

Innovations 2023





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3.5 mm Intrapelvic Acetabular System

Clinical problems and challenges

Due to demographics and an increasingly aging population, pelvic fractures are becoming highly relevant for society and the healthcare system. Moreover, with a shift from nonoperative to operative treatment, the number of surgical procedures worldwide is expected to grow by more than 30% [1, 2]. Nowadays, sustained physical or even sports activity is an inherent factor of the quality of life in this population. Consequently, medium- to low-energy fractures, such as pelvic ring or acetabulum fractures, are more frequent.

Similarly, there are trends within acetabulum fractures of the elderly to include specific fracture patterns and their variants. These include associated both column fractures, anterior column posterior hemitransverse, and anterior column variants. These fracture patterns will have fracture components that include the quadrilateral surface and a portion of the adjacent joint. Screw fixation alone may not be sufficient in some of these patterns because of bone quality. A plate applied to the quadrilateral surface may be required.

These trends define a need for new intrapelvic acetabular devices to be used for stabilization of these acetabular fractures. The possibility to deploy such new devices while using less invasive surgical approaches is of significant benefit to more fragile patients. The solution is to provide a biomechanically

sound implant set that can be adjusted intraoperatively to match the patient's anatomy. Further, a new complete set of instruments including plate trials and plateholders, retractors, reduction forceps, benders, and tools for screw insertion will provide superior ease of use compared with other available solutions.

The system was designed taking into consideration the increasing popularity of the anterior intrapelvic approach and techniques for plate fixation of these fracture types. Emphasis was put on reducing surgical complexity.

Details

The 3.5 mm intrapelvic acetabular plating system offers four anatomically precontoured plates per side to address fracture and patient variation. For each side these include a small and large sized plate in standard and extended version. Implants are provided in sterile packaging and are manufactured exclusively from stainless steel.

The plate offers superior anatomical fit. An extended version includes an additional posterior screw hole, with the posterior tail of the plate extending lateral to the sacroiliac joint. The plate provides contourable quadrilateral surface extension with improved screw anchorage options in the sciatic buttress, ischium, and posterior column.

Angulated screw holes allow for an engagement with the protection sleeve used for placing screws. Recesses on the outer contour of the plate allow for flexibility when placing additional screws outside the plate.

Instruments

Reduction of the system's complexity has also been addressed with new and updated instruments and retractors, designed to ease exposure, plate, and screw insertion.



Fig 1 The new AO Technical Commission approved acetabular plate in the small, extended version shown on a bone model with fracture pattern (black) and screw trajectories (gray).



Fig 2 The acetabular plate in large size and extended version with an additional posterior screw hole.

Specific radiolucent retractors were designed for superior pubic ramus, iliac fossa, and quadrilateral surface. Each offers a method to help maintain retractor position without interfering with the placement of the acetabular plate. The QS retractor includes a channel for the attachment of an optional light strip.

New reduction instruments provide a longer working length compared with standard low-profile pelvic sets. Pointed reduction forceps are offered in right, left, and straight versions. Ball-spiked reduction forceps and ball-spiked pushers can be used with optional spiked discs, if necessary.

A plateholder provides a stable connection to the plate or sizing trials, which are included in small and standard size and for the left and right sides. They ensure that the most suitable plate size is identified to fit the patient anatomy and the fracture pattern. For additional adjustments, ex-situ and in-situ bending instruments allow the surgeon fine-tuning implants to optimize bone-plate contact.



Fig 5 Plate holder with locking mechanism, providing a stable connection while maintaining the required flexibility for plate positioning.



Fig 3 Acetabular plate together with retractors. Maintaining the QS retractor's position is facilitated by its notched tip, whereas the other retractors are held in place using K-wires.



Fig 6 Screw insertion using the multi-purpose sleeve and an innovative through-plate insertion concept to prevent soft-tissue damage.

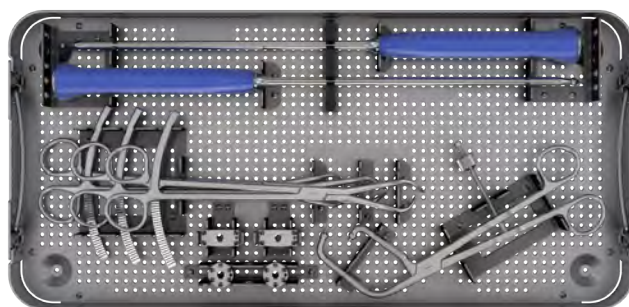


Fig 4 New set of reduction instruments with ball-spiked tips and optional spiked plate extensions in circular and rectangular shapes.

Screw insertion is facilitated by an innovative through-plate screw insertion concept to reduce the potential of soft-tissue exposure to the drill and the risk of losing a screw or its trajectory. Drilling, measuring, and screw insertion is done through one single sleeve. A dedicated measuring device, drill bits, drill guides, and 2.5 hex/T15 screwdrivers support the process of screw insertion.

References

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Biphasic Plate Distal Femur

Severe trauma to the extremities is a leading cause of disability during the wage-earning period. The socioeconomic burden of fracture is substantial—loss of working capacity can account up to 50% of the total costs of the fracture [1]. Optimal outcomes require not only solid bone union but also early and complete recovery of limb function. The current generation of fracture fixation plates focuses on minimizing the impact of surgery and preserving the biological healing potential. However, their design poorly controls a second critical component—the mechanical environment of the fracture. Furthermore, these plates are prone to failure which limits function and delays return to work.

The Biphasic Plate (Fig 1) is designed to provide suitable flexibility for healing and increased implant strength to support early full weight bearing.

Clinical problem

Although distal femoral fractures account for approximately 3%–6% of all femoral fractures [2], they are challenging injuries, often complex, intraarticular, and comminuted in nature [3]. Open reduction and internal fixation (ORIF) with locking plate fixation is the most used treatment modality for distal femoral fractures but is associated with high incidence of complications [4]. A metaanalysis [5] reported a total reoperation rate of 13.6%, with nonunion (4.5%), mechanical failure (3.5%), and deep infection (3.2%) as the leading causes of reoperation.

Despite improvements in implant and technique, early full weight bearing after fixation is usually restricted due to concern of implant failure, and reduced weight bearing is recommended until x-rays indicate callus formation [6]. This is contrary to the preclinical evidence that callus formation is a product of interfragmentary motion [7]. Locking plates can inherently produce stiff constructs that have been known to suppress fracture healing [3, 8].

Biphasic plating is a new plating concept that was proposed by the AO Research Institute Davos (ARI) in collaboration with the Queensland University of Technology (QUT) in Brisbane, Australia, to enhance the existing treatment modalities of locked plating by redesigning the conventional bone plate. On April 21, 2021, the Biphasic Plate DF (Distal Femur) obtained the CE certification as a class IIB medical device. This achievement represents an impressive team effort, made possible by AO's innovation funding of the AO ITC Technology Transfer.

Solution

The Biphasic Plate DF features a transverse slot in a region of increased plate thickness (Fig 2). This new plate design:

- Provides a beneficial and controlled mechanical environment at the fracture site for robust fracture healing (Fig 3)
- Increases implant strength which carries potential to permit full early weight bearing and prevent implant fatigue-related plate failure
- Standardizes; thus, simplifies the surgical procedure



Fig 1 Biphasic Plate Distal Femur.

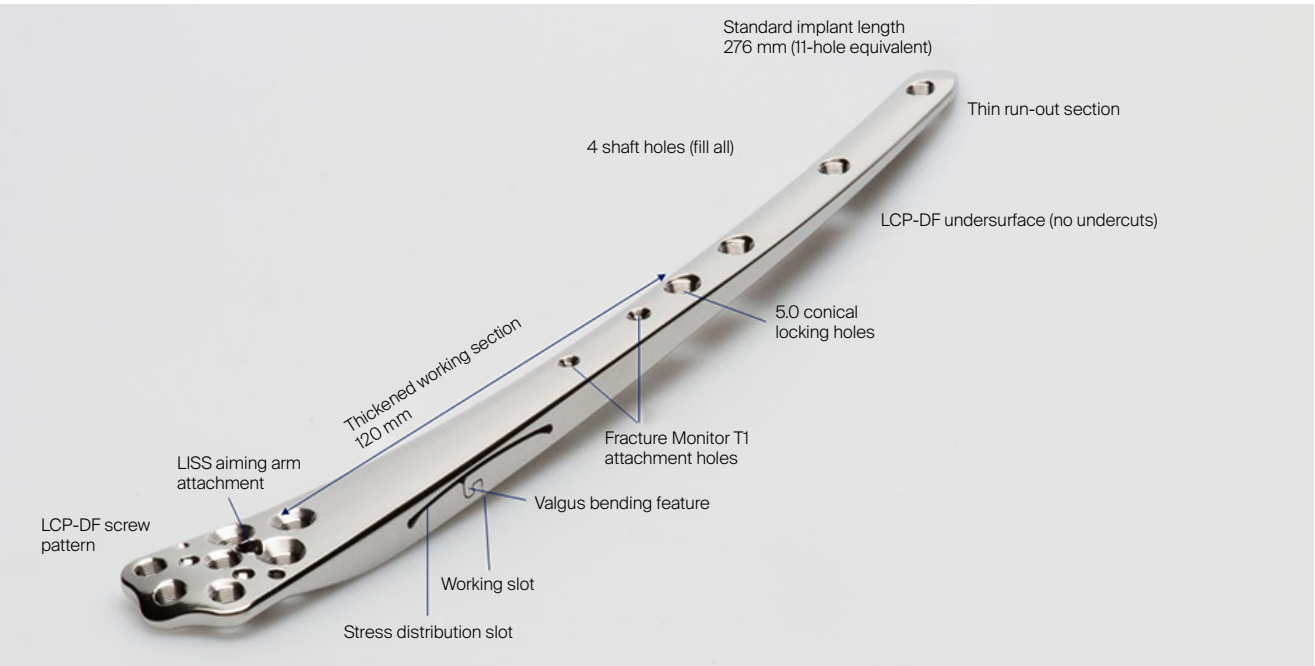


Fig 2 Features of the Biphasic Plate Distal Femur.

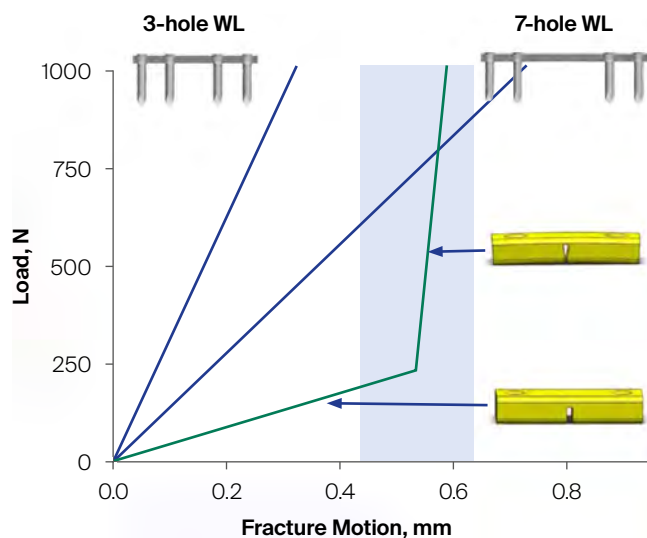


Fig 3 Standard locking plates produce variable fracture motion depending on the working length, whereas the Biphasic Plate provides controlled fracture motion over a wide load range. The light blue area represents the desired fracture gap motion for optimal bone healing.

Indications

The Biphasic Plate DF is indicated for the stabilization of distal femoral fractures, which include:

- Distal shaft fractures
- Supracondylar fractures
- Intraarticular fractures
- Periprosthetic fractures

Preclinical testing

Preclinical results confirmed the feasibility of the biphasic plating concept [9]. Sheep tibia osteotomies stabilized with a biphasic plate prototype showed robust callus formation without implant failure under various simulated fracture conditions [9]. A finite element analysis revealed that the biphasic plate exhibited a bilinear stiffness response; at low loads, the biphasic plate construct was 55% less stiff and at high loads 476% stiffer than the locking compression plate for the distal femur (LCP-DF) [10]. The biphasic plate provided more consistent interfragmentary movement over a wider loading range [10]. Subjected to dynamic loading, the LCP-DF failed on average

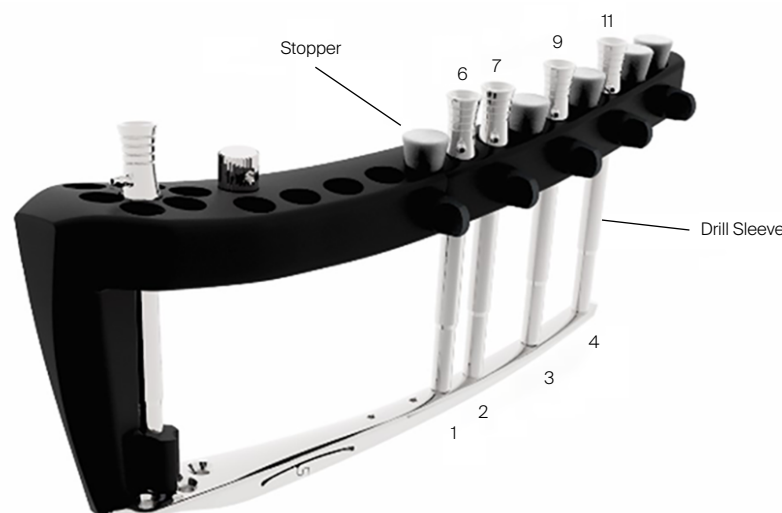
after 322,369 cycles (standard deviation: 57,345), whereas none of the four tested biphasic plates showed any sign of failure at 1,000,000 cycles [11].

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Instruments

The Biphasic Plate DF is designed to be compatible with existing 5.0 mm DePuy Synthes locking screws (stainless steel) and insertion instruments for the LCP-DF.



Clinical cases

Clinical cases from Christoph Sommer (Kantonsspital Graubünden, Chur, Switzerland)

Case 1

A 64-year-old man was involved in a car injury and sustained a complex floating knee injury with a comminuted distal femoral

fracture and a proximal tibial fracture on the left side among various other fractures (Fig 1).

The distal femoral fracture was fixed 3 weeks after injury with ORIF and a Biphasic Plate DF (Fig 2).

The patient healed and returned to preoperative function (Fig 3).



Fig 1 Computed tomographic scans and x-rays revealed the complex floating knee injury of the left leg.

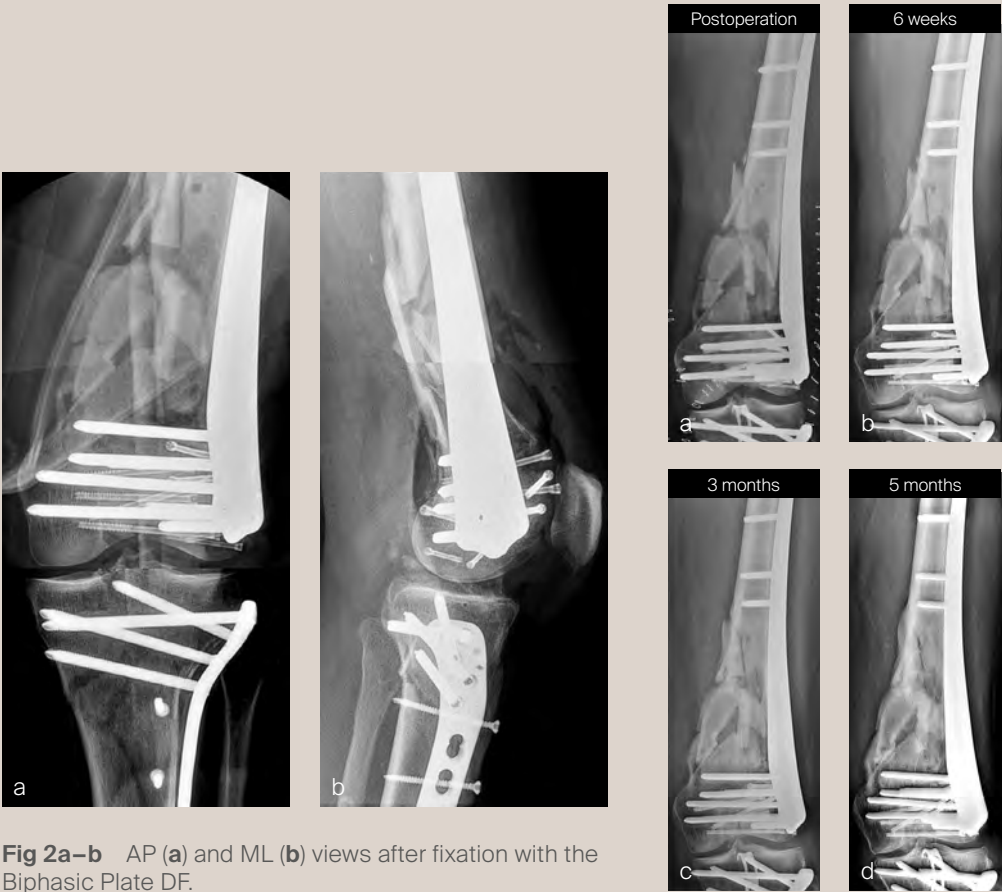


Fig 2a–b AP (a) and ML (b) views after fixation with the Biphasic Plate DF.

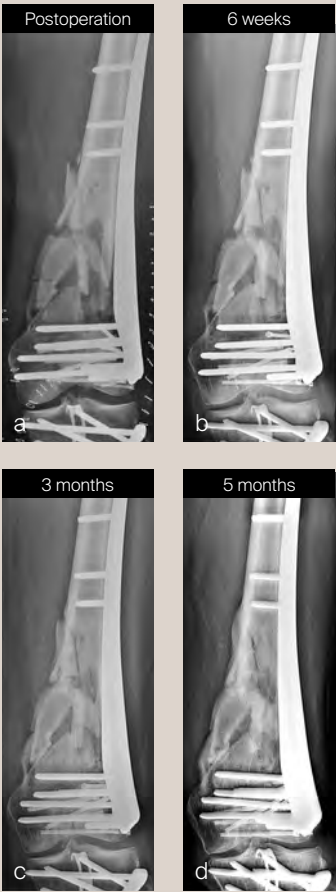


Fig 3a–d Healing progression is visible on AP x-rays over the course of 5 months.

Case 2

An 82-year-old man fell while climbing and sustained a periprosthetic distal femoral fracture (Fig 4). The fracture was reduced and then fixed with a Biphasec Plate DF (Fig 5). The patient was allowed immediate full weight bearing and presented with a decent amount of callus at the fracture site after 6 weeks (Fig 6).

The patient showed uneventful healing and returned to pre-operative function 2.5 months postoperation. Figure 7 shows the callus formation 3 months postoperation.



Fig 4a–b AP (a) and ML (b) x-rays of the distal femoral fracture.



Fig 5a–b AP (a) and ML (b) views after fixation with the Biphasec Plate DF.



Fig 6a–b AP (a) and ML (b) x-rays showing the formation of callus at 6 weeks postoperation.

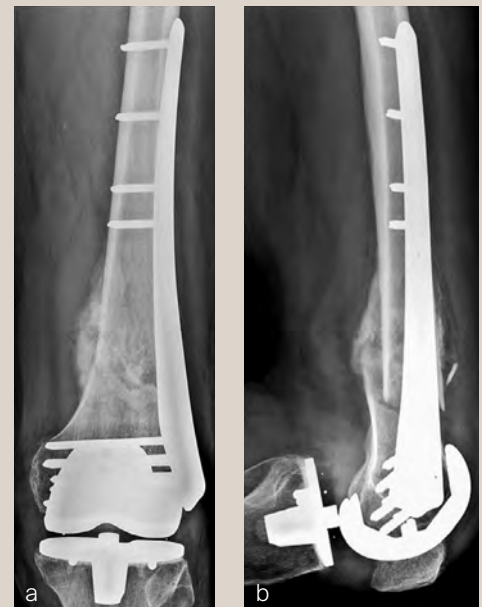


Fig 7a–b AP (a) and ML (b) x-rays showing the formation of callus at 3 months postoperation.

MAXFRAME AUTOSTRUT

MAXFRAME AUTOSTRUT™ Multi-Axial Correction System is a first-of-its-kind fully automated hexapod ring-fixation system. It provides a solution to the drawbacks of hexapod external ring-fixation treatment by automating the strut adjustment process. Patients no longer need to manipulate the struts, leading to a superior experience throughout the treatment, and reducing the risk of negative clinical outcomes caused by unintended strut adjustments.

It further enables smaller, more frequent actuations, up to 20 times per day. This may be better for the surrounding soft tissue, reduce pain, and improve the quality of the bone regenerate vs larger and less frequent strut adjustments.

The multiaxial correction system MAXFRAME™ has now firmly established itself as an integral part in the treatment of any bone deformity, be it posttraumatic, infectious, or congenital in origin.

The implementation of new hardware components, such as the previously presented linear struts, have again increased the versatility and stability, and made the application simpler. The temporary use of the polyaxial struts is particularly helpful in the case of a strut change, as they guarantee high stability while performing a strut change and are easy to install (Fig 2).

An update was also carried out on the software side, seamlessly compatible with previously created treatment plans and allowing direct transfer to the new software. The current web-based user interface can be accessed on <https://www.maxframe3dii.com>.

The new software version addresses and integrates the innovative new hardware components MAXFRAME AUTOSTRUT. It enables full automation of strut adjustments through motorized struts and provides a solution to various drawbacks of a traditional hexapod external ring-fixation treatment.



Fig 1 MAXFRAME AUTOSTRUT control system and 6 MAXFRAME AUTOSTRUT hexapod struts assembled on MAXFRAME rings.

