

# Innovations 2024





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# VOLT<sup>™</sup> Mini Fragment and VOLT Small Fragment Plating Systems

Developed by the Next Generation Plating Task Force of the AO Technical Commission in collaboration with Johnson & Johnson MedTech, the Variable Angle Optimized Locking Technology (VOLT) Mini and Small Fragment Plating Systems are instrument and implant sets intended for the internal fixation of bones and bone fragments of the appendicular skeleton appropriate for the implant size. The main objective of the Task Force was to create a robust system with exceptional locking performance and stability for a wide range of implant shapes and sizes in both stainless steel and titanium.

#### System description

The VOLT system features new variable angle locking technology while maintaining the proven Dynamic Compression Unit (DCU). It delivers the stability of the Locking Compression Plate (LCP) system and the flexibility of the Variable Angle Locking Compression Plate (VA-LCP) system. The VOLT System includes mini (2.0 mm, 2.4 mm, and 2.7 mm) and small (3.5 mm, and 4.0 mm) fragment generic plates and VA locking, cortex, and cancellous screws (Figs 1–4) as well as instruments for open reduction and internal fixation of bone fragments.

VOLT implants are available in stainless steel and titanium in all sizes.

Both the Mini Fragment and Small Fragment Plating Systems are intended for adults, children (2–12 years), and adolescents (12–21 years) in which growth plates (physes) have fused, or in which unfused growth plates will not be compromised by fixation.

The indication is such that the plating systems support auxiliary plating techniques and education. Instructions for use and surgical technique are available from Johnson & Johnson MedTech with details of indications, contraindications, side effects, warnings, and precautions.

The new plates are designed to offer various options regarding plate shape and profile as well as hole density appropriate to different fracture patterns. The instrument functionality has been improved and a consistent look and feel has been implemented to ensure ease of use.

The Mini Fragment and Small Fragment Plating Systems are designed in a modular way, to be assembled according to customers' preferences. Color-coded universal and size-specific instrument and implant trays support the surgeon and the tech staff in choosing the right instruments for the selected plates.

#### **Mini Fragment implants**



Fig 1 Overview of the VOLT Mini Fragment generic plates.

Note: The Quarter Tubular Plate is an existing non-locking plate, not a new VOLT plate.

Cortex Stainless Steel	Cortex Titanium	Locking Stainless Steel	Locking Titanium
1			Ī
	C		
Silver	Bronze	Aqua head	Aqua
	Driver Type	Driver Size	Screw Lengths
2.0 mm	StarDrive™	Т6	6–20 (1 mm increments) 20–50 (2 mm increments)
2.4 mm	StarDrive™	T8	6–20 (1 mm increments) 20–60 (2 mm increments) 60–90 (5 mm increments)
2.7 mm	StarDrive™	T8	6–20 (1 mm increments) 20–60 (2 mm increments) 60–90 (5 mm increments)

Fig 2 Overview of the VOLT Mini Fragment screws.

#### **Small Fragment implants**

#### Straight Plate



Holes: 4, 5, 6, 7, 8, 9, 10, 12, 14, 16, 18, 20, 22

#### Recon Plate



Holes: 4, 5, 6, 7, 8, 9, 10, 12, 14, 16, 18, 20, 22

#### 1/3 Tubular Plate



Holes: 2, 3, 4, 5, 6, 7, 8, 10, 12

Fig 3 Overview of the VOLT Small Fragment generic plates.

#### Metaphyseal Plate



Holes: 7, 8, 10, 12, 14, 16, 18, 20





Cortex Stainless Steel	Cortex Titanium	Locking Stainless Steel	Locking Titanium	Cancellous Stainless Steel	Cancellous Titanium
				00000000000000000000000000000000000000	<b>6</b>
Silver	Bronze	Aqua head	Aqua	Silver	Bronze
Screw Diameter	Driver Type	Driver Size		Screw Lengths	
3.5 mm	StarDrive™	T15	10–60 (2 mm increments) 60–110 (5 mm increments)		
4.0 mm (Cancellous screws only)	StarDrive™	T15	10–40 (2 mm increments) 40–100 (5 mm increments)		

Fig 4 Overview of the VOLT Small Fragment screws.

#### **VOLT locking technology**

A key innovation of the VOLT platform is the novel variable angle locking technology (Figs 5–6). The VOLT holes appear round but actually have a subtle triangular shape with threads that are precisely engineered with tight manufacturing tolerances. The unique shape of the VOLT holes enables the plate threads to adapt to the screw threads as the screw is inserted. The result is excellent plate to screw engagement and robust cantilever strength. The technology allows for a screw angulation of up to 15°, hence a locking cone of 30°.

The cantilever strength of a VOLT plate/screw (2.4 mm, 2.7 mm, 3.5 mm) interface at nominal (0°) is equivalent to the LCP plate/

screw interface at nominal (0°), yet VOLT delivers variable angle capability (Static Cantilever Strength; Fig 7). Thus, the VOLT technology combines the advantages of an LCP with the option of variable angle locking technology. Also, the new combi holes benefit from the VOLT locking technology in the locking part of the combi hole.

All VOLT hole types accept the use of either locking or cortex and cancellous screws. Accordingly, the same fixation principles apply as with previous LCP and VA-LCP systems, facilitating education and transition to VOLT.



**Fig 5** Shown here on a 3.5 metaphyseal plate are examples of all VOLT hole types: VOLT hole, VOLT combi hole, and VOLT elongated combi hole. The combi and elongated combi hole incorporate the DCU, known from the LCP and Limited Contact Dynamic Compression Plate (LC-DCP) systems, as well as the variable angle locking screw hole.



**Fig 6a-b** VOLT variable angle locking is designed to enhance engagement between the screw and the plate for maximum interface locking strength. The combi holes feature the new locking technology in the locking part of the combi hole as well as the proven DCU functionality in the non-locking part of the hole.



**Fig 7** Static cantilever strength of 3.5 mm locking interfaces at 0° screw insertion. Values above 4Nm indicate that something other than the plate/screw interface failed. This means that the plate/screw interface is stronger than the implants.

#### Screws

A combination of locking, cortex, and cancellous screws offers versatile options tailored to the VOLT plates. To streamline the surgical steps, instruments are color-coded according to screw diameter. Additionally, a single- or double-band etching assists in identifying complementary parts.

Screws, equipped with an optimized Stardrive recess design (Fig 8), along with new screwdrivers, are intended to enhance the user experience. In addition to the optimized recess design, cortical and cancellous screws have lower profile heads compared to previous designs due to soft-tissue considerations.

The locking screws are designed for locking performance, while offering cutting flutes for ease of insertion and a rounded screw tip (Fig 8), both designed to reduce the risk of soft-tissue irritation.

In the VOLT Small Fragment system, the 4.0 mm cancellous screw offers better hold in the bone compared to the 3.5 mm cortical screw and remains an important fixation option in epi-metaphyseal zones. To support removal, the cancellous screw features back-cutting flutes.

The system offers longer screws compared to its predecessor, providing greater versatility (2.0 mm: up to 50 mm; 2.4 mm and 2.7 mm: up to 90 mm; 3.5 mm: up to 110 mm).

#### Plates

The VOLT Mini and Small Fragment Plating Systems feature a wide range of generic plates (Fig 1). Generic plates, also called non-anatomic or utility plates, are a key pillar in trauma surgery due to their adaptability and versatile application as primary fixation or as an auxiliary fixation device to other implants. All new generic plates feature VOLT technology (Fig 9). Several new plate shapes and lengths have been introduced. Design features on the plates such as rounded profiles and tapered tips are beneficial as they respect soft tissue and can be used in less invasive surgical techniques. VOLT plate shapes and screw hole patterns are intended to optimize plate function, whether for locking, compression, or buttressing, ensuring efficacy and stability in various orthopedic applications. Furthermore, plate options with increased screw hole density are available, offering more fixation options and thereby providing surgeons with greater flexibility and precision to meet daily fracture fixation challenges.

VOLT titanium plates and screws are anodized and then treated with an electropolish finish. Electropolishing the titanium plates and screws produces a surface texture (Fig 10) similar to stainless steel. This smooth surface finish reduces bony ongrowth and soft-tissue adhesion, which has been shown to ease implant removal.





Low profile screw head

Locking screw head optimized for locking performance in titanium and stainless steel.



Locking screw tip with cutting flutes supporting insertion while having a rounded tip.



Fig 8a-h Screw features that aim to provide excellent handling and fixation.





#### Plate types and features Straight plates

Straight plates are available for all sizes and are optimized for strength. The proven plate undercuts from LC-DCP and LCP are maintained to give the plate a widely uniform stiffness, supporting continuous bending while limiting contact with the bone when applied with non-locking screws. While keeping the rounded, smooth tip to support less invasive insertion, holes are also placed close to the ends of the plate, offering a wide fixation range (Fig 11). Two K-wire holes give an additional option for temporary fixation. The 2.0 mm, 2.4 mm, and 2.7 mm plates are also available in a compact version.



VOLT Stainless Steel



**Fig 10** Electropolishing VOLT titanium implants generates a surface smoothness similar to stainless steel.

#### **Mini Fragment generic plates** Adaption plates

Adaption plates offer the surgeon greater freedom to adapt the plate to specific anatomical situations. Accordingly, they are optimized to allow in-plane, out-of-plane, and torsional bending and cutting to trim the plate to the length needed. Additional focus was given to producing a low and smooth plate profile as these plates are often used in soft-tissue critical zones. Depending on the adaption plate type, the plates offer the VOLT hole, combi hole, elongated combi hole, or a combination thereof (Fig 12). Adaption plates were developed for sizes 2.0 mm, 2.4 mm, and 2.7 mm.

#### Straight adaption plates

These plates are available with a combi hole and in a compact version (Fig 13). The plates are offered in a length of up to 20 holes.



Fig 12 Adaption plate profile with various hole options.





Fig 11a-b Straight plate with K-wire holes and tapered tips to support insertion. The holes at either end of the plate are very close to the tip.



Fig 13a-b 12-hole adaption plate. Combi hole and compact versions.

#### Condylar, Y, and T plates

These plates feature a head element (Fig 14) and are suited for fracture situations where additional fixation options are required.

#### Hook plates

The hook plate's adaptability and sharp hooks (Fig 15) allow the plate to grab and hold small fracture fragments close to a

joint and compress them to the shaft. A recess between the hooks (Fig 16) supports the secure placement of a cortical screw if needed.

#### Triangle plates

The triangle plate (Fig 17) is designed to offer a broader buttressing surface with multiple fixation options. Therefore, the plate has a triangular head shape.



**Fig 14a-d** Condylar, Y, and T Plates (3- and 5-hole T). 10-hole plate versions offer two elongated combi holes to address extended fractures.



Fig 15 6-hole 2.7 mm hook plate.



Fig 16a-c Recess between the hooks supports seating of a screw head.



**Fig 17** 10-hole triangle plate with two elongated combi holes.

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#### **Tine plates**

The tine plate (Fig 18) was developed to give a broader buttress surface and to offer additional support to hold small fragments. Therefore, the plate features a two-hole wide head and two tines that grab the bone.

#### Small Fragment generic plates

#### Metaphyseal plate 3.5 mm

The long taper at the tip of the metaphyseal plate 3.5 mm (Fig 19) supports buttressing techniques and plate adaption to different anatomies as well as having a low prominence considering the often delicate soft-tissue situation. There are three VOLT holes that have an initial screw trajectory of 7° that accommodate plate bending to avoid the joint surface. The longer plates also contain two elongated holes in case of fractures extending into the shaft. The shaft of the plate otherwise offers the same characteristics as the straight small fragment plate.

#### T plate 3.5 mm

The VOLT T-Plate (Fig 20) is a thin flat plate, intended mainly for buttressing applications in multiple different indications. The plate is offered with a 4- and 3-hole T section. Frequently used close to joints, the plate is designed with K-wire holes with undercuts to facilitate suturing (Fig 20).

