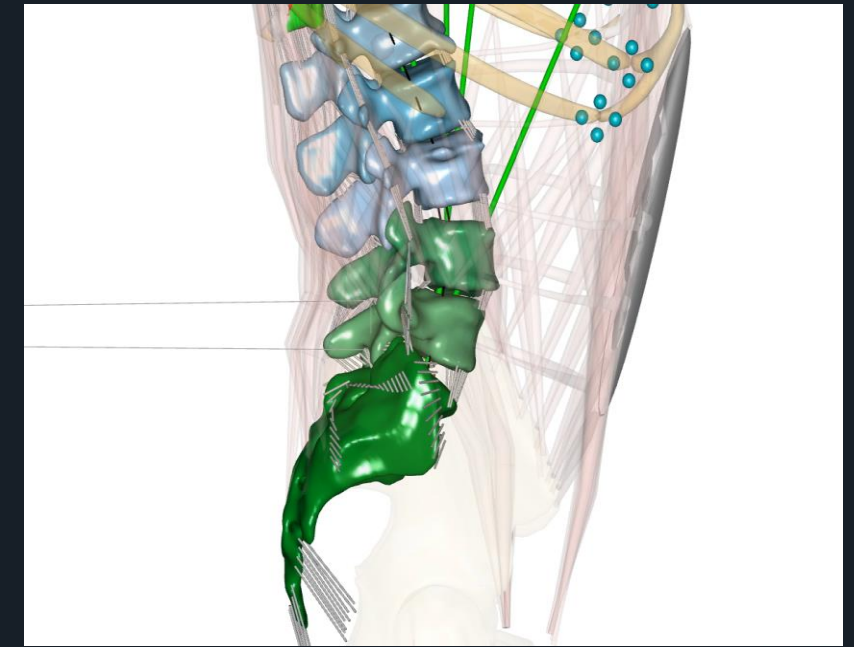
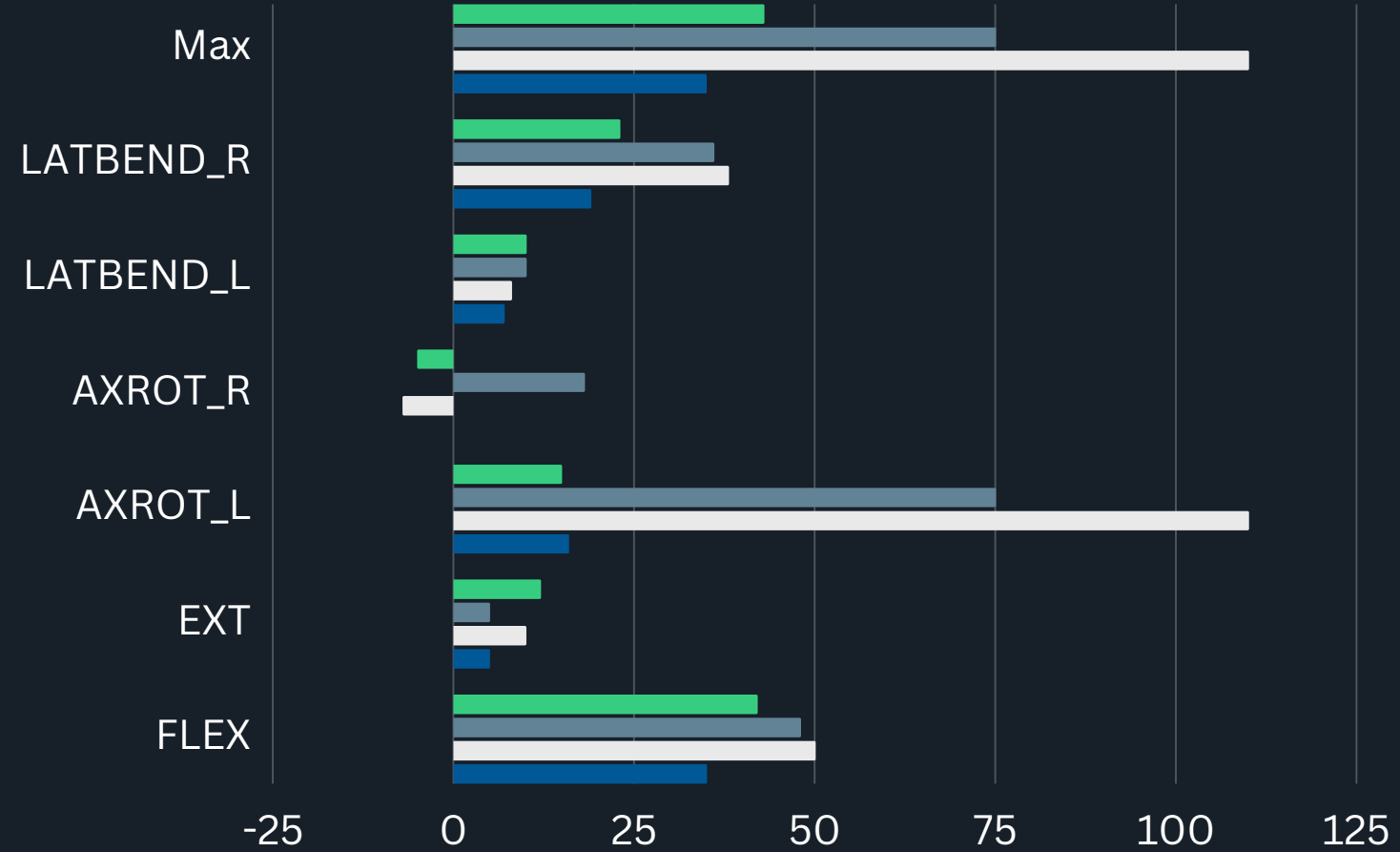


AUTOMATED ADJACENT SEGMENT

Force Simulation & Analysis

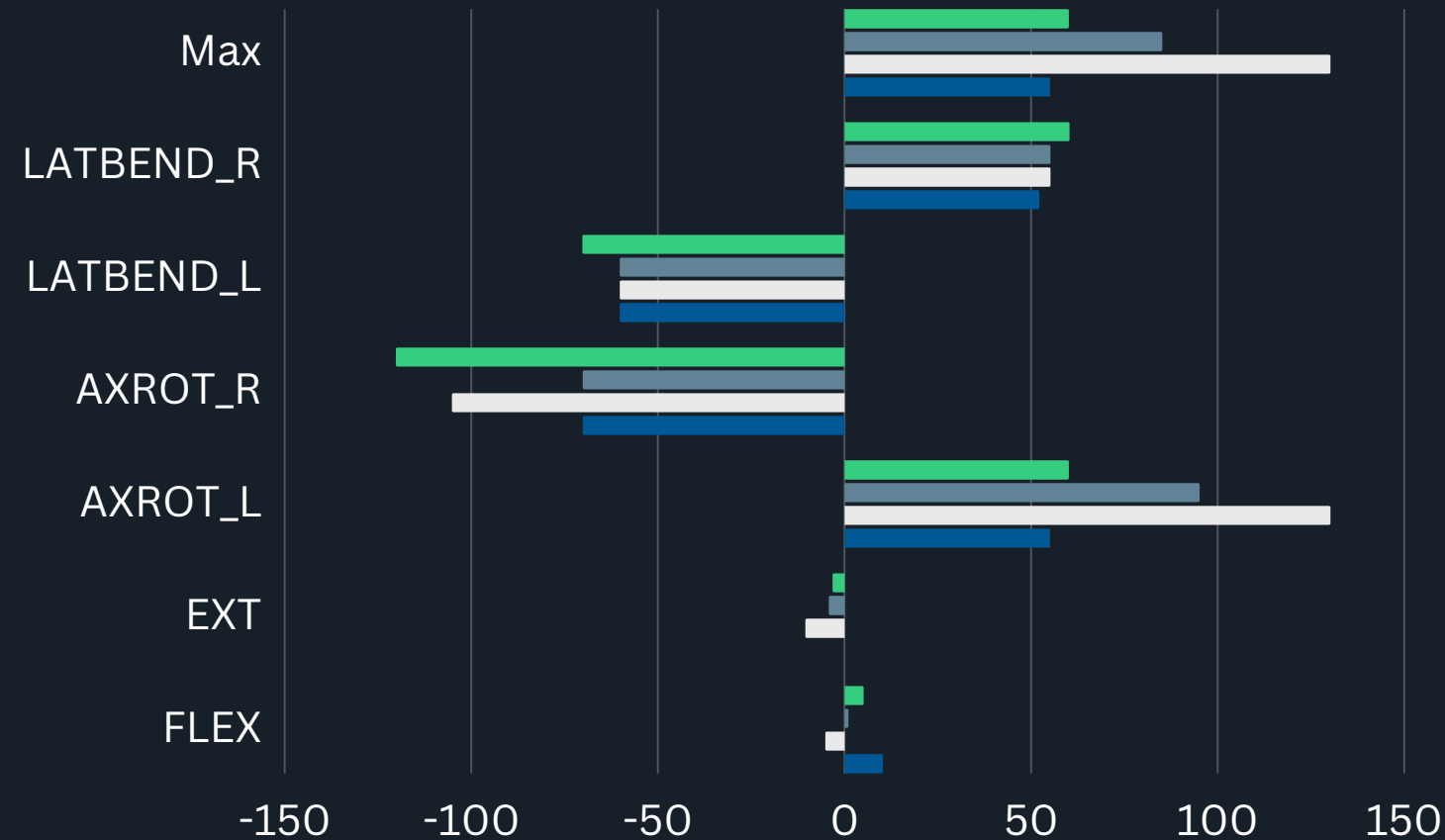


L3L4 AP Disc Shear forces [N]



- Pre-op
- 5 deg cage
- 10 deg cage
- 15 deg cage

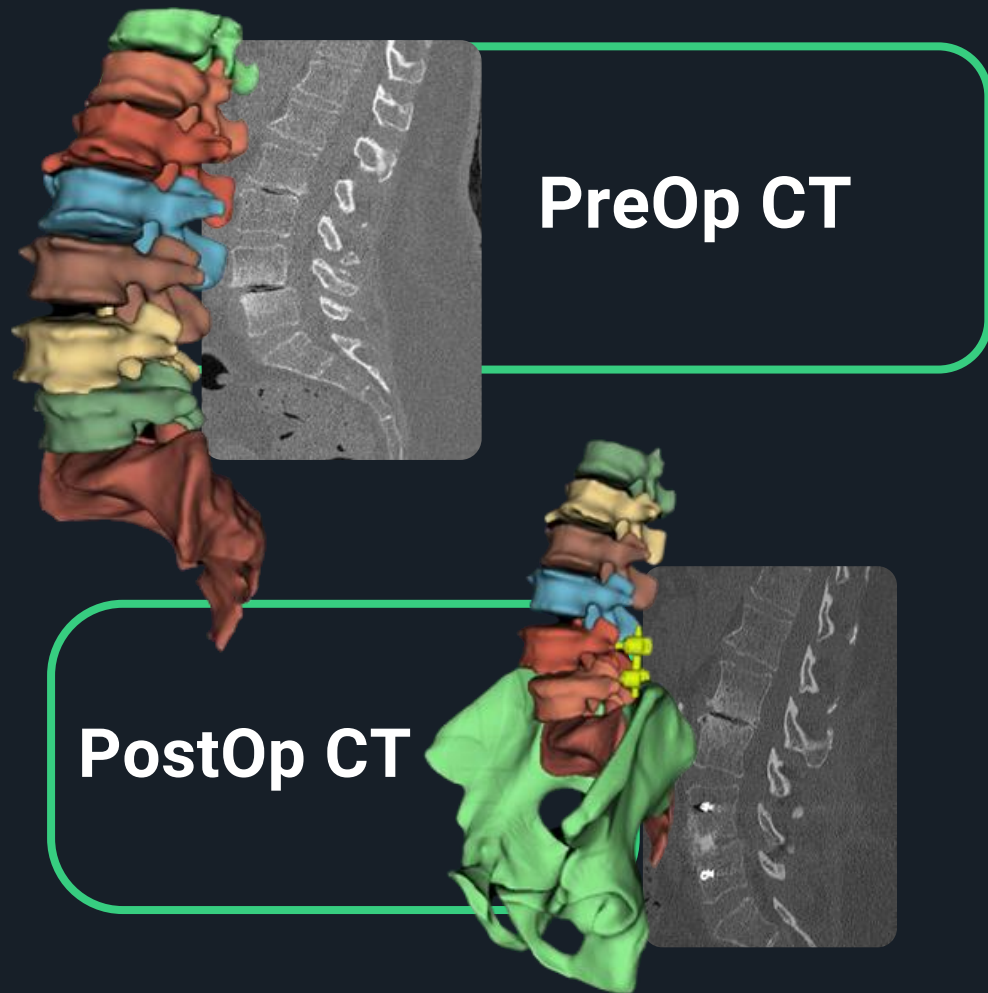
L5S1 AP Disc Shear forces [N]