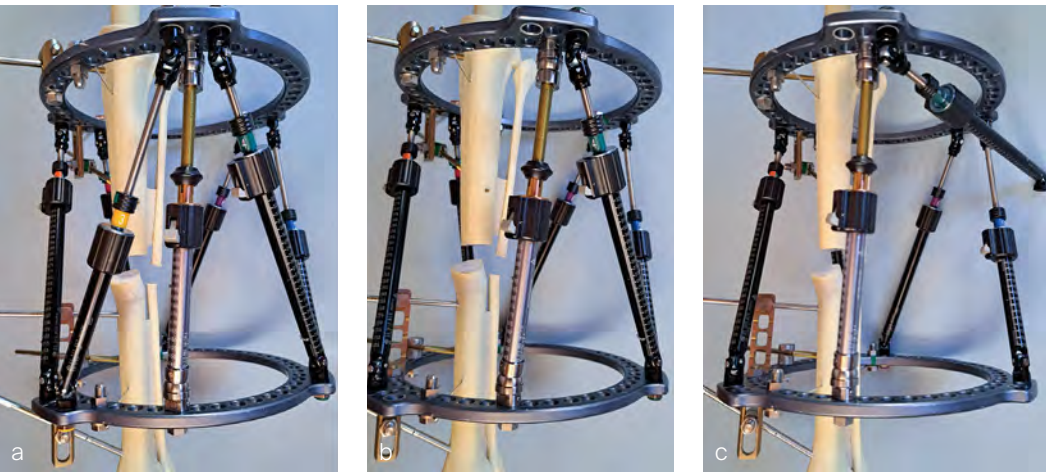


Fig 2a–c Polyaxial strut for planned strut change demonstrated on a bone model: Goal; changing strut 3 (yellow ID band) and strut 4 (green ID band).
a Polyaxial strut is mounted and locked between strut 3 and strut 4.
b Strut 3 is removed and frame is still stable.
c Strut 4 is also removed and even now, the frame is still stable because of the blocked cardan joints.

MAXFRAME AUTOSTRUT allows more frequent actuations and higher distraction rates, which may improve callus formation. Simultaneously, it takes into consideration the surrounding soft tissue and nerves, which experience a gentler distraction process when using MAXFRAME AUTOSTRUT vs manually operated struts. Patient discomfort and pain may be also reduced using a larger number of adjustments per day with smaller actuation steps. Currently, up to 20 steps per day are possible. Closed nonunion treatment particularly benefits from this increase in cycles per day while at the same time not increasing demands on manipulations executed by the patient. The system operates completely autonomously and fully automated, not even requiring recharging throughout a treatment.

It is a preference for surgeons and patients not to be concerned with strut adjustments, especially during the night. This is achieved with MAXFRAME AUTOSTRUT. Automated strut adjustments may further reduce the risk of negative clinical outcomes caused by unintended or wrong manipulation.

MAXFRAME AUTOSTRUT may additionally allow surgeons to evaluate the progressing stability during the bone-healing phase. Consequently, it is possible to better estimate the load-bearing capacity of the bone at a certain stage of treatment, and potentially allow an earlier removal of the hexapod frame.

The original [MAXFRAME hexapod system](#) with the existing software is fully compatible with MAXFRAME AUTOSTRUT.

Specific features and benefits in detail

MAXFRAME AUTOSTRUT System consists of both hardware and software components as follows:

- Hexapod Struts available in three sizes: short, medium, and long (Fig 3)
- Automated Hexapod Control System Kit. Control system consists of control unit with a wired connection to six motorized struts (Fig 4)
- Software allowing physicians to download the treatment plan to the device, chart patient progress and, if required, adjusting the treatment plan and schedule (Fig 5)
- Accessories



Fig 3 MAXFRAME AUTOSTRUT hexapod struts without motor; struts are attached to frame rings in the operating room or by pre-assembling the frame preoperatively.



Fig 4 Control system elements (transducer/interface and motors).

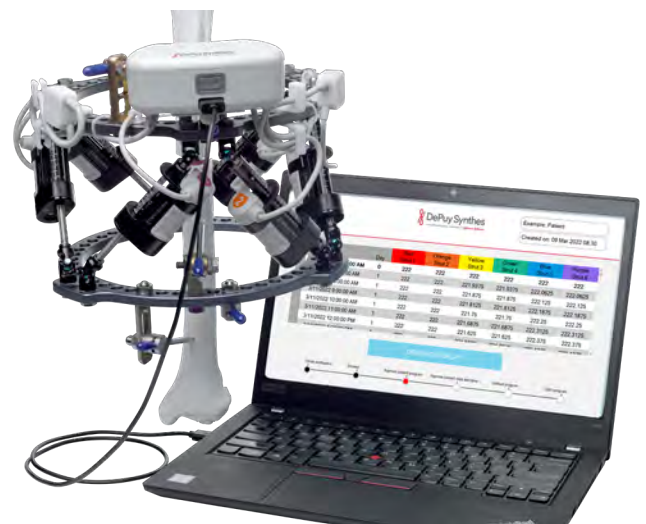


Fig 5 Control system connected with Laptop (offline mode) for system function test and treatment plan upload.

Main indications

A. According to the disease/problem:

- Bone transport
- Lengthening
- Rotational corrections
- Multiaxial corrections
- Nonunions (cycle treatment)

B. Conforming to the patient ability:

- Patients with limited manual ability
- Elderly patients
- Noncompliant or only partially compliant patients
- Children

Operating system and computer hardware:

MAXFRAME AUTOSTRUT Software is provided on DPS workstations—the surgeon does not need to understand the operating system. There are some requirements for MAXFRAME 3D II.

For more information and the physician user manual, refer to <https://www.orthospin.com/>

(Case provided by J Spence Reid, Penn State Health Milton S. Hershey Medical Center, Pennsylvania, USA.)

- 47-year-old woman s/p separate femur and tibia trauma
- Valgus knee with external rotation through femur
- Deformity analysis revealed that the angular deformity was coming from her proximal tibia.

The treatment plan was to remove the femoral intramedullary (IM) nail and to perform a derotational osteotomy of the femur with an internal saw and then to refix the femur with a new antegrade IM nail.

The tibial deformity was planned to be managed with a MAX-FRAME AUTOSTRUT™.



Fig 6 Preoperative standing alignment film.

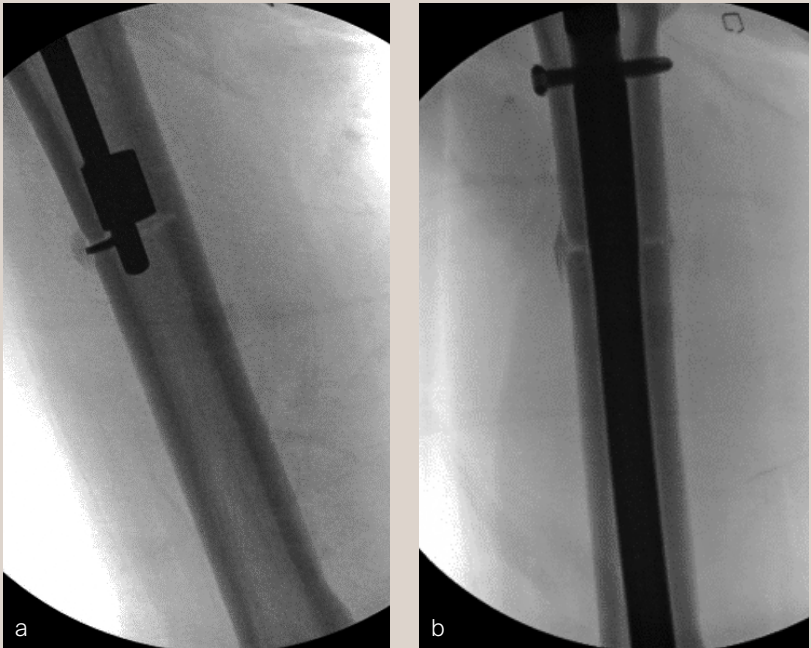


Fig 7a-b The use of the intramedullary saw (a) and the new antegrade intramedullary nail (b) in the femur.

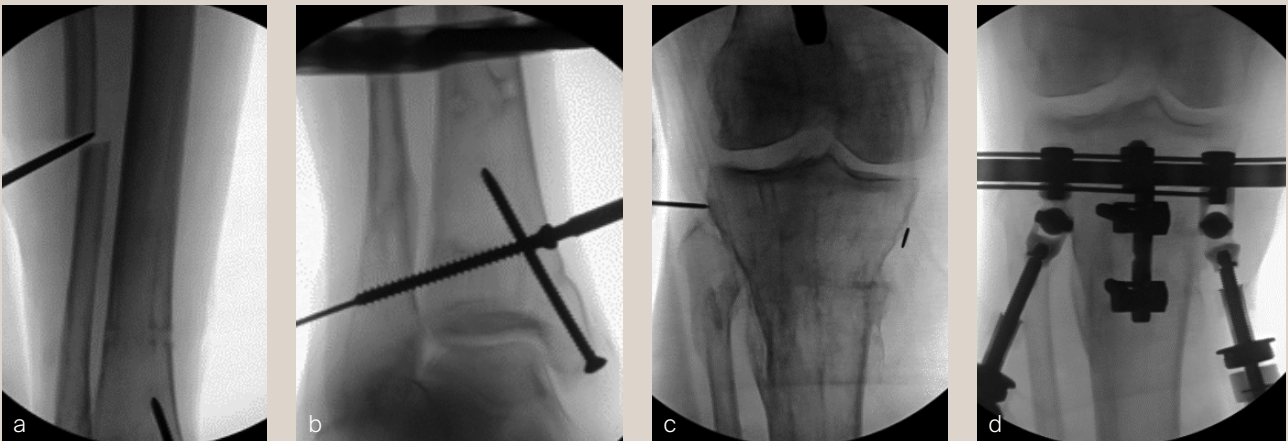


Fig 8a-d Management of the tibial deformity: Creation of the fibular osteotomy (a); tibia/fibula stabilization using a cannulated screw (b); level of the proximal positioning wire for the first proximal ring; optimally placed in parallel to the tibia plateau (c); the definitive position and fixation of the frame with the proximal part and the master tab in front. Recognize the sagittal fixation with two Schanz screws between struts 1 and 2; this is possible because the rings allow different (non-default) strut attachment points (d).

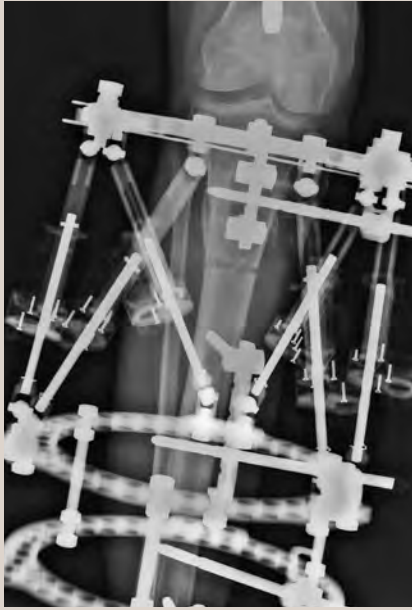


Fig 9 The three-ring MAXFRAME construct at the tibia. The Gigli saw technique was used to create the proximal tibial osteotomy. Additional stability is provided by extra Schanz screws.

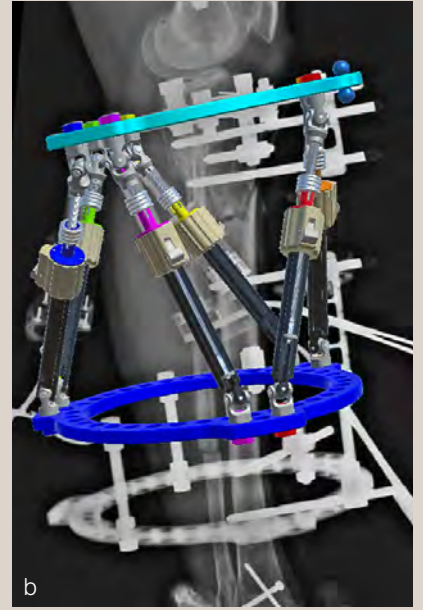
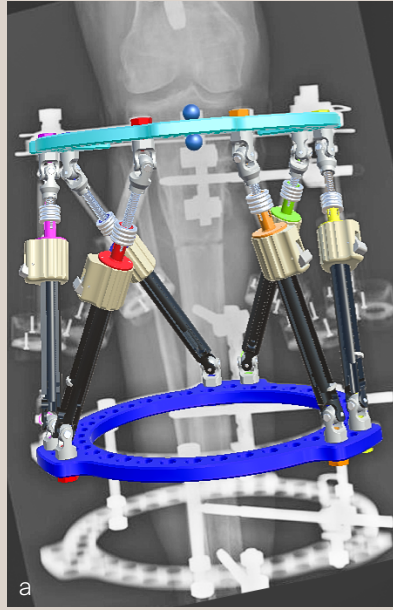


Fig 10a-b Using the Perspective Frame Matching feature in the planning software, the frame configuration is imported into the software.

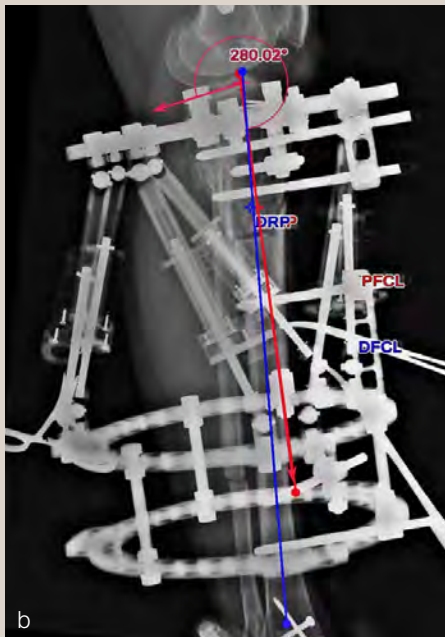
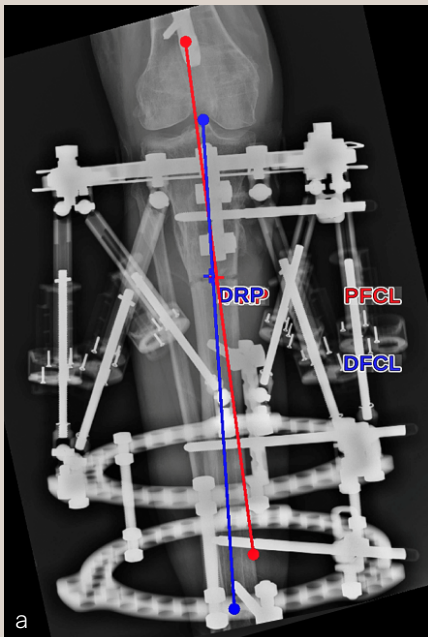


Fig 11a-b Deformity analysis with the help of the Perspective Frame Matching software. PRP indicates proximal reference point; DRP, distal reference point; PFCL, proximal fragment center line; and DFCL, distal fragment center line.

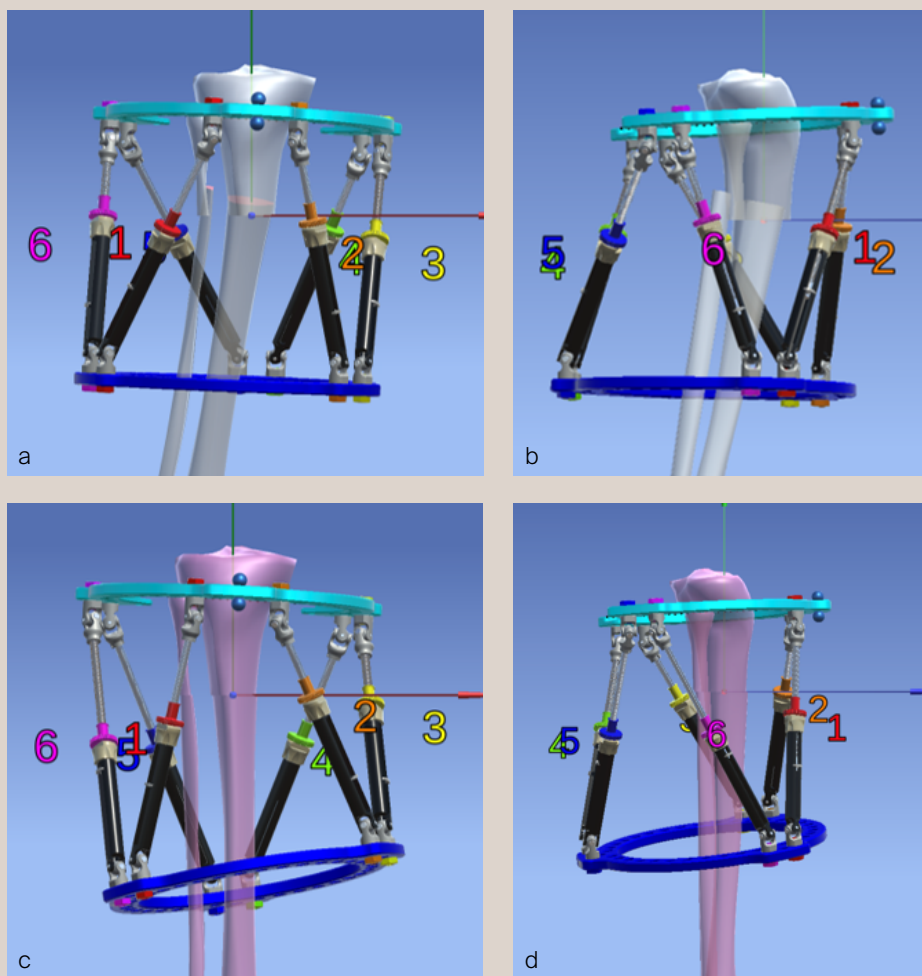


Fig 12a–d 3D simulation of the MAXFRAME initial configuration and bone position in the AP (a) and lateral view (b). The bone is overlapping at the osteotomy level since a lengthening was planned. MAXFRAME configuration and bone position at the end of the correction in the AP (c) and lateral view (d).

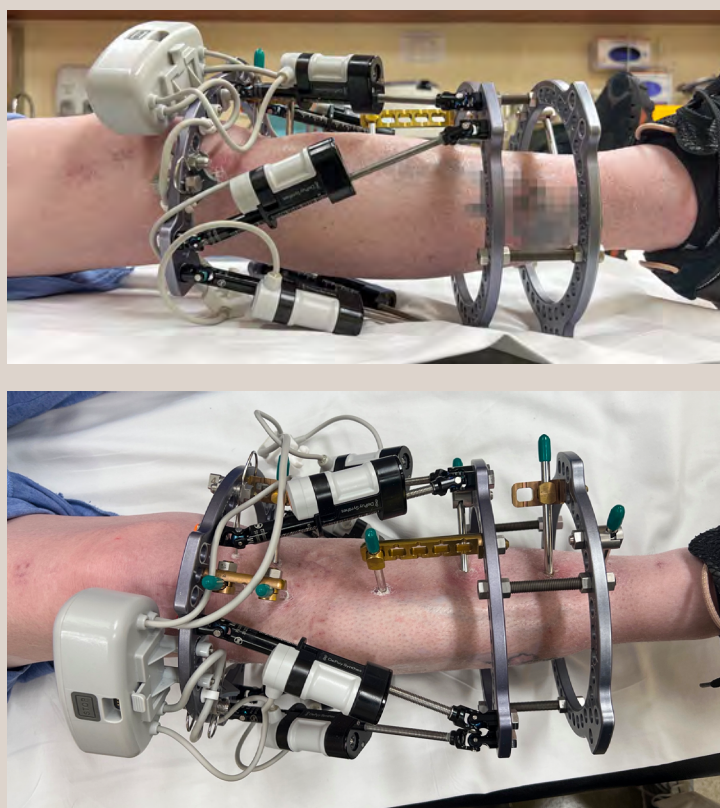


Fig 13 Clinical situation at the end of the correction in different views with the AUTOSTRUT System still mounted to the frame.

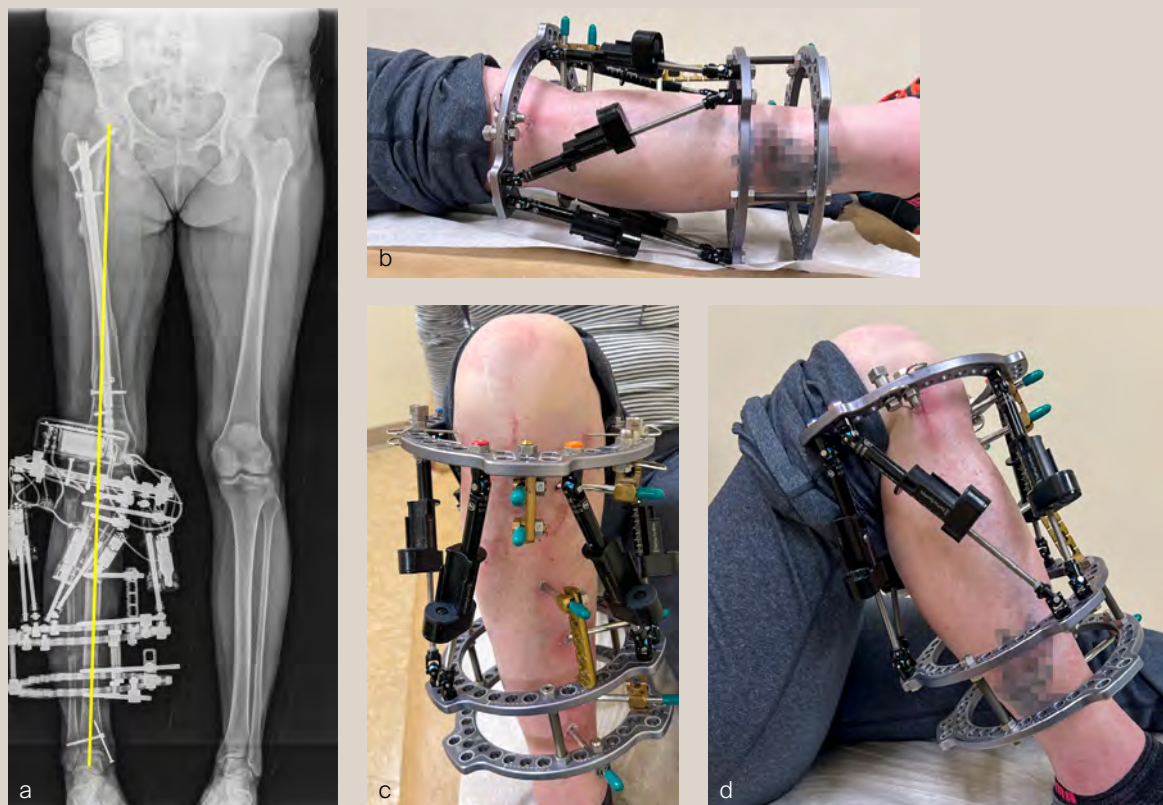


Fig 14a-d Confirmation of the corrected limb alignment on a standing film (a). After confirmation of the corrected limb axis, the AUTOSTRUT motors and control unit were removed. The frame remains mounted for the remaining phase of bone healing (b-d).