#### **Reconstruction plate**

The versatile reconstruction plate (Fig 21) is designed for situations where bending in different planes is required. It is therefore optimized for in- and out-of-plane bending and for torsional bending, while broadly keeping hole functionality.

#### 1/3 Tubular plate

The 1/3 tubular plate (Fig 22) maintains its position as a key implant in today's surgery. Of critical importance was the integration of VOLT technology to incorporate the advantages of VA locking fixation into the plate, while maintaining the elastic properties and thinness of current plates.



Fig 20a-c Top view of a 3-hole T-Plate. Three undercuts that support suturing are highlighted in the 4-hole head T-Plate.



**Fig 21a-b** Reconstruction plate. In addition to the bending properties, special care was taken to achieve the rounded end shape.



Fig 22 8-hole 1/3 Tubular plate.

#### Instruments

Instrument handling is critical for successful surgical outcomes and must be intuitive and simple. Therefore, great efforts were made to improve instrument handling during the development of the VOLT Mini and Small Fragment Plating Systems. Key points are highlighted here.

#### Provisional fixation options

Forceps, K-wires, plate reduction wires, or compression wires can be used to provisionally position and fix the plate to the bone prior to screw insertion (Fig 23). Fracture reduction can be performed using visualization, if necessary, with or without fluoroscopy. After reduction, fragments are stabilized as needed with implants, K-wire(s), the innovative cannulated fragment reduction tool (Fig 24), or reduction forceps. Alternatively, the fracture can be reduced using the plate by means of non-locking screws in the combi or elongated combi holes. In addition to forceps with a standard rachet (Fig 25), VOLT offers three new forceps with long rachets, that can provide a wider span (Fig 26, 27).



Fig 23a-c Temporary fixation options.





Fig 24 Fragment Reduction Tool.



Fig 25 Standard rachet forceps.



Fig 26 Long rachet forceps.



**Fig 27** Long rachet forceps can provide a wide span. Shown here used on a tibia in an anatomy lab.

#### Depth gauge and measurement

The VOLT depth gauges are color-coded according to screw diameter and are available in different lengths. The depth gauges feature a new tip shape designed to improve hook engagement on the far cortex for accurate and reliable measurements. Independent of the measuring situation, screw size, and screw type, the depth gauge reliably measures the length of the screw needed without additional calculations (Fig 28).

Additionally, the depth gauge is designed to support different handling preferences (Figs 29, 30).

#### **Drill bits and drill guides**

A key focus is the handling of the drill and mating drill guides. Both the screw type and the drill bit diameters are displayed. The marking features are standardized across the VOLT system.



Fig 28 Depth gauge measurement.



**Fig 29** Two-handed use (3.5 mm depth gauge).



Fig 30 One-handed use (2.0 mm depth gauge).



The VOLT drill bits are available in short and long lengths. Calibration numbers are clearly etched on them. To simplify reading, each number is etched twice onto the drill bit to make it visible regardless of the position of the drill.

During the development of the threaded drill guides, special care was taken to allow for easy attachment to plate holes, even in plates bent within the bending guidelines. Handling of the threaded drill guide, including insertion and removal, can be supported with the screwdriver in the following sizes: 2.4 mm, 2.7 mm, and 3.5 mm (Fig 33).

Insertion and removal of the threaded cone drill guide is enhanced by a dedicated inserter (Fig 34).

#### **Drill guides and their function** VOLT Cortex/Locking Double Drill Guide

- The locking end of the VOLT Cortex/Locking Double Drill Guide is used for free-hand variable angle drilling for locking screws.
- The non-locking end of the VOLT Cortex/Locking Double Drill Guide can be used for neutral and eccentric drilling in the DCU.

#### VOLT Double Drill Guide

 The VOLT Double Drill Guide is used for drilling for cortex screws, within a plate hole or independent of a plate, and can also be used for drilling the glide hole in the lag screw technique.



**Fig 32** Calibration marking on a 2.5 mm drill bit from the Small Fragment system.



**Fig 33** The threaded drill guide mates with holes even in bent plates. The screwdriver fitting recess in the drill guide supports handling. Displayed is the 2.7 mm threaded drill guide with centering sleeve for a 1.25 mm K-wire.



**Fig 34** The 3.5 mm version of the threaded cone drill guide is shown, with and without the inserter.



**Fig 35** VOLT Cortex/Locking Double Drill Guide for 2.7 mm plates.



Fig 36 VOLT Double Drill Guide for 2.7 mm plates.

#### **VOLT Threaded Cone Drill Guide**

• The VOLT Threaded Cone Drill Guide can be used to limit drilling within the 30° allowed for locking screws.

#### Color coding

Color-coded universal and size-specific instrument and implant trays help the surgeon and the tech staff to select the right instruments for the selected plates (Annex Fig 39-43). Mini 2.0 mm-blue Mini 2.4 mm-purple

Mini/Small 2.7 mm–orange Small 3.5 mm–black

#### Plate contouring (cutting and bending)

The different cutting and bending instruments can be used to contour and size the plate(s) to the fracture and patient anatomy. Prebending or contouring can be a useful technique to achieve adequate compression across the entire fracture surface.

The newly developed bending pins for the 2.0 mm and 2.4 mm plates can be used to bend the plates either prior to insertion or in-situ.

#### **Postoperative treatment**

Postoperative treatment with VOLT Mini and Small Fragment plates and screws does not differ from conventional internal fixation procedures.

#### **General information**

The VOLT system is not yet registered in all markets. It will be released progressively in different markets.

The VOLT Mini and Small Fragment systems are base platforms with a wide range of generic plates and applications. They will be progressively supplemented with anatomical preshaped plates that also utilize VOLT technology. Over time, it is envisioned that the VOLT Platform will gradually replace existing LCP and VA-LCP plating systems.

#### Annex

#### VOLT instruments overview

All instruments are color coded according to the size of the implants. Instruments which can be used for different sizes are grey.







Fig 38 Bending pins.



Fig 39 Overview of instruments within the VOLT Mini Fragment and Small Fragment Plating Systems.

Double Drill Guides (cortex)				
Locking/Non-Locking Drill Guides				
Drill Bits and Taps			000000 0000000000000000000000000000000	
Screwdriver Shafts		0 a		
Depth Gauges				§
Handles, TLA				
Reduction Tools		£}e	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	2
Bending and Cutting	€m €1 <sup>m</sup>			

Fig 40 Overview of all VOLT Mini Fragment base and generic instruments.



Fig 41 Overview of all VOLT Small Fragment base and generic instruments.

VOLT delivery - case and trays



**Fig 42** VOLT Mini Fragment case with trays, showing one set option. The set content is modular and can be selected. Aluminum trays are displayed, but case and trays are also available in stainless steel.





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**Fig 43** VOLT Small Fragment case with trays, showing one set option. The set content is modular and can be selected. Aluminum trays are displayed, but case and trays are also available in stainless steel.

# MatrixSTERNUM<sup>™</sup> Fixation System

#### Abstract

The innovative MatrixSTERNUM™ Fixation System provides a low-profile plating solution for sternotomy and thoracotomy repair that is based on the locked plating technology offered in the MatrixRIB Plating System. Containing a variety of 1.5 mm titanium sternal body and thoracotomy locking plates, screws, screw guides, instruments, modules, and trays, the Matrix-STERNUM™ Fixation System addresses the critical need for faster and more precise plate fixation following cardiac surgery, particularly for high-risk patients. The system includes dedicated multi-hole screw guides that reduce the number of steps and intraoperative time required for plate placement and screw insertion by the surgeon.

The MatrixSTERNUM<sup>™</sup> Fixation System is designed for strength, operating room efficiency, and ease of use. The system is proven to provide three times greater construct locking strength compared to current products on the market. In addition, multi-hole Screw Guides result in 43% faster screw insertion compared to current products on the market. The low-profile plates in the system are 1.5 mm thick for contourability and low palpability.

#### **Clinical needs addressed**

Every year in the U.S., approximately 200,000 people undergo coronary artery bypass graft (CABG) surgery, making it the most common type of heart surgery [1]. Ensuring chest-wall stability post-surgery is critical for patient recovery. Surgeons need a fast, simple, and easy-to-use solution for rigid sternal fixation that minimizes primary closure time after an oftenlengthy cardiothoracic procedure. Additionally, plate thickness is a significant concern as surgeons wish to simplify plate contouring and reduce the palpability of the implants.

Current sternal fixation systems often lack sufficient locking strength and are time-consuming to implant. Furthermore, they offer thicker plates that can be noticeable under the skin and uncomfortable for patients. Innovations in sternal fixation techniques are urgently needed to promote better healing, reduce complications, and reduce recovery times.

The MatrixSTERNUM<sup>™</sup> Fixation System addresses these clinical needs by offering enhanced locking strength, faster and more precise fixation, and low-profile, highly contourable plates. This advanced system addresses the specific needs of patients, surgeons, and healthcare providers, and aims to provide better outcomes and improved patient comfort.



Fig 1 Sternal closure using a three-plate MatrixSTERNUM™ construct.



Fig 2 Plate fixation using the multi-hole Screw Guide.

#### **Product details**

The MatrixSTERNUM™ Fixation System (Fig 3) consists of two families of plates and screws:

MatrixSTERNUM™ Sternal Body Plates (Fig 3 and Fig 7): indicated for internal fixation of bone discontinuities following sternotomy.

- 12 plate shapes/sizes, color-coded for size (width)
- Material: CP Ti Grade 4
- Plate thickness: 1.54–1.60 mm

### MatrixSTERNUM<sup>™</sup> Fixation System Plates & Screw Guides





MatrixSTERNUM™ Thoracotomy Plates (Fig 3): indicated for internal fixation of bone and/or cartilage discontinuities following thoracotomy.

- Three plate shapes/sizes
- Material: TAN
- Plate thickness: 1.54 mm

The plates are available in different shapes and sizes and are made from titanium alloy or commercially pure titanium. The sternal body and thoracotomy plates are designed for emergent re-entry.

MatrixSTERNUM™ Self-Drilling Locking and Non-Locking Screws (Fig 3 and Fig 4): designed for stabilization and fixation of bone in the anterior chest wall.

- Locking Screws: Ø2.7 mm, self-drilling, 8-20 mm long, 1 mm increments
- Non-Locking Screws: Ø2.7 mm, self-drilling, 10 mm and 12 mm long
- Material: TAN

The system's locking screws are offered in 1 mm-increment lengths for better bicortical fit and fixation, with lengths ranging from 8–20 mm.

The implants are color-coded, simplifying the plate fixation procedure for the surgeon.

#### MatrixSTERNUM™ Instruments

The system also includes non-implantable dedicated-use Screw Guides (Fig 2 and Fig 3), a Screw Guide Handle (Fig 5), trays and modules for storage, and general use instruments to be used as accessories with the implants (Fig 6). These include Sternal Reduction Forceps, Bending Pliers, Plate Cutters, and In-Situ Benders.



**Fig 4** MatrixSTERNUM<sup>™</sup> Self-Drilling Locking Screw







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**Fig 5a-c** Components of the Matrix-STERNUM™ Fixation System: (**a**) Sternal Reduction Forceps, X-Plate and Single-Hole Guide; (**b**) X-Plate and 8-Hole Screw Guide; (**c**) 8-Hole Screw Guide with Handle.



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Bending Pliers

Plate Cutters





#### Key features and benefits

The MatrixSTERNUM™ Fixation System offers several key benefits:

- Enhanced locking strength: The system provides three times greater construct locking strength compared to the market-leading product, ensuring better fixation of the sternum during the critical postoperative healing period.
- **Speed and efficiency:** The multi-hole Screw Guides allow for rapid and precise plate fixation, significantly reducing the surgical procedure time via a reduced number of steps for plate placement and screw insertion. Overall, screw insertion is 43% faster compared to the market-leading product.
- Low-profile design: The 1.5 mm low-profile plates are thinner, making them less palpable under the skin and enhancing patient comfort.
- **Contourability:** The plates are highly contourable, allowing them to be adapted to the sternal and rib anatomies. In-situ Bending Instruments, Combination Bending Pliers, and Bending Pliers are offered with the system.
- **Comprehensive plate offerings:** The system features a wide range of plate options. This reduces the need for plate cutting to adapt plates to the sternal and rib anatomies.

