

**SENSE** 2nd International  
Spine Expert Symposium

June 23 – 25, 2022 / Valencia – Spain

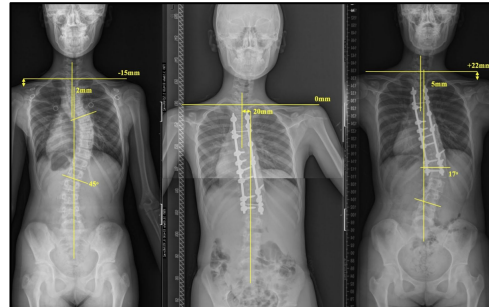
# ADVISE<sup>™</sup> Augmented technology platforms: A clinical perspective

Dr. V. A. Mehta, FACS FAANS

*Newport Beach, California Hoag  
Hospital*

# Where is the Market Going?

## Pre-OP & Post-OP Imaging for measurement and planning



## Intra-OP screw navigation and rod bending



What's  
Missing?

**Intra-OP AI/AR correction navigation and  
full patient specific construct**

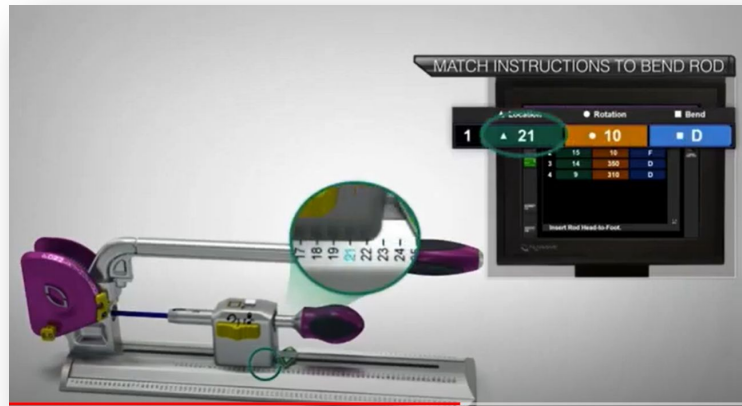
# Patient Specific Rod Systems

Currently available rod system technologies were aimed to:

- A reduction of OR time

*AND studies on these have shown that*

- ***A perfect fit of the rod to the screw heads is an important factor to reduce rate of implant failures; screw pull-out, implant breakages***



Bendini® Spinal Rod Bending System



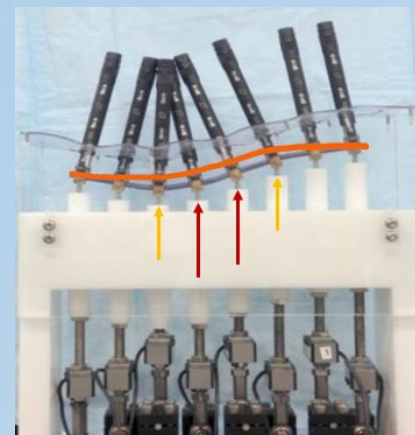
UNiD - patient-specific spinal rod

# Bendini® Spinal Rod Bending System

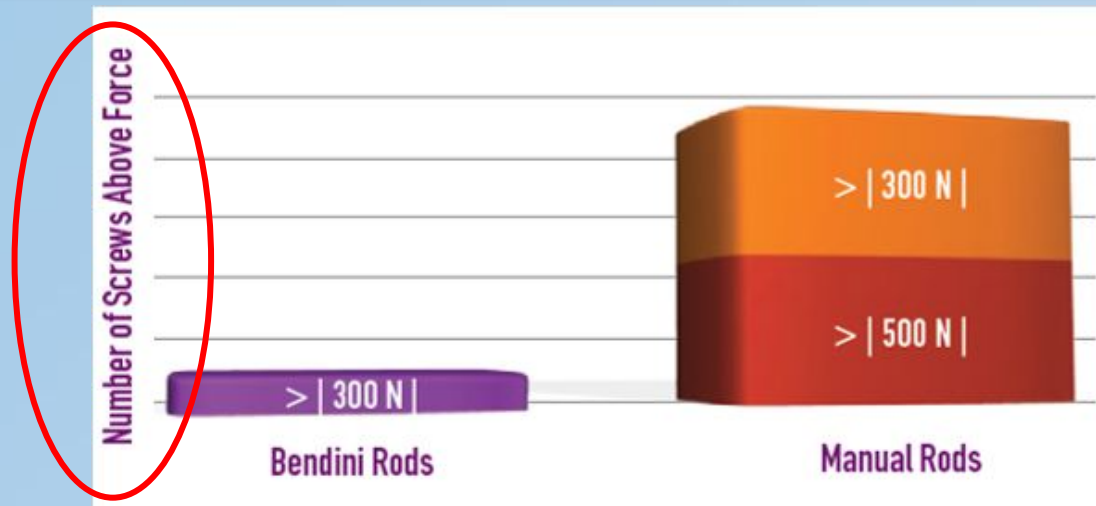
NuVasive®, Inc.  
May, 2014

---

**Long Construct Pedicle Screw Reduction and Residual Forces are Decreased Using a Computer-Assisted Spinal Rod Bending System**  
*Antoine G. Tohmeh, MD; Robert E. Isaacs, MD; Zachary A. Dooley, MS; Alexander W. L. Turner, PhD*



60% lower residual force for the computer-assisted rod vs. the manually bent rod



20% of screws with a load peak > 500N  
39% of screws with a load peek > 300 N  
for the manual rod bending

According to the research of Wagnac E, et al.

- >300 N – Cancellous bone failure
- At 628 N – Cortical bone failure



# Bendini® Spinal Rod Bending System

PRIMARY RESEARCH

Utility of a Computer-assisted Rod Bending System to Avoid Pull-out and Loosening of Percutaneous Pedicle Screws

*Tetsuro Ohba, MD, PhD, Shigeto Ebata, MD, PhD, Kotaro Oda, MD, Nobuki Tanaka, MD, and Hirotaka Haro, MD, PhD*

- Clinical retrospective study
- The influence of Manual vs. Computer-assisted (Bendini) rod bending techniques on pedicle screw pull-out during rod reduction and final tightening.
- Screw loosening rates at 1 year post op.