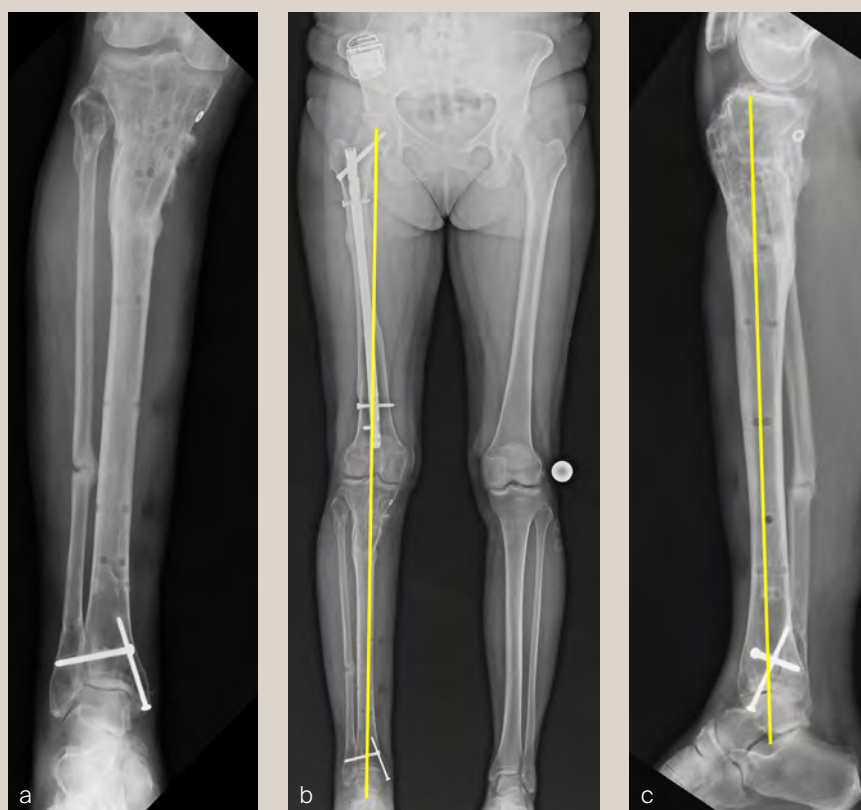


Fig 15a-c Final radiographs after frame removal.

TELIGEN System

Introduction

Minimally invasive surgical transforaminal lumbar interbody fusion (MIS-TLIF) is typically performed using tubular retractors with visualization aided by surgical loupes or a microscope. More recently, endoscopic TLIF has been introduced. In addition to reducing surgical morbidity, endoscopic techniques place the camera within the surgical wound. The angled optics enable the surgeon to “see” around corners which is beneficial when working in the constrained space of a minimally invasive procedure.

In November 2022, the AO Spine Technical Commission approved the TELIGEN™ System, which is indicated for facilitating endoscopic access and visualization in spinal procedures and aims to combine the positive attributes of tubular retractors and endoscopy. It provides surgeons skilled in MIS-TLIF with the advantages of endoscopic TLIF (eg, wide-angle, directed optics placed near the anatomical structures) without the difficult learning curve associated with adopting a completely new skill set.

Clinical problem

Transforaminal lumbar interbody fusion (TLIF) is a common surgical technique performed via a posterior approach with favorable fusion rates [1]. Open TLIF, however, can present clinical challenges, including greater soft-tissue disruption [1], increased complication risk [2–5], slower recovery [6, 7], and variable long-term outcomes, such as greater back pain and disability [7].

The MIS-TLIF techniques have evolved to reduce complications seen with open TLIF [1]; however, they may be linked with certain limitations, such as lack of consistent visualization and

steep learning curve [8], and occupational hazards to the surgeon [9,10].

Solution

TELIGEN™ System is a technology platform that facilitates MIS-TLIF procedures through digital tools for visualization and access. Its first clinical application is a beginning-to-end procedural solution for MIS-TLIF surgery (DePuy Synthes VueLIF™-T Procedure). Other enabling technologies, like neuromonitoring and navigation, can be integrated into the workflow.

TELIGEN™ System overview/instruments

The system components are centrally controlled from the TELIGEN Digital Control Center (tower). Included in the tower are the monitor, the camera control system (CSS), the camera wash box with foot pedal control, and the vacuum pump for discectomy (Fig 1).

The TELIGEN HD CCS operates the TELIGEN™ Camera, which is used for illumination and visualization of the surgical site. The image collected at the TELIGEN™ Camera is transferred to the CCS and then displayed on the monitor.

The TELIGEN™ Camera provides an opportunity to see beyond the boundaries of the port. Placing the camera at the distal end of the port enables line of sight past the edge of the port, expanding the field of view of the surgical site. Visual interference from the surgical instruments is reduced compared to traditional visualization methods (eg, surgical microscope, loupes, exoscope). The camera has a field of view (FOV) of 70°, direction of view (DOV) of 22.5°, and a depth of field (DOF) of 8–120 mm (Fig 2).



Fig 1 Monitor (32" Medical Display 4K Mo 32" Medical Display 4K Monitor) and Camera control system (CSS). Camera wash box with foot pedal control.

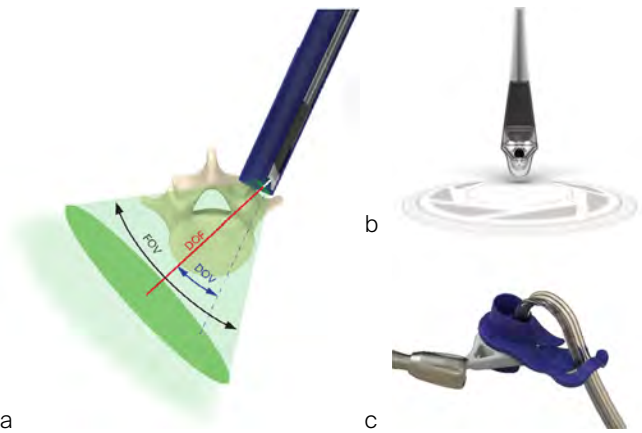


Fig 2a–c
a Field of view (FOV), direction of view (DOV), and depth of field (DOF).
b Camera.
c Cable wing of the port holder.

Two LEDs located near the tip of the camera provide light across the field of view.

The camera is self-retained in the channel of the port allowing for hands-free use. The camera cable is held by the cable wing of the port holder, securing the camera's position, and preventing interference within the surgical workspace. This allows for bimanual control of instruments during the procedure.

The camera view can be rotated around the access port axis during the procedure. After the camera is rotated within the patient, pressing the corresponding clock position on the CCS's user interface will match the on-screen orientation (Fig 3).

The TELIGEN™ **Camera Wash Box** assists the surgeon in maintaining a clear visual field during endoscopic spine surgery by cleaning the lens of the camera. The camera lens and surgical site can be irrigated in-situ without removal from the working channel. The cleaning cycle is activated by foot pedal or from the CCS touchscreen.

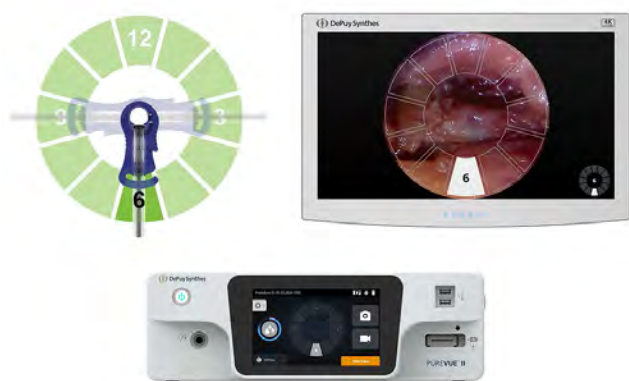


Fig 3 The on-screen view can be adjusted when the camera is rotated for ease of orientation.

TELIGEN™ comes with a **disposable procedure kit** and a **set of reusable instruments**. The contents of each of these sets may vary in some markets. These components are designed to facilitate the entire procedure beginning to end introducing procedural efficiencies along with features that are complimented using the TELIGEN™ camera.

VueLIF-T™ Procedure Kit contains sterile, single-use instruments to allow for access, visualization, discectomy, and graft delivery. It includes the camera, ports, and port holder, TELIGEN™ Clear (MIS discectomy device, former CONCORDE Clear), soft-tissue retractor, port cutter cartridge, and bone graft delivery instruments (Fig 4).

The set of reusable instruments include table mounting instruments, dilators, port adjuster and port cutter, graft delivery cannula, suction tubes, and Kerrisons, etc (Fig 5).

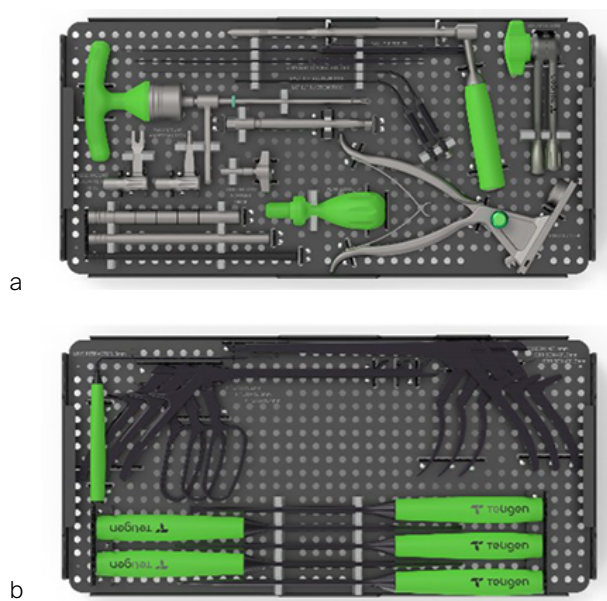


Fig 5a-b Set of reusable instruments.



Fig 4 VueLIF-T™ Procedure Kit. Sterile instruments for MIS-TLIF procedures.

The head-up display allows surgeons to maintain **ergonomic posture** during procedures (Fig 6) [11]. This may help avoid significant musculoskeletal pain commonly reported by spine surgeons, especially low back and neck pain [12,13].

Conclusion:

TELIGEN™ System provides an advanced visualization experience and will first be applied to MIS-TLIF. The system is intended to provide minimally invasive access to the spine without the difficult learning curve associated with the adoption of full endoscopic surgery.

The heads-up display allows surgeons to maintain an ergonomic posture during the procedure. Furthermore, this visualization and display facilitates teaching of trainees as well as engagement by operating room personnel, potentially increasing operative efficiency.

TELIGEN™ System was thoroughly tested and approved by the Lumbar Degenerative Expert Group (Fig 7).

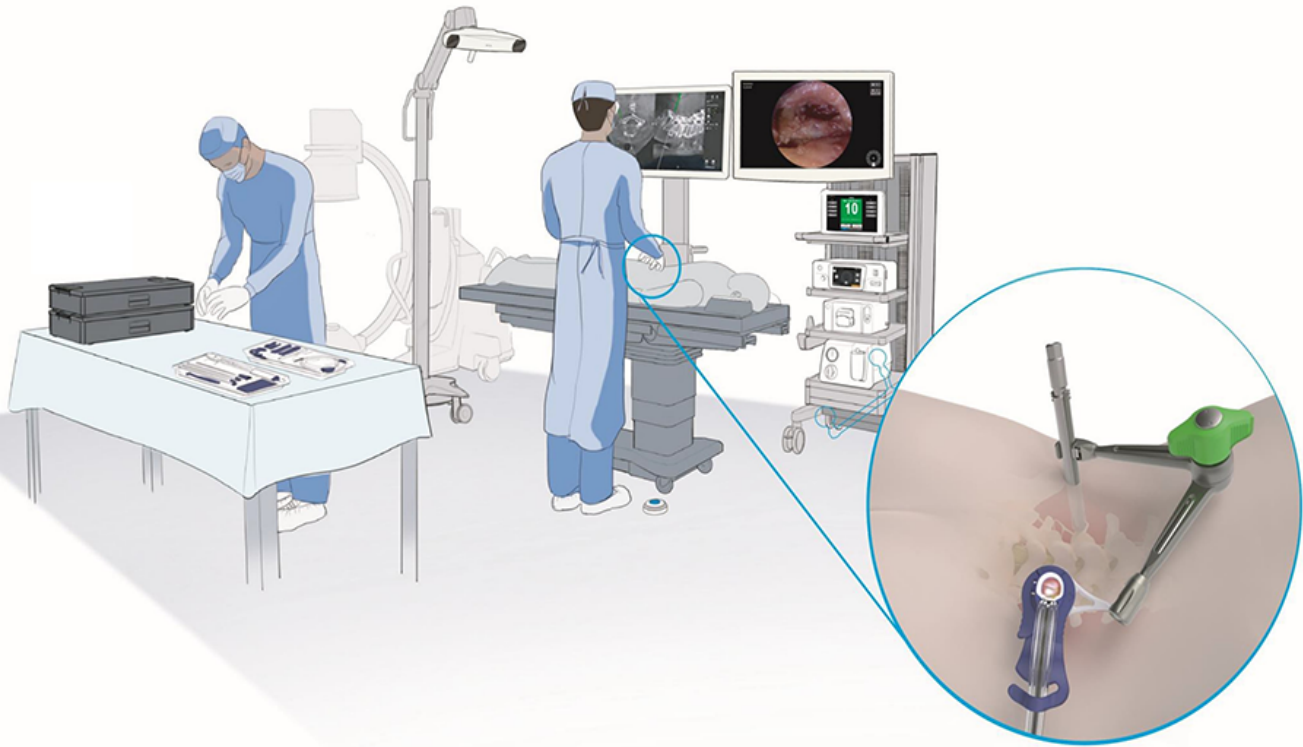


Fig 6 Operating room setup with TELIGEN™.

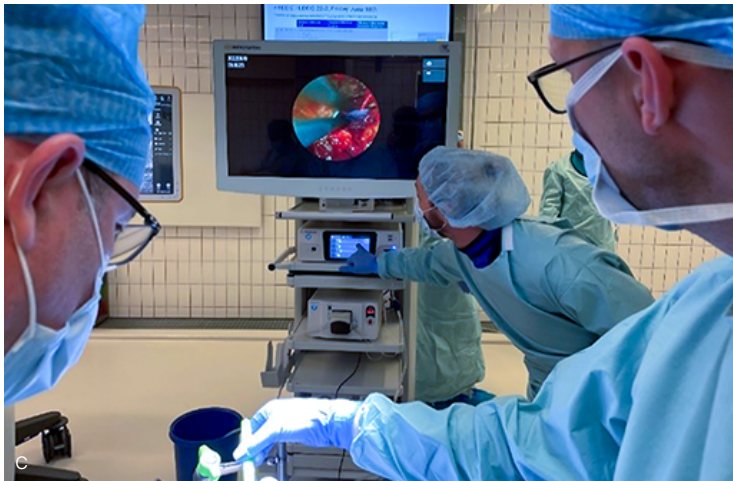


Fig 7a–f Images taken in an anatomy laboratory with the Lumbar Degenerative Expert Group.

Clinical case

This clinical case is from Michael Y Wang, MD, University of Miami Hospital and Sasha Vaziri, MD, Sarasota, Florida, USA.

Case

- A 73-year-old woman
- Severe and worsening low back pain, left lower extremity numbness, and radiculopathy
- Failed multiple rounds of conservative management including epidural steroid injections, physical therapy, and medications

- Imaging revealed L4/L5 spondylolisthesis and a left-sided synovial cyst (Fig 8)
- Diagnosis: lumbar spondylolisthesis and radiculopathy

Surgical treatment: Left L4/L5 VueLIF™ Procedure utilizing the TELIGEN™ System

- Patient-mounted TELIGEN™ tubular access system using a MIS-TLIF approach (Fig 9)
- Discectomy with TELIGEN™ Clear
- VIPER PRIME™ Screws and CONCORDE™ Bullet Interbody Cage (Fig 10)

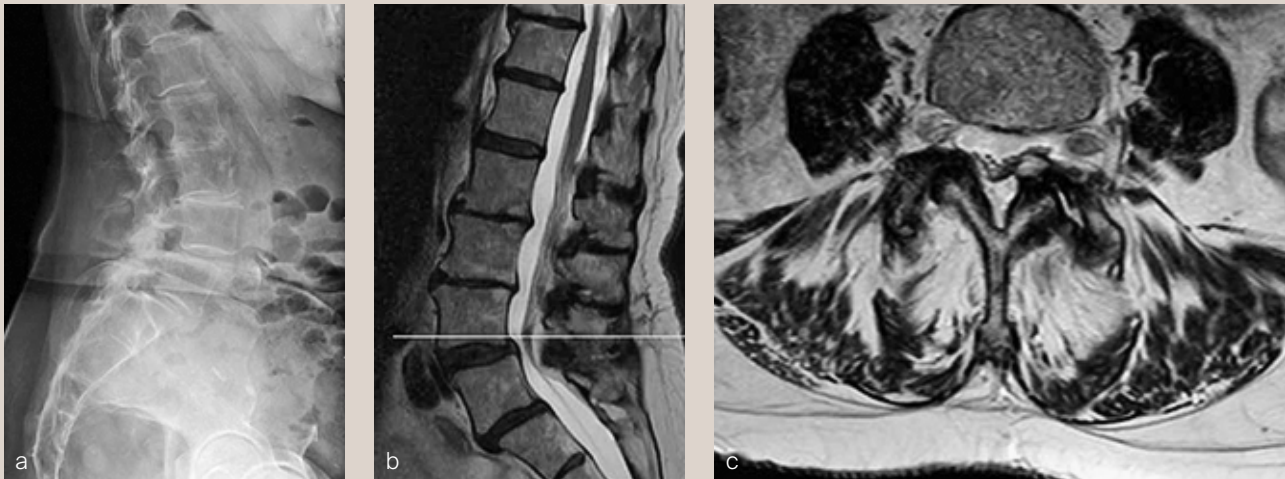


Fig 8a–c

a Preoperative standing radiograph reveals mobile spondylolisthesis at L4/L5.

b–c Preoperative magnetic resonance imaging demonstrating left sided synovial cyst and spondylolisthesis at L4 L5.

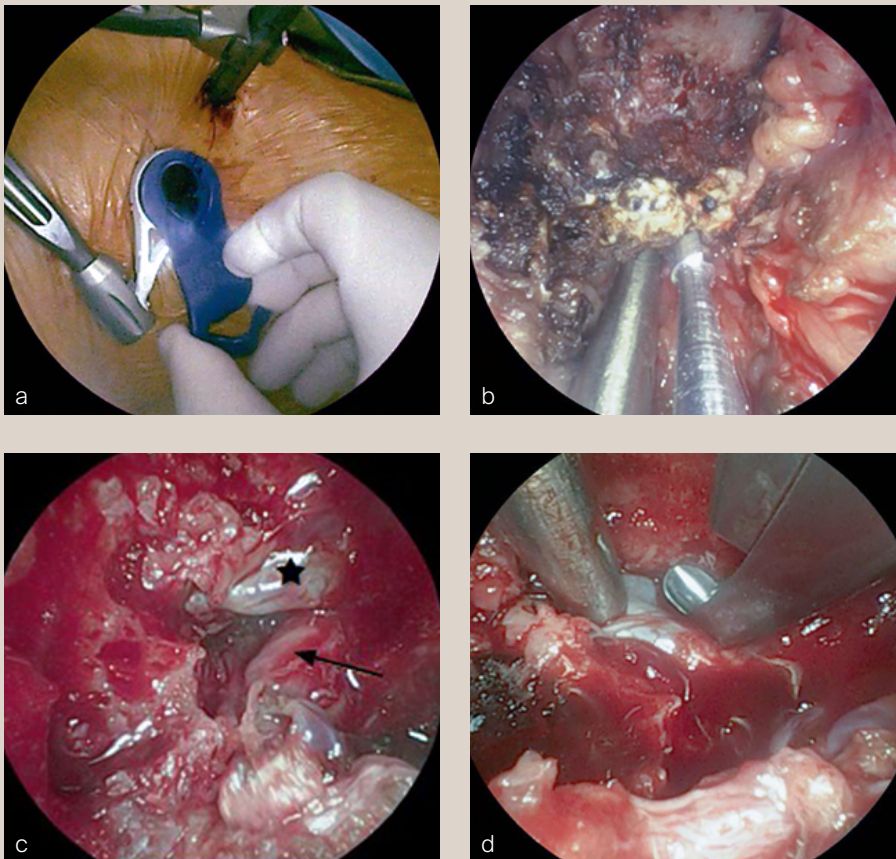


Fig 9a–d Intraoperative images using the TELIGEN™ Camera System.

a Patient-mounted TELIGEN™ tubular access system. Port is mounted to a VIPER PRIME™ pedicle screw.

b Standard drill is used to remove facet through the TELIGEN™ 15 mm port. Camera is located at the distal end of port which reduces visual interference from surgical instruments vs traditional methods (ie, surgical microscope, loupes).

c View of Kammin's Triangle with the thecal sac (star) and exiting nerve root (arrow).

d Central decompression performed with the thecal sac visualized below the Kerrison.