#### Indications

The MatrixSTERNUM™ Fixation System is indicated for use in adults with normal bone quality.

- MatrixSTERNUM™ Sternal Body Plates are indicated for internal fixation of bone discontinuities following sternotomy.
- MatrixSTERNUM<sup>™</sup> Thoracotomy Plates are indicated for internal fixation of bone and/or cartilage discontinuities following thoracotomy.



**Fig 7** The MatrixSTERNUM<sup>™</sup> Fixation System offers plates that are low-profile and highly contourable.

#### Contraindications

• MatrixSTERNUM™ Thoracotomy Plates are contraindicated for screw attachment or fixation to the clavicle or spine.

#### **Clinical impact**

Recent research indicates that compared to wire cerclage, using rigid plates for fixation following sternotomy can help to reduce sternal complications for high-risk patients, reduce perioperative mortality rates, and shorten hospital stays [2].

Wire cerclage is a long-established and low-cost solution for sternal closure that offers adequate outcomes [3]. However, the ability of wire cerclage to provide rigid fixation and prevent sternal movement is limited [3]. The resulting sternal instability can be associated with complications including bony nonunion, infection, and dehiscence, especially in high-risk patient populations [4]. In contrast, rigid fixation of the sternum may prevent sternal instability and complications, particularly in high-risk patients, compared to conventional wires and cables [2, 5].

A recent randomized trial showed that compared to wire cerclage, patient-reported outcome measures were better in rigid plate fixation, including reduced sternal pain, better sternal healing and quality-of-life scores, and improved upper extremity function. Furthermore, economic outcomes (total costs) were similar between wire cerclage and rigid plate fixation at 90 days post-surgery [3].

A 2018 prospective study found that when compared to wire cerclage, rigid plate fixation resulted in better sternal healing scores and higher sternal union rates at 3- and 6-months post-surgery, and fewer sternal complications at 6 months post-surgery [6]. However, a 2019 study highlighted the surgical challenges inherent to high-risk patients, indicating that despite the use of rigid plate fixation, smokers remained at increased risk for surgical site infection and sternal dehiscence [4].

The 2019 consensus recommendations for sternal closure published by Enhanced Recovery After Surgery (ERAS) advise that rigid sternal fixation has benefits in patients undergoing sternotomy and can be useful to improve or accelerate sternal healing and reduce mediastinal wound complications. Furthermore, the guidelines advise that rigid sternal fixation should be especially considered in individuals at high risk (eg, patients with a high body mass index, previous chest-wall radiation, severe chronic obstructive pulmonary disorder, or steroid use) [7].

In line with the advantages of rigid plate fixation over wire cerclage noted above, the MatrixSTERNUM™ Fixation System provides stronger, faster, and thinner solutions for rigid plate fixation that streamline sternotomy and thoracotomy procedures and offer surgeons greater flexibility to meet patient needs.

The development of the MatrixSTERNUM™ Fixation System (Fig 7) involved close collaboration with expert surgeons from the AO Technical Commission. This ensured direct input from leading professionals in the field, addressing real-world clinical challenges and optimizing the system for practical use in surgical settings.



**Fig 8** Plates of the MatrixSTERNUM™ Fixation System include the Angled Plate (4 holes, top) and the X-Plate (8 holes, middle and bottom).

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# **TRUMATCH<sup>™</sup> Graft Cage – Long Bone**

The treatment of segmental bone loss due to trauma or infection remains a challenging clinical problem with variable outcomes. The TRUMATCH™ Graft Cage – Long Bone (Fig 1) is an innovative solution allowing improved healing of critical size defects in skeletal long bones (femur, tibia, and humerus). Personalized and bioresorbable, the implant is designed to contain morselized bone graft and can be tailored to the specific anatomy of the defect. The graft cage is intended for use in the second stage of the Masquelet technique in conjunction with rigid fixation and holds bone graft in position for the duration of healing. The cage structure helps prevent the collapse of bone graft, and the mesh design allows vascular ingrowth and nutrient access for tissue remodeling (Fig 2).

#### **Clinical problem**

Large bone defects are difficult to treat and are associated with a high reintervention rate. High risk of complications such as nonunion, malunion, deep infection, and significant healthcare costs are not uncommon [1]. 68% of large defects occur in the tibia following trauma, and 22% in the femur [2,3]. The rate of nonunions can be as high as 66%, malunions 12%, and donorsite complications (following bone-graft harvesting) as high as 21% [4]. Surgical challenges in managing such large bone defects include the eradication of infection, achieving bone



Fig 1 The TRUMATCH™ Graft Cage - Long Bone

union, and achieving stability/fixation. A further complicating factor is the anatomy of bone defects, which are highly variable. The defect can range from 2.5 cm to 30 cm, with a cross-sectional shape dependent on the bone and the location of the defect, and end geometry ranging from angled or jagged in trauma cases to parallel and smooth in oncology resections [2,3].

#### State of the art

Whilst there is no standard treatment protocol for large bone defects, the two most common techniques are the induced membrane technique (Masquelet technique) and distraction osteogenesis by bone transport. The Masquelet technique is a relatively recent treatment option consisting of two stages. In the first stage a biological membrane is formed around a cement spacer which is inserted in the bone defect. In the second stage, the spacer is carefully removed and the membrane filled with bone graft [5]. The induced membrane functions to contain the graft and stimulate bone-graft remodeling. Distraction osteogenesis or internal bone transport is based on the regeneration of bone by gradually separating bone segments with fixation devices (eg, external fixator, distraction nail) creating a gap that stimulates new bone formation. The treatment choice depends on the location and size of the defect, patient physiology, and surgeon skill set.

The Masquelet technique offers several advantages over distraction osteogenesis:

- The Masquelet technique creates a favorable biological environment for bone regeneration. The induced membrane formed during the initial stage of the procedure promotes the development of new blood vessels and supports the integration of the bone-graft material. This environment encourages the formation of new bone and facilitates healing.
- Despite being a two-stage procedure, patient treatment with the Masquelet technique is generally simpler and less time-consuming compared to distraction osteogenesis.
- The Masquelet technique avoids the following risks associated with distraction osteogenesis: pin-track infections, device-related issues, and the need for hardware removal after bone consolidation.
- The Masquelet technique can address limitations of distraction osteogenesis regarding the maximum defect length and defect shape amenable to treatment.
- The fixation devices and materials required for the Masquelet technique can be less expensive compared to more sophisticated bone transport devices (eg, for motorized distraction).
- There is no patient intervention required for the Masquelet technique, whereas patient compliance is needed to initiate or perform the individual distraction steps in distraction osteogenesis.

However, there are also challenges associated with the Masquelet technique, including the availability of sufficient graft material, adequate containment of bone graft, the mechanical stability of the graft in larger defects, and risk of introducing deep infection. Some of these challenges are addressed in the design features of the graft cage.

#### **Clinical solution**

The TRUMATCH<sup>™</sup> Graft Cage – Long Bone (Fig 2) is a 3D-printed, patient-specific, resorbable implant. The cage material comprises 96% polycaprolactone and 4% hydroxy-apatite which resorbs slowly over 2-4 years. Thus, the graft cage provides internal structural support to the graft material for the duration of healing, while providing large pathways through the mesh openings for nutrient flow and revascular-ization from the surrounding tissues. The hydroxyapatite/ calcium phosphate coating is osteoconductive, promoting mineralization at the surface of the implant and eventual conversion to bone.

#### **Design features**

The outer mesh of the graft cage (Fig 2) can be produced to approximate the cortical surface of the missing bone within the defect, thereby mimicking the previous bone shape. The two halves of the outer mesh are hinged such that they can be opened to facilitate graft packing. Large windows in the outer mesh allow exposure of the packed bone graft to the surrounding soft tissues for vascular ingrowth. The tube-intube design supports vascular ingrowth both circumferentially and through the intramedullary canal.

The inner mesh is made to approximate either the intramedullary canal or an intramedullary nail. The smaller window size in the inner mesh prevents graft subsidence into the intramedullary region of the implant while still allowing nutrient inflow. The tubular graft construct reduces the amount of graft needed compared to filling the entire defect. The inner mesh is hinged to allow the entire implant to open for ease of insertion over an intramedullary nail. The interstitial shelves are porous, are spaced equally along the length of the implant, and provide vertical support throughout the graft.

#### Preoperative workflow

The process begins with a CT scan of the defect being generated at the hospital (Fig 3). Computed tomographic data is sent to J&J MedTech where proprietary software segments the CT data and customizes the implant. Following clinician approval of the final design, the graft cage is then 3D printed and given an osteoconductive coating. The implant is packaged, terminally sterilized via ethylene oxide, and shipped to the patient.



**Fig 2** TRUMATCH<sup>™</sup> Graft Cage – Long Bone consisting of an outer mesh, an inner mesh, and interstitial shelves. The fixation tabs are positioned for fixation of the implant to healthy bone.

#### Operative workflow

In the operating room, rigid fixation (an orthopedic plate, external fixation, or an intramedullary nail) is applied (see Clinical case for details). Bone graft is then harvested, either from the iliac crest or via the reamer-irrigator-aspirator (RIA). The outer mesh of the graft cage is opened for packing graft inside, then the cage is implanted. An inner mesh opening is provided for fitting around an intramedullary nail during this step. The graft cage offers benefits over other technologies in that it contains shelves to support the graft, as well as patient-specific contouring better suited for complex anatomies.

# Value proposition/benefits of the TRUMATCH™ Graft Cage – Long Bone

The graft cage retains bone-graft material at the desired location, which has the potential to increase bone-union rate, decrease the time-to-union, and reduce the requirement for revision surgeries [6]. Additionally, the graft cage may drive cost savings for the provider and payer by reducing complications such as nonunions, reducing the number of surgeries, and reducing allograft usage. Overall, both patient satisfaction and procedure efficiency may be improved.

#### Intended use (United States only)

The graft cage is intended to be used in the treatment of large, segmental, nonarticular bone voids or surgically created resections of the humerus, femur, or tibia in conjunction with traditional, rigid fixation. The TRUMATCH<sup>™</sup> Graft Cage – Long Bone

is intended as an implantable structure that can support grafting materials in these procedures.

#### Indications (United States only)

- Maintaining the relative position of bony tissue such as bone grafts, bone-graft substitutes, or bone fragments from comminuted fractures within nonarticular bone voids or surgical resections of the humerus, femur, or tibia
- Load-bearing applications, only when used with traditional, rigid fixation
- Skeletally mature adults and adolescents
- Skeletally immature adolescents, as long as the device is not used across open physes

#### **Contraindications (United States only)**

- Bone voids or surgical resections that include articular surfaces
- Bone voids or surgical resections that use the device across open physes
- Load-bearing applications where no traditional, rigid fixation is present
- Use in the spine
- Patients with a compromised ability for bone healing (eg, active infections, poor bone quality, insufficient blood supply, etc)
- Use in patients requiring acute/emergent treatment due to the time requirements to personalize, manufacture, and deliver the device

		Surgeon request	<ul> <li>Fill in the Patient Request Form</li> <li>Use CT Protocol outlined in request form to obtain CT scan of defect</li> <li>Sales Consultant assists surgeon and radiologist with</li> </ul>
		CT scan	upload of request form and CT scan to secure portal
	↓		
<b>3-5</b> business days		Cage design	<ul> <li>Upon receipt of Patient Request Form and CT scan of defect, engineering checks the details provided</li> <li>If all information is available, engineers proceed to design the graft cage</li> </ul>
	↓		
		Surgeon approval	• Surgeon approves design via email
		Communication regarding payment	<ul> <li>Hospital is encouraged, although not required, to issue purchase order based on approved design</li> </ul>
	1		
		Manufacturing	<ul> <li>Manufacturing starts upon receipt of approved design and purchase order</li> </ul>
14			
calendar days	Y Y	Delivery	• Sales Consultant will be provided with tracking information and delivery confirmation. The implant must be delivered directly to the account paying for the implant, and may not be delivered to HCP office.