**48%**

less loosened screws seen at 1 year Post OP for the Computer-assisted Rod Bending System

*Manual rod bending: 15.5% vs CA rod bending: 8.1%*

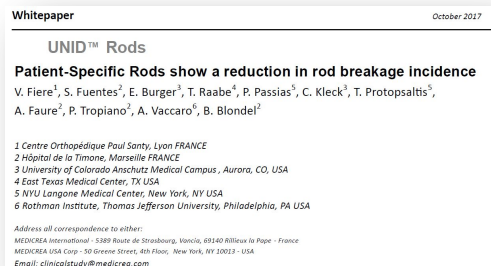
Over all **89.3%** of loosened pedicle screws had developed the screw pull-out during the rod connection.

”Our recent study showed screw pull-out during rod connection was a serious risk factor for screw loosening when using the percutaneous pedicle screws technique”.

”The importance of a precise rod bending technique in open spinal surgery has been reported”.

”The present study indicated **the precision of the Computer Assisted rod bending has significant clinical importance-**”

# UNiD™ - Patient Specific Rod



Review of an **anonymized AE database**, based on surgeons feedback (Medicrea) on ASD patients treated and > 1 year FU

Parameters	All Patients
Total patients implanted with UNiD™ Rods at the end of June 2017	1515
UNiD™ Rod ASD surgeries performed before June 2016	453
UNiD™ Rod ASD surgeries with PSO performed before June 2016	127
Total ASD patients having UNiD™ Rod breakages	10 (2.2%)
Total ASD patients with PSO having UNiD™ Rod breakages	6 (4.7%)

Rod breakage incidence in the current literature them [2]. Overall rod breakage incidence is reported as high as 14.9% in patients following ASD surgery [3-6]. When a pedicle subtraction osteotomy (PSO) is performed, the rod fracture rate increases to 22%

**CONCLUSION**  
**Reduced risk of rod breakage**  
2.2% at 1 year post op vs. literature (14.9%)

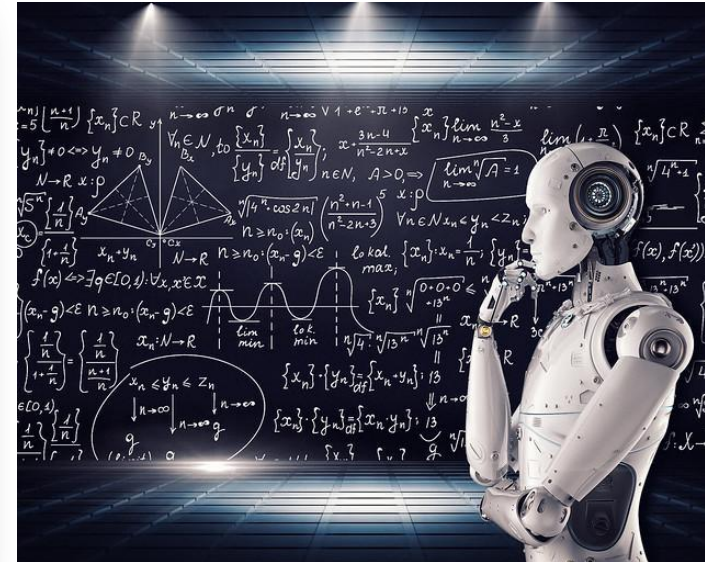
# Technological Gap

## Objectives of Spinal Fusion Surgery

Neo<sup>®</sup>

Alleviate pain  
(intra-op decompression & long term fusion)  
+  
Restore anatomical alignment & Correct biomechanical balance  
=  
**FUNCTIONAL FUSION**

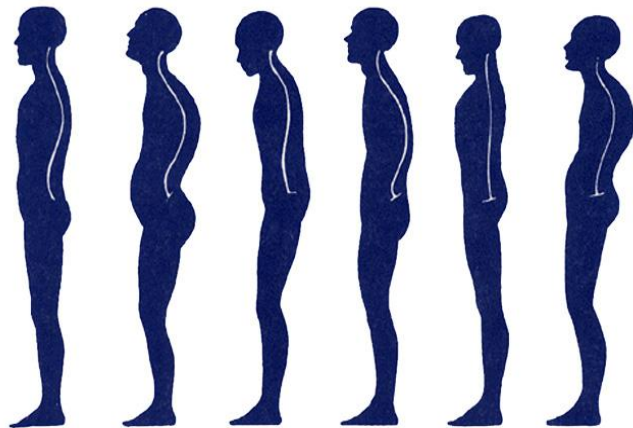
Spinal implants are used to create and/or  
preserve spinal alignment & balance correction



**No intraoperative tool available to support the surgeon monitor, manage and achieve the right level of correction**



# ADVISE™ - Your Intraoperative Advantage



- To objectively measure intraoperatively the patient's specific conditions compared to our pre-surgical plan.
- To build a patient customized construct to optimize correction, fixation and outcomes.
- To treat every patient as special...WHY?