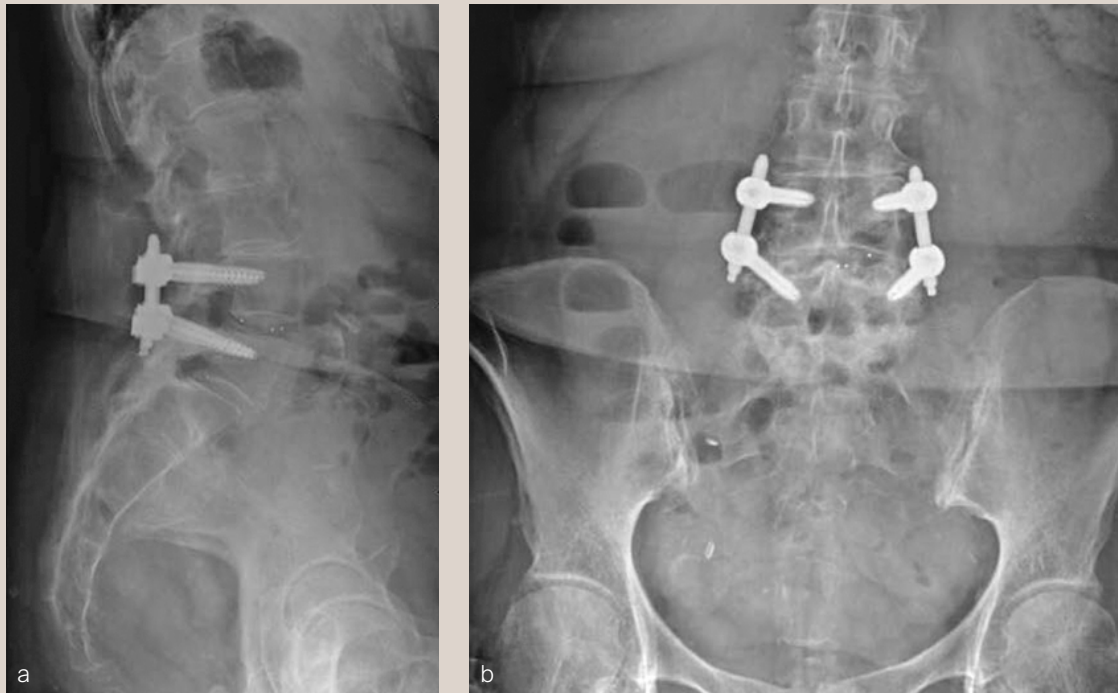


Fig 10a–b Postoperative radiographs.

- a** Lateral view.
- b** AP view.

Outcomes

- The patient did well and stayed one night at the hospital.
- At the 6-week postoperative follow-up she was pain free.

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ALTALYNE Ultra Alignment System

Introduction

Scoliosis is an abnormal curvature of the spine, and adolescent idiopathic scoliosis (AIS) is the most common spinal deformity in the pediatric population, with a worldwide prevalence ranging from 0.47% to 12% [1–7]. Surgical treatment of AIS traditionally involves 3D correction with rods and fusion of the spine.

Intraoperative rod flattening is a common challenge faced by surgeons which often results in failed kyphosis restoration and a suboptimal postoperative sagittal profile.

The ALTALYNE Ultra Alignment System is designed to specifically address the challenges of intraoperative rod flattening and its high bending yield strength helps maintain its rod contour to restore the ideal thoracic kyphosis for patients.

Background

Restoration of ideal thoracic kyphosis is a significant challenge in adolescent spinal deformities, and in particular AIS because of its inherent thoracic lordotic sagittal profile. Rods with a higher bending yield strength are more resistant to intraoperative flattening, which means the rods can maintain their customized

contour and help surgeons achieve the desired sagittal restoration for their patients [8]. With Ti and traditional CoCr alloys, surgeons tend to select larger diameter rods (6.0 mm) to increase the bending yield strength of the rod and hence sacrifice on profile.

The solution

Through advanced material science using a special Cobalt Chromium alloy (CoNiCrMo), ALTALYNE Ultra 5.5 mm rods provide improved bending yield strength over existing 6.0 mm CoCr rods [9]. The higher bending yield strength may result in less rod flattening compared with existing rods with the added advantage of being lower profile.

The forces required to bend rods of different materials and diameters are illustrated in Fig 1. The slope of the curve indicates the stiffness of the rod. The points at which the rod permanently deforms, or bends is the yield strength. Fig 1 shows that ALTALYNE Ultra Rods have a higher bending yield strength compared with other rods. The bending yield strength is 36% higher compared to 6.0 mm CoCr rods and 47% higher compared to 6.0 mm Ti rods (Fig 2) [9].

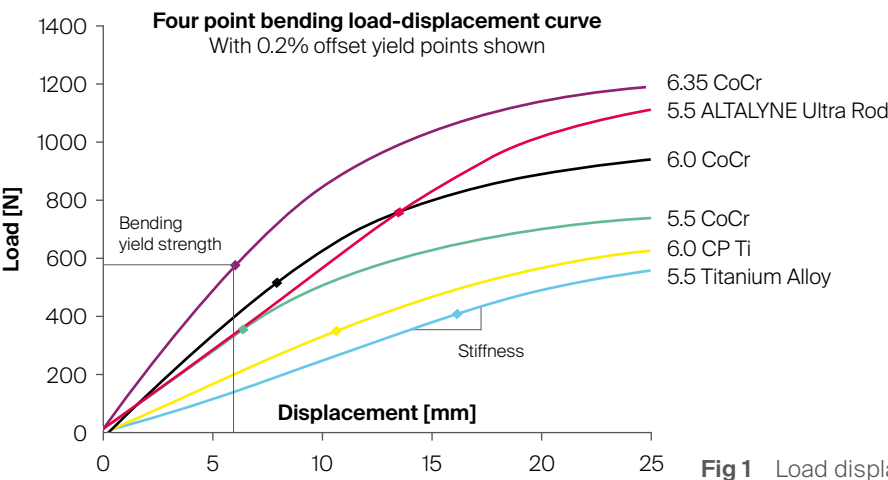


Fig 1 Load displacement curve of different rods.

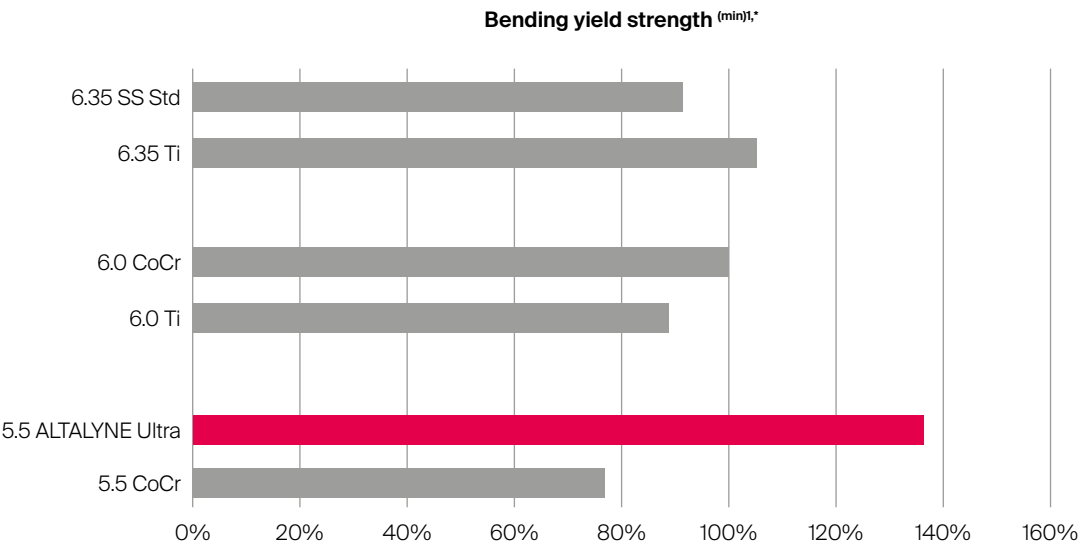


Fig 2 Bending yield strength (force to permanently deform a rod) of different rods.

*All percentages are in comparison to a 6.0 mm CoCr
1. DePuy Synthes Calculation of Bending Yield Strength and Stiffness. July 23, 2021. Adaptiv #103782175 Rev. 1

System overview

The ALTALYNE Ultra Alignment System includes straight and precontoured rods, and the ALTALYNE Ultra French Rod Bender and Tabletop Cutter. Rod Templates are available for estimating rod shape/length.

Rods

The ALTALYNE Ultra Rods are compatible with EXPEDIUM™ 5.5 Spine System and EXPEDIUM VERSE Spine System.

They are available in straight lengths from 120 mm to 600 mm and precontoured (S, M, L, XL) (Fig 3). Clinical literature indicates that rod fractures often occur at notches introduced at the intraoperative bending sites [10]. The ALTALYNE Ultra Rod precontoured configurations require less manual bending than straight rods and reduce notching done intraoperatively.

French Rod Bender and Tabletop Cutter

The force required to cut and contour rods may depend on the rod material selected. In-situ bending is more challenging with CoNiCrMo alloy rods.

To bend and cut ALTALYNE Ultra Rods the instrumentation has been updated, and a dedicated Dual Action French Rod Bender and Tabletop Cutter have been developed (Fig 4). Both instruments have a mechanical advantage over the EXPEDIUM VERSE French Rod Bender (+46%) and the EXPEDIUM Spine System Cutter (+38%) [11, 12].

Conclusion

ALTALYNE Ultra Alignment system provides surgeons with a new treatment option through technologically advanced materials and instrumentation to deliver greater bending yield

strength than traditional rods, and most importantly, the potential for better patient outcomes. The system is expected to help achieve and maintain optimum thoracic kyphosis and improve surgical outcomes in the treatment of adolescent spinal deformities, particularly AIS.

It is important to follow the surgical techniques of EXPEDIUM 5.5 Spine System or EXPEDIUM VERSE Spine System with the ALTALYNE Ultra Rods. Knowledge about different mechanical properties of different rod materials (Ti, SS, CoCr, ALTALYNE Ultra) and their diameters is mandatory for deciding which rod is appropriate.

Limits and contraindications

The surgeon's decision-making process regarding choice of spinal rod material typically involves several factors, including intraoperative material bending properties, postoperative imaging capabilities, clinical experience, and training. Additional patient-specific considerations may include patient age, type, curve stiffness, and bone quality among other factors. ALTALYNE Ultra Rods address the unmet need with intraoperative rod flattening in pediatric spinal deformity surgeries in patients with AIS. Surgeons should be aware that increasing stiffness of the instrumentation in patients with osteoporosis is not recommended.

Do refer to the Instructions for Use (IFU) for more information including a complete list of indications and contraindications.

The rod strength and stiffness should be matched to the patient's bone density in relation to adjacent level failure (PJF – PJK). The treatment of the osteoporotic spine with ALTALYNE rods is not recommended by the AO.



Fig 3 Precontoured rods in different lengths.



a



b

Fig 4a–b ALTALYNE Ultra French Rod Bender and Tabletop Cutter.

Case provided by Firoz Miyanji, BC Children's Hospital, Vancouver, BC, Canada

A 12-year-old girl with AIS underwent T2-T12 posterior spinal instrumentation and fusion.

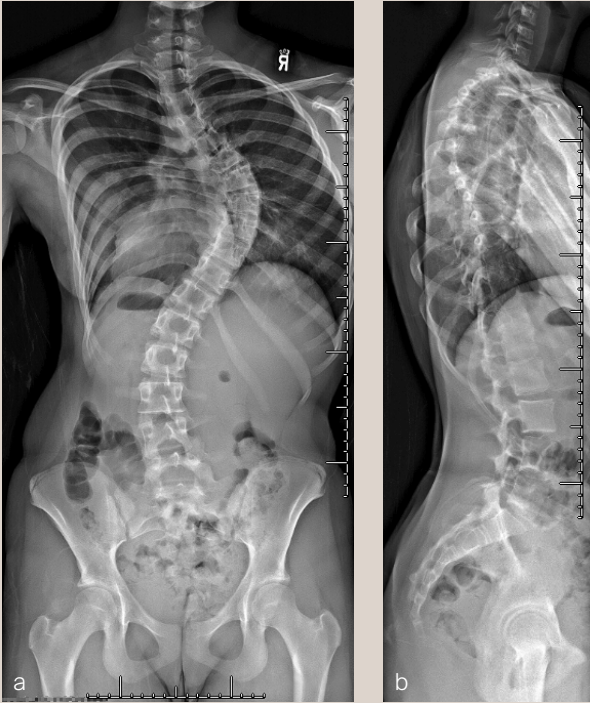


Fig 5a–b Preoperative AP and lateral images.

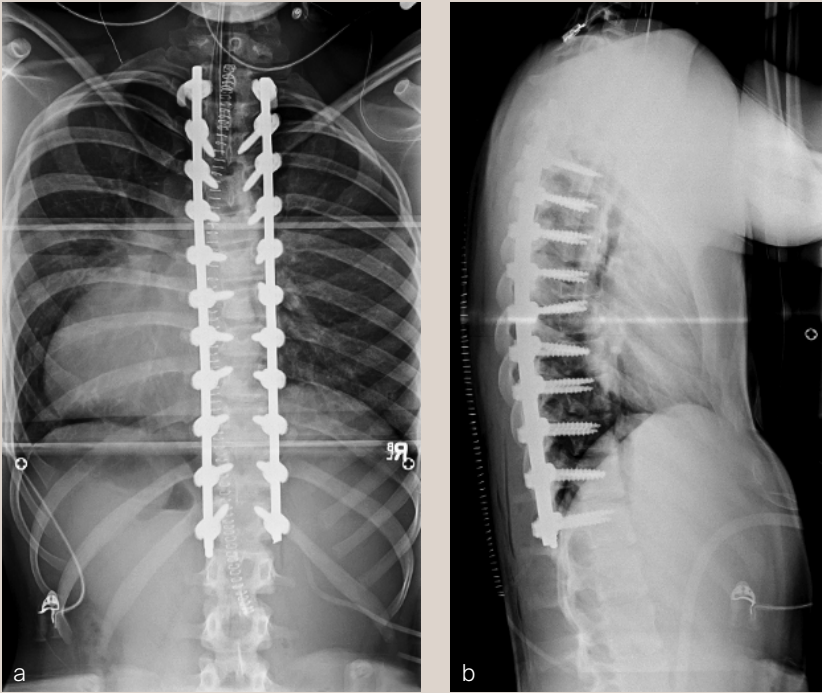


Fig 6a–b Postoperative AP and lateral images.

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Safety and complications associated with cement-augmented pedicle screws—retrospective milestone D report

Introduction and clinical need

With an aging population there is increasing complexity in the treatment of various spinal problems which demand an operative solution. There is a decrease in bone quality resulting in osteopenia and osteoporosis. This may create associated and expected problems of screw pull out, screw loosening, and proximal junctional kyphosis (PJK) or failure (PJF). Preoperative workup and assessment of bone quality is mandatory [1]. This was recently also addressed by the AO Technical Commission Spine in an Osteoporotic Spine Surgery Task Force and recommendations for preoperative workup in elective spine surgery in patients older than 50 years were presented in a [white paper report](#). Still, prevention of PJK and PJF is an ongoing debate for which the ultimate solution has not yet been found. The aim is always to address sagittal alignment and apply secure instrumentation as well as possible. Longer fusion trajectories seem to increase the risk of failure.

What we know is that cement-augmented pedicle screws (CAPS) can be used to provide additional vertebral bone purchase and fixation. A pedicle screw with good purchase will be a pedicle screw that can correct deformity, reduce slip, and maintain vertebral fixation until solid fusion occurs. In the spinal community there is a consensus that augmented pedicle screws are a good alternative in patients with poor bone quality and provide supplementary anchorage compared with traditional nonaugmented pedicle screws ([Fig 1](#)).

The polymethylmethacrylate (PMMA) cement which is used, such as CONFIDENCE™ High Viscosity Spinal Cement (DePuy

Synthes), has excellent adhesive properties, augments the screw-bone interface to prevent screw pull-out, and therefore reduces the risk of screw loosening or failure. Cement-augmented pedicle screws are used both in primary cases and in revision surgery.

The use of CAPS may also be associated with certain risks and potential complications. Cement leakage is one of the most common complications related to cement augmentation. The cement can extravasate into the surrounding tissues, including not intended entry into the spinal canal, and hence compromise the spinal cord, cauda and nerve roots, or damage/invoke blood vessels. This can result in radiculopathy, neural tissue compression, and even vascular compromise and pulmonary embolism. The incidence of cement leakage varies from 6% to 43%, but fortunately leakage is symptomatic in only 0.6–1.9% [2, 3]. During the exotherm-curing process of cement, heat is generated. The heat can cause thermal injury to the surrounding tissues, resulting in neurological deficits, such as sensory or motor dysfunction, radicular pain, and bladder or bowel dysfunction. The risk of thermal injury increases with the use of excessive cement volume [3, 4].

Although cement augmentation enhances screw fixation, there is still a risk of screw loosening, screw migration (2.2%), or screw breakage (0.6%) due to mechanical failure caused by cyclic loading and stress [3, 5]. As with any surgical procedure there is also a risk of infection. The presence of cement may complicate the management of infection due to a potential heightened risk of biofilm formation. Infection incidence is estimated to be 1.1–5.7% [3, 6].

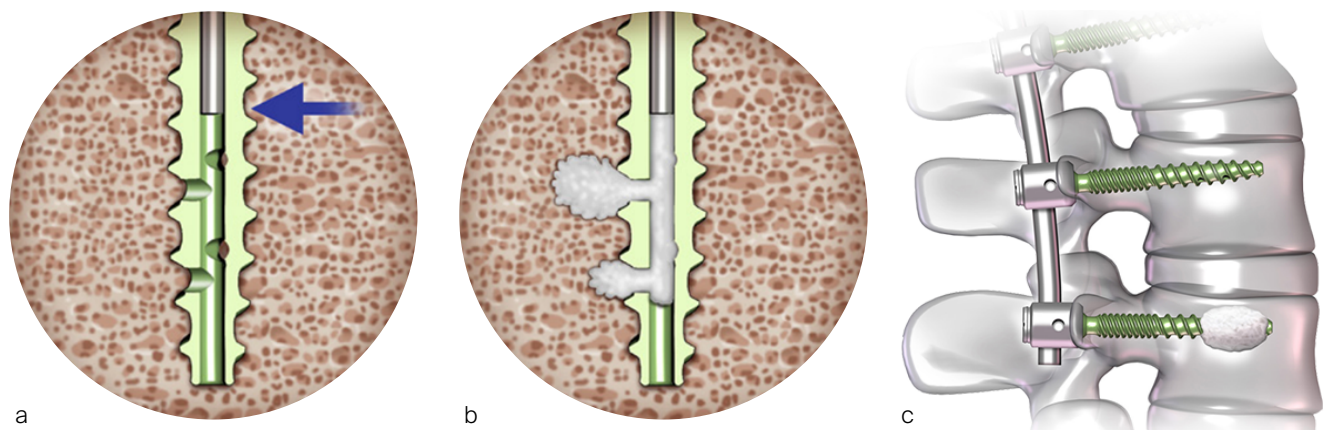


Fig 1a–c Cement augmentation of a perforated pedicle screw.

Material and results

For this Milestone D report, we reviewed 61 patients who had cement-augmented pedicle screw spine surgery between July 2020 and March 2023. In our hospital we use Expedium Verse Advanced Fenestrated Cortical Fix Polyaxial Screws® (DePuy Synthes). The group included 9 men and 52 women with an average age of 62.5 years (range: 31–83 years). Of 61 operations, 19 (31%) were revisions of earlier constructs due to hardware failure or PJK/PJF. The other 42 cases were primary fusions with the need to use cement-augmented screws because of poor bone quality, osteopenia, or osteoporosis. (Table 1) shows the trajectory of fusion in primary and revision surgery. Most cases included five or more fusion levels. In 61 patients we used a total of 464 fenestrated screws. Cement augmentation was used in 233 screws.

	Primary surgery	Revision surgery
1 level	5	3
2 level	4	4
3 level	2	2
4 level	5	2
≥ 5 level	26	8

Table 1 Trajectory of fusion in primary and revision cases.

Cement leakage

We had four cases (four screws) with cement leakage (1.7%). One patient had an anterior vertebral cortical breach due to placement of the screw. Another sustained a lateral breach of the pedicle wall with leakage into the transverse process. In both patients, leakage was noticed during surgery as we always augment each pedicle screw under image intensifier control. Augmentation was ceased the moment leakage was observed.

Two other patients had cement leakage into the neuroforamen which caused motor and sensory dysfunction of the affected nerve root. In retrospect the chosen screw length was too

short for the vertebra; therefore, the most posterior located perforation in the screw was located within the pedicle (Fig 2).

Other complications

Six (9%) of 61 patients developed a surgical site infection. All had a debridement, antibiotics, and implant retention in the operating room and antibiotic therapy for 3 months. There is extensive variability in literature on the incidence of infection after instrumented spine surgery [7]. Zhou et al [7] described an incidence of 6% in degenerative cases (non-instrumented and instrumented combined). The infection risk is higher in instrumented surgery and the risk increases with prolonged surgery and higher amount of perioperative blood loss. Still, 9% infection rate in our series is relatively high, especially compared with our overall institutional spinal infection rate of 2%. This may be due to multiple revisions in these 6 patients (50%) and the long fusion trajectory with large exposure and longer duration of surgery (33%).

Instrumentation failure occurred in 7 (11.5%) of 61 patients. One patient developed loosening of the three most caudal nonaugmented screws in a long fusion construct. Two patients had screw loosening after a proven infection (one of them with augmented screws). One developed screw loosening due to a pedicle fracture. Another had CAPS loosening after traumatic fracture of the L5 vertebral body (Fig 3). Two patients had a screw breakage. In total 3 (0.86%) of 233 cement-augmented pedicle screws in 61 patients failed despite cement augmentation (Table 2).