Fig 3 Planning surgery with the graft cage: steps in the preoperative workflow

For intended use, indications, and contraindications in regions outside the United States, please consult the appropriate local product labeling.

#### Nonclinical testing and validation

In a study comparing the healing of ovine segmental tibial defects treated with Orthomesh or the TRUMATCH™ Graft Cage – Long Bone, the graft cage group had more robust and advanced bone healing after 18 weeks. Animals treated with the graft cage had greater (by 55%) final bone volume, and a faster transition from woven to dense bone. [7,8]

Although there was no significant difference in bone union score, the graft cage group showed significantly higher torsional strength, lower pain scores, suggestive evidence of increased ingrowth/integration of tissue, and favorable biocompatibility [7,8].

Clinical case (Case kindly provided by Dr Brent Norris). Open right supracondylar intracondylar distal femoral fracture following motor vehicle accident

A 34-year-old man was involved in a motor vehicle accident in December 2019 and sustained these injuries (Fig 4):

- Left-sided rib fractures with lung contusion
- Open right supracondylar intracondylar distal femoral fracture with possible vascular injury (limb-threatening injury)
- Closed right bimalleolar ankle fracture
- Closed right talar fracture
- Open left plafond fracture
- Open left talar fracture dislocation
- Open left elbow joint

He had no major previous medical history and worked in the furniture delivery business.



The day following admission, the patient underwent these procedures in the operating room (Fig 5):

- Washout of open injuries right side, including femur and ankle
- Open reduction of the talar injury
- Spanning external fixator of the femur and ankle
- External fixation of the left plafond/talus

At 3 days postoperative, the patient underwent a repeat washout of the right femur and right ankle. The lung injury was still recovering so no definitive fixation was performed at this time. At 5 days post-initial surgery, the lung injury was improved, so the patient underwent open reduction and internal fixation (ORIF) of the right distal femur with resection of devitalized bone and cement spacer placement (Fig 6). Definitive fixation of the other fractures (ankle and ribs) was undertaken over time.

Following the advent of Covid-19 in early 2020, the patient was lost to follow-up for almost one year and was eventually seen again in December 2020 (Fig 7). At this follow-up, a CT scan was planned for the right distal femur and a graft cage ordered. Surgery was scheduled for early 2021.



**Fig 5a-b** On the day following admission, these intraoperative x-rays show (a) lateral and (b) anterior views of supracondylar and intracondylar fractures of the right distal femur.



**Fig 6a-b** On postoperative day 5, intraoperative x-rays show (a) anterior and (b) medial views of ORIF of the right distal femur with resection of devitalized bone and cement spacer placement.



**Fig 7a-b** At 1-year follow-up, x-rays showing (a) anterior and (b) medial views of fixation of the right distal femur and cement spacer.

The clinical decision was made to move to a plate-nail combination for the right distal femur as the patient was very likely to need to weight bear on the plate, and the articular block looked to be healed. Recent data shows that nails are better than plates for defect management [9]. Revision surgery was performed in early 2021, during which existing fixation and the cement spacer were removed (Fig 8) and a graft cage inserted (Fig 9). The graft cage (Fig 9b-c) was filled with bone graft harvested from the left femur via RIA (Fig 9a, Fig 10).



**Fig 8a-d** Revision surgery: intraoperative x-rays showing (a) AP and (b) lateral view of existing fixation; (c) AP and (d) lateral view following removal of the existing fixation and cement spacer.



**Fig 9a-c** Revision surgery: clinical intraoperative photos showing graft cage preparation (filling the cage with bone graft: **a-b**) and (**c**) insertion of the filled graft cage in the segmental defect in the femur.







**Fig 10a-c** Intraoperative images of (a) RIA being performed in the left femur and (**b-c**) the plate-nail construct and filled graft cage in situ.

At the 3-week follow-up (post-graft cage, Fig 11), the patient's wounds were healthy. He had a range of motion (ROM) of 0-80 in his right knee. He was allowed weight bearing as tolerated (WBAT) with crutches.

At the 3-month follow-up (Fig 12), the patient had a ROM of 0–120 in his right knee. His quadricep muscles had significantly recovered and he was able to WBAT with support from a cane.

At the 6-month follow-up (Fig 13), the patient was able to WBAT on the right lower extremity. He had some ankle pain and a ROM of 0-125 in his right knee. The patient was able to walk without any assistance device.

At the 9-month follow-up (Fig 14), the patient reported nominal knee pain, but more pain in his ankles. The patient had returned to work. He was not undertaking any heavy lifting but was driving the truck and supervising the team. Overall, the patient was happy with the current outcome of surgery.



**Fig 11a-b** At the 3-week follow-up x-rays showing (**a**) medial and (**b**) posterior views of the plate-nail construct and graft cage.



**Fig 12a-b** At the 3-month follow-up x-rays showing (a) medial view and (b) posterior view of the plate-nail construct and graft cage.





**Fig 13a-b** At the 6-month follow-up x-rays showing (a) medial view and (b) posterior view of the plate-nail construct and graft cage.



**Fig 14a-b** At the 9-month follow-up x-rays showing (a) lateral view and (b) AP view of the plate-nail construct and graft cage, with interval consolidation of the graft and healing of the defect.

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# **CODA<sup>™</sup> Anterior Cervical Plate System**

Anterior cervical discectomy and fusion (ACDF) is a common surgical procedure for treating cervical spine disorders such as degenerative disc disease, herniated discs, and cervical radiculopathy. The CODA™ Anterior Cervical Plate (ACP) System was developed to improve outcomes of anterior cervical fusion surgeries.

The CODA<sup>™</sup> ACP System (Fig 1) includes low-profile titanium plates in various lengths (Fig 2 and Fig 3). The low profile is intended to reduce the incidence of dysphagia and other postoperative complications. The plates have bone grafting windows for better visibility during the surgical procedure and can accommodate variable angle and constrained angle screws with a double-lead screw thread. The combination of high screw angulation and the shorter 10 mm one-level plate could potentially reduce the incidence of adjacent vertebral-level degeneration and ossification. The plates have an integrated active locking mechanism that prevents screw loosening.

This innovative plating system potentially improves the efficiency of the surgical workflow by having one locking mechanism per level instead of one per screw. The instrumentation is streamlined, meaning that the same screwdriver can be used to insert the screw and deploy the locking mechanism. The threaded screwdriver included in the system (Fig 6b) secures the screw attachment and controls the screw during screw insertion [1].

#### Current clinical challenges in ACDF Dysphagia

Dysphagia has long been recognized as a potential complication following ACDF [2, 3]. Despite its high incidence rate, the pathogenesis of this condition and associated risk factors are not well defined. A recent systematic literature review found a mean dysphagia rate of 19.4% following ACDF. Furthermore, zero-profile implants seemed to reduce dysphagia risk [2]. Therefore, the enhanced low-profile plate design of the CODA™ ACP System could offer as a key potential benefit a reduction in the incidence of dysphagia following ACDF procedures.

#### Adjacent segment degeneration

Although ACDF is clinically a highly successful procedure for disorders including cervical degenerative disc disease, adjacent segment degeneration (ASD) has been reported as a complication at the spinal level secondary to the rigid fixation. A recent study found that ASD occurred after single-level ACDF in 54% of cases, most commonly after C5/6 fusion (28%) [4]. The innovative design features of the CODA™ ACP System, including high screw angulation and shorter 10 mm one-level plate, may potentially reduce the occurrence of adjacent-level degeneration following ACDF.

#### **Product details**

The CODA<sup>™</sup> ACP System consists of single-use titanium alloy (Ti-6AI-4V ELI) plates and screws that are available in both sterile and nonsterile sets. The plates are offered in various lengths and are low profile with a height of 1.9 mm (one- to three-level plates) and 2.1 mm (four- to five-level plates). The plates have bone grafting windows that allow optimal visualization of the graft, vertebral bodies, and endplates. The plates have an integrated active locking mechanism and can accommodate constrained angle and variable angle screws. The system includes nonsterile reusable instruments and sterile single-use instruments, designed to facilitate proper implantation of the plate and screws.



**Fig 1** Two-level plate from the CODA<sup>™</sup> Anterior Cervical Plate System.



**Fig 2a-c** Two-level plate (**a**) oblique, (**b**) lateral, and (**c**) anterior views showing bone grafting windows, locking mechanism, and screws with double-lead screw thread.

#### Plates

The CODA™ ACP System plates are available in these lengths (Fig 3):

- One level (lengths: 10–30 mm, increments of 2 mm)
- Two levels (lengths: 24–44 mm, increments of 2 mm)
- Three levels (lengths: 42-66 mm, increments of 3 mm)
- Four levels (lengths: 60–88 mm, increments of 4 mm)
- Five levels (lengths: 75–105 mm, increments of 5 mm)

The plate profile is 1.9 mm in 1-3-level plates, and 2.1 mm in 4-5-level plates. The screw locking mechanism is flush to the plate. The plate width is 17 mm at the widest point and 13 mm at the waist.

#### Screws

The screws (Fig 4) are available as both sterile and nonsterile and feature a double-lead screw thread. Variable angle screws are available as self-drilling Ø3.5 mm screws (lengths: 10–18 mm), self-tapping Ø3.5 mm screws (lengths: 10–18, 20, and 22 mm) and self-tapping Ø4.0 mm screws (lengths: 12, 14, 16, and 18 mm). The plate screw holes permit a screw angulation of  $\pm$ 15° with cephalad/caudad range end holes from 2° to 32°.

Constrained angle screws are available as both self-tapping Ø3.5 mm screws (lengths: 10–18, 20, and 22 mm) and self-tapping Ø4.0 mm screws (lengths: 12, 14, 16, and 18 mm).



**Fig 4a-b** (a) Variable- and constrained-angle screws from the CODA<sup>™</sup> ACP System; (b) screw angulation permitted by the plate screw holes (±15° with cephalad/caudad range end holes from 2° to 32°).

#### Instruments

Instruments included in the CODA™ ACP System include drivers (threaded and tapered), temporary pins for fixation (push

pins and threaded pins), templates, plate bender, awl, drills, taps, and screw guides (Fig 5 and Fig 6).



Fig 5 Instruments included in the CODA™ ACP System.



**Fig 6a-b** Screw-hole preparation using a drill guide (a); threaded driver providing secure attachment and control during screw insertion (b).

#### Key features and benefits

- Patients:
- A low profile plate may potentially reduce incidence of dysphagia.
- High screw angulation and shorter 10 mm one-level plate may potentially reduce occurrence of adjacent-level degeneration.

#### Surgeons/healthcare professionals:

- Efficiency of surgical workflow is enhanced by having one locking mechanism per level instead of per screw. The positive stop on the locking mechanism is consistent for all plate levels.
- The same T10 screwdriver can be used to insert screws and deploy the locking mechanism.
- The threaded screwdriver provides secure attachment and control during screw insertion.

#### Indications (United States only)

The CODA™ ACP System is intended for anterior fixation of the cervical spine (C2–7) as an adjunct to fusion in skeletally mature patients. Specific indications include degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (ie, fracture or dislocation), spinal stenosis, deformities or curvatures (ie, scoliosis, kyphosis, and/or lordosis), tumor, pseudarthrosis, and failed previous fusion.