# What Can AI/AR Technology Deliver?



Accessible Hardware  
Simple Learning Curve  
Immediate Intra-OP Application



Continuous Machine Learning  
& Increasing Functionality



Patient specific  
construct treatment



Pre-Op vs. Intra-OP  
Comparison



Applications for  
all indications



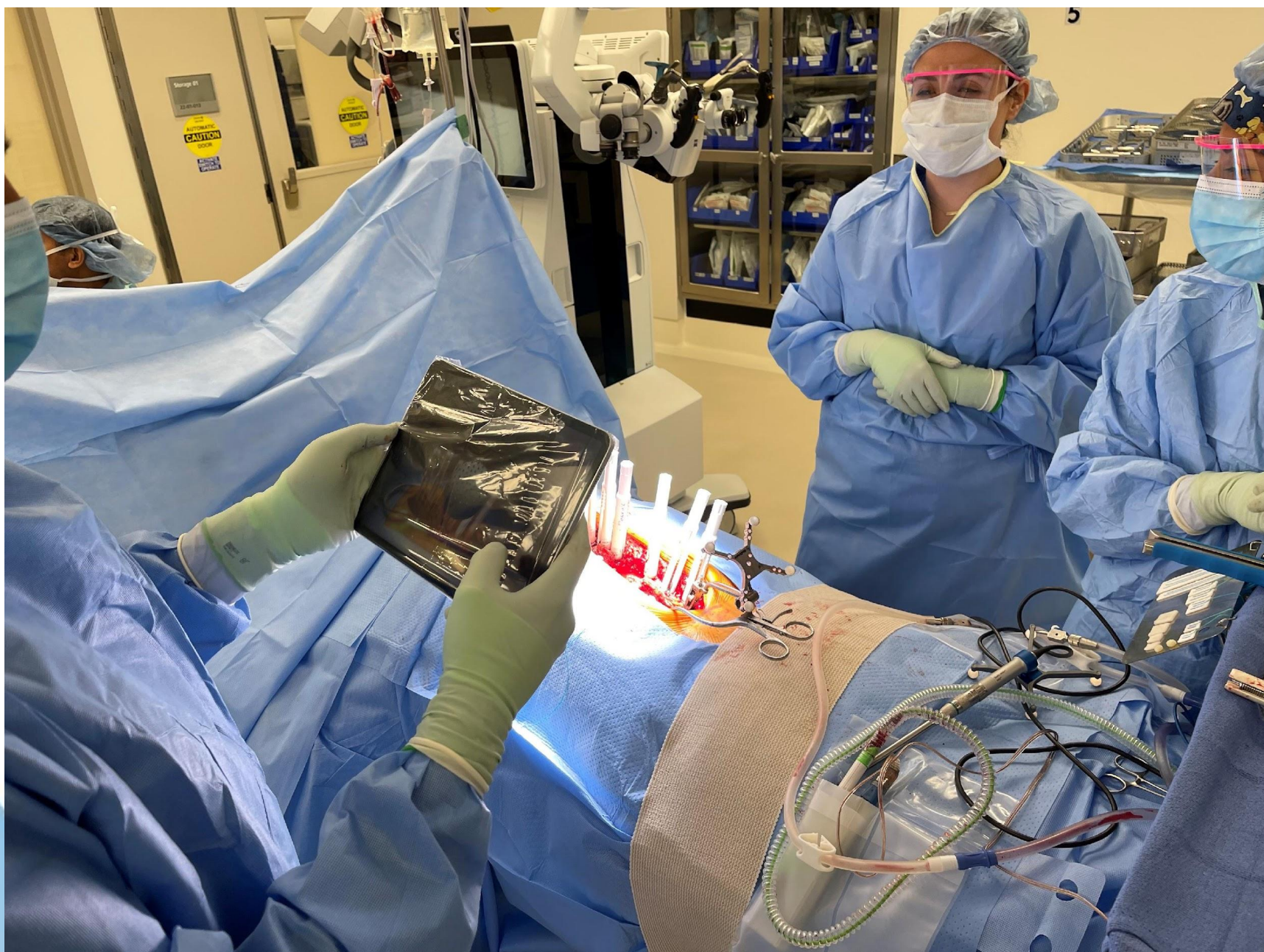
Radiation  
Free

Every spine surgeon is a  
deformity surgeon....you are  
either fixing deformity or  
creating deformity