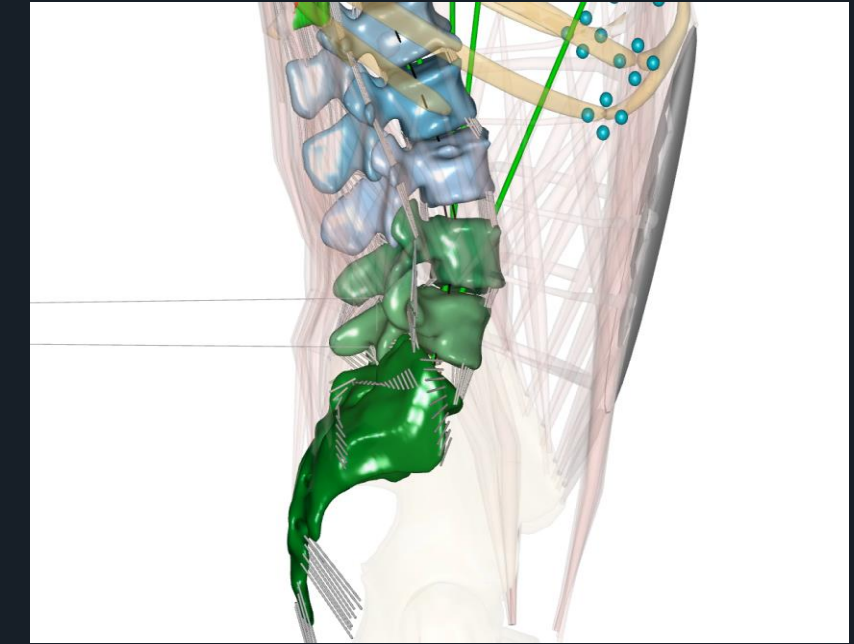
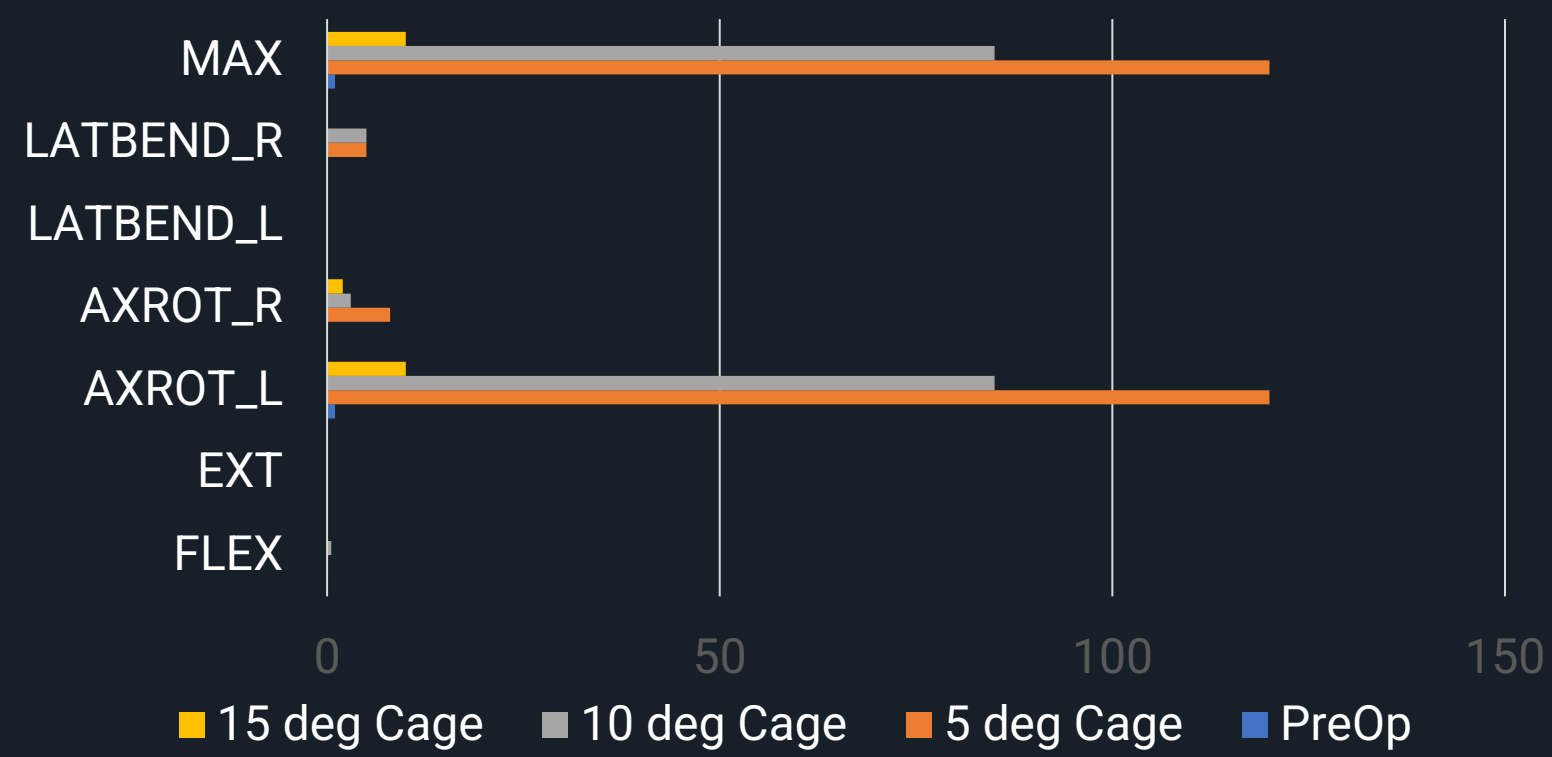


AUTOMATED ADJACENT SEGMENT

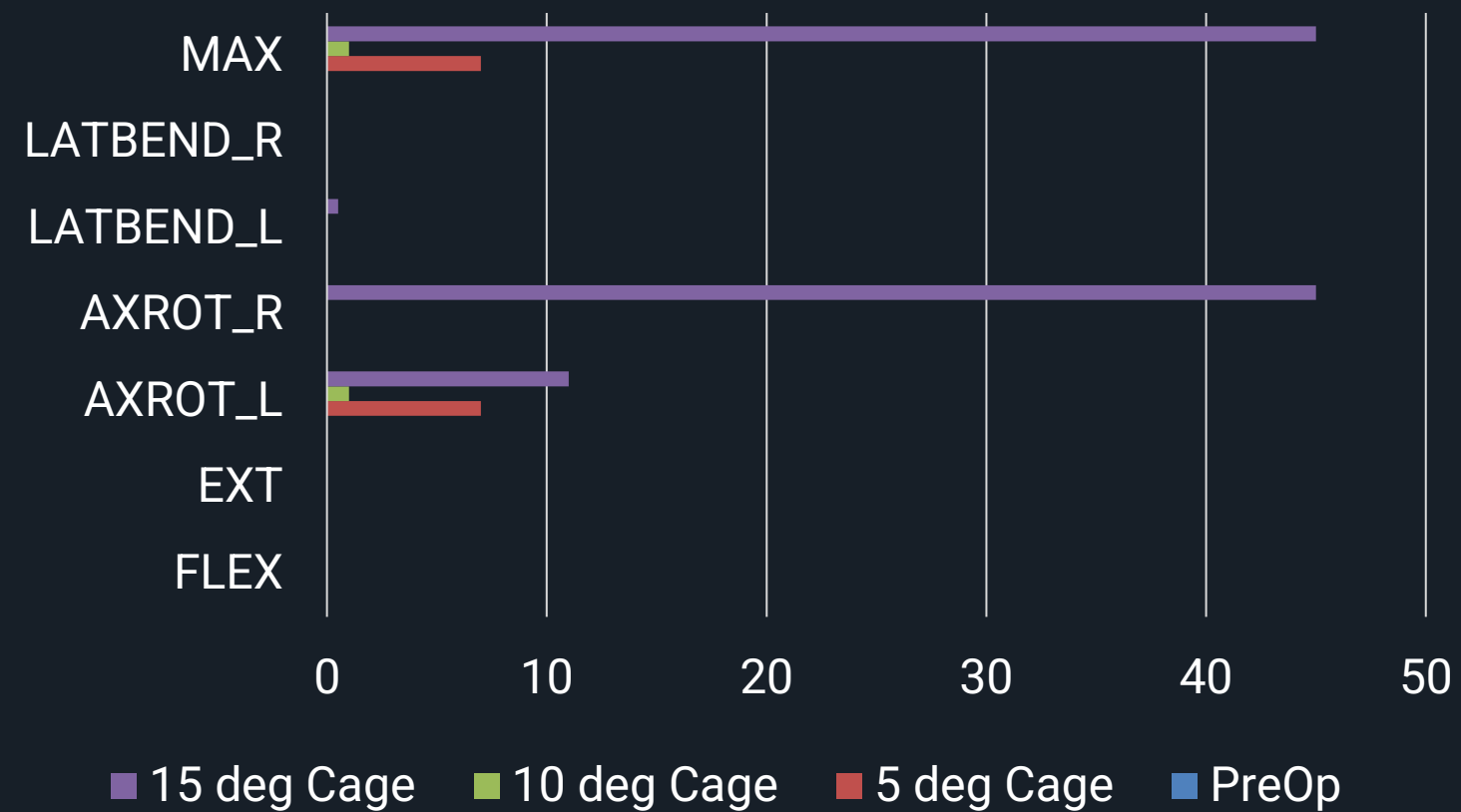
Force Simulation & Analysis

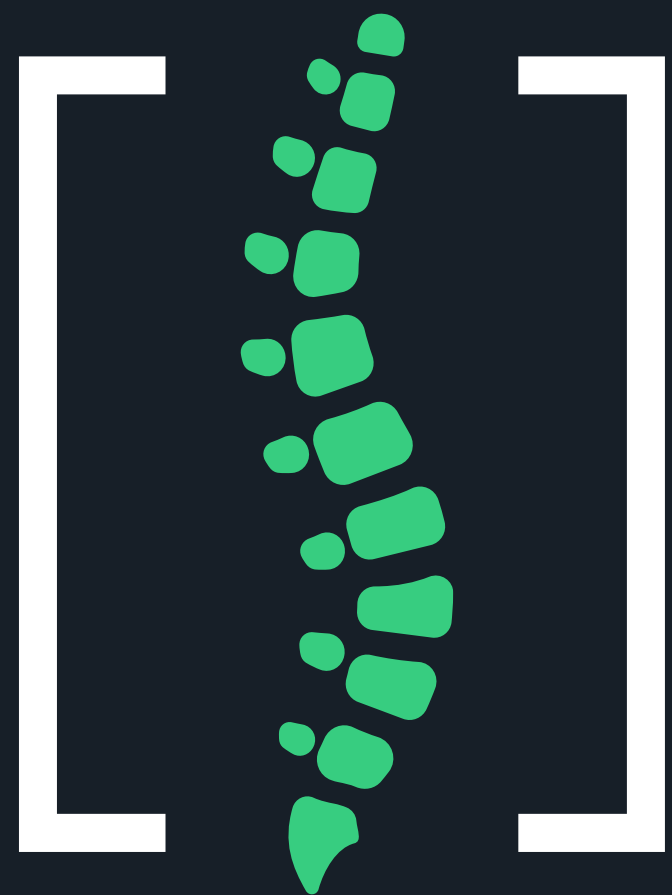


L3L4 Facet Joint forces [N]



L5S1 Facet Joint forces [N]