#### **Contraindications (United States only)**

In adults, contraindications of the CODA<sup>™</sup> ACP System and spinal fixation surgery include:

- Active systemic infection or an infection localized to the site of the proposed implantation, including presence of fever
- Severe osteoporosis which may prevent adequate fixation of screws and thus preclude the use of this or any other spinal instrumentation system
- Patients who have been shown to be safely and predictably treated without internal fixation
- Open wounds
- Relative contraindications include any entity or condition that totally precludes the possibility of fusion (eg, cancer, kidney dialysis, or osteopenia), obesity, alcoholism or drug abuse, smoking, pregnancy, mental illness, certain degenerative diseases, and foreign body sensitivity.

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#### **Clinical cases**

(Cases kindly provided by Rick Bransford, Harborview Medical Center, Seattle)

Case 1: 46-year-old man with Central Cord Syndrome following a fall down stairs

A 46-year-old man presented for evaluation of the cervical spine with magnetic resonance imaging (MRI) evidence of C4/5 mild retrolisthesis with central cord compression.

#### Initial injury: February 8, 2024

The patient tripped and fell down three stairs on February 8, 2024, landing face-first onto a cement floor. He was noted to have deficits to all limbs at the time of injury, with decreased grip strength. He denied neck or back pain. Magnetic resonance imaging and CT scans were performed, demonstrating C4/5 retrolisthesis, and no acute fractures but evidence of central stenosis at C4/5. The patient was offered surgery at the time of initial hospital admission but declined so that he could return to family in the US.

#### Assessment at spine clinic: February 26, 2024

The same patient presented at the spine clinic for evaluation of the cervical spine. The chief complaint was of bilateral upper extremity weakness and hyperesthesia affecting shoulder to fingers bilaterally. The patient reported dexterity problems in his hands and the inability to hold small objects, such as a pen. He also reported pain radiating bilaterally from elbow to fingers. The patient was not engaged in formal physical therapy. Without medication, the patient reported pain of 6/10. No relevant past medical or surgical history was reported.

Physical examination of the upper extremities showed bilateral muscle weakness (elbow, wrist, and hand), and areas of hyperesthesia on the left side.

Imaging was conducted. Plain x-rays (Fig 7) showed:

- No acute fracture
- Evidence of degenerative disc disease at levels C5/6 with focal disc height loss.

Magnetic resonance imaging of the cervical spine performed at the time of injury (Fig 8) was reviewed and showed:

- Spinal canal narrowing at C4/5 with cord compression and associated cord edema
- Bilateral uncovertebral osteophytes with mild bilateral foraminal narrowing
- C5/6 with mild posterior disc bulging causing mild canal narrowing without cord compression
- Mild bilateral foraminal narrowing of C6/7.



**Fig 7** Preoperative x-ray of the cervical spine (lateral view) shows no acute fracture and evidence of degenerative disc disease at levels C5/6 with focal disc height loss.





**Fig 8a-b** Magnetic resonance imaging of the cervical spine performed the day after the injury, showing (**a**) spinal canal narrowing at C4/5 with cord compression (sagittal view) and (**b**) axial T2 cuts at C4/5 demonstrating central stenosis.

A diagnosis was made of cervical spinal stenosis largely attributable to stenosis at C4/5, with lesser stenosis at C5/6 and cord compression causing sub-acute central cord syndrome. Anterior decompression was recommended to alleviate symptoms, and C4/5 anterior cervical discectomy and fusion (ACDF) was performed on March 7, 2024. Fig 9 shows postoperative imaging.

#### September 9, 2024: 6-month follow-up

At 6-month follow-up, muscle strength was greatly improved with physical examination showing 5 out of 5 strength throughout both upper extremities. Sensation was normal in both upper extremities. The patient had a good range of motion in the cervical spine. He continued to have some problems with fatigue whilst handwriting. There was some residual pain and neuropathy bilaterally, in a small area from the mid-forearm to the mid-bicep. The nerve symptoms tended to fluctuate throughout the day. Continued improvement was anticipated with ongoing physical therapy.

#### Imaging at follow-up:

Anteroposterior and lateral, flexion, and extension x-rays showed that the graft at C4/5 appeared to be in the original position as expected. There was no evidence of loosening of the screw-plate construct. Some bridging fusion was present between the superior C5 endplate of the graft. There continued to be incomplete consolidation between C4 and the graft but no motion of the graft itself. Flexion/extension films did not show any instability.



**Fig 9a-b** Postoperative x-rays of the cervical spine showing (a) lateral view and (b) anterior view of the single-level CODA<sup>TM</sup> plate in situ.

Case 2: 34-year-old man injured following fall from 10-m height

A 34-year-old man with a history of alcohol use disorder and prior seizures was admitted to hospital after being found outside his house having reportedly fallen from a second-story window. The patient had numbness and left-sided deficits, did not recall the circumstances of the fall, and was very intoxicated in the emergency department.

Full-spine imaging (Fig 10) showed injuries including a C6 flexion distraction with significant burst fracture (AO C6 B2 A4) with retropulsion into the canal and associated kyphosis, with

an associated mildly displaced C6 spinous process fracture, C7 displaced spinous process fracture, occipital condyle fractures without extension into the facets, and transverse process fractures of T11, L1, L2, L3, and L4.

Other injuries included fractures of ribs 10–12 on the left side, left pneumothorax and lung contusion, left vertebral artery occlusion, and hemorrhagic contusions of frontal lobes and temporal lobes.

Physical examination showed muscle weakness in the left upper extremity, especially in the hand, and reduced sensation in the left upper extremity (C5–T1). The lower extremities had normal muscle strength and sensation.



**Fig 10a-b** Cervical spine CT (**a**) and MRI (**b**) scans showing a C6 fracture with retropulsion into the canal and associated kyphosis.

The patient underwent a C6 corpectomy with removal of fractured C6 vertebral body, restoration of height and placement of a Synmesh cage filled with autograft from the fracture. Following restoration of height and vertebral body reconstruction, a CODA™ ACP plate was applied anteriorly with screws into the C5 and C7 vertebral bodies. Given the psychosocial nature of the patient and the fracture pattern, the patient was then placed prone and underwent posterior instrumentation with Symphony instrumentation with lateral mass screws into C5 and C6 bilaterally and pedicle screws into C7 followed by placement of 4 mm rods along with fusion. (Fig 11).

The patient did well postsurgery (Fig 12) and was discharged according to protocol, but was unfortunately then lost to follow-up.



**Fig 12a-b** Postoperative x-rays in upright sitting position show (**a**) anterior and (**b**) lateral views of the cervical spine with anterior and posterior constructs as described from C5 to C7.

## 3.5 mm Tibial Plateau Leveling Osteotomy (TPLO) Plate with Advanced Radial Compression (ARC)

The TPLO System (Fig 2) is meticulously designed for stabilizing osteotomies of the canine proximal tibia, ensuring stable fixation, and reliable healing. Developed in collaboration with and approved by the AO Technical Commission, the TPLO ARC plate comprises two 3.5 mm plates, for both left and right applications.

This innovative system is engineered to deliver precise compression across the osteotomy, leveraging specialized compression holes along the shaft. This targeted compression not only fosters direct bone healing but also bolsters resistance against potential rock-back failures. Moreover, it streamlines the contour of the proximal plate and optimizes screw placements, reducing the necessity for plate contouring while ensuring dependable locking screw positioning. The design features a consistent locking interface between the plate and the locking screws, reinforcing stability and integrity.

The accompanying array of specialized instruments, including drill guides, TPLO jigs, saw guides, and saw blades, facilitates surgical execution, versatile implant positioning, pinpoint accuracy in osteotomy location, and guided stability of the saw blade. The TPLO ARC Plate stands out for its continuous, precisely directed compression across the osteotomy site. Notably, the proximal section of the TPLO ARC Plate is angled in a slightly more caudal direction to accommodate diverse patient anatomies. Furthermore, the trajectories of proximal locking screws are designed to steer clear of the articular surface while engaging the central mass of the proximal tibia, ensuring optimal fixation and stability.

#### **Details**

The currently available 3.5 mm TPLO Plate (Fig 1) is generally applied at a slight angle relative to the mechanical axis of the tibia. While this has proven to be an ideal angle from a compression standpoint, there may be instances where the distal-most screw is close to the cranial cortex of the tibia and the third most distal screw is close to the caudal cortex. In extreme cases these screw locations could cause increased bone stress in those regions.

The newly innovated implant, 3.5 mm TPLO ARC Plate, locates these screws closer to the center of the bone while preserving the clinically-proven angle of compression.



**Fig1** Screw locations with currently available 3.5 mm standard TPLO Plate.



**Fig 2** Screw locations with 3.5 mm TPLO ARC Plate.

#### **TPLO ARC Technology**

The TPLO ARC Plate provides continuous, controlled, and directed compression across the osteotomy via a unique system of holes that serves to translate and rotate the plate simultaneously during compression (Fig 3). The resultant direction of compression has been designed to match that of the standard TPLO plate, which is clinically proven to provide excellent healing and improved resistance to rock-back.

Additionally, the proximal section of the TPLO ARC Plate is more caudally oriented to provide better anatomical fit on some patients.

And, as with all TPLO plates, the proximal locking screw trajectories are designed to avoid the articular surface and engage the central mass of the proximal tibia.

#### System content and description

The TPLO ARC Plate comprises two 3.5 mm plates, for both left and right applications (Fig 4a–b).



Fig 3 TPLO ARC Plate before and after compression.

#### **Clinical cases**

Case 1: Bentley Hoe, male neutered Golden Retriever, 32 kg (Case provided by Alexis Bilmont, West Midlands, England)

A 32 kg male neutered Golden Retriever presented with a recent deterioration of chronic right hind limb lameness. Physical examination revealed a cranial cruciate ligament rupture (Fig 5a-b).

A standard TPLO was performed via a medial approach. The 3.5 mm TPLO ARC Plate provided a good fit to the proximal tibial anatomy with improved screw placement in both the proximal and distal screws. In addition, the design of the ARC hole improved the degree of compression of the osteotomy.

Follow-up x-rays at 8 weeks postoperatively (Fig 6a–b) revealed stable implants, stable bone segments, and healing of the osteotomy. The clinical outcome was satisfactory.



#### Fig 4a-b

- a TPLO ARC Plate, left application.
- **b** TPLO ARC Plate, right application.



Fig 5a-b Preoperative x-rays.



Fig 6a-b Postoperative x-rays.

# Case 2: Rosie, 3-year-old black Labrador Retriever, 23.3 kg

(Case provided by William B Saunders, Texas, USA)

A 23.3 kg, 3-year-old spayed female black Labrador Retriever presented with a history of chronic, progressive left pelvic limb lameness. Her clinical examination was suggestive of left cranial cruciate ligament (CCL) rupture (Fig 7a–b). Medical and surgical treatment options were discussed with the clients. They elected to have Rosie's knee treated with arthroscopy and TPLO.

Left stifle arthroscopy was performed and a partial CCL rupture with incompetent remand was identified. The remaining CCL was debrided with a motorized shaver. The meniscus was healthy/noninjured based on visual inspection and probing. Arthroscopy portals were closed, and exposure of the proximomedial tibia was performed. Based on preoperative templating, a 21 mm radial saw blade was used to perform an osteotomy of the proximal tibia. The plateau was leveled to a final target slope of 5° and the osteotomy was stabilized with a 3.5 mm TPLO ARC Plate (Fig 8a–b).

In Rosie's case, the plate fit was excellent and the TPLO was performed without complication. Postoperative x-rays illustrate excellent plate position and screw placement and compression across all aspects of the osteotomy. Rosie recovered uneventfully from surgery and at the time of recheck (7 weeks postoperatively) (Fig 9a-b) was using the operated limb without visible lameness. The knee examination was unremarkable, and x-rays demonstrated robust healing of the TPLO.



Fig 7a-b Preoperative x-rays.



Fig 8a-b Postoperative x-rays.