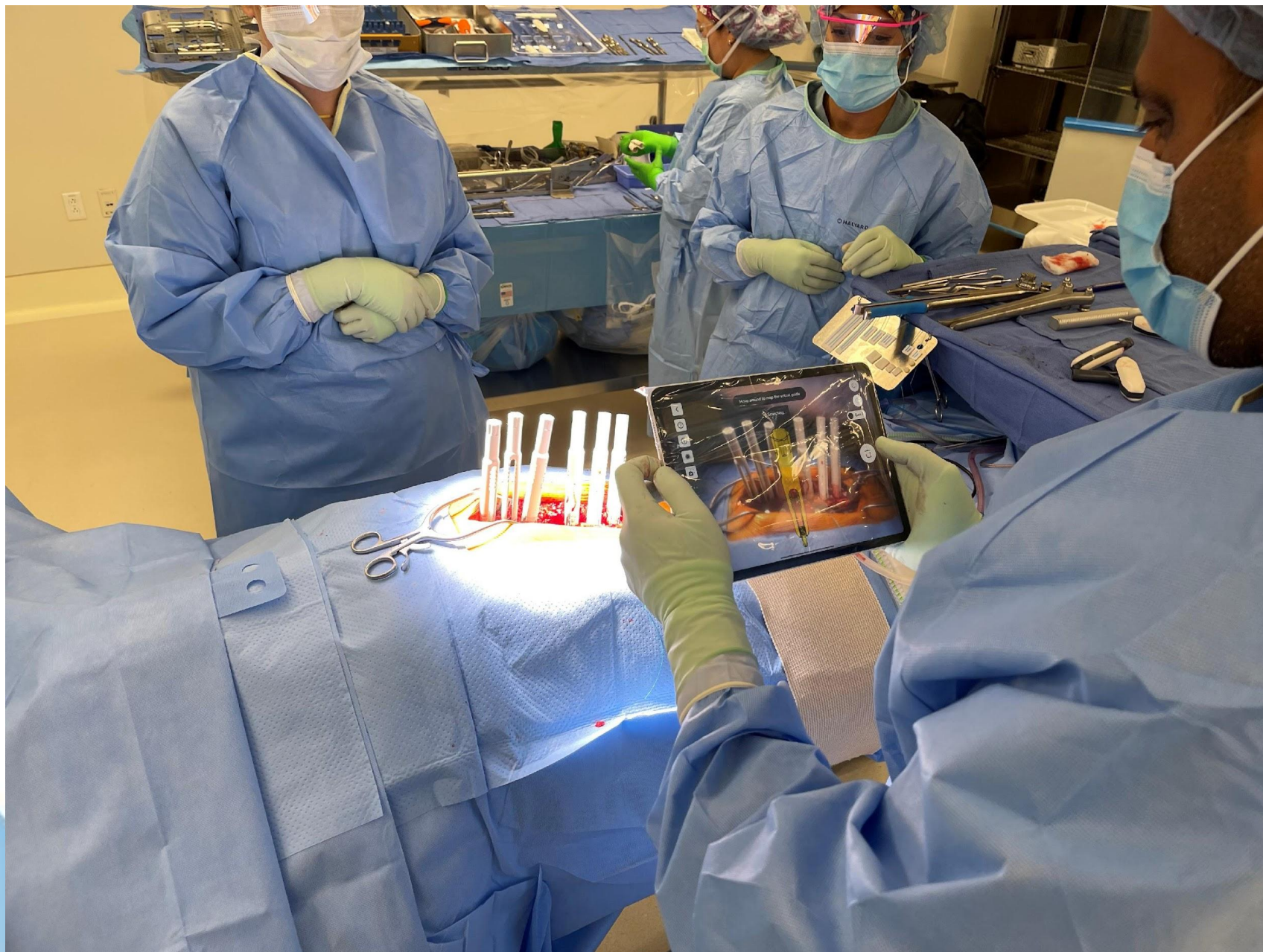




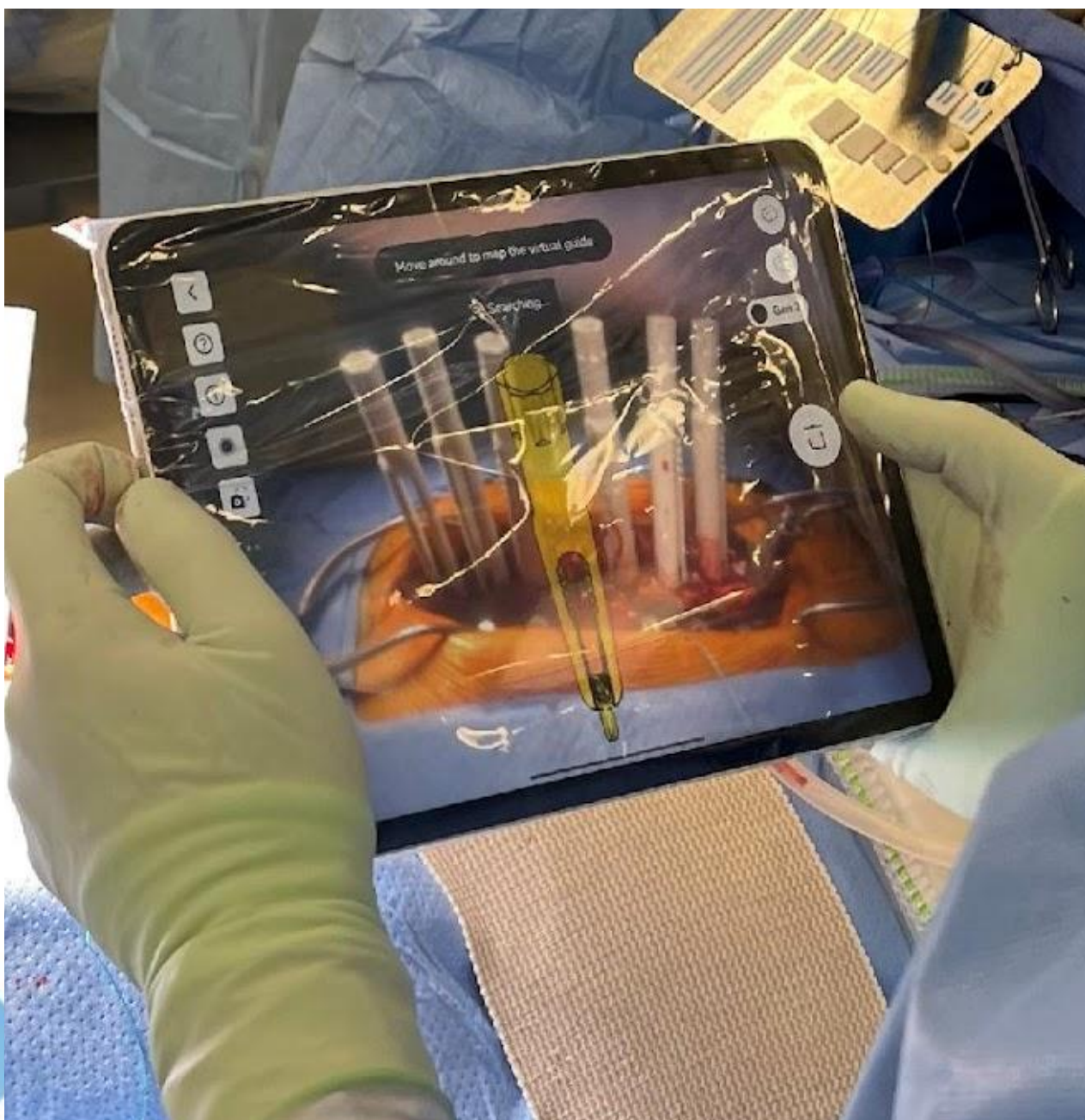