AGADA

Defining the Future of
Spine Surgery

Kobi Blank
kobi@agada-medical.com

Isador Lieberman
izzy@agada-medical.com

Samuel Shannon
samuel@agada-medical.com

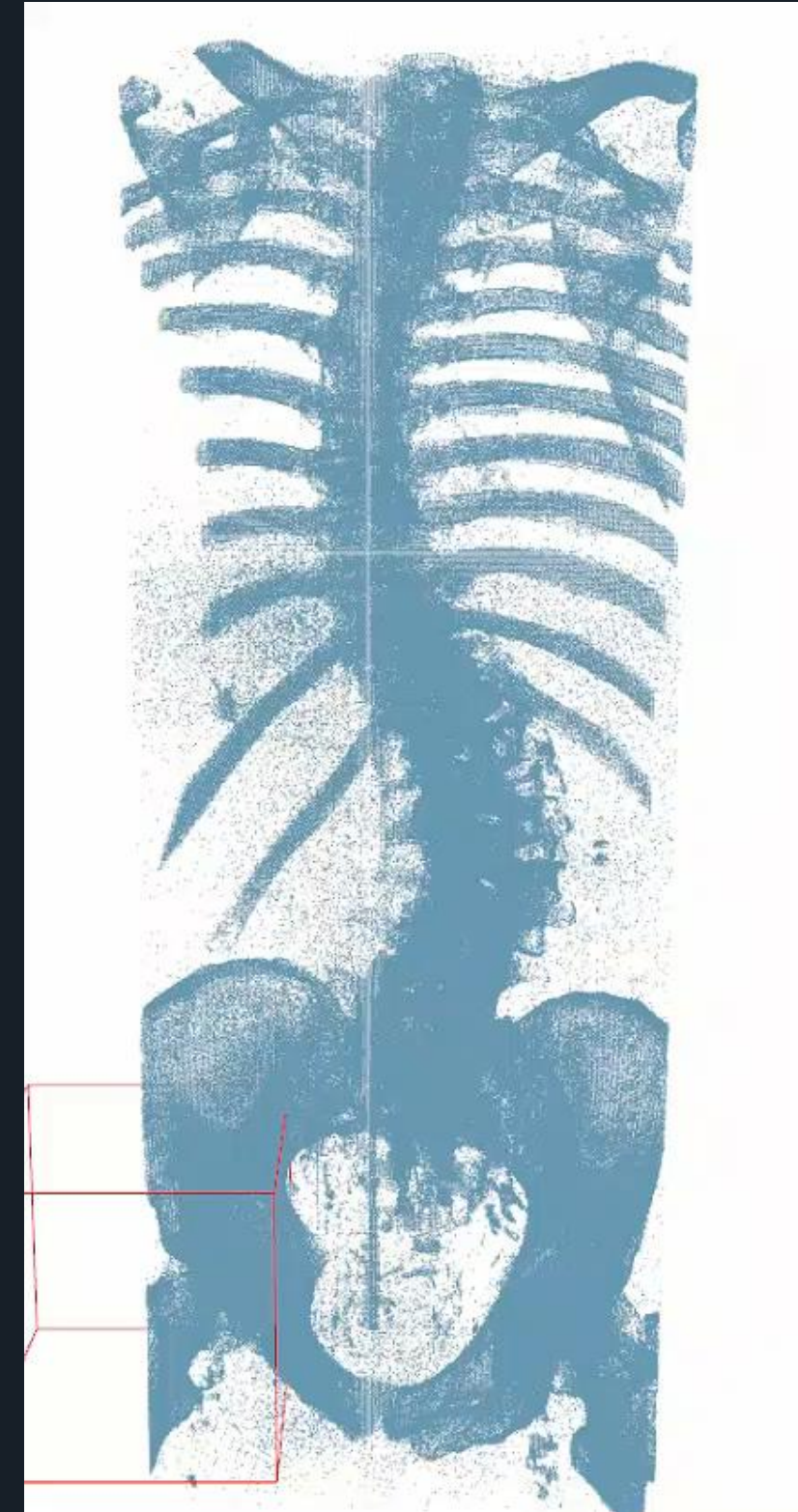
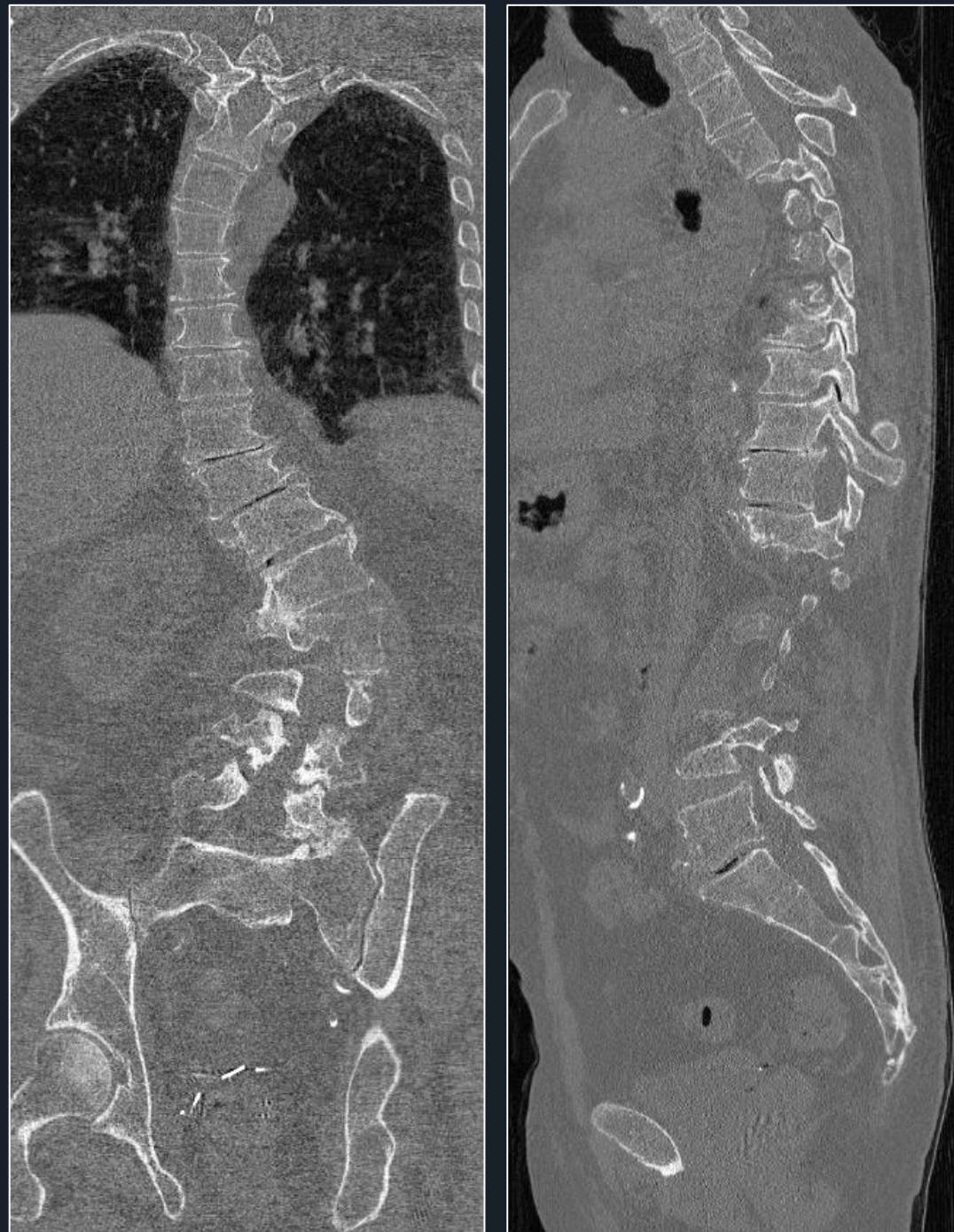


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**Automatic Spine
Segmentation Module**

Automatic Spine Segmentation Algorithm

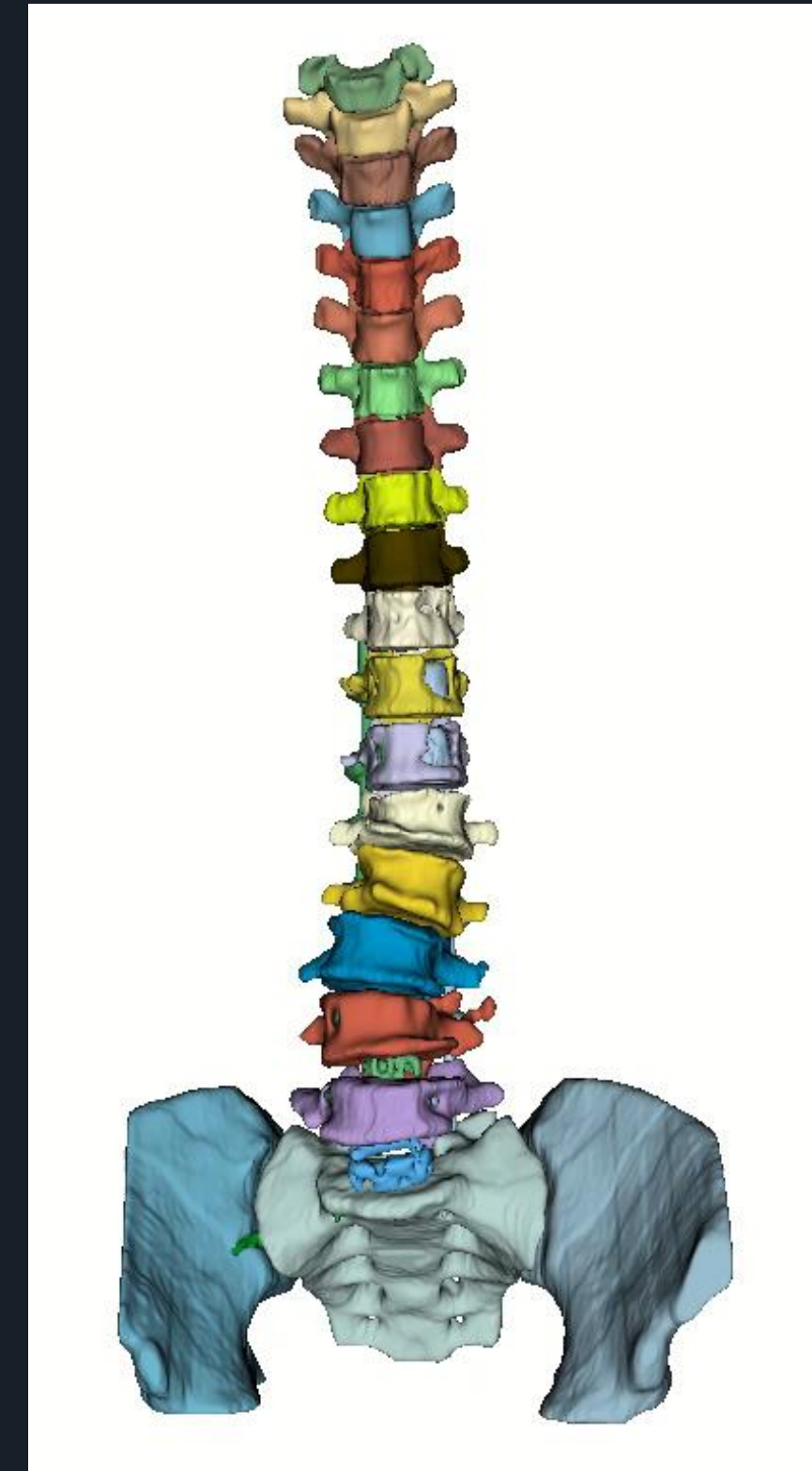
Automatic segmentation of Pre-operative CTs:



Segmentation performance: Dice = 0.965 (std=0.018), Precision = 0.953 (std=0.029), Recall = 0.978 (std=0.011)

Automatic Spine Segmentation Algorithm

Automatic segmentation of CTs with implants:

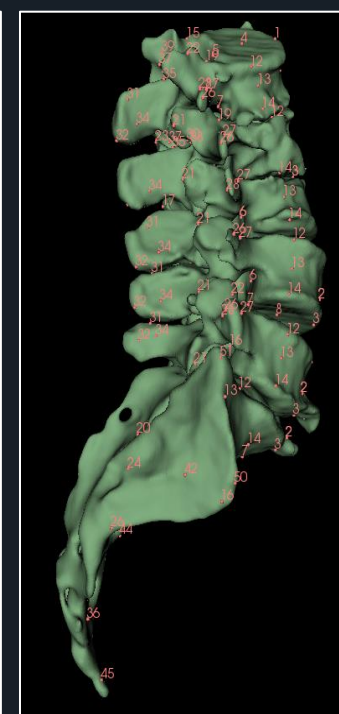
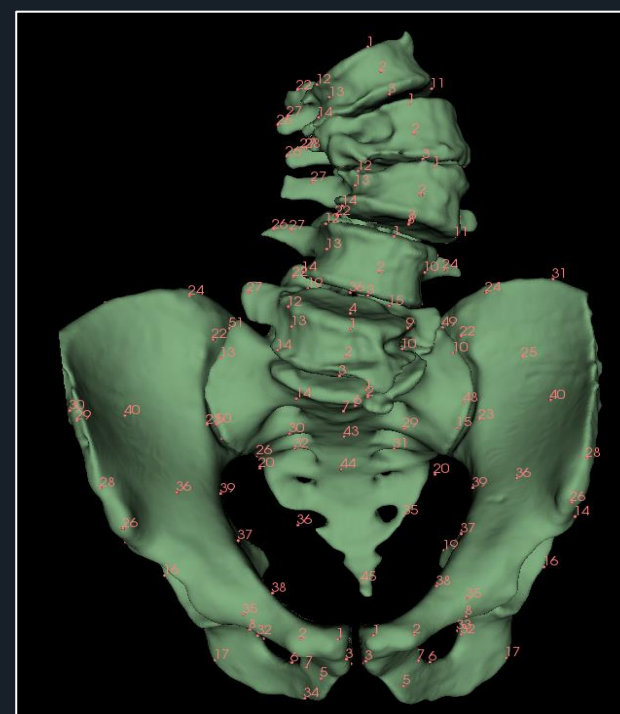
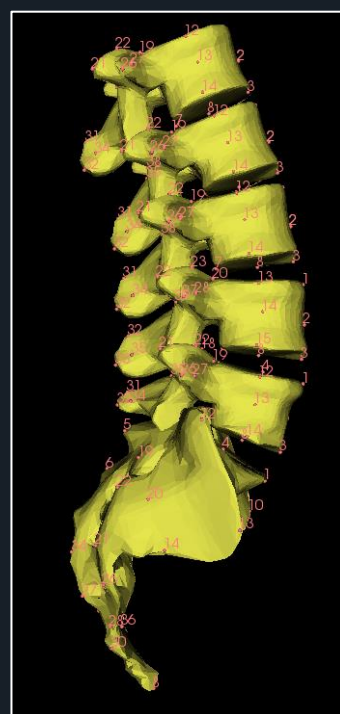
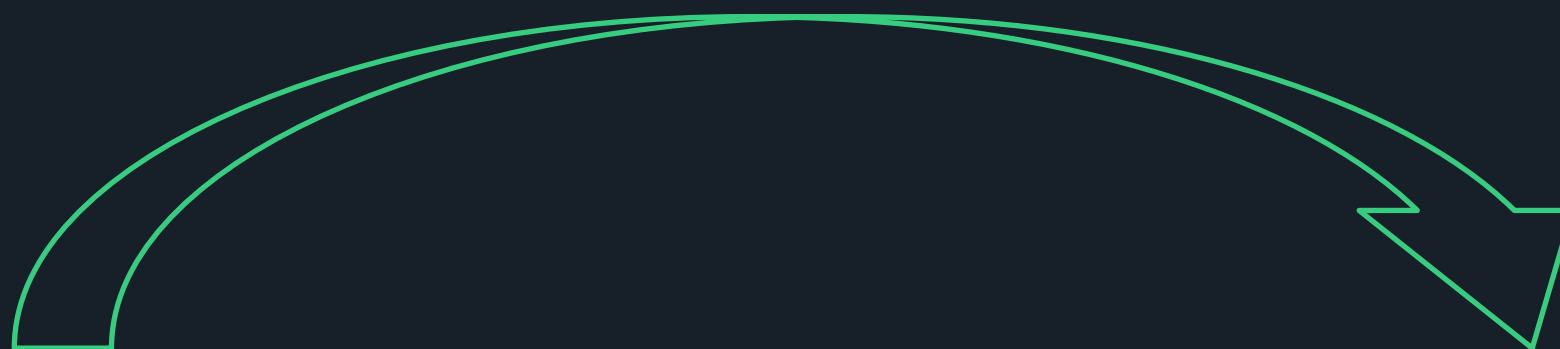


Segmentation performance: Dice = 0.965 (std=0.018), Precision = 0.953 (std=0.029), Recall = 0.978 (std=0.011)



Automatic patient-specific spine reconstruction

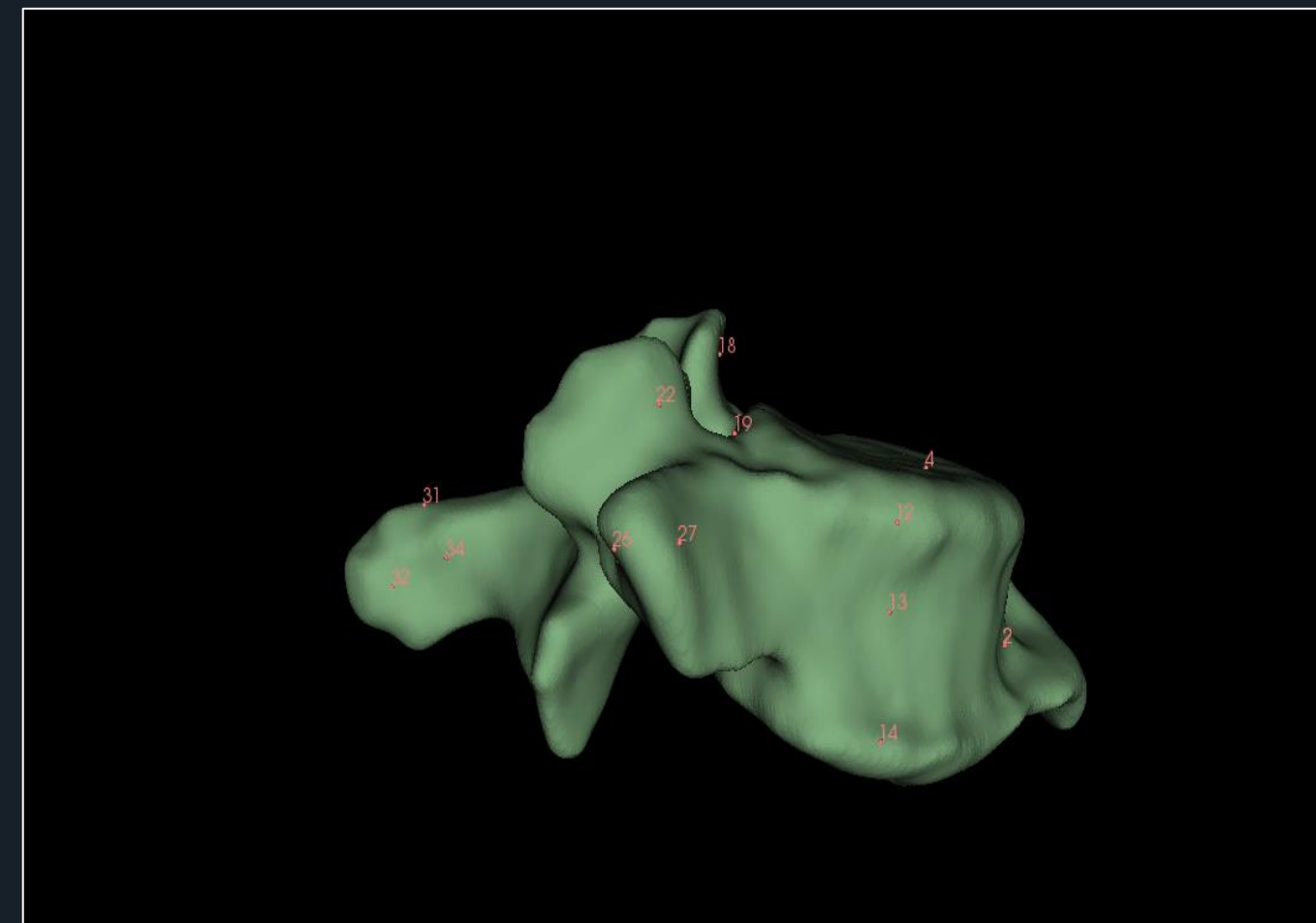
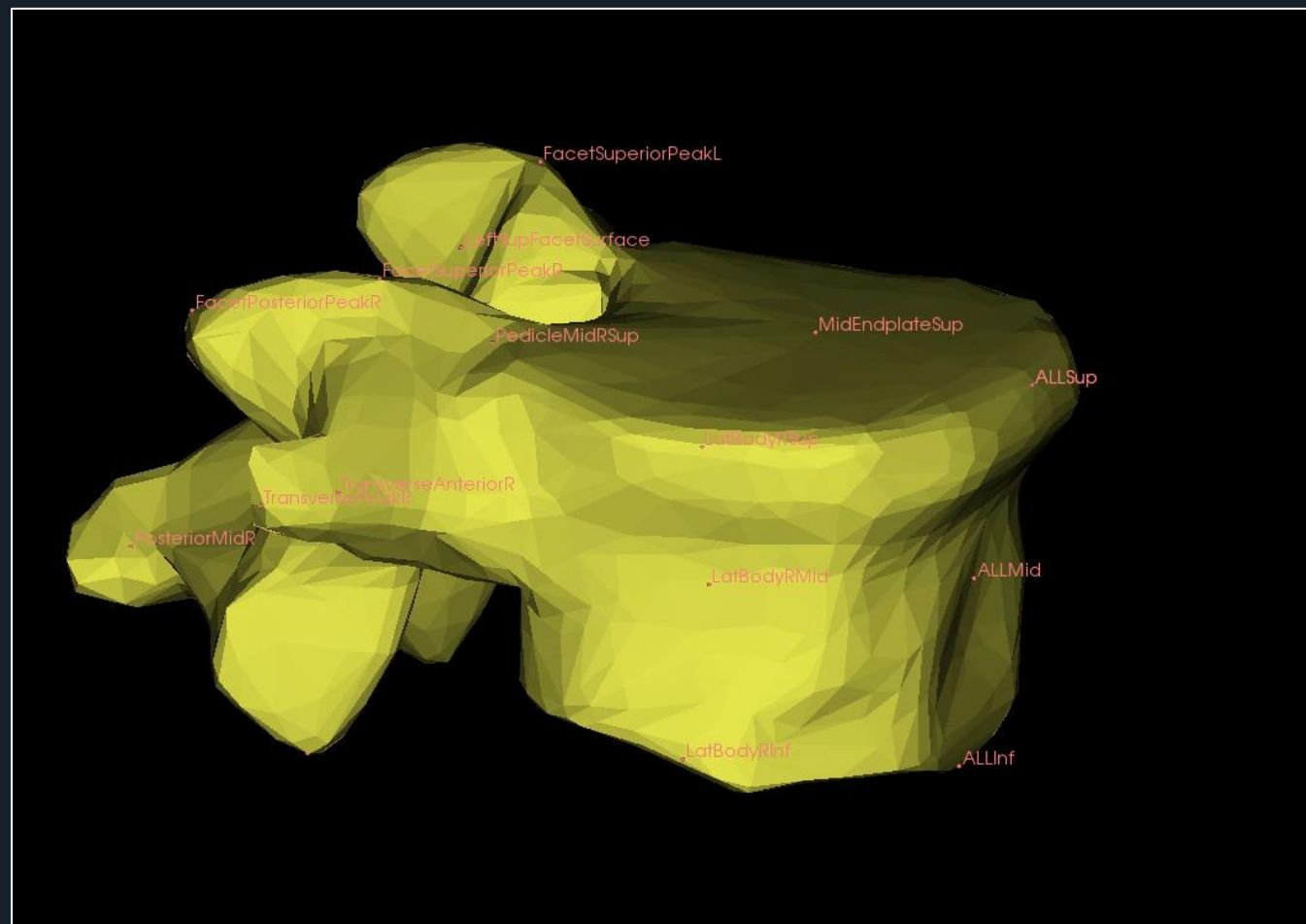
Automatic mapping a generic model to the patient-specific segmented model:





Vertebra mapping

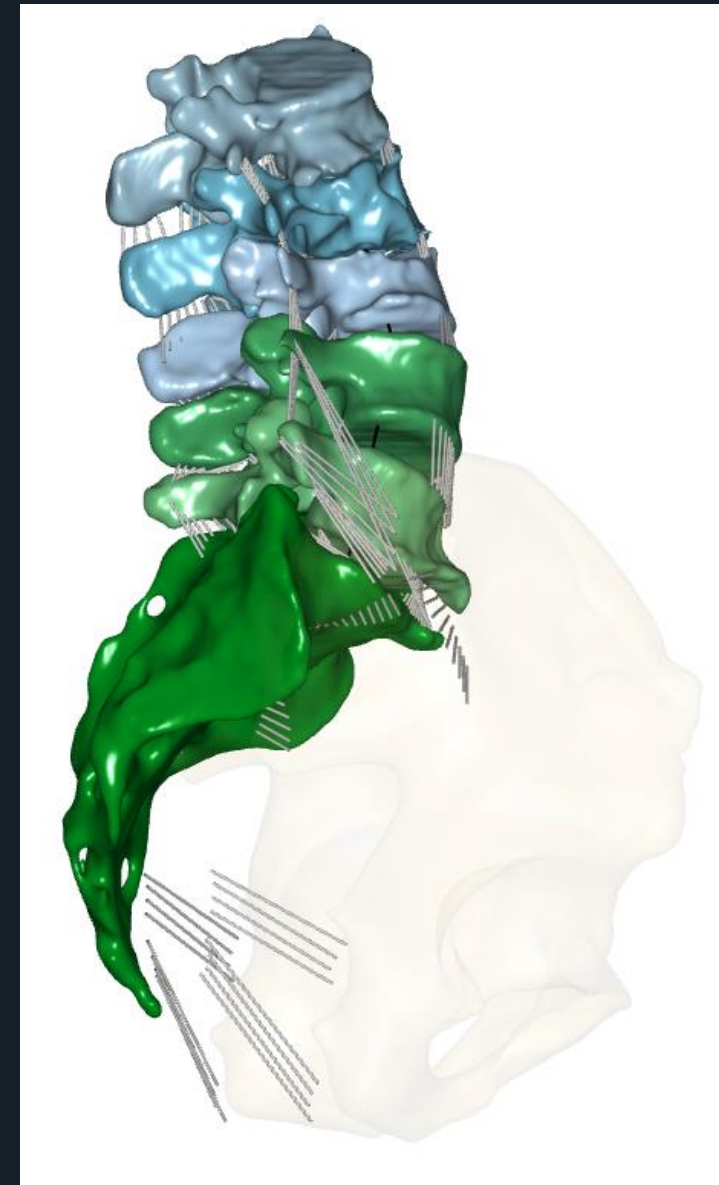
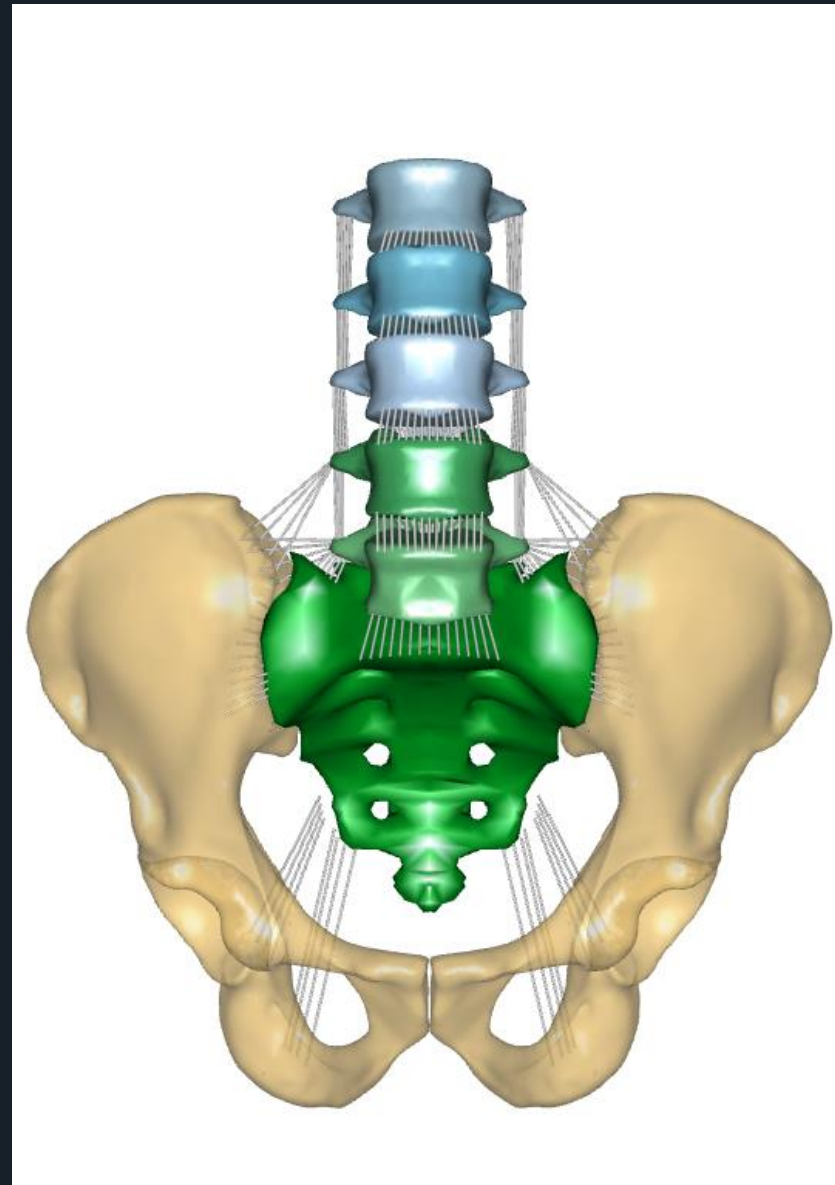
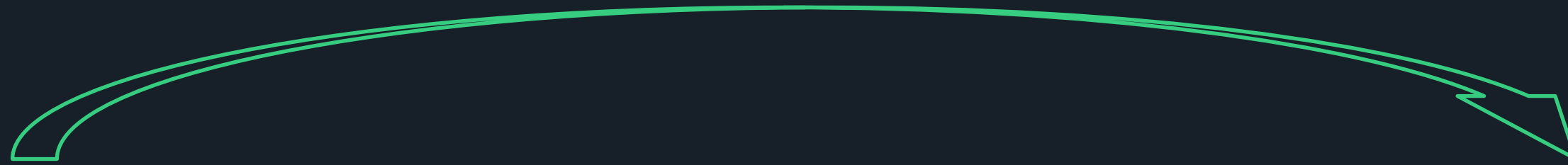
Automatic Landmarks detection and morphing:

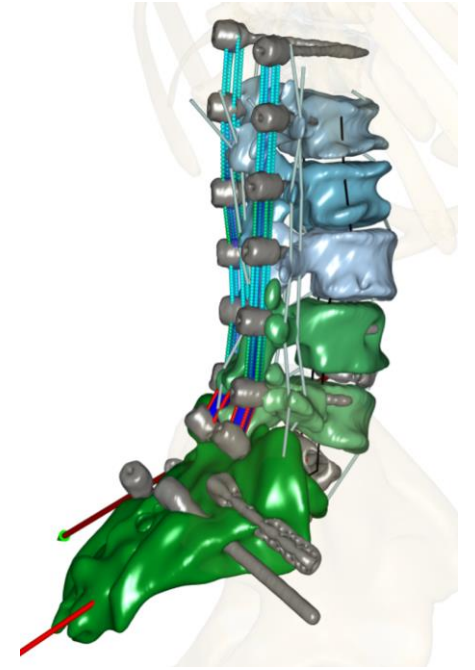




Automatic patient-specific spine reconstruction

Reconstruction of the spine:





Simulation module

PATIENT-SPECIFIC MUSCULOSKELETAL TWIN & DYNAMICS ANALYSIS

Background

- AnyBody Technology assists Agada-Medical in developing a musculoskeletal modeling module of the Spine Oracle™ that creates a **patient-specific musculoskeletal model** and quantifies a surgery-specific state of the patient's spine
- Objectives:
 - **Create a high-fidelity musculoskeletal model accurately representing the patient**
 - Simulate activities of daily living in pre-operative and post-operative states for retrospective studies to enable AI-based solutions
 - Analyze alternative surgical strategies, e.g. different spinal implant placement, soft tissue resection, etc. for pre-operative planning
 - **Establish seamless fully-automated data flow between components of the Spine Oracle™ and MSM module**

Patient- and surgery-specific simulation module

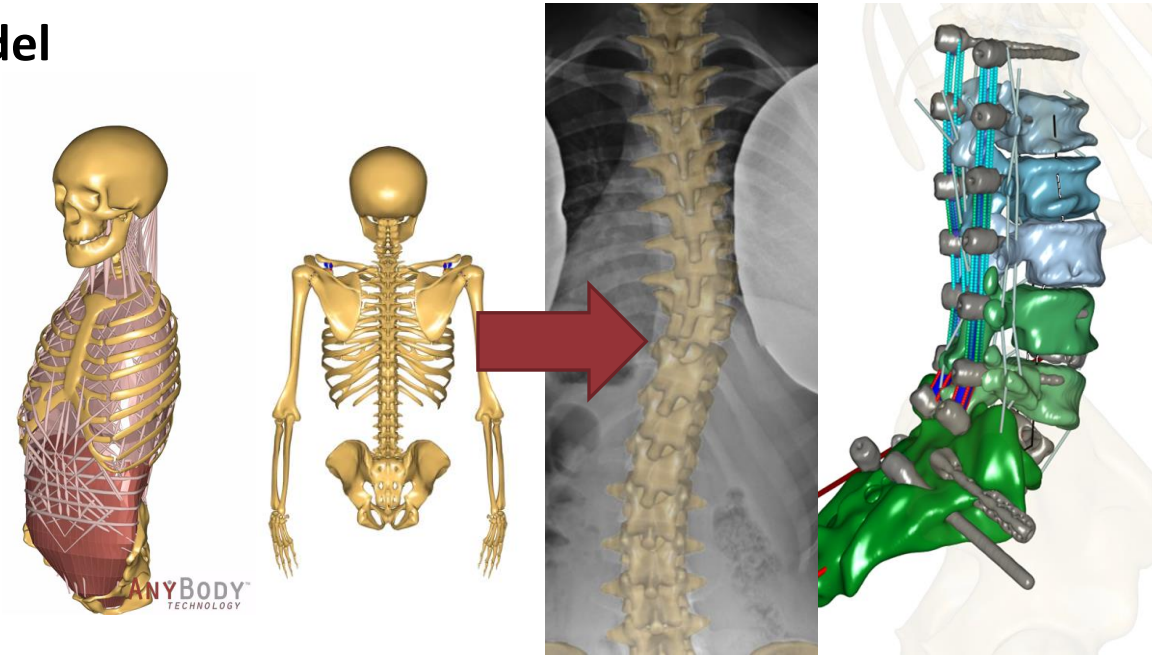


Patient-specific model

Objective: Create a high-fidelity musculoskeletal model accurately representing the patient

Patient reconstruction procedure:

- **Morph generic model into the patient geometry**
 - **Construct facet joint contact pairs based on the geometry**
 - Calibrate, adjust soft tissues in case-specific configurations
 - Add spinal implants from the library according to the retrospective data or surgical plan (if any)
 - Apply surgical techniques: facetectomy, ligament resection, etc.
-
- Functional measurements (ongoing development)
 - Motion capture (ongoing development)



**Generic AnyBody model
(Incl. ribcage and thoracic column)**

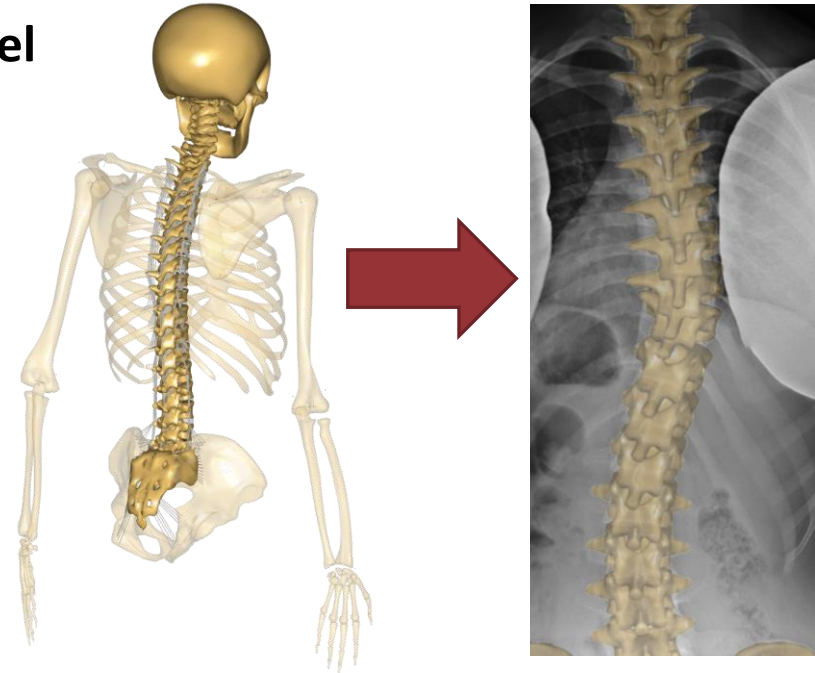
**Patient-specific model
reconstructed from patient data**

Intervertebral discs & Ligaments

Objective: Create a high-fidelity musculoskeletal model accurately representing the patient

Patient reconstruction procedure:

- Morph generic model into the patient geometry
- Construct facet joint contact pairs based on the geometry
- **Calibrate, adjust soft tissues in case-specific configurations**
- Add spinal implants from the library according to the retrospective data or surgical plan (if any)
- Apply surgical techniques: facetectomy, ligament resection, etc.
- Functional measurements (ongoing development)
- Motion capture (ongoing development)



Generic AnyBody model
(Incl. ribcage and thoracic column)

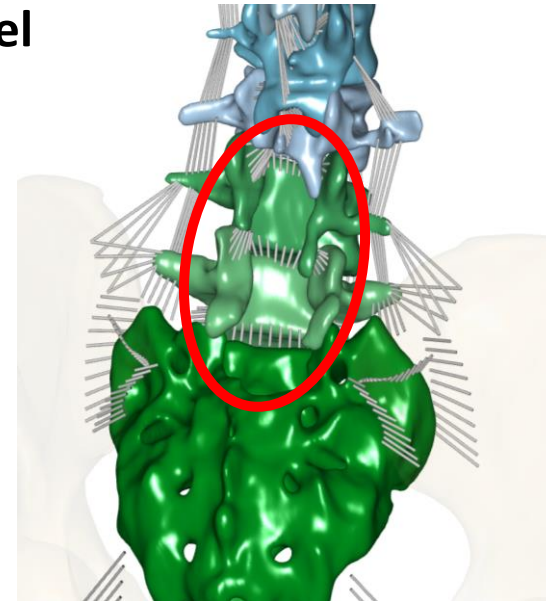
Patient-specific model
reconstructed from patient data