Fig 9a-b Postoperative x-rays at 7 weeks follow-up.

Daniel Buchbinder, Nils-Claudius Gellrich, Michael Grant, Jaewon Heo, Philippe Korn, Isaac Liau, Gerson Mast, Damir Matic, Alf L. Nastri, Majeed Rana, Gregorio Sánchez Aniceto, Alexander Schramm

# **CMF White Papers**

The AO Technical Commission's expert CMF surgeons have recently published practical guidelines on the use of patient-specific implants in CMF procedures including reconstruction of the cranium, midface and mandible; orthognathic surgery; and reconstructive orbital surgery. As well as recommendations for optimizing outcomes, the white papers include an evaluation of the advantages and limitations of CAD/CAM in cranio-maxillofacial surgery and technological workflow considerations. To access the white papers please click on the links below.

Patient-Specific Solutions for Cranial, Midface, and Mandible Reconstruction Following Ablative Surgery: Expert Opinion and a Consensus on the Guidelines and Workflow Majeed Rana, Daniel Buchbinder, Gregorio Sánchez Aniceto, Gerson Mast

Patient-Specific Orthognathic Solutions: Expert Opinion on Guidelines and Workflow Alf L. Nastri, Isaac Liau, Jaewon Heo, Alexander Schramm

Guidelines for Orbital Defect Assessment and Patient-Specific Implant Design: Introducing OA2 (Orbital Assessment Algorithm) Nils-Claudius Gellrich, Michael Grant, Damir Matic, Philippe Korn



# Journey of the Smart Digital Solutions Task Force (SDSTF)

Formed as a key initiative of the AO Technical Commission, the Smart Digital Solutions Task Force (SDSTF) vision was to enhance the patient journey in trauma care through the integration of advanced digital technologies. From 2019 to 2024, the group (Fig 1) has transitioned from assessing existing digital technologies to establishing new strategies for wearable-based outcome measurement. This article highlights the key milestones and contributions of the SDSTF. The group's commitment to knowledge dissemination has resulted in numerous presentations at prestigious conferences such as ICORS, EORS, ORS, DKOU, OTA, and AAOS. Their work has also been published in prominent journals, such as *Injury* and *EFORT Open*, contributing significantly to the academic and clinical discourse on digital solutions in orthopedic trauma.



**Fig 1** Members of the Smart Digital Solutions Task Force with guests at their final meeting in Hamburg during the EFORT Annual Meeting in 2024. From left: Sureshan Sivananthan (member), Andrew Hanflik (consultant), Bernd Grimm (member), Meir Marmor (member), Benedikt Braun (chairperson), Ursi Styger (AO TC Manager), and Boyko Gueorguiev (ARI guest). Peter Richter (member) is missing from the photo.

#### From assessing existing technologies

One of the first major goals of the SDSTF was to evaluate the available digital technologies and their potential applications in orthopedic trauma surgery. This effort culminated in the publication of the 2020 Finding NEEMO white paper, which outlined how current digital solutions could meet the needs of orthopedic trauma surgery. The NEEMO framework (Fig 2: Need, Ease, Environment, Modularity, Ownership) was introduced to guide the development and application of new digital technologies in the field [1].



**Fig 2** Need Ease Environment Modularity Ownership (NEE-MO). A guiding framework to aid developers, researchers, and clinicians when using digital solutions to address their needs.

#### To analyzing: systematic review and survey

During the COVID-19 pandemic, despite the challenges of limited physical meetings and restricted research capabilities, the SDSTF undertook a comprehensive systematic review of studies on wearable activity monitors used in fracture management over the past decade. From more than 2,000 identified studies, 136 were analyzed, focusing on technology, treatment, outcomes assessed, and general usability characteristics. This study was presented at the DKOU and SICOT annual meetings and published in the *Indian Journal of Orthopaedics* [2].

In addition, the SDSTF and AO Trauma conducted a survey with more than 400 respondents to analyze the current use and future needs for wearable technology in orthopedic trauma. This survey revealed that smartphones are the most widely used wearable system for measuring general patient activity. It also identified key outcome parameters, such as general patient activity, kinematic and kinetic gait parameters, and general gait analysis. The results of this survey were published in the journal *Injury* and presented at national and international conferences, highlighting the clinical relevance and potential of wearable technologies [3].

## To defining: Bring Your Own Device (BYOD) study and new strategies

Building on insights gained from their initial assessments and surveys, the SDSTF launched a pioneering feasibility study known as the Bring Your Own Device (BYOD) study. This study aimed to evaluate the effectiveness of patient-owned smartphone and wearable technology in tracking functional recovery from pre-injury to post-injury. By analyzing daily step counts normalized to each patient's pre-injury maximum, the study successfully visualized the recovery trajectory of patients from pre-injury to full recovery (Fig 3).

#### Trend of mean daily steps with interquartile range



**Fig 3** Example of the recovery journey as tracked with the individual patient step count from pre-injury (left of the red dashed line) to post-injury (right of the red dashed line). Mean step counts and interquartile range are shown for a cohort of more than 100 orthopedic trauma patients, providing a clear visualization of the recovery process.

The BYOD study demonstrated the feasibility of using personal wearable devices to assess functional recovery and showed significant potential for predicting recovery outcomes. In addition to tracking recovery, this approach enabled early identification of patients at risk for prolonged healing, as demonstrated by a logistic regression model used in the study. The results were published in an AO special issue of *Medicina* and further discussed in *Injury* [4; 5].

#### **Challenges and future directions**

The SDSTF identified several challenges to the widespread adoption of wearable technology. Key barriers included cost, data validity, patient compliance, and the need for standardized parameters for clinically relevant outcomes. The group emphasized the need for further research to resolve these issues, particularly in understanding baseline wearable data in relation to physical function and exploring the potential of different wearable systems from other medical fields. To address these challenges members of the group have begun collaborative projects together with the AO Technical Commission's Upper Extremity Global Expert Committee (UEGEC), and the Elbow Task Force (EBTF) to advance the process of creating a comprehensive digital outcome parameter.

The SDSTF's journey from 2019 to 2024 has been marked by significant achievements in the evaluation and application of digital technologies in orthopedic trauma [6 and 7]. Their work has laid a strong foundation for future research and develop-

ment and made substantial contributions to the field. Their experience will now culminate in and be transferred to the newly formed Trauma Digital Expert Group. So, the digital journey continues.

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# AO Recognition Award 2024 – Keith Mayo

The AO Recognition Award is awarded by the AO Foundation's supervisory body, the AO Foundation Board, to honor individuals within the AO Technical Commission (TC) who have had significant involvement with the AO Foundation throughout their career and made a meaningful impact to product innovation and patient care.

Keith Mayo, MD, of Washington, United States, is the worthy recipient of the 2024 AO Recognition Award. He has been an active member of the AO TC since 1991, with roles including membership of the Pelvic Expert Group, the Computer Assisted Surgery Working Group, the AO TC Trauma and the Next Generation Plating Task Force. Additionally, he showed exceptional leadership as Chairperson of the Pelvic Expert Group between April 2005 and June 2015.

As a highly experienced and world-renowned orthopedic and trauma surgeon, Keith's involvement with the AO TC began with the conceptual design and development of the Pelvic System, which comprises innovative implants and instruments to address nearly every aspect of pelvic and acetabular surgery. More recently, his vast experience and inventive mind have guided the AO TC's collaborative partnership with key industry partners and upheld the AO TC's quality monitoring role via the approval of new solutions indicated for the area of Trauma.

Keith has consistently demonstrated true innovation in product development via his inclination towards disruptive technologies, often supporting substantial adaptations to surgical techniques and procedures if the result is improved functional outcomes for his patients. In addition to his practical ability to drive the development of new solutions, Keith is an outstanding teacher, excelling as a keynote lecturer at AO TC Trauma Experts Symposia and imparting decades of knowledge and experience as an AO educator at pelvic courses. In particular, his students appreciate his sharing of tips and tricks for complex surgical situations.

The AO TC honored Keith Mayo for his unflagging dedication to the improvement of patient care by supporting research and development, fostering clinical evidence, and conveying his knowledge and experience to the next generation of surgeons via educational courses.



Keith Mayo, MD



Award ceremony for the AO Recognition Award 2024. AO President Tim Pohlemann (left) and Keith Mayo (right).

# **AO TC Innovation Prize 2024**

The AO Technical Commission is delighted to announce the former Shoulder and Elbow Task Force (SETF) as the honored winner of the 2024 Innovation Prize. The SETF has been recognized for its innovation in developing the VA Clavicle System, the next generation system for internal fixation of medial, lateral, and shaft fractures of the clavicle.

The new system addresses the foremost clinical challenge in the current surgical treatment of clavicle fractures: a high reoperation rate for hardware removal due to tissue irritation and pain caused by poor plate fit and plate prominence.

The VA Clavicle system evolved from meticulous analysis of various anatomical parameters of the clavicle, allowing the new plate design to closely match the bow and contour of the clavicle for low construct prominence and enhanced plate-tobone fit. By improving overall plate fit, intraoperative plate placement is less challenging and the need for hardware removal is reduced.

The AO Technical Commission commends the SETF's outstanding contribution to advancing trauma care. The VA Clavicle System stands as a testament to the group's commitment to innovation, ultimately improving outcomes for patients undergoing clavicle surgery.

Members of the former SETF were:

- Simon Lambert (United Kingdom)–Chairperson
- Stefaan Nijs (Belgium)
- Martin Jaeger (Germany)
- Chunyan Jiang (China)
- Harry Hoyen (United States)
- Joyce Koh (Singapore)
- Frank Beeres (Switzerland)



AO Technical Commission award ceremony for the 2024 Innovation Prize. From left to right: former Shoulder and Elbow Task Force (SETF) members Stefaan Nijs, Martin Jaeger, Simon Lambert (former chairperson SETF), Joyce Koh, Harry Hoyen and Frank Beeres.

# AO Technical Commission Meet the Experts sessions 2024

The AO Technical Commission (AO TC) ran five "Meet the Experts" sessions at the Davos Courses in 2024, offering course participants the opportunity to view live stage shows showcasing the latest and most innovative AO TC approved medical devices. Expert surgeons closely involved in the development of the new implants and techniques led interactive practical sessions demonstrating surgical techniques and the benefits of the new solutions for both patients and surgeons. All "Meet the Experts" sessions were held in the award-winning mobile operating room, "The Shard", at the AO Davos Courses in December. An overview of the different technologies presented is given below. Full-length video recordings can be accessed by clicking the links.

# VOLT<sup>™</sup> Mini Fragment and VOLT<sup>™</sup> Small Fragment Plating System

This "Meet the Experts" session focused on the next-generation plating technology for orthopedic surgery, Variable Angle Optimized Locking Technology (VOLT™). Presented by experts Christoph Sommer and Karl Stoffel, the session introduced advancements in plating systems including the new plate and screw designs available in stainless steel and titanium across all sizes. The session emphasized standardization for improved operational efficiency, enhanced soft-tissue preservation, and innovative features like adaptive plate profiles, high-polish surfaces, and advanced locking mechanisms. The demonstration included enhanced implants and instruments including the threaded drill sleeve, depth gauge, and new screw types, showcasing improved handling, strength, and compatibility. Procedures for complex fractures were shown, such as the use of hook plates for medial malleolus fixation, with live demonstrations of reduction, fixation, and plating techniques. Watch the video here.

#### VOLT™ Proximal Humerus Plating System

In this "Meet the Experts" session, expert surgeons Simon Lambert and Joyce Koh highlighted design innovations in the VOLT<sup>™</sup> Proximal Humerus Plating System, including the incorporation of Variable Angle Optimized Locking Technology (VOLT<sup>™</sup>) and self-locking screws, features which enable precise placement and enhanced outcomes for proximal humerus fractures, particularly in small-statured patients. The session included a live demonstration of a deltopectoral approach, showcasing surgical techniques for exposure, plate positioning, and screw placement. Enhanced features such as low-profile screw heads, improved suture placement options, and variable angle screw trajectories were emphasized for reducing complications like acromial impingement. Watch the video here.