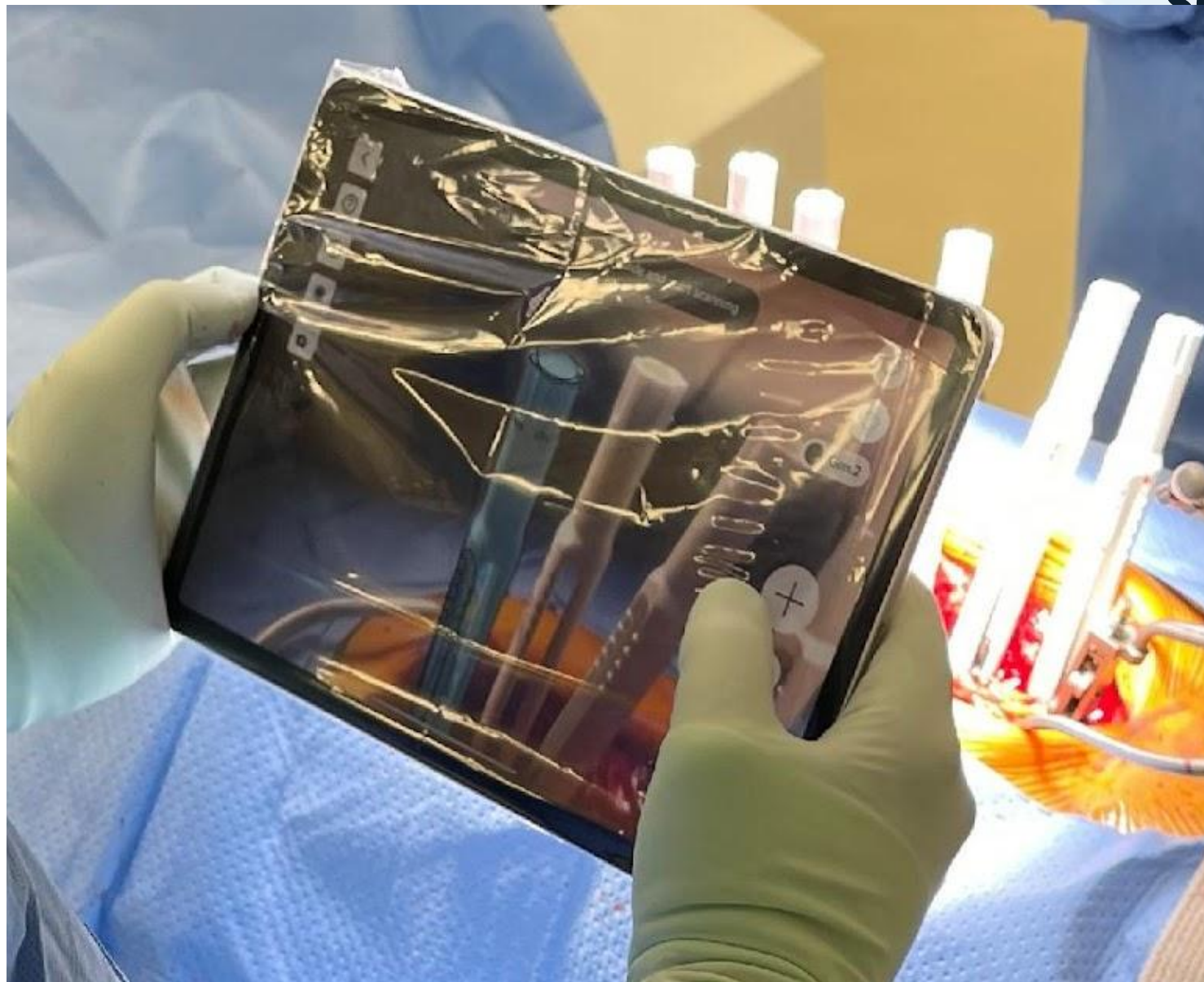




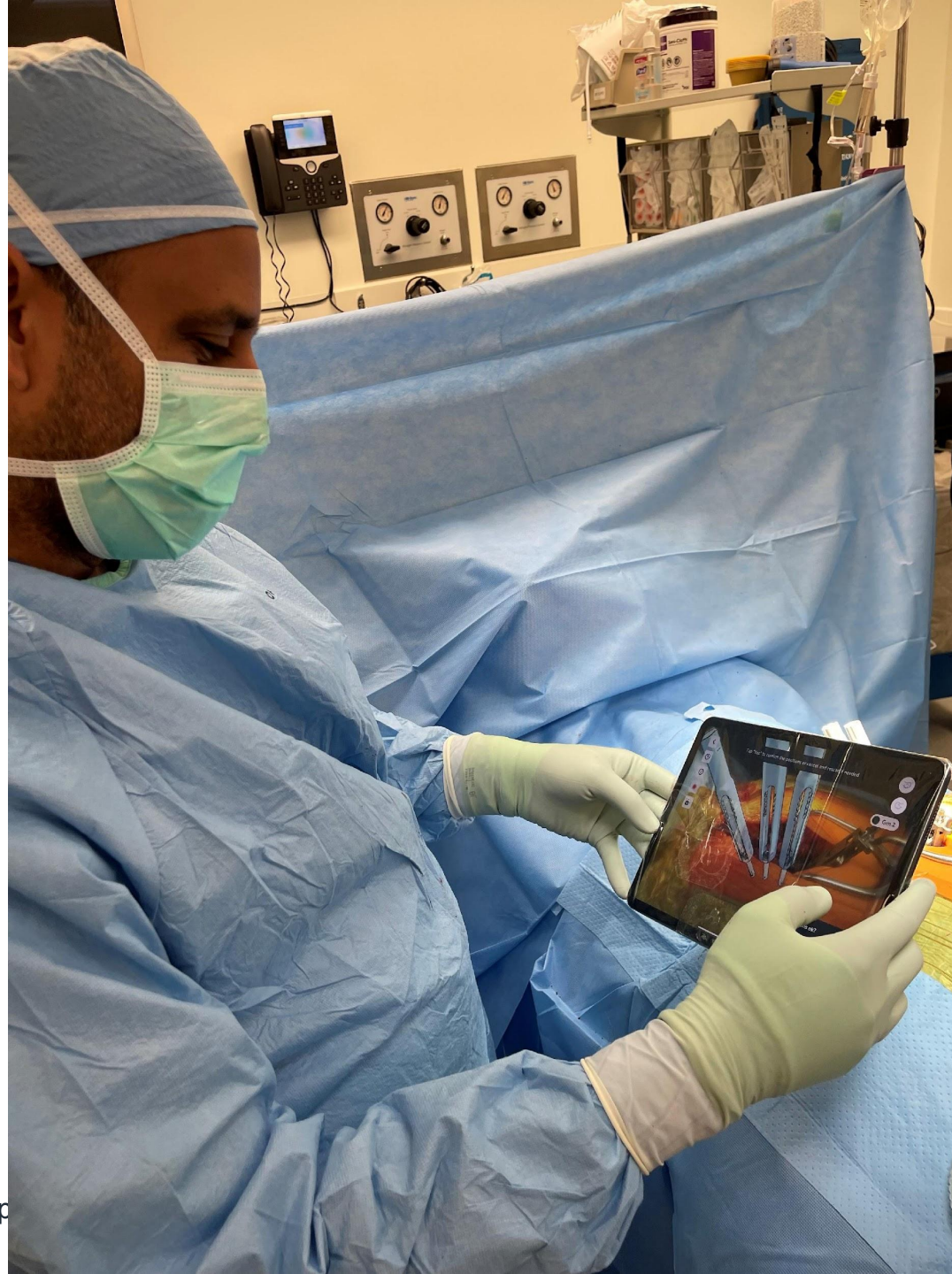




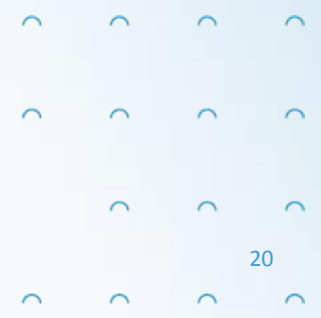