Surgery-specific model elements

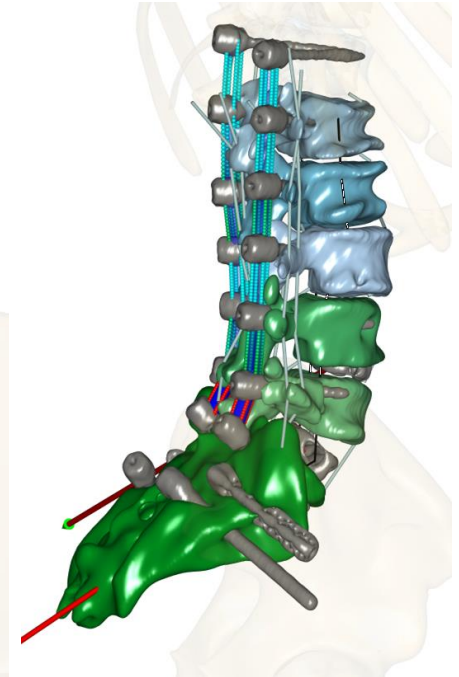
Objective: Create a high-fidelity musculoskeletal model accurately representing the patient

Patient reconstruction procedure:

- Morph generic model into the patient geometry
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- **Add spinal implants from the library according to the retrospective data or surgical plan (if any)**
- **Apply surgical techniques: facetectomy, ligament resection, etc.**
- Functional measurements (ongoing development)
- Motion capture (ongoing development)



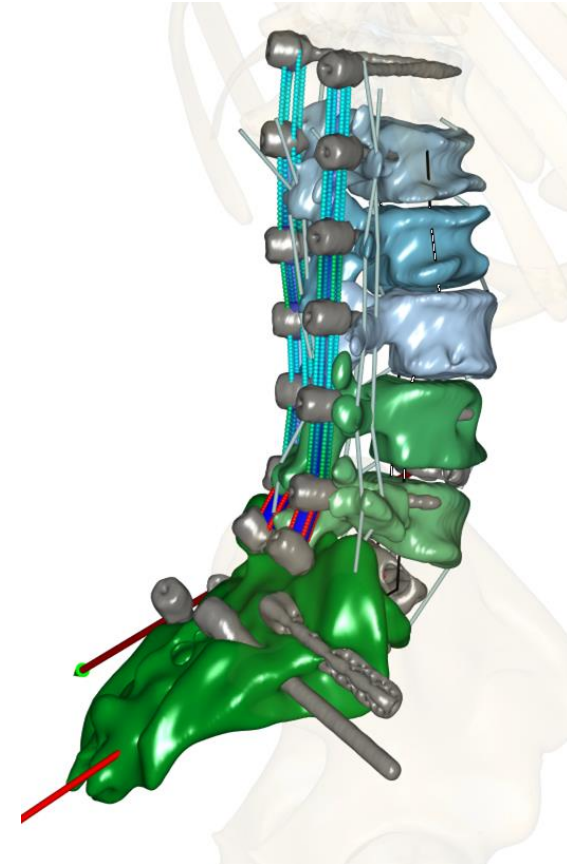
Facetectomy in a patient-specific model



A system of rods, screws, and cages

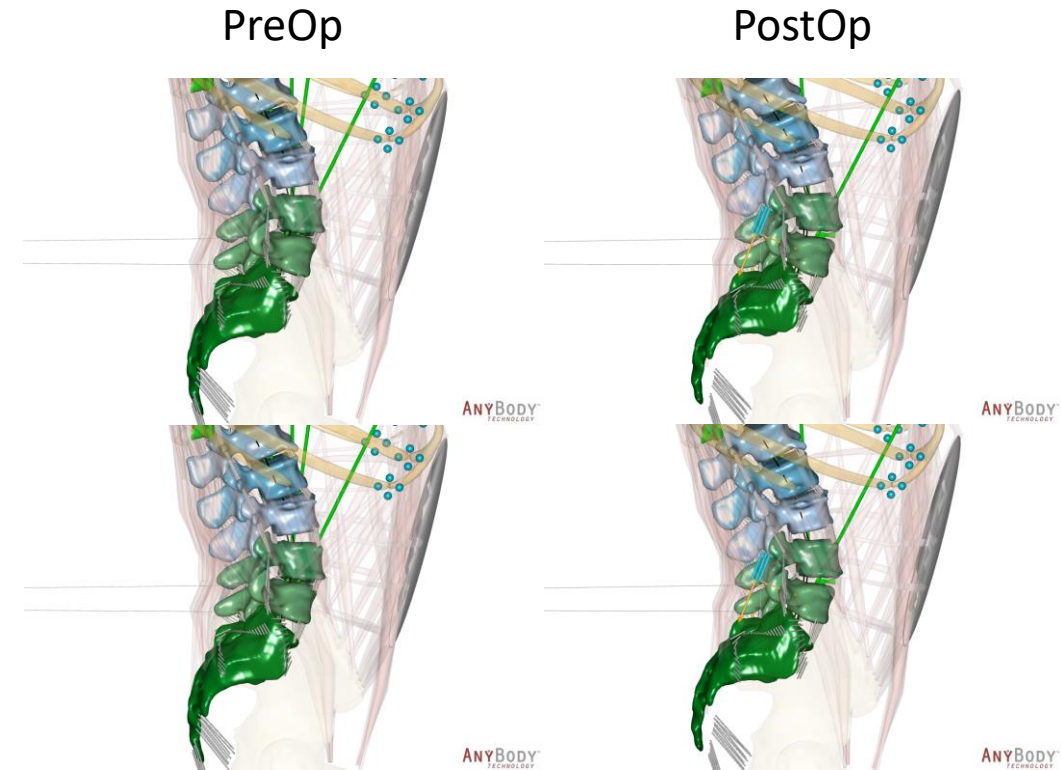
Library of spinal implants

- Commonly used in the industry spinal implants:
 - Rods
 - Cages
 - Intervertebral disc replacements
- Implemented for known geometric dimensions and mechanical properties
- Producer-specific and custom implants (ongoing development)



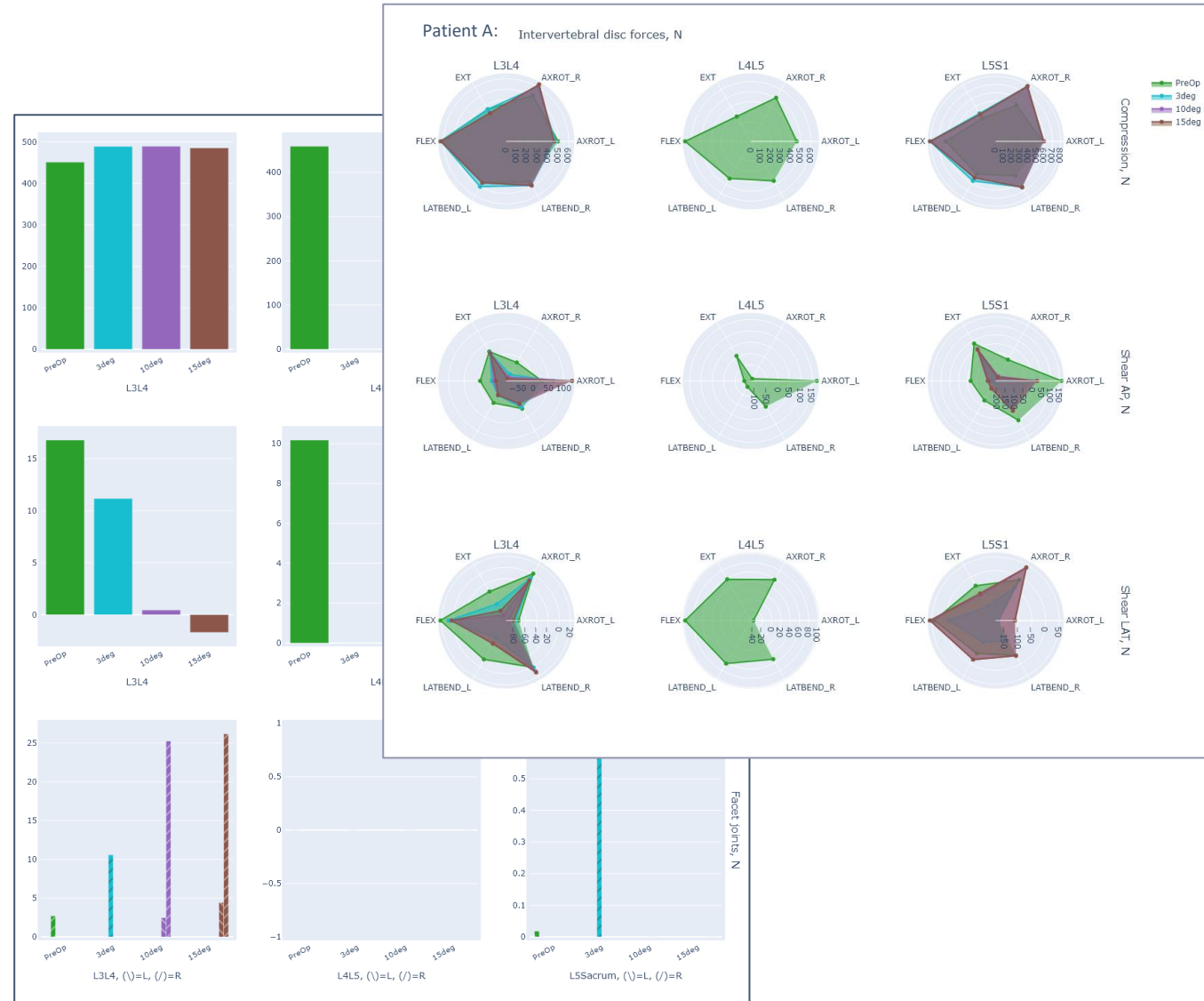
Simulation

- Analysis strategies
 - Understand biomechanics of primary movements
 - Flexion-Extension
 - Lateral bending
 - Axial rotations
 - Variate loads to assess response of passive structures
 - A torque applied at the cranial end in different planes
 - Follower loads



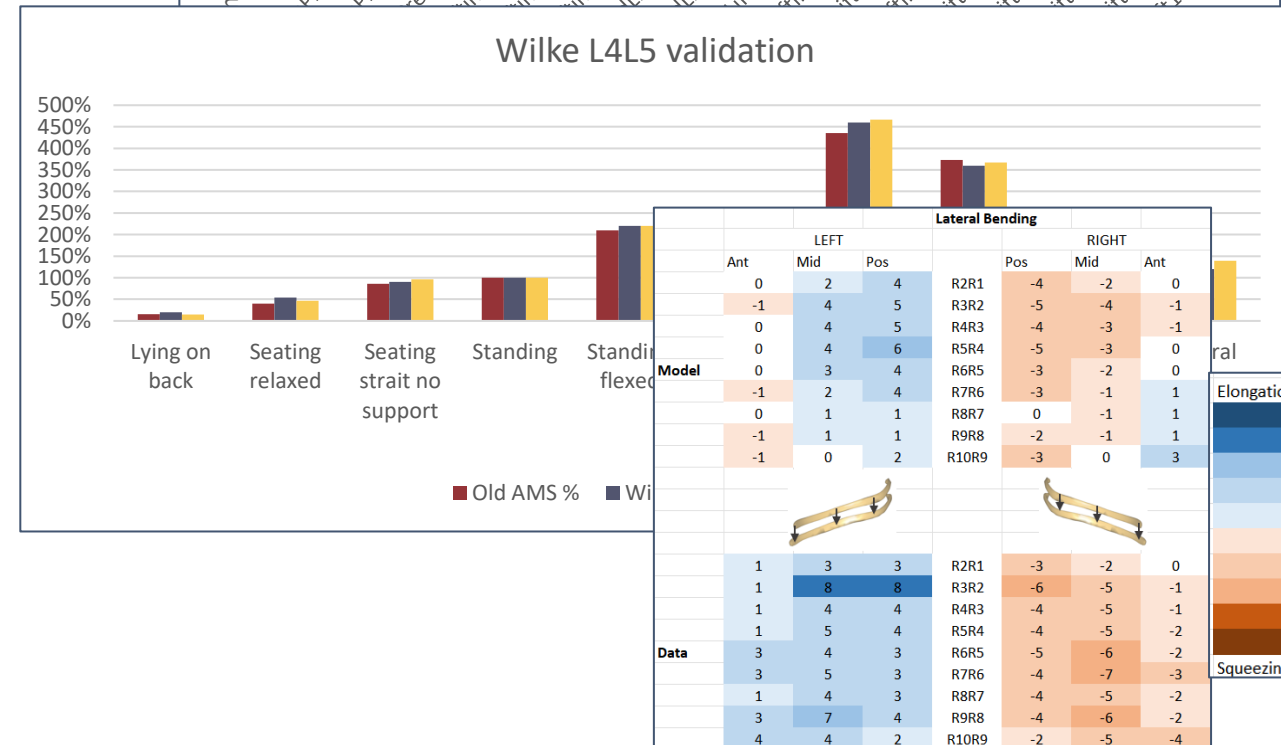
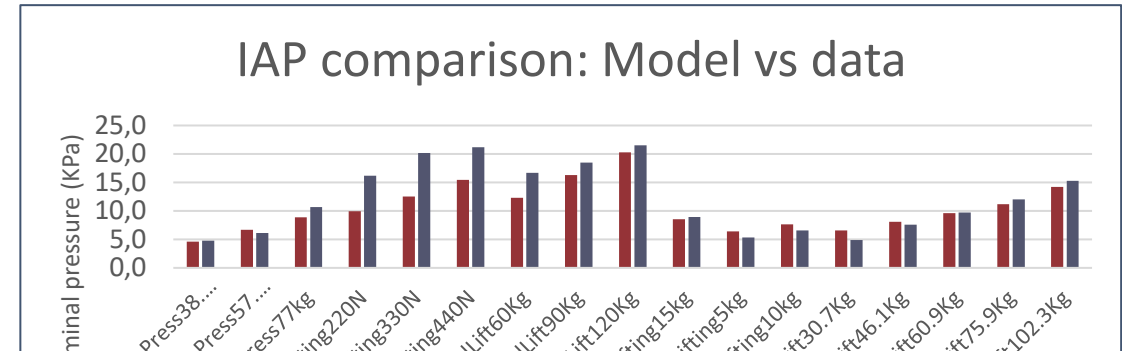
Output example