**Fig 1a-b** (a) Expert surgeons Christoph Sommer (center) and Karl Stoffel (left) in "The Shard", demonstrating the novel VOLT Mini Fragment and VOLT Small Fragment Plating System; (b) The VOLT Mini Fragment and VOLT Small Fragment Plating System.



**Fig 2a–b** (a) Expert surgeons Simon Lambert (left) and Joyce Koh (center) in "The Shard", showcasing the innovative features of the new VOLT Proximal Humerus Plating System; (b) The VOLT Proximal Humerus Plating System.

#### **VOLT™ Wrist Treatment System**

In this "Meet the Experts" session, expert surgeons Martin Langer and Alex Lluch demonstrated the VOLT™ Wrist Treatment System, a comprehensive plating solution designed to address the entire spectrum of wrist fractures. The session highlighted features of the new technology, including standard volar and dorsal fixation for basic fractures, specialized plating options for more complex fractures, dedicated implants for elective procedures, and wrist-specialized instrumentation. The practical application demonstrated how the new technology allows fixation of very distal wrist fractures without invading articular space or causing postoperative soft-tissue concerns. The presenters emphasized how the new system allows low-profile plating with exceptional stability, and how the enhanced design facilitates the entire surgical procedure, offering easier fracture reduction, plate placement, and screw insertion. Watch the video here.



**Fig 3a–b** (a) Expert hand surgeons Martin Langer (left) and Alejandro Lluch (center) introducing the innovative VOLT Wrist Treatment System in The Shard; (b) Participants of the Davos Courses 2024 watching the "Meet the Experts" session in "The Shard".

#### MatrixSTERNUM<sup>™</sup> Sternal Fixation System

This "Meet the Experts" session featured a live demonstration of the MatrixSTERNUM™ Sternal Fixation System, led by expert cardiothoracic surgeons Mario Gasparri and Stefan Schulz-Drost. The session began with an overview of the clinical challenges associated with traditional sternal closure methods, such as the use of wires, which carry risks of failure and complications like sternal dehiscence and wound infections. The presenters emphasized the benefits of rigid plate fixation, which include increased stability, reduced postoperative pain, and improved healing. The demonstration showcased the system's innovative design, featuring low-profile titanium plates, locking screws, and specialized instruments for precise application and contouring. The discussion also addressed concerns about adoption, such as procedural safety, time efficiency, and compatibility with patient anatomy, alongside strategies for rapid reentry in emergencies. The session concluded by highlighting the system's potential to improve surgical outcomes and reduce complications in high-risk cardiothoracic patients. Watch the video here.

#### **Distal Radius Intramedullary Nail (DRIM-Nail)**

In this "Meet the Experts" session, expert surgeons Andreas Schweizer, Martin Langer, and Alejandro Lluch demonstrated the Distal Radius Intramedullary Nail (DRIM-Nail), an intramedullary implant indicated for unstable A3 and A2 extraarticular fractures of the distal radius. The presenters highlighted how the design features of the new nail address various clinical complications which may follow fracture fixation using current state-of-the art techniques, including closed reduction percutaneous pinning (CRPP) and open reduction and internal fixation (ORIF) techniques. The session included a practical demonstration of nail insertion using both a bone model and a prefractured anatomical specimen. The presenters concluded by highlighting a range of clinical cases successfully treated with the DRIM-Nail. Watch the video here.



Fig 4a-b (a) Expert cardiothoracic surgeons Mario Gasparri (right) and Stefan Schulz-Drost (left) introducing the MatrixSTERNUM Sternal Fixation System in "The Shard"; (b) The MatrixSTERNUM Sternal Fixation System.



**Fig 5a–b** (a) Expert hand surgeons Andreas Schweizer (left) and Martin Langer (right) demonstrate insertion of the DRIM-Nail in "The Shard"; (b) From left: Andreas Schweizer, Alejandro Lluch and Martin Langer in "The Shard".

# **AO Technical Commission Experts Symposia 2024**

The Experts Symposia of the AO Technical Commission (AO TC) are well-established events which aim to improve patient treatment by fostering exchange between the AO TC's surgeons and industrial partners. The symposia provide a confidential setting in which participants critically review the clinical performance of implants, instruments, and techniques, identify potential device improvements, and discuss refinements to surgical procedures. The Experts Symposia are fundamental to the product development cycle and allow the AO TC to fulfill its quality assurance mandate when newly developed devices are released to surgeons. The information gathered at Expert Symposia is invaluable, both for defining unmet clinical needs and supporting the initiation of new development projects with industrial partners. Two symposia were held in 2024: one in Asia Pacific and one in Europe.

#### 14<sup>th</sup> AO TC Trauma Experts Symposium (Asia Pacific), South Korea

After four years, the 14<sup>th</sup> AO TC Trauma Experts Symposium (Asia Pacific) took place in Seoul, South Korea, on April 5–6, 2024. Chaired by the local expert trauma surgeon JK Oh, the event saw attendance from 66 surgeons representing 18 countries. The symposium featured six sessions, showcasing 39 case presentations.

The topics covered included diagnosis of fracture-related infection (FRI), FRI management with critical-bone defects, knee-joint-preservation techniques, treatment of distal femur fractures (including periprosthetic fractures), management of distal tibia fractures, and experiences with Trochanteric Femoral Nail Advanced (TFNA).

Through lively and robust discussions, participants and faculty identified several development challenges for the AO TC.



Participants of the 14th AO TC Trauma Experts Symposium (Asia Pacific), South Korea, April 2024.

#### 16th AO TC Trauma Experts Symposium (Europe)

The 16<sup>th</sup> AO TC Trauma Experts Symposium (Europe) took place from August 30–31, 2024, in Florence, Italy. Chaired by Michael Raschke, the successful event brought together 52 surgeons from 22 countries for in-depth discussions and knowledge sharing regarding the latest advancements in trauma surgery. The symposium featured five sessions in collaboration with the AO's key industry partner, focusing on cutting-edge innovations in the field. Key topics included acetabular fractures, proximal and distal femur fractures, ankle fusion, and the potential for intelligent implants. A highlight of the symposium was a special session with the AO's key industry partner J&J MedTech, where participants had the opportunity to gain insights into their nail portfolio.



Participants of the 16th AO TC Trauma Experts Symposium (Europe), Florence, Italy, August 2024.

## Nail fixation of unstable trochanteric fractures with cement augmentation is cost-effective in different health-care settings

Proximal Femoral Nail Antirotation (PFNA), an intramedullary implant for the treatment of unstable trochanteric femoral fractures, can be used together with augmentation using Traumacem™ V+ Injectable Bone Cement and has been the subject of recent studies. In the original publication of a large, multicenter randomized controlled trial (RCT), PFNA with cement augmentation had comparable clinical outcomes to PFNA without augmentation, although a trend toward a lower risk of mechanical complications with cement augmentation was observed [1]. To understand whether this lower risk could translate into potential cost savings, a cost-effectiveness analysis was conducted in collaboration with Christian Kammerlander, MD, Julia Schneller,



**Fig 1** Regardless of the willingness-to-pay threshold, fixation with augmentation was more likely to be cost-effective than no augmentation.

MD, AO ITC Clinical Science, and Johnson & Johnson MedTech. Proximal Femoral Nail Antirotation with augmentation compared to PFNA without augmentation was shown to be cost-effective in the German health-care setting, as published in 2022 [2].

Whether similar results existed in other settings was the question that led the authors to perform a cost-utility study for the US health-care setting, published in February 2024 [3]. The short-term decision-tree model and long-term Markov model used in the German setting and the cost data were adapted to the US health-care setting, with clinical data taken from the original RCT. Based on this data, both in the German and the US health-care settings, fixation with cement augmentation was more cost-effective (Fig 1). In the US health-care setting, a cost saving of \$130,765 per QALY was demonstrated, and in the German health-care setting, there was a cost-saving of €8,821 per QALY. The cost savings in both health-care settings were mainly driven by the prevention of additional costs due to treatment-related complications (mechanical failures).

With the current growing emphasis on value-based medicine, the results of these two recently published studies may help support surgeons in their medical decision-making and be informative for policymakers when it comes to coverage and reimbursement.

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## AO innovation resources support development of new spinal screw

A new spinal screw offering better fixation, stability, anduniquely-removability could be on the market in the next 4-5 years due to the collaboration of AO's innovation funding and the Australian company REX Ortho.

In late 2023 the AO, REX Ortho, and Switzerland's 41medical started collaboration on the S-REX Screw project to apply novel fixation technology and develop a new spinal screw (Fig 1). The AO with its global network of more than half a million health-care professionals will support the project with input on clinical usability, biomechanical know-how, clinical trials, market access, and funding; 41medical will contribute expertise in regulatory clearance, prototyping, manufacturing, and more.

REX Ortho Executive Chair Ian Brown declared that the S-REX pedicle screw which is the latest innovation in the company's platform technology is targeting a design that will provide a clinically meaningful increase in fixation strength by expanding and increasing the contact area and engagement with the bone. At the same time, the screw is un-expandable to facilitate easy removal.

"In fact, REX Ortho presented data at the Orthopaedic Research Society (ORS) in February 2023, demonstrating that the company's F-REX hip screw could survive more than five times the number of simulated-loading cycles compared to competing screws," commented Brown. The F-REX Screw is designed for patients with limited bone quality and should be both easy to use and easy to remove, he added.

#### Listening to the voice of surgeons

Significantly, as part of the solution's development, the REX Ortho team decided early on to listen to the voice of surgeons. "What we've found is that surgeons want to be able to remove screws, if necessary, because of infections or other complications," noted Brown. The S-REX Screw project is focused on addressing these concerns, Brown explained. He added that significant interest in REX Ortho technology inspires new approaches to unmet needs in implant fixation solutions in orthopedics, dovetailing perfectly with the AO's mission of promoting excellence in patient care and outcomes in trauma and musculoskeletal disorders.

#### **Recognizing an unmet need**

The inception of the S-REX Screw goes back to 2014, when orthopedic surgeons and AO members Phil Hardcastle, Markus Kuster, and Gabriel Lee recognized the need for improved fixation and stability in orthopedic surgery. They contacted biomedical engineers Intan Oldakowska and Matt Oldakowski at the Curtin University, Perth, Australia, who then investigated the problem and the failure modes. The result was a concept that includes removability in the device design. In a first 2022 animal study REX Ortho evaluated the removability of its technology.

With the AO's innovation funding and expertise, REX Ortho is advancing with the S-REX project to evaluate the innovation's feasibility, establish proof of concept, verify the design, and prepare for clinical trial.

"It is exciting to have the AO team along with its world-leading surgeons supporting our REX technology," Brown stated. "The S-REX screw promises to deliver what the surgeons have asked for: improved fixation, improved stability, and improved removability all in one fixation screw."

Brown's advice for other innovators is simple: "If you believe your innovation has the potential to be best in class and have a real impact on patient outcomes, we recommend you work with the AO as they are best-in-class in innovation optimization, technology transfer, and commercialization," he said. "Our collaboration with the AO has already lifted our project to a whole new level. We are super excited about the future."



Fig1 Simulated image of the REX Ortho product under development.

# AO XR integrates mixed-reality technologies into surgical education



Fig 1 Participants of the AO XR event held at the AO CMF FACE AHEAD summit in Prague, Czech Republic, April 2024.

Backed by AO innovation funding, two innovative clinicians are collaborating with digital technology company Brainlab and the AO Education Institute (AO EI) to develop and deploy an in-person educational platform leveraging mixed-reality technology to take the AO's popular small group case discussions to the next level of engagement and knowledge retention at on-site courses.