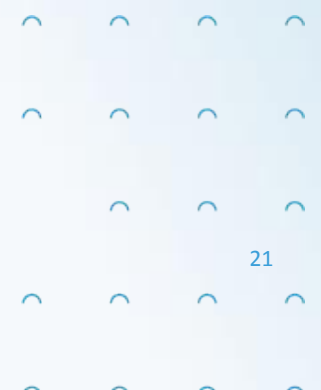
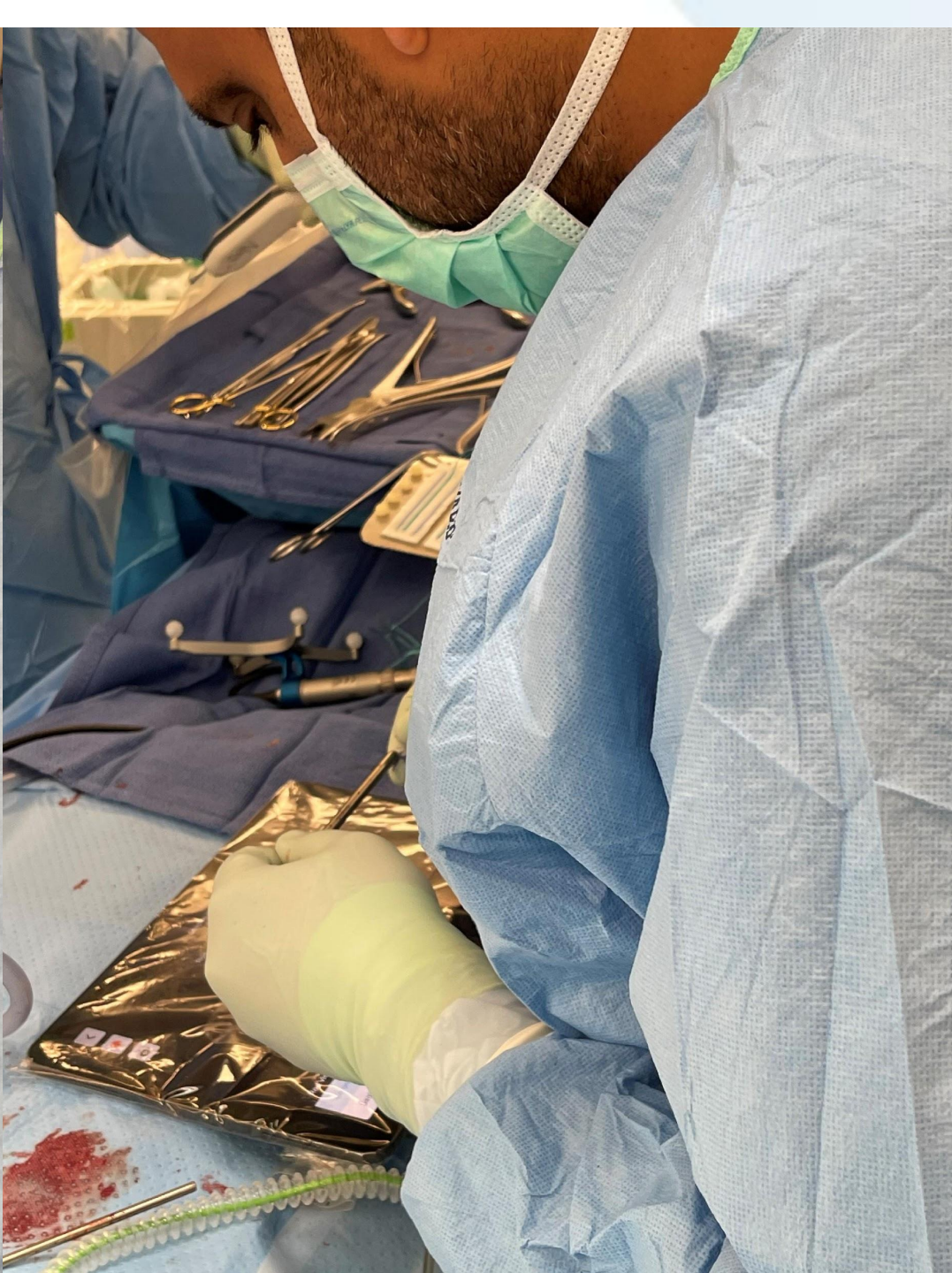




