	Nonaugmented PS*	CAPS*
Screw loosening	1	0
Infection + screw loosening	1	1
Pedicle No. + screw loosening	1	0
Screw breakage	1	1
Vertebral No. + screw loosening	0	1

Table 2 Cases of instrumentation failure in nonaugmented and augmented screws. *PS indicates pedicle screw; CAPS, cement-augmented pedicle screws.

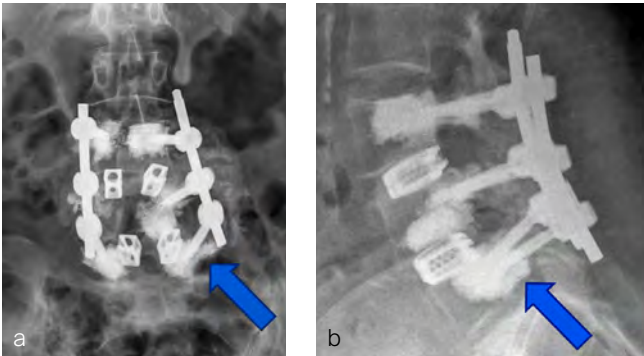


Fig 2a–b Cement leakage into the neuroforamen L5–S1 on the left side.

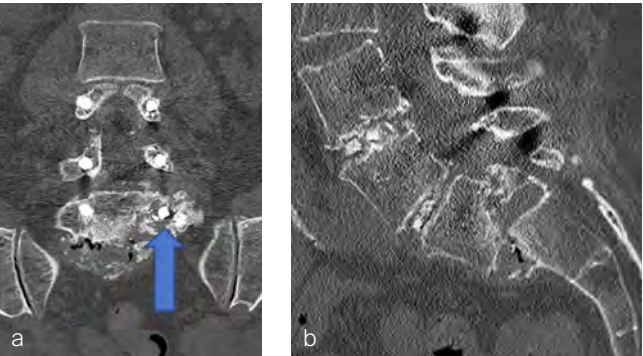


Fig 3a–b Computed tomographic images demonstrating L5 vertebral body fracture and spondylolisthesis with loosening of the L5 cement-augmented screw on the left side.

Clinical case

A 70-year-old woman with adult spinal deformity (ASD) was referred to our hospital for a second opinion. Her medical history included rheumatoid arthritis for which she was given long-term methotrexate therapy and courses of corticosteroids. She presented with a severe degenerative deformity and right L3 radiculopathy. The patient was completely off balance with a right coronal shift and a positive sagittal balance with a SVA of 10 cm+ (Fig 4). Figure 5 reveals full spine images and pelvic parameters. She led a sedentary lifestyle because of the disturbance of balance and back and right leg pain. The patient opted for surgery after a shared decision process and informed consent.

The surgery was planned as a posterior approach to correct the spinal deformity and restore coronal as well as sagittal

balance with direct and indirect decompression of the right L3 nerve root. The preoperative bone assessment and DEXA scan indicated osteopenia and considering her medical history the decision was to use cortical fix screws that also allowed cement augmentation.

We performed a posterior fusion and correction of Th8-S2-SI-Ilium (Fig 6). In Th9, Th10, Th11, and Th12 we instrumented only unilateral pedicle screws due to small pedicle diameters. A S2-SI-Ilium screw was placed on the left side. A supplemental translaminar screw was used at L5-S1 on the right side. We augmented the screws in Th8, Th9, Th10, L2, L3, and L4. Additionally, a TLIF approach was performed on L2-3 and L3-4 with autogenous bone as interbody support. No complications occurred during nor after surgery, and she remained in good balance during the 1-year postoperative follow-up.

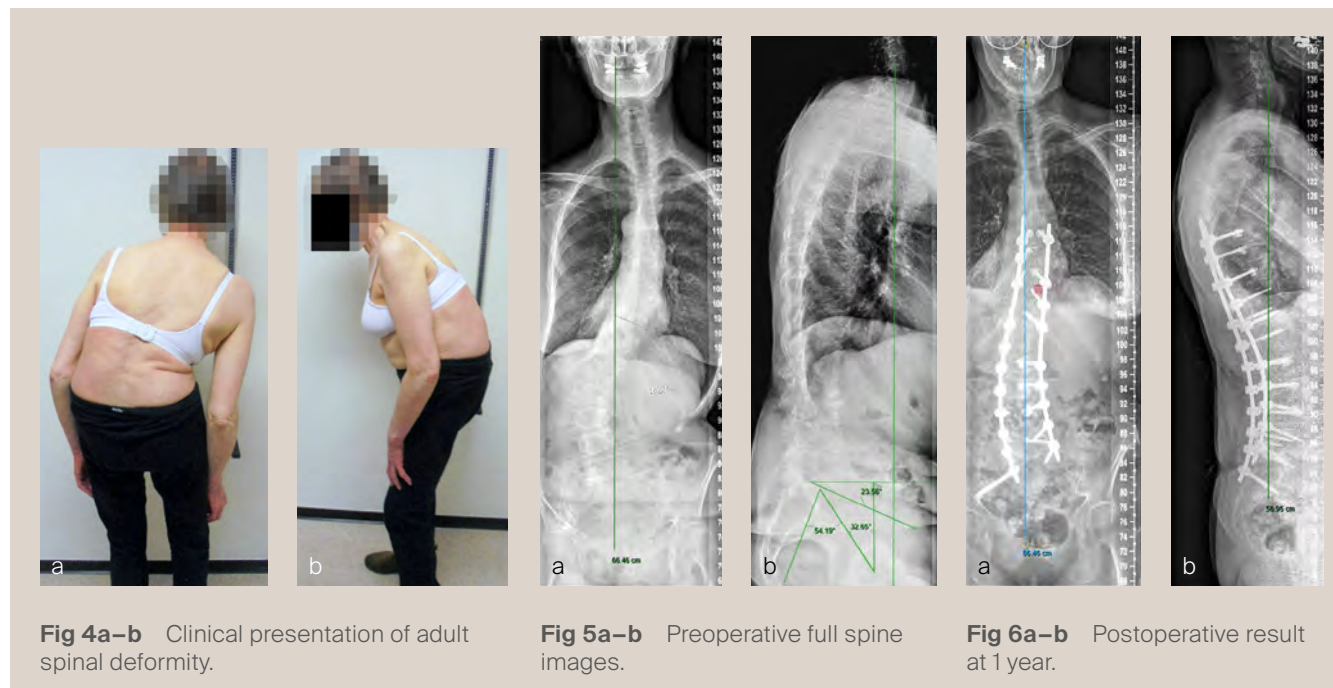


Fig 4a–b Clinical presentation of adult spinal deformity.

Fig 5a–b Preoperative full spine images.

Fig 6a–b Postoperative result at 1 year.

Conclusion

Cement-augmented pedicle screws are effective and safe to use in patients with poor bone quality who require spinal instrumentation. Accurate surgical technique and safe cement augmentation under image intensifier guidance is mandatory. Cement leakage in this Milestone D report is 1.7%, which is low compared with published data. Cement-augmented screw failure is 0.86%. Other complications are not related to this type of instrumentation but to the surgical procedure itself.

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Veterinary Screw Targeting Clamp

Background

A targeted screw placement system permits improved accuracy of screw insertion when used in conjunction with intra-operative imaging. Improved accuracy of screw insertion gives more consistent, confident fracture repair, particularly through minimal invasive approaches and in challenging anatomical locations, such as distal phalanx and navicular bone fractures. It is also a safe and accurate placement of specific screws into subchondral bone cysts close to joint space.

The Screw Targeting Clamp (STC) developed by the AO Technical Commission's Foot and Ankle Expert Group has many useful features for veterinary use. However, available drill guides for the STC do not accommodate the screw sizes frequently used in large animal surgery. Therefore, large animal veterinary-specific sleeves were created for the existing STC to allow placement of 3.5–5.5 mm screws entirely through the STC maintaining alignment.

Details

The Foot and Ankle Screw Targeting Clamp was designed to provide the ability to maintain compression and targeted screw insertion. When evaluated in equine bone, clamp bending was observed on application of the compression function. The aiming arm was modified to improve stiffness for use in equine bone, and sleeves were developed to accommodate the screw sizes used in equine surgery. Angled outer sleeves were designed to secure placement of the STC on oblique bone contour (Fig 1).

With its unique design, the STC will hold a bone fragment in reduction and applies a modest amount of interfragmentary compression to maintain stability of the fragments during the procedure. The STC can be associated with standard bone clamps placed adjacent to it if a stronger compression is needed. It also allows all processes necessary for insertion of a cortex screw in lag fashion to be completed through the clamp, from initial drilling to final screw tightening. Screw sizes supported include 3.5, 4.5, and 5.5 mm screws. An adjustable rail helps to ensure ideal screw placement.

Once the fracture is reduced, the STC is placed using imaging control to verify that the trajectory of drilling and screw placement is precise. With the provided insert sleeves, the screw hole is prepared, and the screw is placed while the STC remains in position to protect the adjacent tissues. The STC aids in retaining interfragmentary reduction throughout the entire process of positioning the cortex screw in lag fashion. Once the fracture is reduced and the clamp confirmed to be in the correct location, screw placement can be completed without further imaging.

Feedback from surgeons who tested the new Veterinary Screw Targeting Clamp stated that a more accurate placement of screws can be achieved, and that the system is more stable than the existing targeting clamp and standard drill guides.



Fig 1 Rendering showing the positioning of the Screw Targeting Clamp (STC) for management of a parasagittal fracture of the third phalanx. Angled outer sleeve allows secure placement of the STC on oblique bone contour.

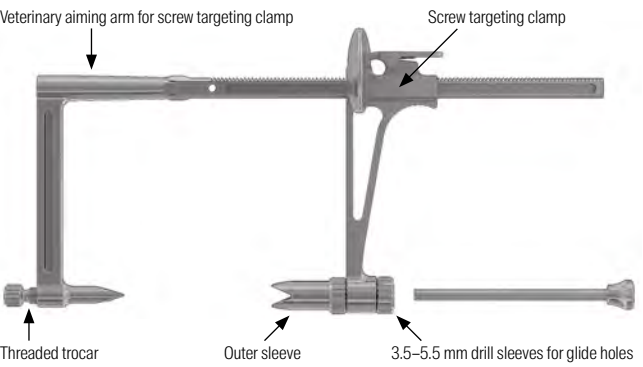


Fig 2 Components of the Screw Targeting Clamp.

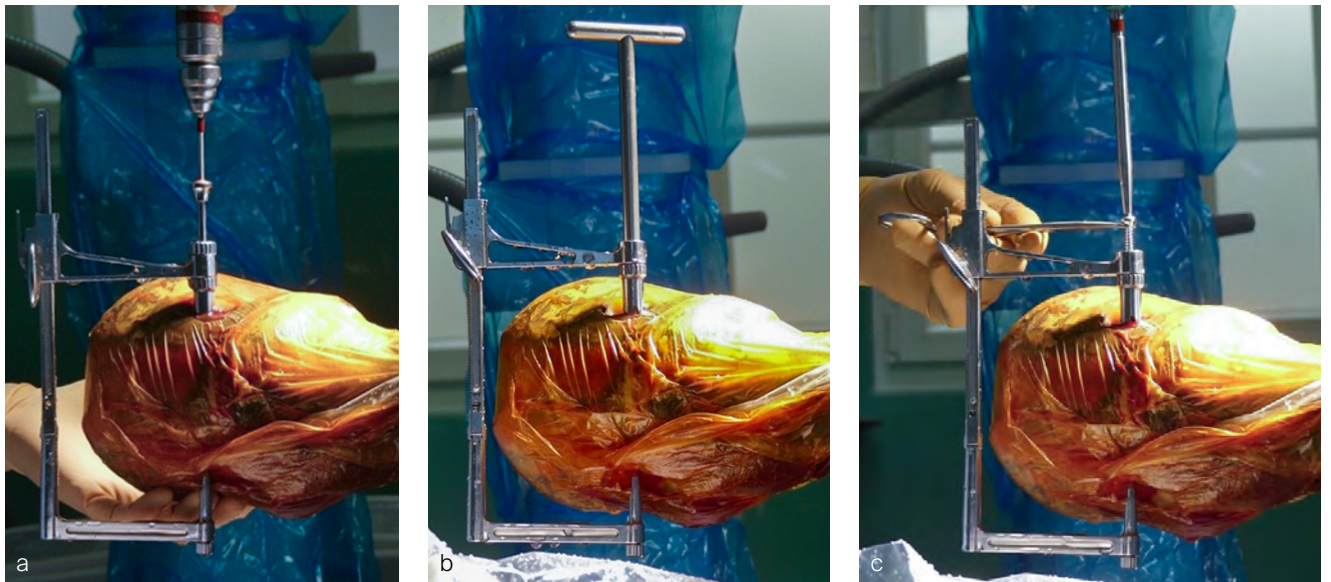


Fig 3a–c External surgical view of the positioning of the Screw Targeting Clamp (STC) for fracture fixation of a parasagittal fracture of the third phalanx. Note that the STC is maintained during the entire procedure from drilling to screw tightening.

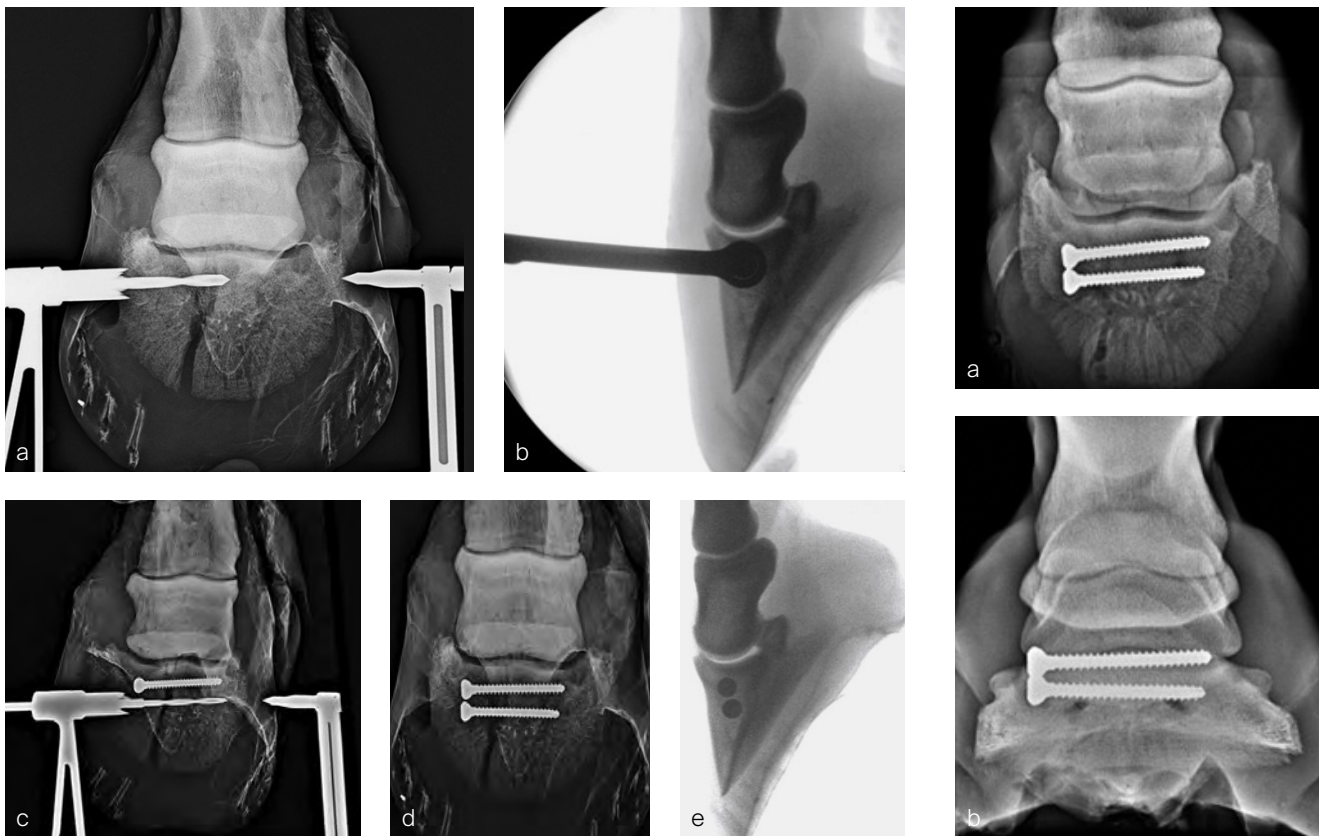


Fig 4a–e Radiographic and image intensifier views of the procedure.

Fig 5a–b Control radiographs 3 months postoperatively indicating complete healing of the fracture.

Case 1: Subchondral bone cyst at the distal aspect of the middle phalanx

(Case provided by Fabrice Rossignol, Ariane Campos, Grosbois Equine Clinic, Paris, France)

A subchondral middle phalanx bone cyst was identified on a clinically sound 3-year-old Warmblood Gelding during radiographic screening. The osseous lesion was located at the medial and distal aspect of the middle phalanx on the left front limb. Radiographs indicated mild sclerosis of the trabecular bone surrounding the cyst. A magnetic resonance imaging examination confirmed discrete communication with the distal interphalangeal joint (Fig 1). The treatment of choice was surgery, which included placing a cortical lag screw or compression screw across the subchondral bone cyst. This technique aims to promote new bone formation by altering the biomechanical bone environment. A 4.5 mm headless compression screw was placed across the cyst with the veterinary screw targeting clamp.

The horse was routinely anesthetized and positioned in left lateral recumbency to be able to access the medial side of the left front limb. The lower limb was aseptically prepared and draped appropriately to isolate the solar region of the hoof from the surgical area, and to allow visualization of the coronary band. The targeting clamp was assembled with the straight outer sleeve and the 4.5 mm drill sleeve. It was positioned under radiographic and image intensifier guidance in an oblique direction to avoid drilling through the proximal hoof wall. Once the surgeons were satisfied with the position of the targeting clamp, the location of the trocar was marked on the draping

and a stab incision was made at the level of the outer sleeve. The outer sleeve was inserted in the skin incision and the adjustable rail of the targeting clamp was tightened. The 4.5/3.2 mm insert sleeve followed by the 3.2/1.6 mm insert sleeve (provided in the 4.5 mm headless compression screw kit) were placed in the 4.5 mm drill sleeve (Fig 2).

A 1.6 mm guide wire was advanced through the bone to assess the correct positioning of the targeting clamp. The guide wire is centered within the cyst. At this stage, the ideal screw length was measured on the perioperative radiographs. When using these headless cannulated compression screws, remember that the shaft thread length is approximately 40% of the screw length. Ideally, the threaded shaft of the screw is positioned on the trans-side of the cyst. The 3.2/1.6 mm insert sleeve was then removed and the bone was drilled with a cannulated 3.2 mm drill bit to the required length (Fig 3). Considering the high-bone density at this location, the entire length of the drill hole was tapped by hand with a cannulated 4.5 mm tap through the 4.5 mm drill sleeve. Next, a 4.5 mm headless compression screw was inserted through the 4.5 mm drill sleeve and tightened by hand (Fig 4). The stab incision was closed routinely. The horse was covered with a two-layer bandage. The total surgery time was 30 minutes.

Postoperative radiographs showed accurate screw positioning (Fig 5). The horse was box-rested for 2 weeks and hand-walked for another 6 weeks. Ridden work was resumed after 2 months. The horse remained sound in the postoperative period. Four months after surgery, the radiographic definition of the cyst margins was markedly decreased.

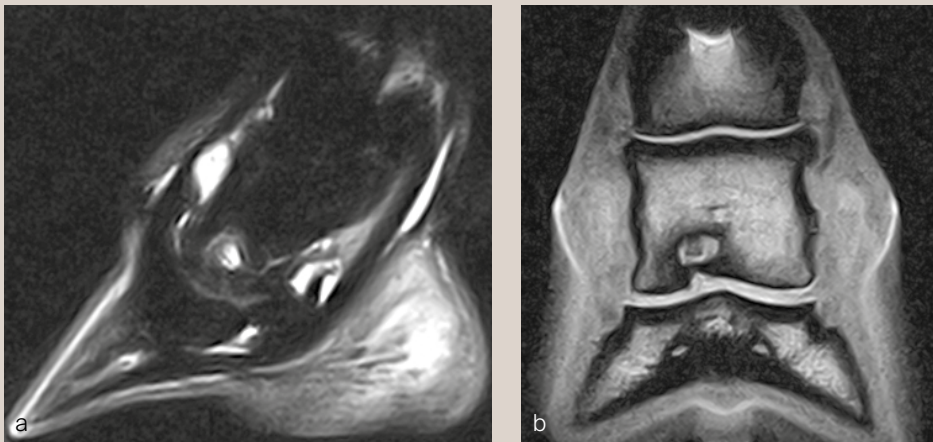


Fig 6a–b Preoperative magnetic resonance imaging revealing the subchondral bone cyst at the distal aspect of the second phalanx: (a) parasagittal and (b) frontal views.

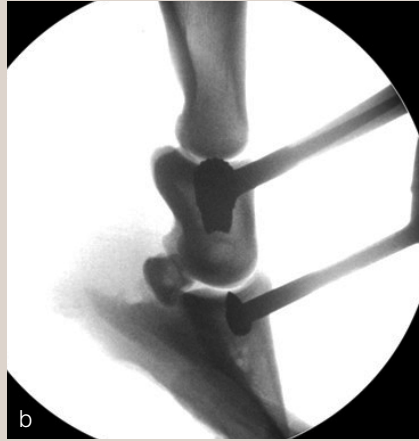


Fig 7a–c A targeting clamp is positioned under radiographic and image intensifier guidance: (a) perioperative, (b) lateromedial image intensifier view, and (c) dorsopalmar radiograph.