The 2-year project's kick-off meeting was held during the AO Davos Courses 2023. It is driven by coinvestigators Marc Christian Metzger, MD, DMD, and Edward Bradley Strong, MD. Metzger is a professor and vice chair of the Department of Craniomaxillofacial Surgery, Universitätsklinikum Freiburg, Germany. Strong is professor, vice chair, and division chief of the Department of Otolaryngology, University of California Davis (UC Davis) Medical Center, Sacramento, US, and director of the UC Davis 3D Printing and Visualization lab. Both had been long-term members of the AO TC Computer Assisted and Image Guided Surgery Global Expert Committee.

"The idea for this project arose during an AO course in Tampa, United States, three years ago," Metzger explained. "We had a very large [AO CMF] course where, among other things, companies presented their latest developments. Brainlab was represented with its Mixed Reality Viewer on the Magic Leap augmented reality device and offered the opportunity for every participant to try it out. Ultimately, the idea was then developed and discussed with other faculty members."



"Mixed reality integrates digital content into the real world and allows AO small group case discussion participants to interact simultaneously with both physical and virtual objects." Marc Metzger

Mixed reality (MR), the principal investigators explained, is an umbrella term for a technology that brings together elements of both

virtual reality (VR) and augmented reality (AR). The VR immerses users wearing a VR headset that replaces their real surroundings with a completely virtual environment, while AR superimposes digital imagery onto the user's field of vision, enhancing the physical environment.

"MR encompasses both VR and AR technologies: It integrates digital content into the real world and allows AO small group case discussion participants to interact simultaneously with both physical and virtual objects," Metzger pointed out. "MR experiences are more immersive and interactive than traditional AR because virtual objects can respond to and interact with real-world objects."

Strong noted that the AO's extended reality in-person platform (AO XR) will allow more in-depth small group case discussions about anatomy, allowing faculty and learners to point at, measure, and experience virtual anatomical features in greater depth.

"As part of the study associated with this project, we are studying how people are learning, whether they feel they're learning better, or faster, for example," he commented. "We hope to publish our conclusions in the next 12-18 months." The AO XR project was successfully trialed at the AO CMF NA Course–Contemporary Management of Orbit and Midface Trauma near Boston, US, and at the AO CMF FACE AHEAD summit in Prague, Czech Republic.



"As part of the study associated with this project, we are studying how people are learning, whether they feel they're learning better, or faster, for example." Brad Strong

"Eighty-five percent of learners at both events rated the small group case discussions with MR 'outstanding' or 'very valuable," Strong

declared, adding that the platform will be in the spotlight at the AO CMF Masters Course–Emerging Technologies in Orthognathic Surgery during the AO Davos Courses 2024.

Metzger and Strong emphasized that in addition to enhancing interaction and visualization, enabling real-time collaboration

among participants, overcoming resource scarcity, and increasing engagement and retention, AO XR is adaptable, customizable, and can easily be deployed across the AO's other clinical divisions—AO Trauma, AO Spine, and AO VET.

"This represents a cutting-edge approach to surgical education in training, leveraging MR technologies in innovative ways," Metzger observed. "The project pioneers the integration of these technologies including VR and AR into surgical education. This allows for immersive, interactive, and realistic surgical procedures and anatomical structures."

In addition to collaborating with the AO EI and Brainlab, Metzger and Strong remarked their project has benefited from the expertise of Prof Florian Thieringer, codirector of the multidisciplinary 3D Print Lab at Universitätsspital Basel, Switzerland; Prof Majeed Rana, senior physician and deputy director of the Clinic for Oral, Maxillofacial and Facial Plastic Surgery, Universitätsklinikum Düsseldorf, Germany.

Watch Strong's AO TV interview, How Mixed Reality Is Making a Difference in AO CMF Education, recorded at the AO Davos Courses 2023



Fig 2 Marc Metzger showcasing the AO XR experience during FACE AHEAD 2024.

# Digitally enhanced hands-on surgical training (DEHST)—from idea to product

Three years after its first concept, the AO project enabling digital solutions for hands-on training (DEHST; Fig 1) is being deployed under the AO Milestones trauma program.

DEHST is a novel skills-training platform expanding practical exercises with advanced digital technologies. The system features a miniature model of an intraoperative image intensifier (C-arm) with an artificial x-ray imaging engine generating radiation-free simulated x-rays allowing an enhanced training spectrum and a new type of user experience.

Now fully embedded under the AO Education Institute's (AO EI) activities, DEHST is a showcase of how an idea, triggered by an unmet need in a mastered segment (trauma education), has developed into a stand-alone product: "DEHST addresses the need for standardized skills training and assessment, ensuring consistent, high-quality training. By assessing the learner and gathering data on competency gains, we aim to offer micro-credentials, enhancing residents' readiness and proficiency in the OR," explained Marc Stal, Head of Education Portfolio–Focus Programs at the AO EI.

DEHST brings together all three AO institutes, from AO Research Institute Davos' (ARI) Jan Buschbaum, Leader of the Concept Development Focus Area, inventor, and main developer of the DEHST, to the AO Innovation Translation Center (AO ITC) and the innovation funding that carried the project through its seed funding phase, and the AO EI with its AO Milestones trauma program, now offering the O-series of DEHST stations as an additional feature of the AO's signature hands-on trainings.



**Fig 1** Digitally enhanced hands-on surgical training (DEHST) system.



"This project is a great example of a successful cross-divisional effort, delivering an innovative training solution for surgeon education, right when needed." Stefano Crespan

"This project is a great example of a successful cross-divisional effort, delivering an innovative training solution for surgeon education,

right when needed," commented Stefano Crespan, Senior Project Manager Technology Transfer at the AO ITC. "The AO's innovation funding not only provides financial support but is also a catalyst for great ideas to foster on fertile ground." ARI's Jan Buschbaum confirmed that the strategy fund's involvement was much more than just financial: "They were not merely a 'funding body' for this project. Their connections with internal and external stakeholders made it possible for us to showcase our prototype at important events and get connected to people who fostered our ideas."

"The first DEHST prototype showcased its capabilities, earning unanimous support from the AO Milestones taskforce," declared Stal. The first functional module for the free-hand distal interlocking training was developed in 2021, followed by a prototype module for proximal femoral nailing in 2023. The full Nailing Package, consisting of three modules covering the most relevant surgical skills for intramedullary nailing, was completed when the product O-series was delivered for testing during the AO Davos Courses in December 2023. "The gamification and deliberate practice approach are ideal for our needs, to train and assess residents to be better prepared and proficient in the OR, ultimately benefiting the patient. In addition, DEHST's low cost compared with other simulators allows for sustainable training and assessment of future orthopedic surgeons," explained Stal.



"Their connections with internal and external stakeholders made it possible for us to showcase our prototype at important events and get connected to people who fostered our ideas."

Jan Buschbaum

The whole training and assessment station is compact, fits into a padded box, and can

be easily transported to courses, events, or hospitals. Further modules and packages are currently being developed by ARI's DEHST team, which has grown from what Buschbaum calls a "one-man show" to three employees. "The plan is to keep it all in one transportable box, even once additional modules and packages are added." The ARI team has further proven its capacity to drive development, tapping from the AO's network of committed surgeons, when delivering another proof of concept with the pedicle screw for spine applications (Fig 2). Yet another application of DEHST is its potential to train course participants' imaging skills, using the device's miniature C-arm, which simulates intraoperative x-rays. An imaging module involving DEHST will be introduced at the AO Trauma Course-Basic Principles of Fracture Management during the 2024 AO Davos Courses, and additional imaging modules for veterinary and pediatric surgeons are currently being discussed. Meanwhile, two validation studies\* have successfully assessed DEHST's training efficacy.



"The first DEHST prototype showcased its capabilities, earning unanimous support from the AO Milestones taskforce." Marc Stal

"The future of DEHST is promising, with plans to expand its applications to more procedures and skills, covering the standard training needs of orthopedic residents worldwide.

It is amazing to collaborate with the AO Milestones taskforce of experts, shaping the development of new modules that will cover additional anatomical-specific procedures and basic skills. For example, an upcoming module will train the skill to Fig 2 Participant during a training session.

drill and hit a point in space 'blind,' a fundamental skill every orthopedic surgeon must master," said Stal.

\*Digitally enhanced hands-on surgical training (DEHST) enhances the performance during freehand nail distal interlocking | Archives of Orthopaedic and Trauma Surgery (springer.com)

Medicina | Free Full-Text | Validity of a Novel Digitally Enhanced Skills Training Station for Freehand Distal Interlocking (mdpi.com)



## Backed by AO innovation resources, Momentum Health's app is revolutionizing adolescent idiopathic scoliosis (AIS) monitoring



Championed by the AO via its innovation funding as well as in-house expertise and AO Spine's global network of surgeons, Momentum Health's innovative Momentum Spine app became the first AI-enabled medical device approved by the United States Food and Drug Administration (FDA) Office of Neurological and Physical Medicine Devices in October 2023.

The app—commercially available today in Canada and the United States—is upending conventional monitoring of adolescent idiopathic scoliosis (AIS) and empowering patients, their parents, and their care teams to manage the condition remotely, according to Momentum Health CEO Philippe Miller. He notes that Momentum Spine is starting with AIS, but with its upcoming release of dynamic imaging, the company is creating a fundamentally new imaging modality for spine care, providing surgeons with a tool to remotely monitor how patients progress as well as how they look, feel, and function on a day-to-day basis.

"Since these are pediatric and adolescent patients, the parent uses a smartphone to film three laps around the patient, and from those three circles, we're able to create a 3-D model of the patient's body, generate predictions, measure various metrics of asymmetry, and monitor spine curvature progression," Miller explained.

After a scan, the patient's clinician is automatically notified and can instantly evaluate the collected data on the Momentum Spine portal.

"All this data—including predictive Cobb angle and the difference in the curvature since the patient's last visit—automatically appears on the portal," said Miller. "Then the clinician can say either, 'You're good to go until the next scan,' or 'You need to come in and see me.""

By replacing repetitive x-rays—two per year for many AIS patients—radiation exposure is substantially reduced, and by detecting early curve progression, the app can help patients avoid major surgery.

#### Peace of mind

To date, feedback from patients, their parents, and clinicians has been positive, according to Miller.

**Fig 1** Visualization of the patient information on the Momentum Spine portal.

"Peace of mind is one of the patient benefits we often hear about. The patients tell us, 'With the current standard of care, I have an x-ray and then I go home and have to wait six months, with no idea whether my curvature is changing or progressing,'" he said, adding that in November 2024, Momentum Spine users will have the option of app integration with their scoliosis braces to help track compliance, and new features to collect activity levels and gait abnormalities passively will be introduced.

Also coming in November are Momentum Spine's new functional, dynamic health assessments for dynamic sagittal alignment (ie, gait) and the cone of balance (ie, radius of sway) for adult spine patients.

Globally renowned spine surgeon Lawrence Lenke, a longtime AO Spine member and the first chairperson of the AO Spine Knowledge Forum Deformity, called the Momentum Spine app "a game changer" and particularly welcomes its dynamic imaging features.

"Throughout my 33-year career, all of my operative decisions have been based on static imaging: x-rays, magnetic resonance images (MRIs), and computed tomography (CT) scans," he said. "Dynamic imaging is one of the missing links of spine care evaluation leading to better treatments and outcomes. I think it's going to revolutionize what we do."

#### Looking to the future

Miller said Momentum Health's technology has potential applications beyond spine care, including hip, knee, and other areas of orthopedics. For now, though, the team is focusing its efforts on the app's use in AIS monitoring; twelve clinical studies underway in Canada, France, Switzerland, and the United States; and exploring the possibility of applying for a Conformité Européenne (CE) mark which would provide the European market with access to the Momentum Spine app. He emphasized that the accuracy and quality of the app's Cobb angle prediction continue to improve as more data is collected in the ongoing clinical studies. The data collected to date indicates that the app's prediction of patients' Cobb angles is highly comparable to conventional x-rays.

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