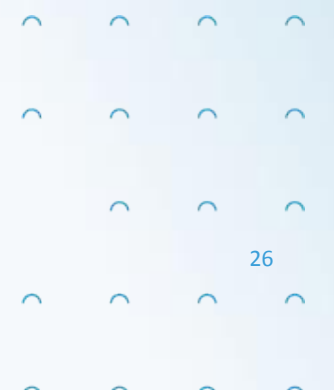
















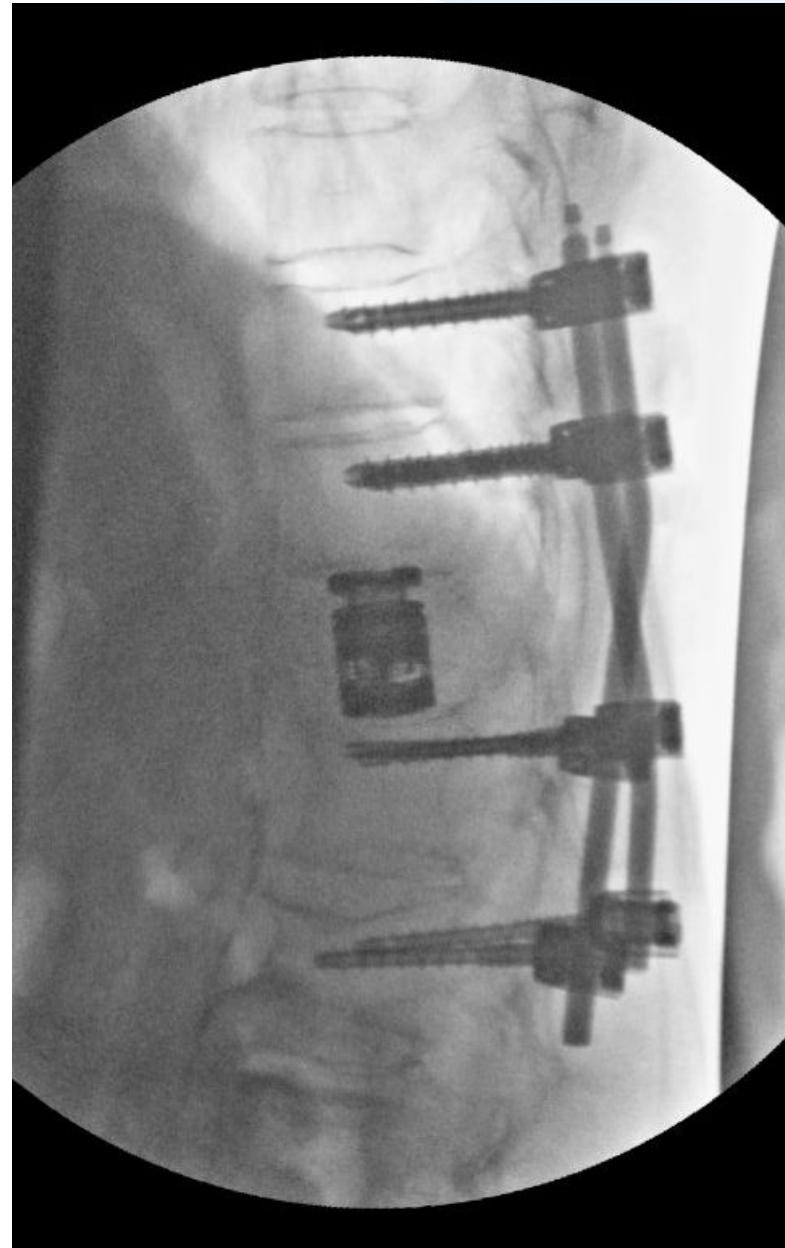
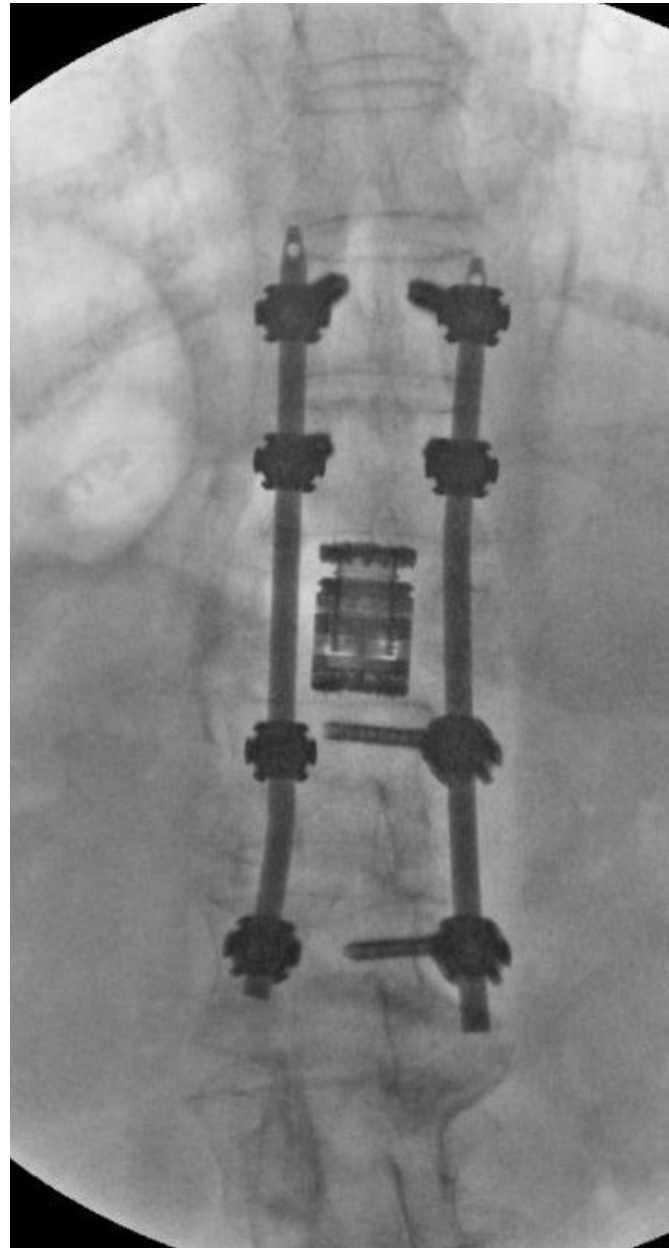