Fig 8a–b

- a A 3.2 mm insert sleeve was used to drill through the cyst using a cannulated 3.2 mm drill bit.
- b Screw insertion through the targeting clamp.

Fig 9a–b Postoperative radiographs: (a) dorsopalmar and (b) lateromedial views.

Case 2: Lateral type II fracture of the distal phalanx repair—3-year-old Standardbred racehorse

(Case provided by Janik Gasiorowski, Mid-Atlantic Equine Medical Center, Ringoes, New Jersey, USA)

An articular fracture of the lateral wing of the distal phalanx was diagnosed at the track in this 3-year-old Standardbred racehorse, which was referred for surgery. Internal fixation was planned with a 5.5 mm cortex screw in lag fashion to restore and maintain articular congruency by fracture reduction and interfragmentary compression. Drill trajectory was planned with computed tomographic (CT) guidance with the horse

awake and standing. Grids of barium paste dots were placed at proposed entry and projected exit sites. Once the ideal dot was selected from each grid the horse was anesthetized and the hoof prepared for surgery. The veterinary Screw Targeting Clamp (STC) was affixed to the hoof at the ideal dot in the entry and exit grids. Drilling, countersinking, measuring, tapping, and screw placement were achieved through the STC. The CT guidance and the STC allowed placement of the screw between the articular surface and vascular canal containing the terminal arterial arch, and in an orientation that resulted in accurate reduction instead of translation of the fracture fragment and parent bone.

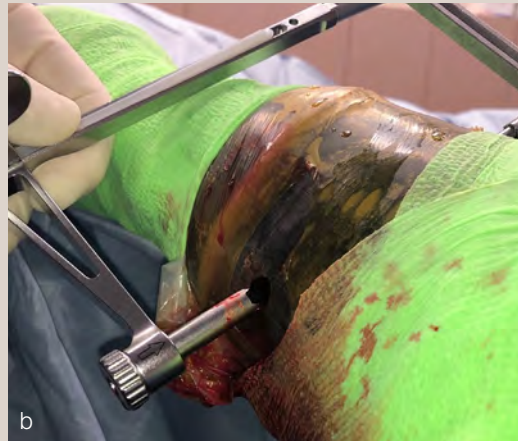


Fig 10a–b Intraoperative images: **(a)** A 3.2 mm hole was drilled at the location of the barium dot in the palmar grid that marked the projected drill exit site of the ideal drilling/screw placement trajectory. The point of the threaded trocar (target end of the Screw Targeting Clamp) is placed in this hole. **(b)** The 5.5 mm drill sleeve is installed in the carriage of the Screw Targeting Clamp and is inserted into the 8 mm hole (surgical approach) in the dorsal hoof wall. The outer sleeve is not used here.



Fig 11a–b
a The Screw Targeting Clamp guides drilling direction, as the glide hole is drilled to the fracture.
b The 4.0 mm drill sleeve is inserted through the 5.5 mm drill sleeve to guide and center the thread-hole drilling.

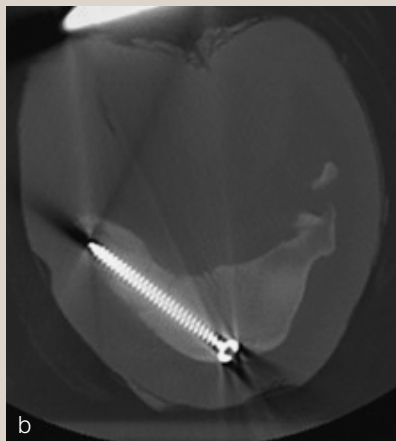


Fig 12 a–b
a Intraoperative radiograph.
b Postoperative CT scan.

Case 3: Frontal plane third carpal bone slab fracture repair; 3-year-old Thoroughbred racehorse

(Case provided by Janik Gasiorowski, Mid-Atlantic Equine Medical Center, Ringoes, New Jersey, USA)

A frontal plane fracture of the third carpal bone was diagnosed at the track in this 3-year-old Thoroughbred racehorse, which

was referred for surgery. Internal fixation was planned with a 3.5 mm cortex screw in lag fashion. The Screw Targeting Clamp (STC) placement was guided using needles with radiographic and arthroscopic imaging. From skin incision to screw placement, lag screw fixation was achieved through the STC without movement or removal of the device.

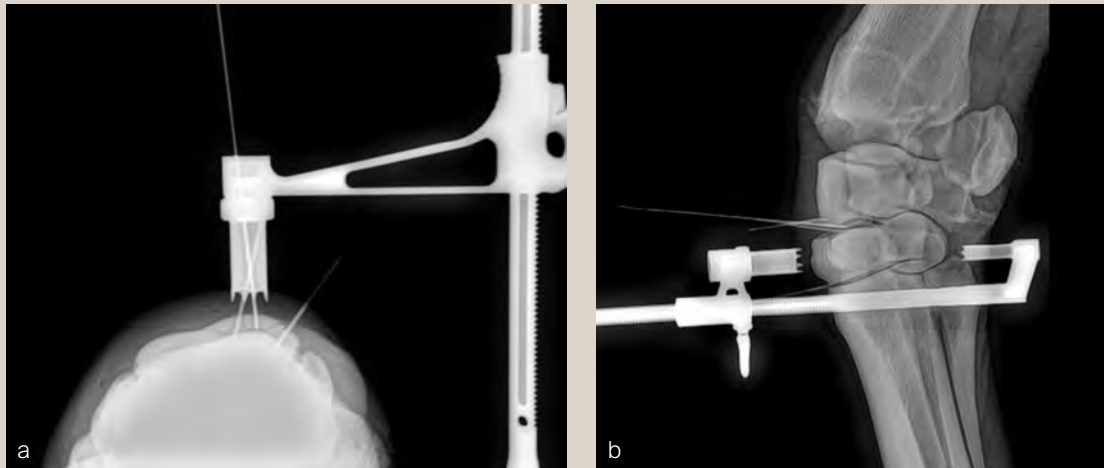


Fig 13a–b Placement of the Screw Targeting Clamp under intraoperative radiographic guidance.



Fig 14a–b

- a** An arthroscopic scalpel is used to make the skin incision through the Screw Targeting Clamp.
- b** Preparation to drill the thread hole through the 2.5 mm drill sleeve. To illustrate the stacking of sleeves, they are not screwed in, so the entire surgery can be accomplished without removal of the Screw Targeting Clamp. The 3.5 mm glide hole has already been drilled through the 3.5 mm drill sleeve, seen here in the middle of the “stack.”



Fig 15 A 3.5 mm tap is used through the Screw Targeting Clamp with the 3.5 mm drill sleeve installed and functioning as a soft-tissue protector.



Fig 16a–b Postoperative radiographs.

Update from the AO Smart Digital Solutions Task Force 2023

Wearable-based tracking of functional recovery

Building on the identified needs from the AO's Wearable Technology survey, the AO Technical Commission's Smart Digital Solutions Task Force (SDSTF) conducted a feasibility study to determine the value of wearable technology in assessing the postinjury functional recovery—the bring your own device (BYOD) study. Results of this study have been published in an AO Special Issue of *Medicina* [1].

Back to normal?—Bring your own device

For this feasibility study, patients with any acute musculoskeletal injury were included that already had a personal wearable system (smartphone, or wrist worn device) prior to their injury (BYOD). By collecting the step counts for each day as a device agnostic parameter and normalizing them to the one time maximum for each patient, a clear recovery trajectory can be seen from the otherwise highly diverse patient group (Fig 1). This allows for a visualization of the functional recovery in relation to the pre-injury, individual function as determined by the daily step count.

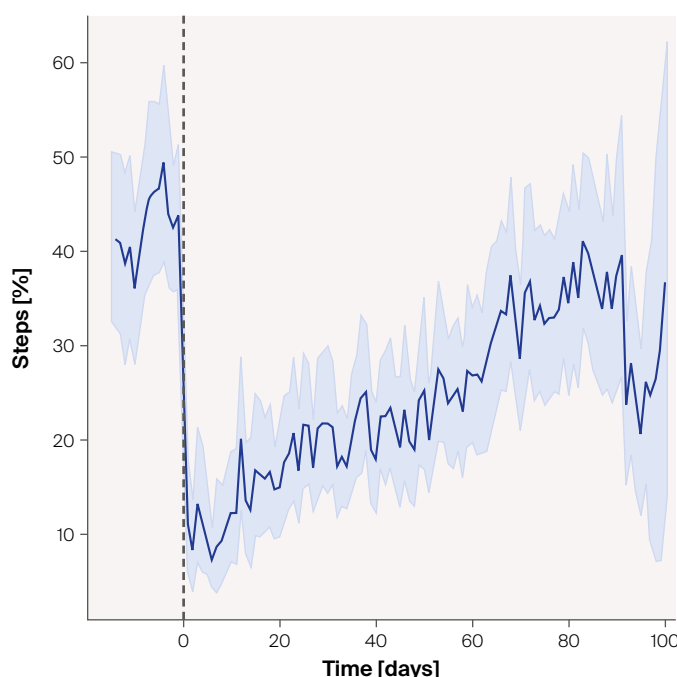


Fig 1 The patient recovery process from 14 days preinjury to up to 100 days postinjury as tracked by the daily step count is shown. The left graph reveals the daily step average for all patients normalized to the one time maximum for each patient (dark blue line) and the 95% confidence interval (light blue shade). The X-axis shows the time in days (0 = day of injury); Y-axis, the normalized step activity in percentage. (Courtesy of **Braun BJ et al. Injury. 2023 Nov 30;55(2):111254.**)

One step further

The feasibility study highlights the main benefits of this new approach, in that the otherwise largely existing blind spot of preinjury functional status becomes readily assessable. Not only can the functional recovery be visualized with this approach but also by further analyzing it with a logistic regression model, predictions about the functional recovery can be made early

during the treatment course (Fig 2). This has the potential to detect patients at risk for a prolonged healing course at an earlier timepoint. The results of this preliminary machine learning approach to assess wearable data have been published [2].

Challenges on the way to the further adoption of BYOD and wearables

The current analysis shows the feasibility of the approach in a clinical setting. Limited patient number and inclusion of a broad range of injuries does not yet allow for a definition of recovery boundaries. More extremity and injury-specific data is required to provide aftercare recommendations based on this technique. Also, our understanding of baseline wearable data (ie, step count) in relation to physical function needs clarification, while the potential of different wearable systems from other medical fields must be explored.

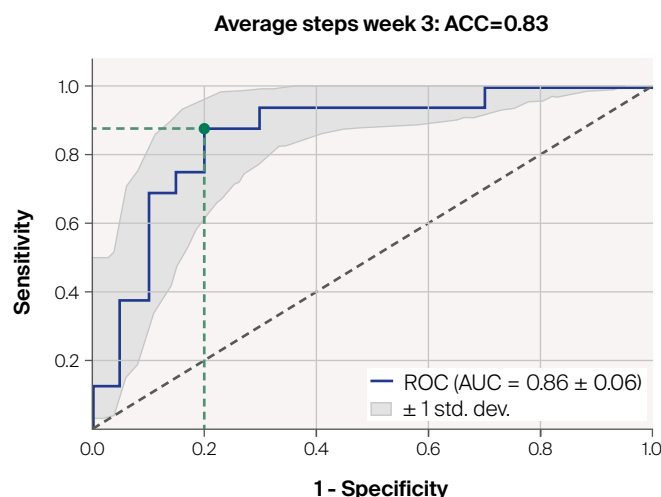


Fig 2 Receiver operating characteristic curve demonstrating the predictive model's performance to detect at least 50% functional recovery of the preinjury activity state by week 6, based on the step data up until week 3. X axis shows 1-specificity; Y axis, sensitivity. The threshold was chosen to maximize (sensitivity + specificity) and is indicated in green. Accuracy was calculated based on this threshold. (Courtesy of **Braun BJ et al. Injury. 2023 Nov 30;55(2):111254.**)

Resolving these new challenges will require dedicated research efforts. The group is already conducting several projects aimed at better understanding the value of different wearable systems, the relation of wearable data, and objective physical function (ie, VO2 max), while looking to increasing the BYOD patient database with simplified data-harvesting solutions. Further updates will follow.

References

1. **Braun BJ, Histing T, Menger MM, et al.** “Bring Your Own Device”—A new approach to wearable outcome assessment in trauma. *Medicina (Kaunas)*. 2023 Feb 19;59(2):403.
2. **Braun BJ, Histing T, Menger MM, et al.** Wearable activity data can predict functional recovery after musculoskeletal injury: feasibility of a machine learning approach. *Injury*. 2023 Nov 30;111254.

AO and icotec ag kick off joint development of a new generation pedicle system

The AO Foundation and [icotec ag](#) announce the successful agreement and kick off of their joint development of a new generation pedicle system optimized for conditions such as osteoporosis. This innovative system will feature optimized construct stiffness by utilizing icotec's BlackArmor® Carbon/PEEK composite implant material and the design freedom of its proprietary manufacturing process injection moulding CFM. This collaboration marks the second technology partnership between the AO and icotec.

Maarten Spruit, Chair of the AO Technical Commission Spine, expressed his enthusiasm about the cooperation: "The AO is thrilled to collaborate once again with icotec, leveraging their groundbreaking technology based on the unique BlackArmor® material. To date, there is no pedicle system available that fully meets the complex requirements for osteoporotic spine surgery and the varying bone qualities of osteoporotic patients. As a result, the AO and icotec have decided to develop a new pedicle system with a modulus of elasticity closer to that of human bone."

At the heart of this innovation is icotec's biocompatible BlackArmor® material, which offers a superior treatment option for spinal osteoporosis. Leading spine surgeons from the global

AO network are collaborating with icotec's cutting-edge capabilities in Carbon/PEEK composites and material properties to develop this technology. In addition to its enhanced structural characteristics, the new system will minimize artifact due to its translucent nature, providing unimpaired visualization of the area of interest which helps surgeons in diagnosing and follow-up, and patients confidence in getting the optimal treatment, especially in case of spine tumors.

Roger Stadler, CEO of icotec, emphasized the significant and lasting impact of this collaboration: "The AO Innovation Translation Center, in particular the AO Technical Commission, serves as the foundation for this development. The extensive expertise of world-renowned spine surgeons inspires us to offer osteoporotic patients an enhanced therapy and the quality of life they deserve." There is substantial clinical need on the optimized treatment options for patients with osteoporosis, that icotec will address with its new project.

icotec ag is a family-owned SME in Altstaetten, Switzerland established in 1999. The company designs and manufactures nonmetallic spinal implants made from BlackArmor® (Carbon/PEEK) material. It is the world leader in spine tumor care and is setting new standards for tumor treatments.



Figure Left to right: Sharon Heller, Kurt Zoller, Maarten Spruit, Richard Bransford, Kota Watanabe, Ramon Hüppi, Christian Mazel, Peter Varga, Lorin Benneker, Laura Hüsken, Nils Diethelm, Naresh Kumar, and Roger Stadler.

AO Technical Commission Innovation Prize awarded to the Pelvic Expert Group

The AO Technical Commission is honored to announce the Pelvic Expert Group (PEEG) as the winner of the 2023 Innovation Prize. The PEEG has been recognized for its innovation in developing the Intrapelvic Acetabular System, which is a comprehensive set of implants and tools offering innovative solutions in pelvic surgery.

The genesis of this system stems from the careful observation of evolving fracture patterns and a paradigm shift from non-operative to surgical treatment in pelvic fractures. The Intrapelvic Acetabular System addresses the complexities associated with fracture types and acknowledges that screw fixation alone may not always suffice. The introduction of a plate applied to the quadrilateral surface proves to be a pivotal advancement.

The AO Technical Commission commends the PEEG's outstanding contribution to advancing orthopedic care. The Intrapelvic Acetabular System is a testament to the group's commitment to innovation, ultimately improving outcomes for patients undergoing pelvic surgery.

The PEEG is comprised of (Figure):

Michael Stover (US)—chairperson
Jorge Barla (Argentina)
Robin Peter (Switzerland)
Ramesh Sen (India)
David Stephen (Canada)



Figure AO Technical Commission award ceremony for the 2023 Innovation Prize. From left to right: AO President Tim Pohlemann, Pelvic Expert Group (PEEG) members Robin Peter, Ramesh Sen, Michael Stover (chairperson PEEG), David Stephen, and Michael Raschke, chairperson AO TC Trauma.

AO Technical Commission Meet the Experts sessions 2023

After a 2-year long break due to COVID restrictions, the AO Technical Commission's popular format "Meet the Experts" was finally back in 2023. The sessions showcase the clinical benefits and the application of the most recently approved medical devices that emerged from the AO Technical Commission (AO TC). Leading trauma, spine, and veterinary surgeons displayed the AO TC's innovations to their peers, course participants, and interested viewers. Six "Meet the Experts" sessions were held throughout 2023: three in the award-winning mobile operating room, "The Shard", at the AO Davos Courses in December, and in early 2023 three sessions were filmed at the RIMASYS studios in Cologne, Germany. Here, an overview of all 2023 sessions is given to access more information on different technologies and the actual "Meet the Experts" recording by clicking the links below.

1. Fibulink

The **FIBULINK Syndesmosis Repair System** combines the benefits of fixation of a screw and the flexibility of a suture. It is the first adjustable syndesmotomic repair system to enable precise, anatomical syndesmotomic fixation. A short, high-strength suture bridge helps to restore the physiological kinematics of the ankle. The fixation concept addresses limitations of suture button constructs including lack of tension control and medial soft-tissue disruption. In this Meet the Experts video, Michael Swords

and Andy Sands explain the function and clinical benefits of the syndesmotomic fixation system. The insertion of the implant is demonstrated in an artificial bone model and in a human anatomical specimen.

"Meet the Experts" video session: [click here](#).

2. MAXFRAME

MAXFRAME AUTOSTRUT Multi-Axial Correction System is a first-of-its-kind fully automated hexapod ring-fixation system. It provides a solution to the drawbacks of hexapod external ring-fixation treatment by automating the strut adjustment process. Patients no longer need to manipulate the struts, leading to a superior experience throughout the treatment, and reducing the risk of negative clinical outcomes caused by unintended strut adjustments. It further enables smaller, more frequent actuations, up to 20 times per day. This may be better for the surrounding soft tissue, reducing pain, and improving the quality of the bone regenerate vs larger and less frequent strut adjustments. Theddy Slongo, originator of the MAXFRAME technology and winner of the highest AO award, the "AO Recognition Award" for lifetime achievements, introduces and describes the device in detail.

"Meet the Experts" video session: [click here](#).



Fig 1 Left to right: Andrew Sands and Michael Swords at the RIMASYS studio in Cologne, Germany, demonstrating the new FIBULINK Syndesmosis Repair System.



Fig 2 Left to right: Om Lahoti and Theddy Slongo at the RIMASYS studio, Cologne, Germany, exhibiting the MAXFRAME AUTOSTRUT system.

3. Veterinary Large Animal Screw Targeting Clamp

The new [Veterinary Screw Targeting Clamp \(STC\)](#) is a valuable addition to equine healthcare. Originally developed by the AO Technical Commission's Foot and Ankle Expert Group, the STC was reinforced and enriched for use in large animals.

The STC is designed to provide the ability to maintain compression and targeted screw insertion. Improved accuracy of screw insertion gives more consistent and confident fracture repair

and allows precise placement of specific screws into subchondral bone cysts close to joint space. Members of the AO TC Large Animal Expert Group (LAEG), Fabrice Rossignol, Kati Glass, and Janik Gasiorowski, held a live demonstration of the device at the AO Davos Courses in December 2023, explaining and showcasing the benefits of the technology and its application.

"Meet the Experts" video session: [click here](#).

4. A new look into TLIF–TELIGEN Vue LIF

The [TELIGEN system](#) facilitates access, enhances visualization in spinal procedures, and aims to combine the positive attributes of tubular retractors and endoscopy. It provides surgeons skilled in minimally invasive surgical transforaminal lumbar interbody fusion (MIS-TLIF) with the benefits of endoscopic TLIF. The digitally enabled TELIGEN Camera offers hands-free visualization during the procedure, along with a multidirectional and expanded field of view. The heads-up display allows surgeons to maintain an ergonomic posture during the procedure. Furthermore, this visualization and display facilitates teaching of trainees as well as engagement by operating room personnel, potentially increasing operative efficiency. In this interactive showcase at the AO Davos Courses in December 2023, Matti Scholz, member of the Lumbar Degenerative Expert Group (LDEG), and Dmitriy Petrov, presented the technology and performed a case with a human anatomical specimen.

"Meet the Experts" video session: [click here](#).



Fig 3 Left to right: Fabrice Rossignol, Kati Glass, and Janik Gasiorowski held a live demonstration from "The Shard" mobile operating room during the AO Davos Courses in 2023.



Fig 4 AO Spine faculty observing the live demonstration of the TELIGEN Vue LIF in "The Shard" operating room performed by Dmitriy Petrov (middle) and Matti Scholz (right).

5. Intrapelvic Acetabular System

Trends in occurrence and treatment of pelvic fractures define a need for new intrapelvic acetabular devices to be used for stabilization. The possibility to deploy such new devices while using less invasive surgical approaches is of significant benefit to fragile patients. The [Intrapelvic Acetabular System](#)

provides a biomechanically sound implant set that can be adjusted intraoperatively to match the patient's anatomy. Further, a new complete set of instruments including plate trials and plateholders, retractors, reduction forceps, benders, and tools for screw insertion provide superior ease of use compared with other available solutions.

"Meet the Experts" video session: [click here](#).



Fig 5 Left to right: Michael Stover, and David Stephen applying the Intrapelvic Acetabular System during the AO Davos Courses in 2023.