- Patient-specific forces
 - Intradiscal forces
 - Facet joint contacts and forces
 - Ligament strain, forces
 - Kinematics
- Spinal implant loads
 - Rod stresses
 - Interface force, i.e. screw pull-out forces
 - Compressive, shear forces
 - Etc.
- Graphical output
 - Video of movement in different planes
 - Screenshots and more



Validation & Verification

- AMMR is a continuously tested software product using a variety of benchmark tests
- Simulation module development is focused on allowing for:
 - verification & validation
 - uncertainty quantification
 - retrospective analyses





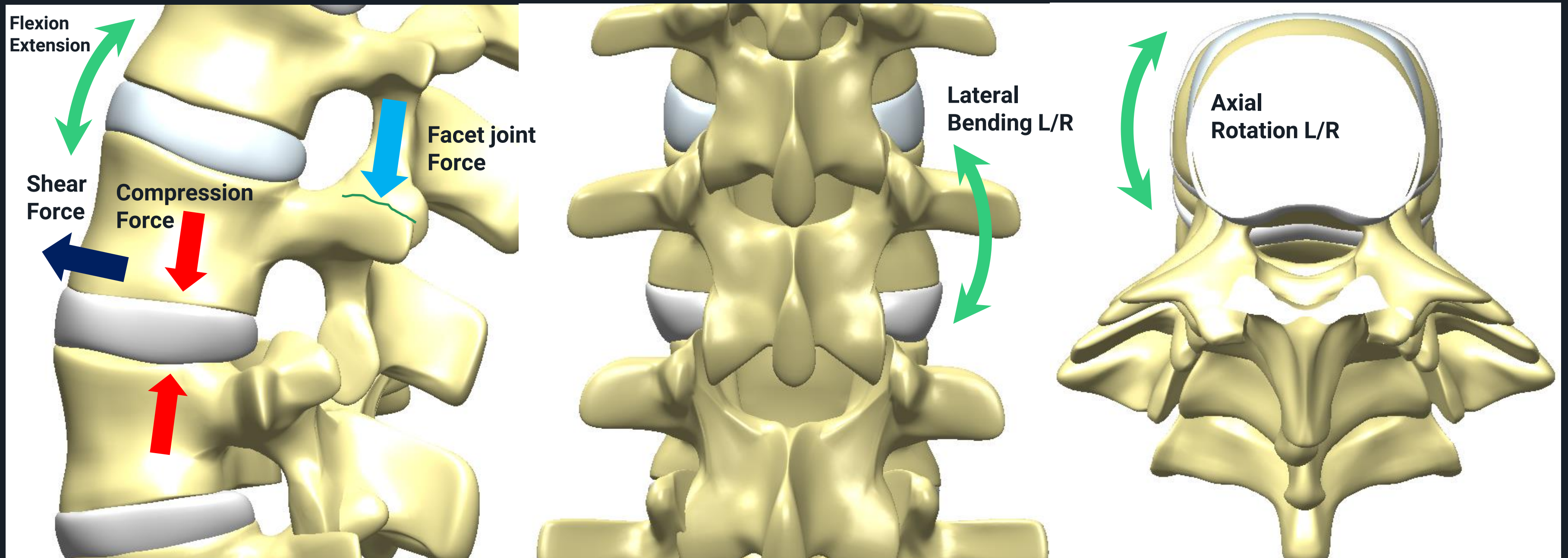
AGADA

The Spine Oracle™
Validation Methods



The Spine Oracle™ Validation Methods

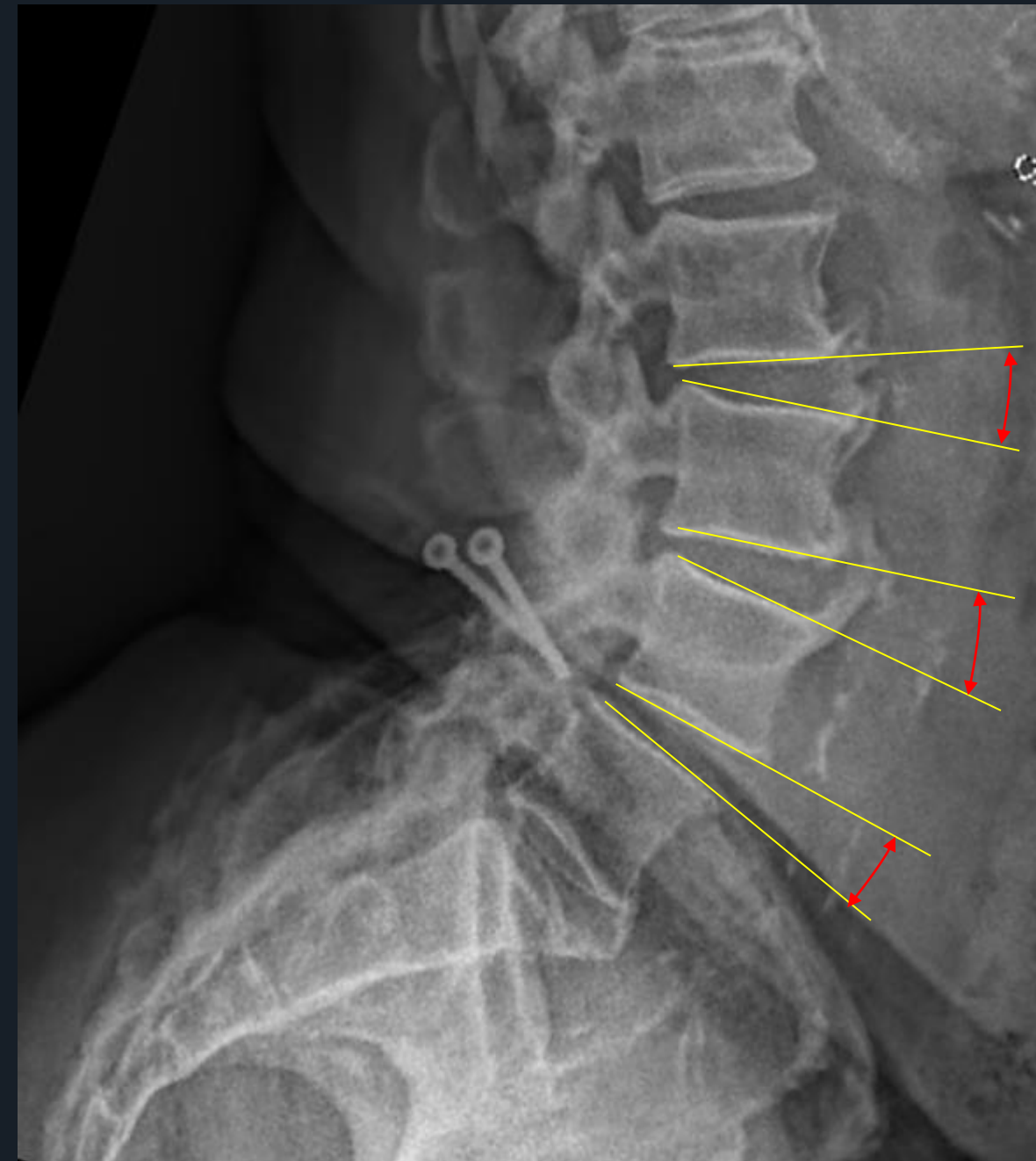
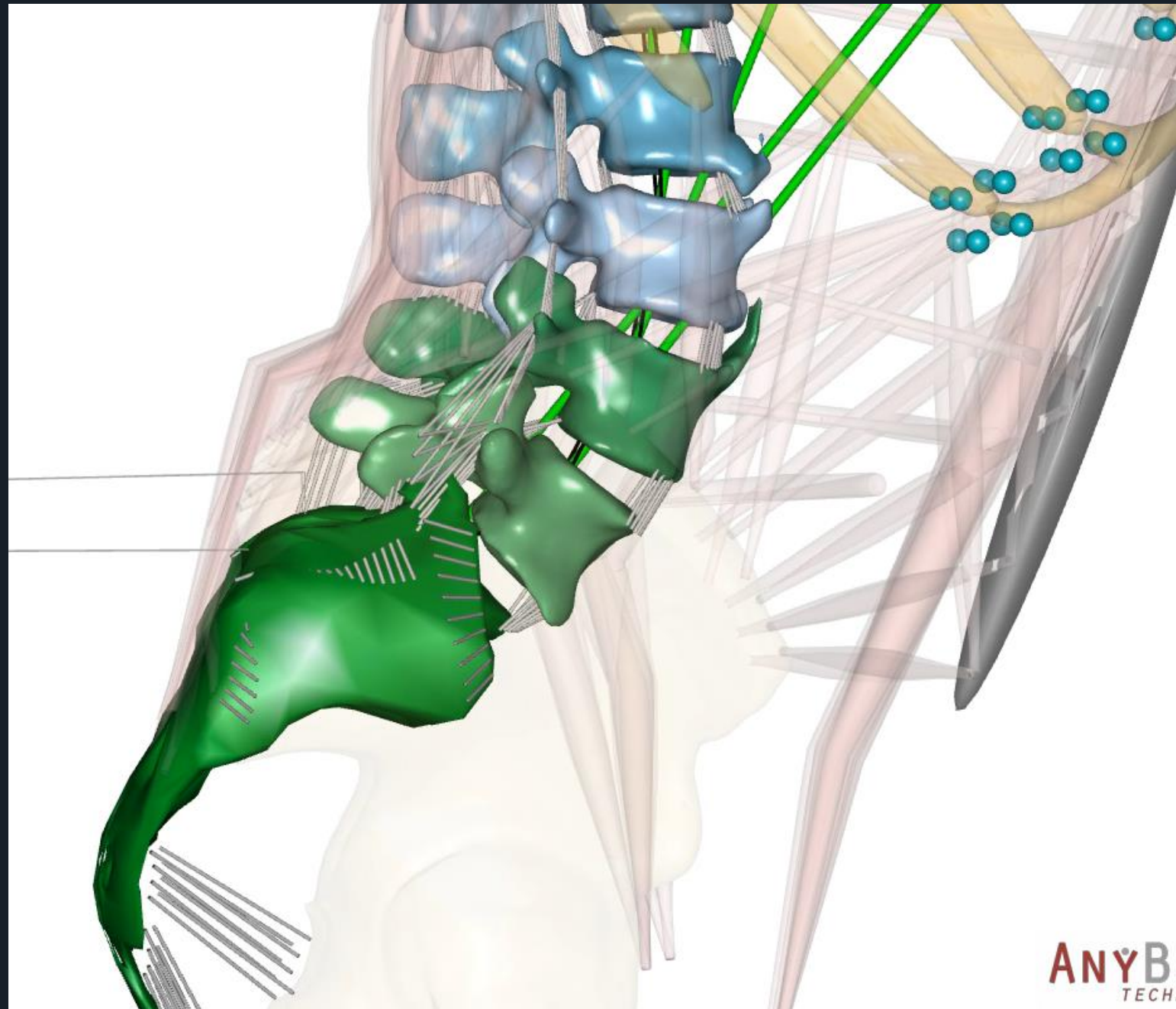
1. Kinematic validation - ABT simulations compare to gait lab and Standing/flexion-extension X-Ray results
2. Force analysis validation planned to perform on cadaver study