# Clinical Case #1





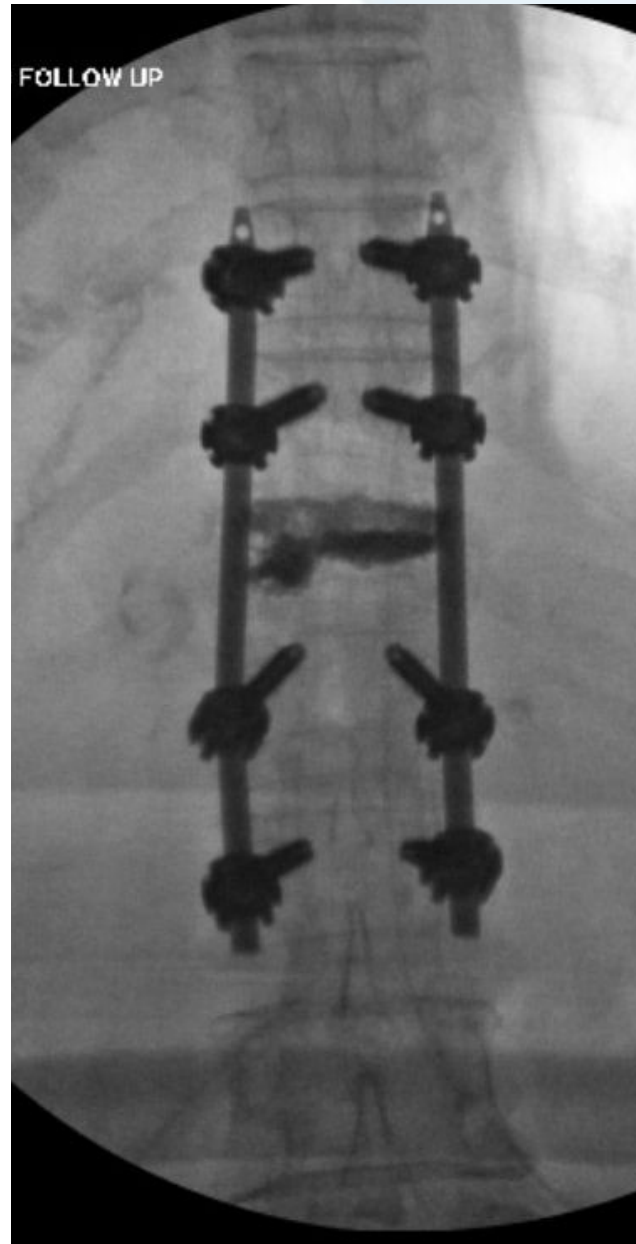


# Clinical Case #2





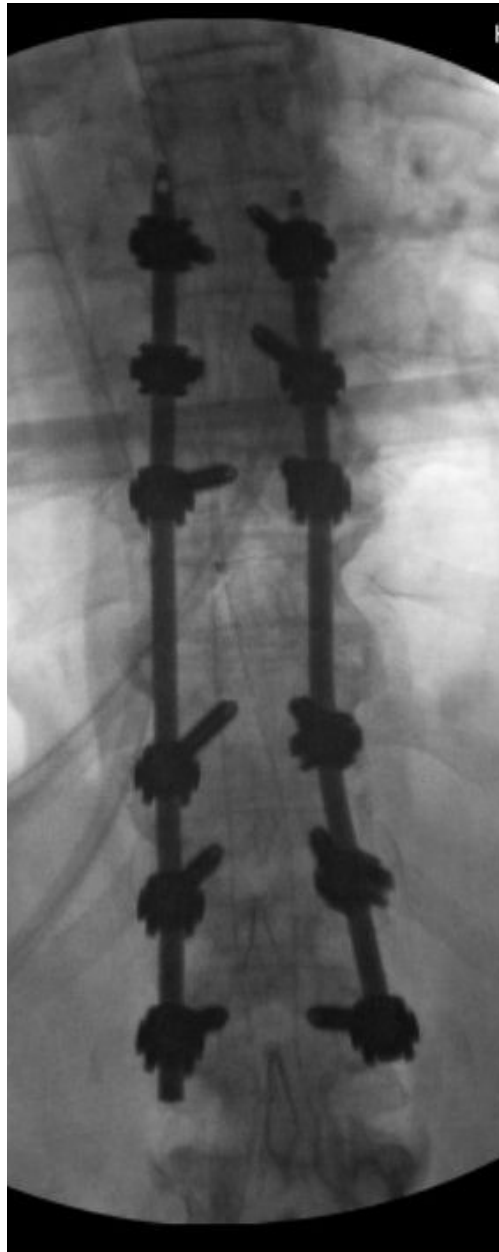






# Clinical Case #3

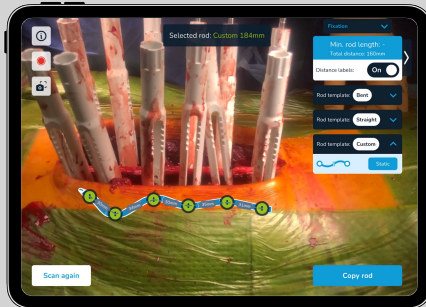




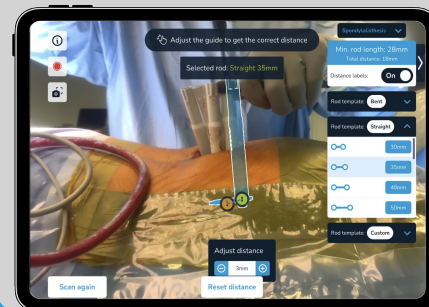


# ADVISE™ - 3D Scanning

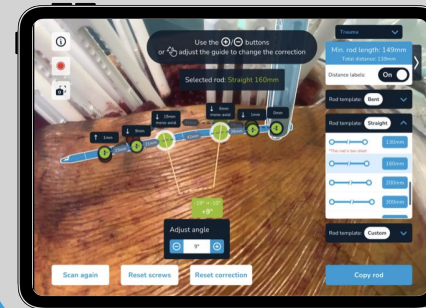
## Fixation Module



## Spondy Module



## Trauma Module



ADVISE™ has been used in >250 clinical cases, in different indications:

% of cases

In Situ Posterior Fixation	Adult Spinal Deformity incl. Iliac Fixation (Open)	33%
	Adult Spinal Deformity incl. Posterior Fixation (Percutaneous)	19%
Correction	Revision Case Extension	0
	Spondylolysis	17%
	Fracture Reduction (Percutaneous)	31%
	Deformity	0

Company estimates until 10/06/22



# Conclusions

- Easy to access and use, an iPad, no expensive equipment needed, easy logistics.
- Short Learning curve, easy of familiarity with iPad based platform
- Less radiation for patient, surgeon and OR staff. If the rod is perfectly bended by using the ADVISE, there is less risk of additional bending steps, with need of additional x-rays to be taken.
- Can be used in all type of cases
- Customized rod bending in patients with compromised bone (cancer patients)
- Potential Time saving in more complex cases.
- Less infection and reduced OR time.
- Clinical data on short- and long-term clinical outcomes will need to be proven



## Key Take Away Points

- Controlled Fixation
- Predictive Correction
- Maximize Outcomes



# References

## References:

1. Ohba T, Ebata S, Oda K, Tanaka N, Haro H. Utility of a Computer-assisted Rod Bending System to Avoid Pull-out and Loosening of Percutaneous Pedicle Screws. *Clin Spine Surg.* 2021 Apr 1;34(3):E166-E171.
2. Barton C, Noshchenko A, Patel V, Kleck C, Burger E. Early Experience and Initial Outcomes With Patient-Specific Spine Rods for Adult Spinal Deformity. *Orthopedics.* 2016 Mar-Apr;39(2):79-86.
3. Moal B, Schwab F, Ames CP, et al. Radiographic Outcomes of Adult Spinal Deformity Correction: A Critical Analysis of Variability and Failures Across Deformity Patterns. *Spine Deform.* 2014 May;2(3):219-225.
4. McCarthy IM, Hostin RA, Ames CP, et al. Total hospital costs of surgical treatment for adult spinal deformity: an extended follow-up study. *Spine J.* 2014 Oct 1;14(10):2326-33.