6. Distal Radius Intramedullary Nail (DRIM-Nail) for the fixation of extraarticular fractures

The [Distal Radius Intramedullary Nail \(DRIM-Nail\) for the fixation of extraarticular fractures](#) was developed in response to various clinical complications following fixation of distal radius fractures using closed reduction percutaneous pinning and open reduction and internal fixation techniques. This session features the newly developed implant that was invented by Swiss surgeons Ladislav Nagy and Andreas Schweizer at Balgrist University Hospital in Zurich and finalized for clinical application in cooperation with the AO Technical Commission's Hand Expert Group (HAEG). Ladislav Nagy and Martin Langer, member of the HAEG, with Paul Grützner as the session moderator were invited to introduce the device during the 2023 World Surgery Tour Festival in Cologne, Germany.

"Meet the Experts" video session: [click here](#).



Fig 6 Left to right: Paul Grützner as moderator of the session, Martin Langer (seen from the back), and Ladislav Nagy showcasing the DRIM-Nail during the 2023 World Surgery Tour Festival in Cologne, Germany.

AO Technical Commission Experts Symposia reconvene in Europe and America

In 2023, three AO Technical Commission (AO TC) Experts Symposia were held in Argentina, the United States of America, and Denmark to bring international experts in trauma and craniomaxillofacial surgery together.

AO TC Experts Symposia are fundamental to fulfilling the AO TC's quality-assurance mandate for newly developed devices when they become available for surgeons; they are invaluable for defining remaining unmet clinical needs that still need to be addressed by existing solutions. The symposia format allows for open, confidential exchanges between clinicians and industry partners to justify initiating new development projects.

The events' engaging format triggered lively exchanges through faculty-led subject introductions and participant-submitted case discussions. These dialogues were further enhanced by symposia moderators who concluded the sessions by defining corresponding clinical needs.

Fifth AO TC Trauma Experts Symposium (Latin America)

The fifth AO TC Trauma Experts Symposium (Latin America) in Argentina, chaired by Carlos Sancineto, was attended by 33 participants from 14 countries.

The program was diverse and divided into five sessions. Each session was chaired by a member of the AO TC Trauma and supported by regional faculty. Various topical issues were discussed, such as infections in fractures, non-healing of

fractures, and deformities. The faculty encouraged interaction among participants and several case discussions were held. At the end of each session, important conclusions were drawn regarding remaining clinical needs in specific areas of infection and fracture fixation.

The sixth AO TC Experts Symposium (Latin America) is scheduled for May 2025.

Seventh AO TC Experts Symposium (North America)

Every 2 years, North America hosts a trauma-related AO TC Experts Symposium. The most recent symposium was chaired by Christopher Finkemeier on September 23–24, 2023, in Bozeman, Montana, and was attended by 29 participants.

The symposium started with an introductory session on Distal Femur Fracture: Biphase Plate—New Fixation Principle, and Christoph Sommer from Switzerland shared initial experiences in Europe.

The symposium program was divided into five key sessions:

- Syndesmosis Injuries—Reevaluating the role of screws
- Patella Plate Innovations
- Managing Bone Defects
- Periprosthetic Plating System Advancements
- Deformity Correction Techniques

The eighth AO TC Trauma Experts Symposium (North America) is scheduled for September 2025.



Participants of the fifth AO TC Trauma Experts Symposium (Latin America), Bariloche, Argentina, May 2023.



Participants of the seventh AO TC Trauma Experts Symposium (North America), Bozeman, Montana, September 2023.

Second AO TC CMF Experts Symposium, Denmark

The second AO TC CMF Experts Symposium, a 1.5-day event convened in Copenhagen, Denmark, in October 2023, was overseen by Daniel Buchbinder and Michael Grant. Nine experts from five countries and 23 participants from seven countries attended. The symposium was structured into three distinct sessions, comprising a total of 18 case presentations, which were as follows:

- Computer-Assisted Planning and Patient Specific Solutions in Orthognathic Surgery
- CAS and PSS in Orbital and Midface Trauma Surgery
- CAS and PSS in Post Ablative Maxillofacial Reconstruction

Throughout the sessions, participants and faculty discussed challenges faced by the AO TC and industry. The AO TC CMF community has pledged to collaborate to address these challenges effectively.

Under the guidance of Nils-Claudius Gellrich, plans are underway for the organization of the third AO TC CMF Symposium in Reykjavik, Iceland on September 6 and 7, 2024



Participants of the second AO TC CMF Experts Symposium, Copenhagen, Denmark, October 2023.

Cement augmented fixation of unstable trochanteric fractures with PFNA is cost-effective

The Proximal Femoral Nail Antirotation (PFNA) is an intramedullary implant for the treatment of unstable trochanteric femoral fractures, with the additional option of augmentation using Traumacem™ V+ Injectable Bone Cement. The PFNA was developed to improve angular and rotational stability of the nails for fracture fixation, with the design of the nail optimized to avoid common mechanical complications after nailing procedures for trochanteric hip fractures. With these procedures, there is a 2.2–12% reported rate of mechanical failures, such as cut-out or cut-through requiring reoperation.

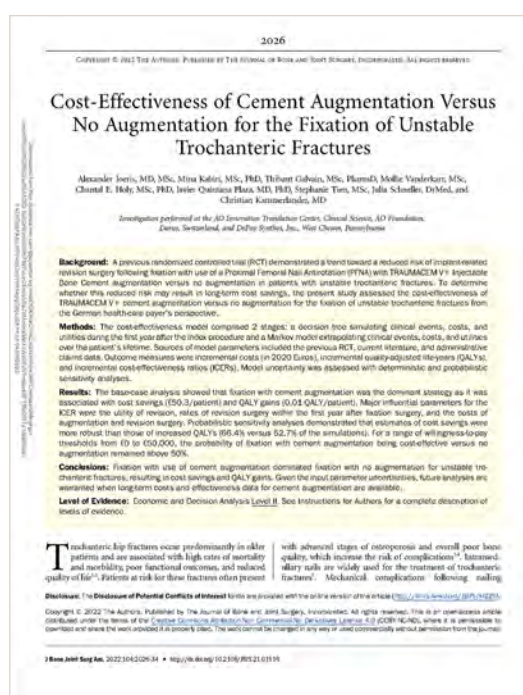
The addition of cement augmentation with the PFNA has been shown to improve biomechanical anchorage of the head element of the nail in the femoral head and provides greater cut-out resistance. Additionally, early mobilization may be enhanced and functional recovery promoted when PFNA is augmented with Traumacem™ V+ Injectable Bone Cement. In a large, multicenter randomized controlled trial (RCT) the outcomes of PFNA use with or without cement augmentation were comparable; nevertheless, there was a trend toward a lower risk of mechanical complications and therefore, a lower risk of implant-related reoperation when cement augmentation

was applied. Whether this lower risk translates into cost savings was the subject of a cost-effectiveness analysis conducted in collaboration with Christian Kammerlander, MD, Julia Schneller, MD, AO ITC Clinical Science, and DePuy Synthes. The result was published at the end of 2022 [1].

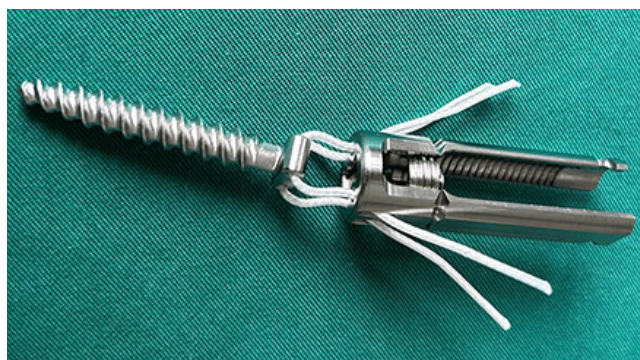
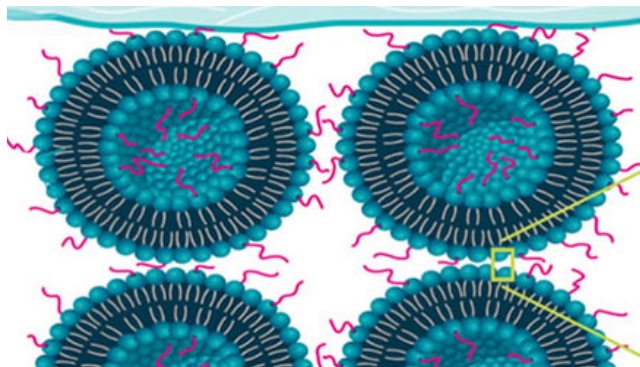
Focusing on the German health-care setting, the cost-effectiveness study used a short-term decision tree model and a long-term Markov model based on data from the original RCT to assess the impact of PFNA with cement augmentation compared with no augmentation for closed trochanteric fracture fixation. The study indicated that based on the RCT data, PFNA with augmentation was the dominant strategy compared to PFNA without augmentation with substantially lower costs and slightly better health outcomes (measured by gains in quality-adjusted life years).

Reference

1. Joeris A, Kabiri M, Galvain T, et al. Cost-effectiveness of cement augmentation versus no augmentation for the fixation of unstable trochanteric fractures. *J Bone Joint Surg Am*. 2022 Nov 16;104(22):2026–2034.



AO's 2023 innovation funding milestones



In 2023, the AO underscored its position as a powerhouse of excellence, using its innovation resources to drive innovators' ideas forward with expertise and funding: from conception to realization. In the past year, the AO's innovation funding supported 21 ongoing projects and resulted in four products gaining regulatory approval, six products in clinical use, and five products applied in AO educational activities.

"After several years of building our [innovation funding](#) platform, we are now seeing real results," commented Roland Herzog, head of the AO's Technology Transfer. "Recipients of the AO's innovation funding experience the essence of the AO: unparalleled collaboration across research, our clinical specialties, and industry through our network of more than a half-million

health care professionals—all in service of advancing new frontiers in orthopedics and improving patient outcomes," he added.

A milestone-filled year for innovation—from bench to bedside

The AO's 2023 innovation funding drove innovation in products and strategic initiatives from bench to bedside, helping select innovators navigate every stage of their projects, especially in the critical phase between ideation and market launch. Read details about the 2023 highlights made possible by AO's innovation funding below.

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Smartphone app empowers patients with scoliosis to manage the condition

Momentum Health, a new digital health app backed by the AO's innovation funding, empowers patients with scoliosis by giving them and their physicians a radiation-free tool for remotely screening and monitoring for the condition while at the same time delivering efficiency gains for a health care system under pressure (Fig 1).

Successful management of adolescent idiopathic scoliosis (AIS), which is a lateral spinal curvature that impacts 2–3% globally, is linked to early detection via close monitoring of the spine. This means two full-length spinal x-rays every 6 months for patients, yet only 10% of patients will require intervention; the remaining 90% are subjected to unnecessary radiation exposure. Beyond reducing radiation exposure for patients with AIS, Momentum Health's new app (Fig 2) will empower them to take charge of monitoring the progression of their condition and eliminate unnecessary visits to the physician. Thus, reducing the demands on an already overburdened healthcare system.

Momentum Health is the brainchild of Evan Dimentberg, a medical student at **Université Laval** (Quebec City, Canada), who in 2018 spent a 2-week internship with AO Technical Commission Spine member **Jean Ouellet**, MD, looking into and understanding scoliosis management practice.

Dimentberg began medical school in 2019 and, just a year later, had extra time on his hands due to the COVID-19 pandemic constraint.

"I began looking into innovation in medicine and reading a lot about digital health," Dimentberg commented. "My mind turned to scoliosis because I had some basic knowledge on the topic from my time with Dr Ouellet. I wrote down my idea for tracking patients remotely to prevent serial scoliosis follow-ups and for radiation-free monitoring—without any specifics on how I would do that," he remarked.

A solution takes shape

Ouellet encouraged him to continue refining the concept, and he ultimately zeroed in on photogrammetry, a 3D coordinate measuring technology that uses photos as the basic metrology medium. He then leveraged an online freelancing platform to find an expert to explain the technology to him, and that person connected him with Dutch photogrammetry experts Frank de Wijk and Leander Goor, who today are Momentum Health cofounders and the company's chief technology officers.

Ouellet was immediately enthusiastic about the refined concept.

"This app is unique because it combines technologies in a way that serves everybody's interests by empowering patients and limiting the number of x-rays they need, freeing up time one spends going to the clinic, and positively impacting access to healthcare," Ouellet declared.



Fig 1 From left to right the Momentum Health team: Leander Goor (Co-CTO), Philippe Miller (CEO), Frank de Wijk (CTO), Evan Dimentberg (COO), and Jean Ouellet, chief medical officer.

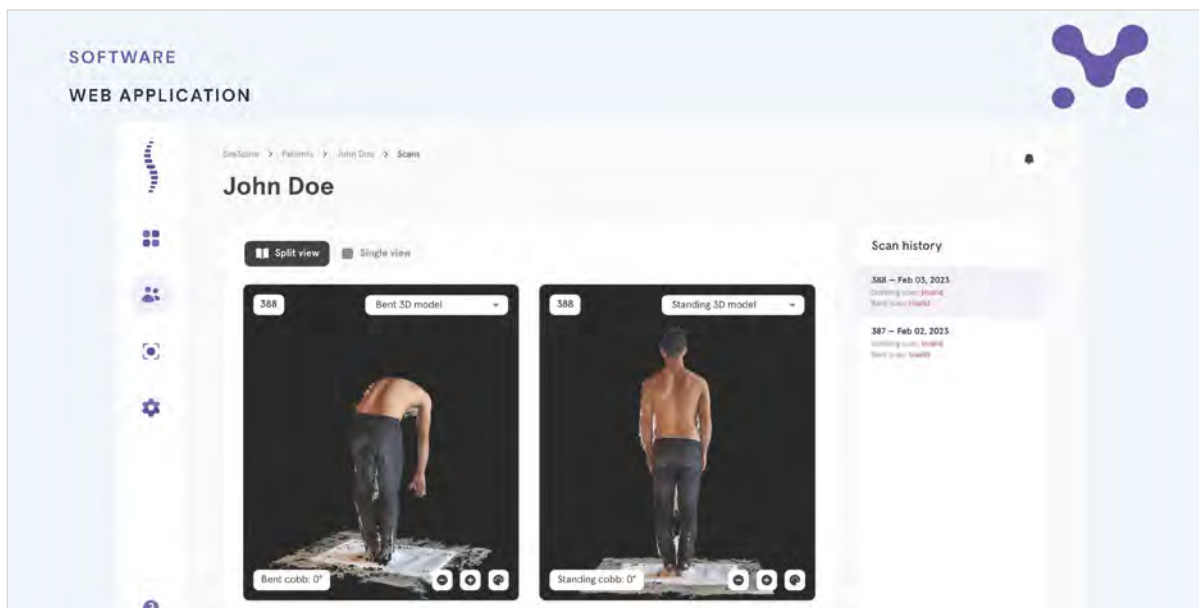


Fig 2 The app generates a true-to-scale 3D model from a smartphone video of the patient's torso. The artificial intelligence (AI) analysis quantifies volumetric asymmetries and calculates spinal curvature parameters.

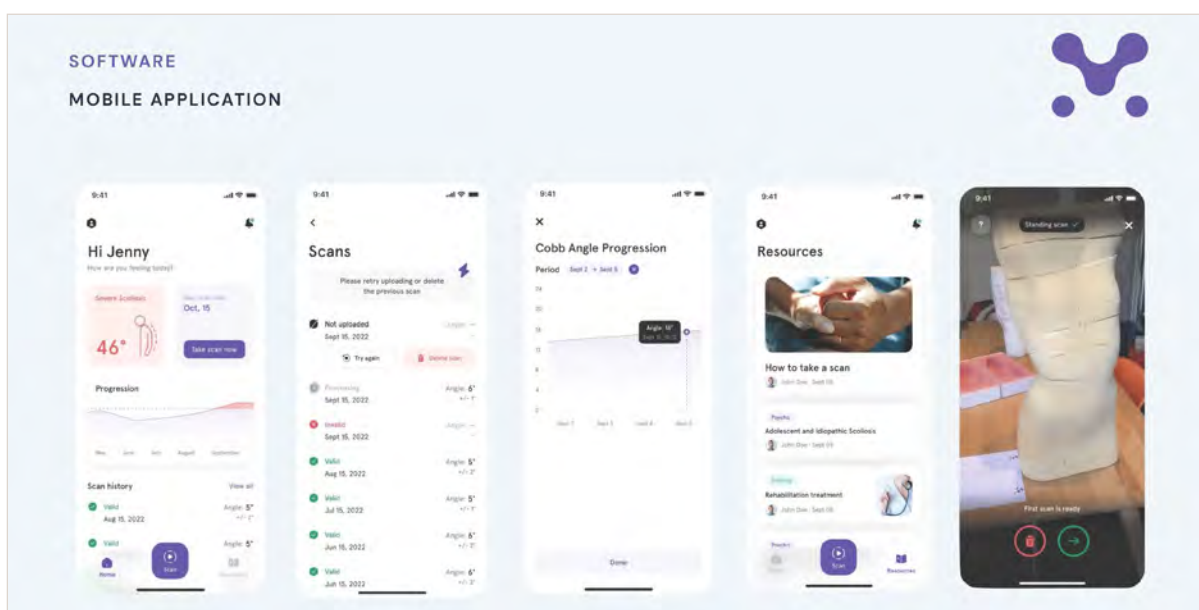


Fig 3 Patients receive detailed feedback on the spine curvature and its history.

'A perfect fit'

In addition to funding, [AO's innovation funding](#) provides the project with access to and visibility within the AO surgeon community as well as support with regulatory filings. The partnership is a perfect fit, according to Ouellet.

"The AO is driven by surgeons for surgeons with the idea of improving patient care. There are 4,000 spine surgeons in AO Spine and half of them see adult or pediatric scoliosis, so the networking and our ability to reach out through the AO is incredible," he pointed out. "Being AO-supported adds credibility to Momentum Health and its mandate—and being able to tap into this rich network to get other surgeons' feedback adds tremendous wealth to our project."

"The app is currently being used in several clinical studies pursuing the objective of generating high-quality datasets to train and validate the app's algorithms. Several hundred datasets have been collected and the correlation between the Cobbs angle predicted by the app and conventional x-ray analysis is now 0.89 and improving."

Momentum Health's app has received 510(k) clearance by the FDA for remotely monitoring and assessing spinal deformities using a smartphone. Data collection in scope of several clinical studies is ongoing in Canada and the US to further demonstrate the app's functionality and commercial activities have been initiated. CE approval is anticipated for late in 2024 with commercial activities planned to start shortly thereafter.

Safe, effective, and easy to use: offering a solution to reduce PJK and improve clinical outcomes

Proximal junctional kyphosis (PJK)—a common complication following instrumented treatment of adult spinal deformity—is a patient problem that [Heiko Koller](#), MD, has encountered throughout his career. With support from [AO's innovation funding](#), he is ready to solve that problem with his invention: the safe, effective, and easy-to-use Tether Pedicle Screw ([Fig 1](#)).

“About 30 percent of adult patients who have had long fusion surgery will have at least PJK, and 30 percent of these will need revision surgery,” said Koller, who practices at Asklepios Klinikum, Bad Abbach, Germany. “PJK really is a societal problem associated with long fusions and it is one of the most common and feared complications.”

Koller said stress riser at the junction between instrumented and non-instrumented levels of the spine can lead to overloading and degeneration of the levels adjacent to the instrumented segment of the spine, affecting not only the intervertebral disc but also the vertebral body. In extreme cases of PJK, the topmost instrumented level can fail due to screw pullout, leading to further collapse of the spine and exaggerated kyphosis.

“Current methods for preventing PJK do not offer all crucial elements: safety, efficacy, and ease of use,” he said. “Dealing

with these problems every day in kids and adults, I wanted to find a solution.”

New concept to prevent PJK

Koller's Tether Pedicle Screw reduces stress discontinuity between the instrumented and non-instrumented levels of the spine ([Fig 2](#)). Allowing a more gradual transition from the stiff section of the spine (which is fused by instrumentation during surgery) and the still-mobile sections above, the Tether Pedicle Screw is expected to reduce the likelihood of PJK while protecting the adjacent intervertebral discs from further degeneration and the vertebral bodies from non-physiological stress patterns. Koller said that gradual transition also benefits the topmost level of the fixed segment.

The project started in June 2021 and is carried out in close collaboration with IGNITE-concepts (located in Attiswil, Switzerland) and its lead engineer, Tom Overes. Today, numerous key milestones have been achieved, including the production of implants and instruments at the [AO Research Institute Davos](#) (ARI) prototype shop and the filing of a patent application in February 2022. Additional mechanical testing and a formal presentation to the AO Spine Technical Commission lie ahead. Next, the project team will seek a commercial partner to finalize the development and make the Tether Pedicle Screw available to surgeons.

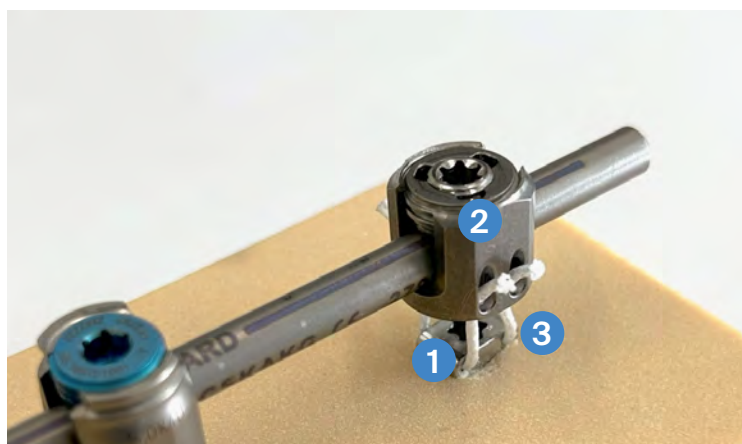


Fig 1 The Tether Pedicle Screw consists of three main components: 1) A screw component, which is anchored in the pedicle, 2) A head component, which clamps the rod and connects to the next levels, and 3) A tether which provides a stable yet flexible connection between the screw and the head.