The Spine Oracle™ Validation Methods

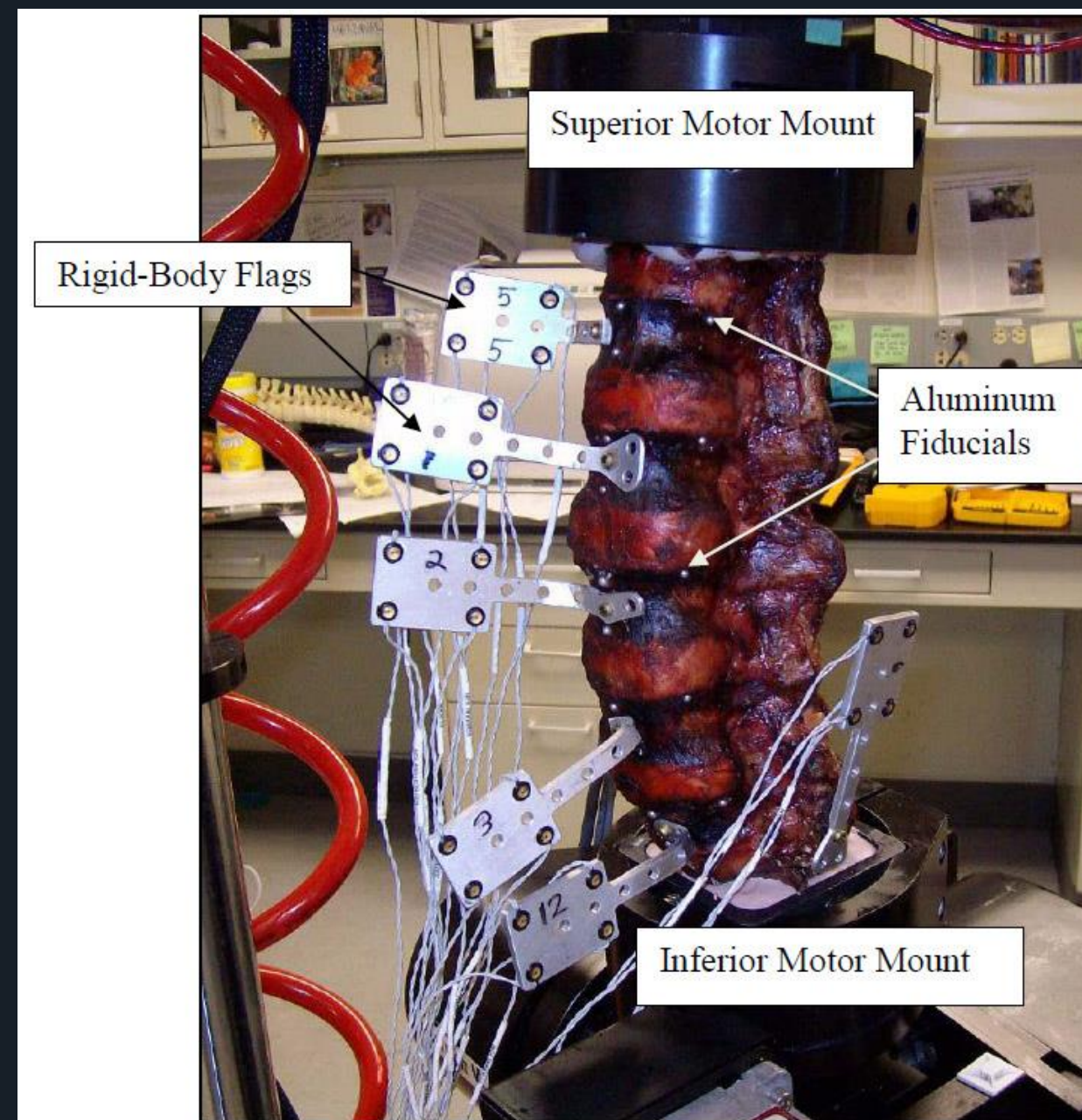
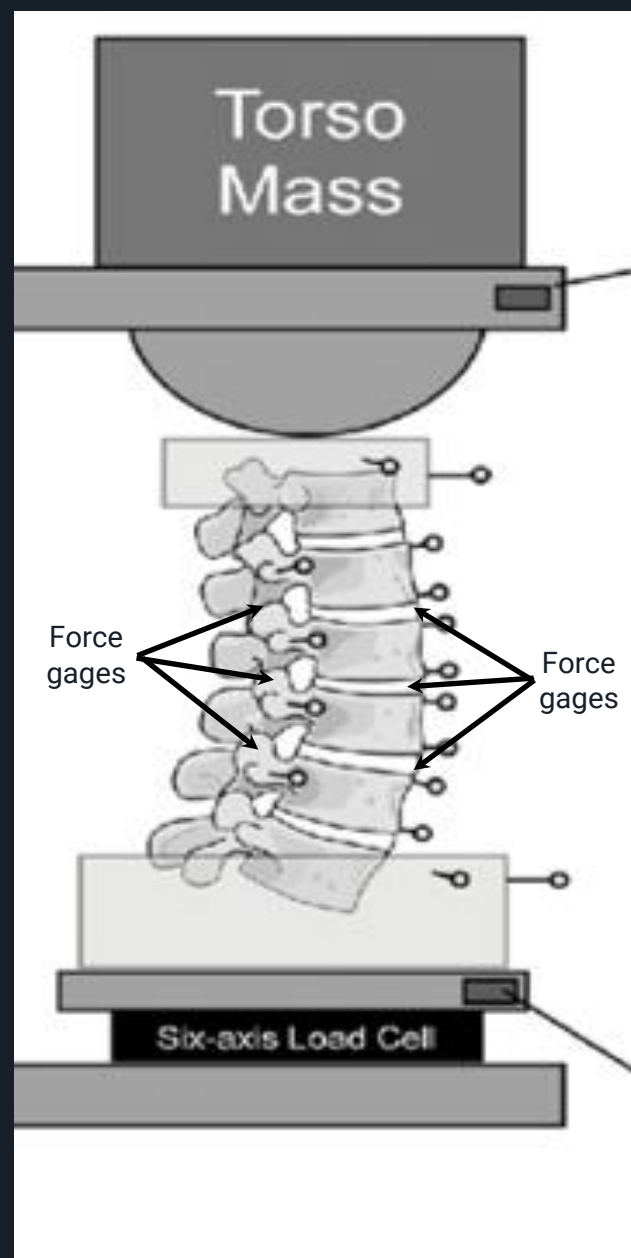
Kinematic validation - ABT simulations compare to gait lab and Standing/flexion-extension X-Ray results





The Spine Oracle™ Validation Methods

Challenge: In-Vivo spine forces measurements is problematic.
Force analysis validation planed to perform cadaver study in one of the Biomechanics labs
Mainly use of *Spine Oracle™* is to compare between surgery planning configurations, the Absolut values and accuracy in the first phase need to be define.



Example for Test setup
from University of
Pittsburgh

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gait methods validation animal sensitivity analysis rehab seating fea occupational health

Body part
knee lower extremity foot spine upper extremity hand shoulder hip mandible wrist trunk elbow ankle leg

NEW

Year 957 Publications

2023	Li H, Peng F, Lyu S, Ji Z, Li Y, (2023), "Study on Two Typical Progressive Motions in Tai Chi (Bafa Wubu) Promoting Lower Extremity Exercise". vol. 20, pp. 2264. [DOI, WWW]	NEW sports lower extremity
2023	Zhu Y, Li H, Lyu S, Shan X, Jan YK, Ma F, (2023), "Stair-climbing wheelchair proven to maintain user's body stability based on AnyBody musculoskeletal model and finite element analysis". vol. 18, pp. e0279478. [DOI, WWW]	NEW consumer products lower extremity fea
2023	Madinei S, Nussbaum MA, (2023), "Estimating Lumbar Spine Loading When Using Back-Support Exoskeletons in Lifting Tasks". pp. 111439. [DOI, WWW]	NEW exoskeleton spine
2023	Bayoglu R, Witt JP, Chatain GP, Okonkwo DO, Ignasiak D, (2023), "Clinical Validation of a Novel Musculoskeletal Modeling Framework to Predict Postoperative Sagittal Alignment". vol. Publish Ahead of Print. [DOI, WWW]	NEW orthopedics spine validation
2023	Scherb D, Wartzack S, Miehling J, (2023), "Modelling the interaction between wearable assistive devices and digital human models—A systematic review". vol. 10. [DOI, WWW]	NEW exoskeleton
2023	Telfer S, (2023), "Chapter 24 - Musculoskeletal Modeling of the Foot and Ankle". Book Chapter, In: Ledoux WR, Telfer S, (Ed), Foot and Ankle Biomechanics, pp. 387-396. [DOI, WWW]	NEW ankle foot
2022	Harada T, Hamai S, Okazawa K, Fujita T, Hara D, Kozono N, Kawahara S, Yamaguchi R, Fujii M, Ikemura S, Motomura G, Nakashima Y, (2022), "Reverse dynamics analysis of contact force and muscle activities during the golf swing after total hip arthroplasty". [DOI, WWW]	NEW orthopedics sports hip
2022	Ignasiak D, Behm F, Mannion AF, Galbusera F, Kleinstück F, Fekete TF, Haschtmann D, Jezzenszky D, Zimmermann L, Richner-Wunderlin S, Vila-Casademunt A, Pellisé F, Obeld I, Pizones J, Sánchez Pérez-Gruoso FJ, Karaman MI, Alanay A, Yigior Ç, Ferguson SJ, Lolbiel M, ESSG European Spine Study Group, (2022), "Association between sagittal alignment and loads at the adjacent segment in the fused spine: a combined clinical and musculoskeletal modeling study of 205 patients with adult spinal deformity". [DOI, WWW]	NEW orthopedics spine
2022	Li J, Zhu Y, Guan T, (2022), "Numerical Simulation Method of Scoliosis Orthosis Considering Muscle Factor". [DOI]	NEW spine fea methods
2022	De Pileri E, Cip J, Brunner R, Weidensteiner C, Alexander N, (2022), "The functional role of hip muscles during gait in patients with increased femoral anteversion". [DOI, WWW]	NEW orthopedics hip lower extremity gait
2022	Zhang W, Wang Q, Xu Z, Shang Y, Xu H, (2022), "Development of a tractor operator-operation environment coupled biomechanical model and analysis of lower limb muscle fatigue". vol. 93, pp. 103407. [DOI, WWW]	NEW automotive lower extremity
2022	Miura T, Hongo M, Kasukawa Y, Kijima H, Kudo D, Saito K, Kimura R, Iwami T, Miyakoshi N, (2022), "Relationship between Intervertebral Disc Compression Force and Sagittal Spinopelvic Lower Limb Alignment in Elderly Women in Standing Position with Patient-Specific Whole Body Musculoskeletal Model". vol. 19. [DOI, WWW]	NEW orthopedics spine
2022	Musso M, Oliveira AS, Bai S, (2022), "Modeling of a Non-Rigid Passive Exoskeleton Mathematical Description and Musculoskeletal Simulations". [DOI, WWW]	NEW exoskeleton upper extremity

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Kobi Blank: kobi@agada-medical.com

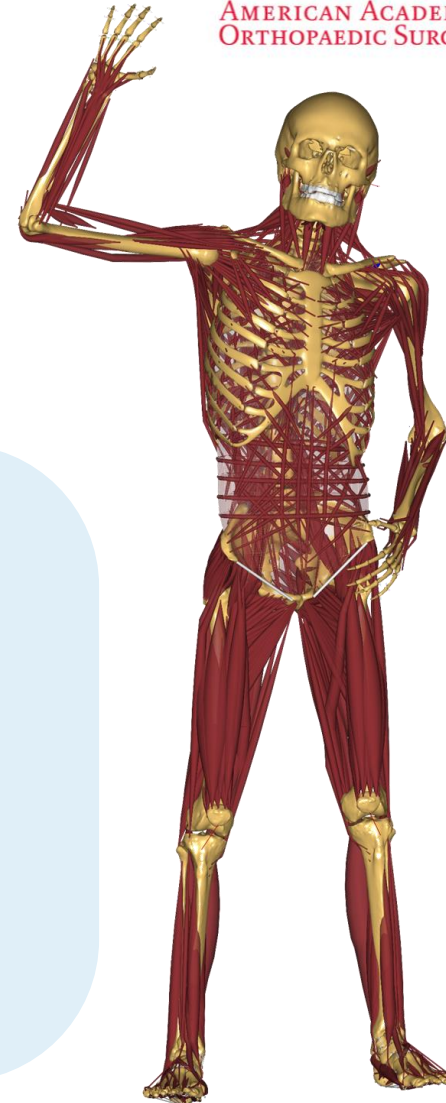
Isador Lieberman: izzy@agada-medical.com

Samuel Shannon: samuel@agada-medical.com

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