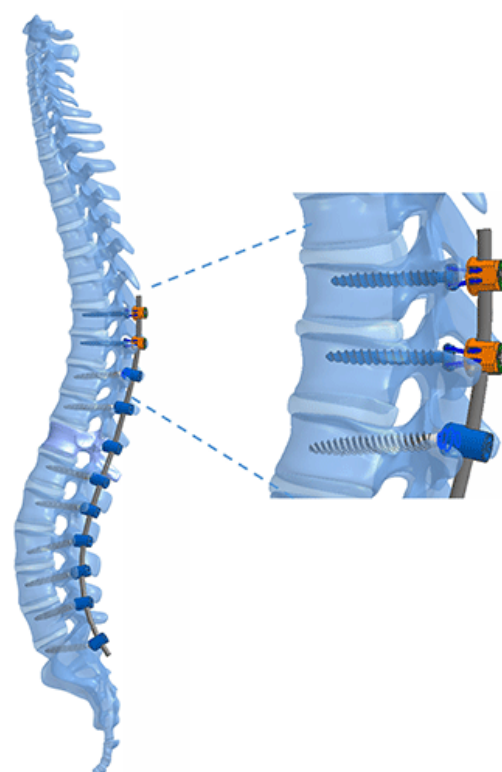


Fig 2 The Tether Pedicle Screws (in orange) top off the segments fused with standard pedicle screws (in blue) and provide a soft transition from the rigid fused segments to the mobile segments.

Artificial intelligence-assisted analysis and classification of pelvic ring fractures



Fig 1 Konrad Schütze, MD, PhD, in Ulm at the academy and annual conference of AO Trauma Germany, May 2023.

While fractures of the pelvic ring—the sturdy ring of bones located at the base of the spine—are relatively uncommon, diagnosis and classification of these painful injuries are fundamental to helping patients avoid immobility, complications, and even death. As a result of [AO's innovation funding](#), [Universitätsklinikum Ulm \(UKU\)](#) senior physician Konrad Schütze ([Fig 1](#)), MD, PhD, senior radiologist Daniel Vogele, and radiological software developer [Mint Medical](#) (a Brainlab company) are harnessing artificial intelligence (AI) as a tool that could revolutionize diagnosis and classification of pelvic ring fractures.

With support from the AO's innovation funding, the 14-month pilot project got underway in December 2022, with the vision of building a cloud-based software solutions with the help of AI algorithms to assist surgeons globally in easily and precisely analyzing and classifying pelvic ring fractures, independently of their level of experience.

Schütze, coordinator of the UKU's geriatric trauma center and level 1 trauma center, remarked that while pelvic ring fractures account for only [2–8% of all skeletal injuries](#), they are among the most complex to diagnose and to classify.

"A patient with such an injury usually presents in the emergency department and is seen by a physician in training who has encountered few pelvic ring fractures. Even advanced residents probably haven't seen many of these fractures, so our technology will be a very good support for them as well as for the attending radiologist," he explained. "Radiologists can identify a pelvic ring fracture better than a surgeon, but they usually are not trained to classify it—and if you don't classify the fracture, you probably can't plan your treatment accordingly," he declared.

The developed technology will detect fractures in a patient's computed tomography (CT) scan and use AI to classify the fracture ([Fig 2](#)): The surgeon will upload CT images into the cloud and analyze them with help from the software; the surgeon will then mark all parts of the pelvic ring fracture. In a second step, the AI will help identify all parts of the fracture and independently classify it.

"The surgeon would then only need to verify correct marking and could use the structured report for treatment planning," Schütze commented. Based on the AI provided AO classification the surgeon may directly go to AO Surgery Reference to receive best in class advice how to plan the respective surgery.



Fig 2 Mint Medical software

Effective joint-lubrication to reduce wear-related knee joint pain: AO-supported injectables could transform the treatment of knee osteoarthritis

Scientist Ronit Goldberg, PhD, did not set out to become an entrepreneur but 13 years after becoming coinventor of a groundbreaking liposome-based lubrication technology, she is CEO of [Liposphere](#), an innovative women-led, Israeli biomedical start-up spun out from the [Weizmann Institute of Science](#) in early 2019 (Fig 1). Today with support from AO's innovation funding the company's [AqueousJoint](#) injectable (Figs 2–3) has the potential to help patients with osteoarthritis (OA) regain mobility and could set new standards in the continuum of osteoarthritis care.

Osteoarthritis is characterized by the degradation of the lubricious cartilage surface, and patients with OA suffer from pain, loss of function, and poor quality of life. There is no cure for OA; in the end, patients will undergo total knee replacement surgery.

Due to the lack of curative therapies, the current standard of care focuses on pain management, including nonsteroidal anti-inflammatory drugs and intraarticular injections of hyaluronate-based viscosupplementation.



Fig 1 Liposphere cofounders Ronit Goldberg (left) and Sabrina Jahn (right).

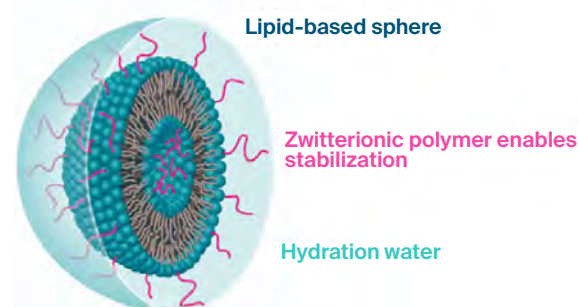


Fig 2 Visual scheme and composition of AqueousJoint liposome; the liposomes consist of more than 95% water.

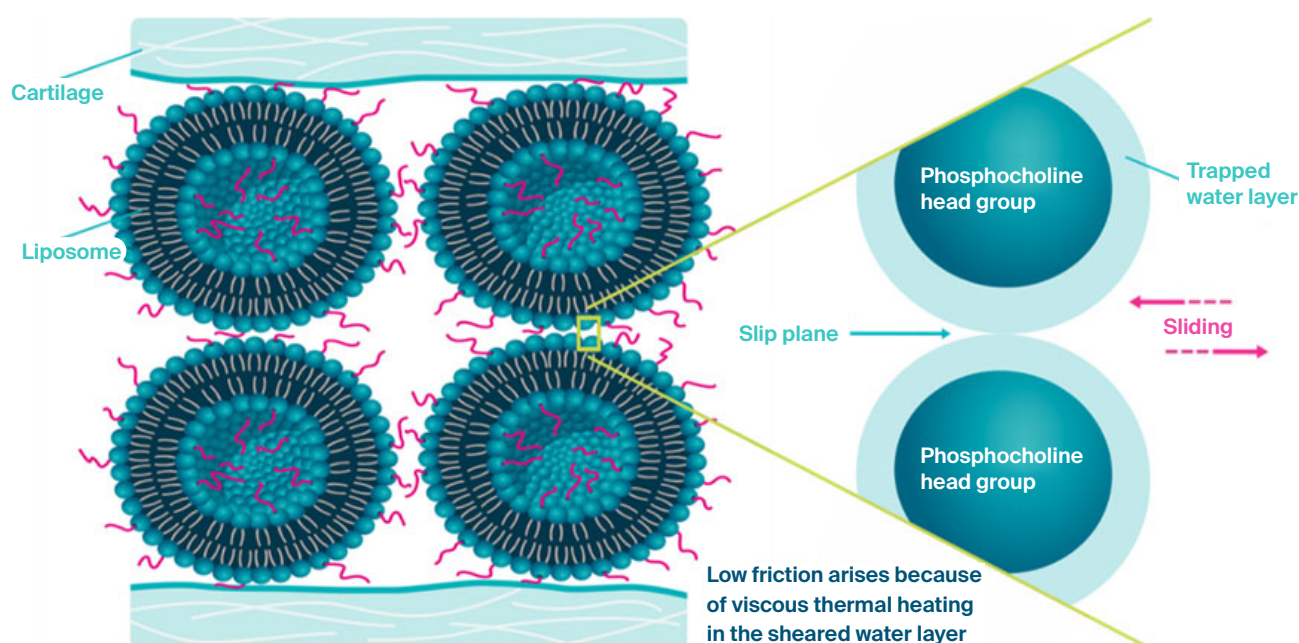


Fig 3 Visual scheme of the hydration lubrication mechanism of AqueousJoint; the effect of the liposomes is comparable to a layer of oil trapped between sliding surfaces.



Fig 4 Liposphere received the best early-stage company award in recognition of AcqueousJoint at the Alliance for Advanced Therapies in Orthopaedics annual conference, Berlin, Germany, May 2023.

“These materials showed extremely low friction and wear. We were able to measure, as far as I know, the lowest shear forces ever measured under high pressures between articulating surfaces covered with these materials,” Goldberg noted. “So, it was a real discovery.”

In 2010 the institute filed a first patent detailing the use of specific liposomes to reduce friction—with Goldberg among the coinventors—and, eventually, six more related patents. Goldberg explained that she and a colleague from Weizmann Institute of Science, physicist Sabrina Jahn, PhD, successfully negotiated the right to commercialize the technology and cofounded their start-up, Liposphere, in early 2019.

“With increasing longevity, there is a need to find an efficient treatment for patients with OA and postpone the surgery to avoid more than one knee replacement procedure.” Ronit Goldberg, PhD

The scientific community sees the technology’s potential: [The Spinoff Prize 2020](#), organized by Nature and Merck KGaA, recognized Liposphere as one of the 44 most exciting,

science-based firms spun out of academic environment. In 2023 the company ([Fig 4](#)) was voted best early-stage company during the yearly conference of the [Alliance for Advanced Therapies in Orthopaedics](#), Berlin, Germany.

It is important to collaborate with experts in the orthopedic field to bring their insights, Goldberg said. It was cofounder Jahn’s connection to vice director [Mauro Alini](#), PhD, at the AO Research Institute Davos (ARI) who recommended that Liposphere submit a project to AO’s innovation funding.

The AO is supporting Liposphere with ex vivo investigations at ARI to study AqueousJoint’s mechanical properties and a sheep study, also at ARI, to investigate the performance of the product. Additionally, the AO provides support to establish a quality management system and technical documentation for Liposphere’s orthopedic product.

Following a 150-patient clinical study that is now underway, upscaling of AqueousJoint production, and filing for a CE mark, the product could be available to surgeons and patients in 2025.

Proof of concept project aims to explore new ways of using surgical videos in education



For years the AO has been successfully using high-quality standardized surgical videos for education purposes. Now, with the support of AO's Strategy Fund, a project is underway to investigate the expansion of formats and applications of surgical videos for educational purposes.

The 11-month proof of concept project began in May 2023 and is led by AO faculty Tobias Fritz in collaboration with the AO Education Institute (AO EI) and AO strategic partner RIMASYS.

Passion for innovation

"This project arose from discussions between AO President Tim Pohlemann, AO Education Commission chairperson Mark Reilly, and AO EI Executive Director Tobias Hüttl," Fritz mentioned, an associate professor at Saarland University, Germany. "I am a friend of innovation and improvement of surgical techniques, I'm very interested in education, I'm a video guy, and I love to create content. This project allows me to combine these passions."

This dedication and learners' need for increasingly high-quality, standardized educational material positioned Fritz to lead the project. To prove the concept, Fritz and colleagues will create high-quality surgical video material with multichannel application and the possibility of integrating 3D elements showing the surgeon's perspective during an operation.

Raising the standard

"Compared to the current standard for surgical videos, we are innovating with the multichannel acquisition of motion and still pictures in 8K resolution," Fritz explained. Based on multiple video streams, including 3D, video material can be remixed and reedited for various uses, including:

- Full-length surgical video, including an introduction, the approach, and fracture reduction and stabilization

- Short videos for social media, with a focus, eg, on the most important aspects of a procedure or on a specific aspect
- Use of the video material as a "re-live" presentation with a surgeon and moderator providing live commentary on the video to create an authentic live atmosphere
- Exploration of 3D video options which could open a virtual learning space

Fritz remarked the video content can also supplement existing high-value tools like the AO Surgery Reference.

"For example, if you're a surgeon looking to refresh your skills before a surgery, you could choose between a longer video covering all aspects of a surgical procedure or opt for a quick refresher video," he explained, noting that short "reels" have the potential to fortify the AO's social media presence and play a role in community development.

Vast expertise under one roof

Proving such an ambitious concept requires funding, expertise, and management, and when it came time to seek resources, Pohlemann who chairs the Department of Trauma, Hand, and Reconstructive Surgery, Saarland University Hospital, steered Fritz to the AO's innovation funding.

"The AO's innovation funding has brought a lot of resources together for us, from the AO Education Institute which is providing project management and connecting us to internal resources like the AO Surgery Reference and to strategic partners, to RIMASYS for expertise on manuscript preparation, organizing the film crew, and accessing anatomical specimens," Fritz stated. "The AO team is easy to work with: They help you think and rethink your whole project, and they provide valuable guidance and access to internal and external expertise, and because it's the AO, there's a lot of expertise all under one roof."

Patient convalescing following first-in-human AO Fracture Monitor application

Sixty-five years after the AO was established to champion revolutionary internal fixation techniques that continue to achieve unprecedented results in fracture healing, its legacy of improving patient outcomes continues with the first-in-human application of the AO Fracture Monitor (Fig 1) developed by the AO Research Institute Davos (ARI) with the AO's innovation funding. In an important step toward regulatory approval, the safety of this implantable telemetric sensor system is now being validated in a multicenter clinical trial at four hospitals in Germany.

Attached to a DePuy Synthes Variable Angle LCP™ Curved Condylar Plate and implanted by Benedikt Braun (Fig 2) an orthopedic trauma surgeon at BG Unfallklinik Tübingen, Germany, on October 2, 2023, the AO Fracture Monitor has since been continuously monitoring the healing of a 61-year-old German patient who sustained a significantly comminuted fracture in a 3m fall from a ladder (Fig 3).

"X-rays are not especially reliable for fractures in the diaphyseal region in terms of assessing bone healing," Braun

remarked, pointing out that while the data collected by the AO Fracture Monitor are currently not available to him nor to the patient due to the study design, which focuses on the safety of the device but does not allow data of the fracture monitor to interfere with any treatment decision. The system ultimately will enable surgeons and their patients to continuously track load-bearing right after their surgical fracture treatment.

"With this system, you can get a glimpse of the fracture healing over time: If the load on the implant decreases, it means that there is more load sharing by the fracture site indicating increasing fracture consolidation. Eventually, you want the load on the plate to be zero because the bone should support all the load. The AO Fracture Monitor will allow surgeons and patients to continuously monitor the individual healing trajectory and detect and react to healing disturbances early on, rather than waiting for x-ray or computed tomography [CT] scans at different timepoints, sometimes quite late during the treatment process," Braun declared.

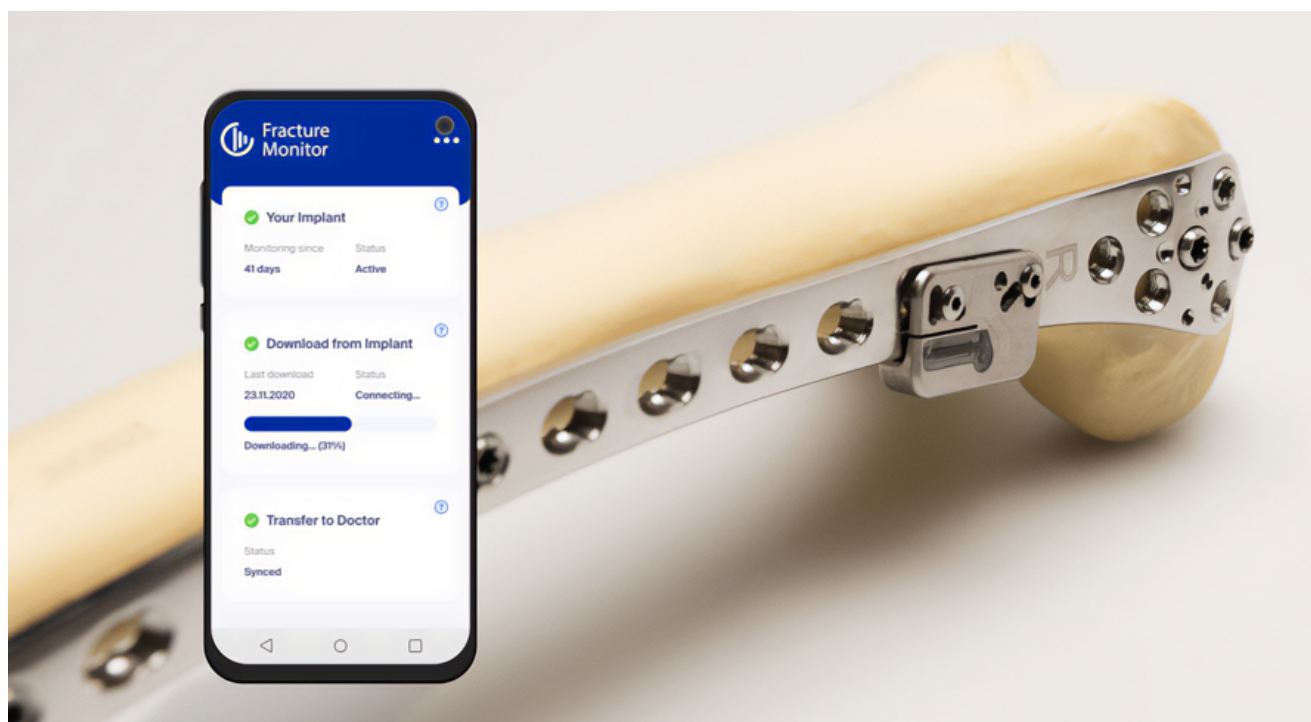


Fig 1 The novel AO Fracture Monitor System for remote monitoring of implant load.

Braun, principal coordinating investigator for the current clinical investigation and chairperson of the AO Technical Commission (AO TC) Smart Digital Solutions Task Force, examined the patient on November 27, 2023, for the 8-week follow-up.

“He’s doing great and is very excited to be part of this study. All he has to do is check from time to time on the smartphone

app that the data is transferred,” Braun commented. “The patient is recovering on schedule and is happy with the treatment and study so far—but he would love to see the data, of course. My hope for this patient is that when he comes back another 6 to 8 weeks from now, he will be back to his preinjury condition.”



Fig 2 From left to right: Aleksandra Vidakovic, Benedikt Braun, and Manuela Ernst, site initiation visit, Tübingen, Germany.

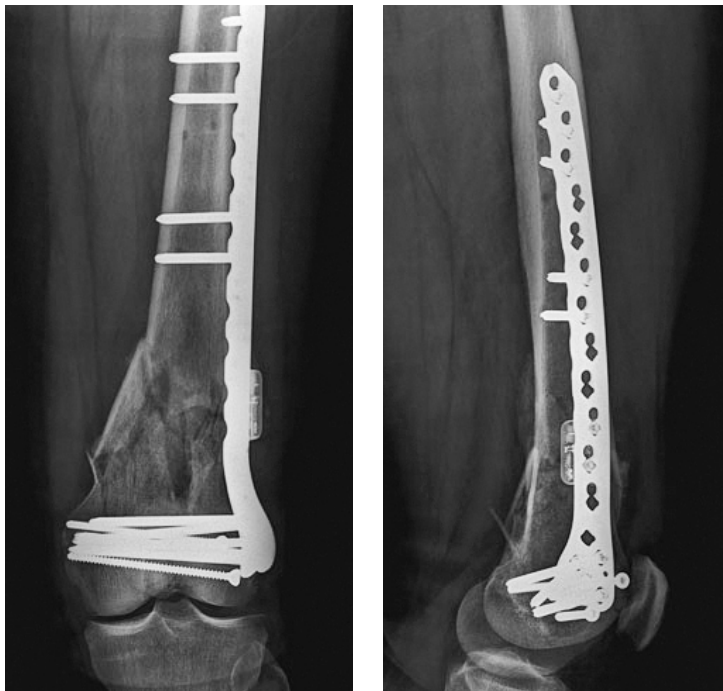


Fig 3 X-ray images of the first patient enrolled in the clinical investigation at the follow-up examination after 8 weeks.

Many milestones

AO Research Institute Davos (ARI) Senior Project Leader Concept Development Manuela Ernst said the first-in-human application of the AO Fracture Monitor is just the latest of several milestones in the project's history, but the most awaited one (Fig 4).

The system, that represents an innovative approach to individualizing patient rehabilitation, emerged from talks between former ARI Focus Area Leader Concept Development, Markus Windolf, and AO Foundation founding father and longtime ARI Director, Prof Stephan Perren. After many design iterations and fine-tuning, and eventually formal product development, a new type of telemetric system was created, and now the development team has an active implantable device ready for clinical application. The current clinical study got underway in autumn 2023 with two patients enrolled. Over the next months, a total of 37 patients will be recruited in Germany at the participating hospitals [BG Klinik Tübingen](#), [Universitätsklinikum des Saarlandes](#), [Universitätsklinikum Ulm](#), and [Universitätsklinikum Münster](#).

The first-in-human application of the AO Fracture Monitor is a milestone, Ernst said.

"It was an incredible experience to be able to observe the first surgery and actually see how the AO Fracture Monitor was implanted in a patient after so many years of development," she recalled. The current study is expected to conclude in spring 2025 and provide the missing data for the subsequent conformity assessment by the notified body for market approval in Europe. "We anticipate a CE mark by the end of 2025 and availability for larger clinical studies by early 2026," Ernst noted.

'A full-service resource'

Braun emphasized that AO innovation funding is critical in bringing new technologies to clinicians and promoting excellence in patient care and outcomes in trauma and musculoskeletal disorders.

"The AO Fracture Monitor is revolutionary in that it represents a step away from relying on traditional modalities like x-rays and toward a much more patient specific and accurate ways of monitoring bone healing," he stated. And added, "The AO is helping make this project possible with not only funding but expertise at every step of development. To make a great idea a reality, you need strong partners, and the AO—with the AO Innovation Translation Center, including AO's innovation funding and Clinical Evidence teams, all the way to ARI—is truly a full-service resource."



Fig 4 Surgical team led by Benedikt Braun (third from right) after the successful first-ever clinical application of the AO Fracture Monitor implant.

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