

# Innovations 2021







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# **Editorial**

Welcome to the 2021 edition of the AO ITC *Innovations* magazine, which brings you the latest innnovations from across the AO Innovation Translation Center (AO Technical Commission, Clinical Evidence, and Technology Transfer) in collaboration with the AO Research Institute Davos (ARI) and AO Education Institute. AO Technical Commission (AO TC) is proud to announce the launch of 12 new products across trauma, spine, craniomaxillofacial, and veterinary. Despite a further year of restricted travel and face-to-face engagement since the release of our last magazine in December 2020, the digitization of meetings and anatomy laboratories has enabled us to proceed with product innovation at an impressive rate.

The increased productivity demonstrated by the AO TC throughout this turbulent time has been noticeably driven by Daniel Buchbinder who, up until June 2021 chaired the AO Technical Commission Executive Board (TCEB). In this edition of the *Innovations* magazine, we thank Dr Buchbinder for his commitment and acknowledge his influence in the formation of the AO TC. Subsequently, we welcome Maarten Spruit as the new Chair of the AO TC and support his mission to position the AO TC at the heart of the AO ITC driving technology innovation and serving the needs of trauma, veterinary, craniomaxillofacial, and spine surgeons.

The AO TC Trauma, chaired by Michael Raschke, approved a record number of eight new products, a marked increase compared to 2020. In our lead article, we introduce the Variable Angle Locking Patella Plate, a combined effort in innovation from the Lower Extremity Expert Group and Patella Task Force. Due to the potentially disabling consequence of inadequate treatment and despite the relatively low incidence rate of patella fractures, medical members from both groups recognized the need for a better fixation solution in this anatomical area. Following the identification of five main criteria necessary for optimal patella fracture fixation including the preservation of blood supply and low implant prominence, two new plating solutions were developed. We hope you enjoy reading about the 2.7 mm Variable Angle Anterior Patella Plates.

Retaining a focus on trauma and following several years in development, the Upper Extremity Global Expert Committee (UEGEC) is pleased to introduce the Variable Angle Clavicle and Variable Angle Clavicle Hook Plate 2.7 Systems. While launched independently of each other, these systems demonstrate a significant breakthrough in the treatment of both isolated clavicular fractures and those associated with a ligamentous disruption. Dedicated plate shapes possess an enhanced fit and accommodate the bow and curvature of the clavicle at corresponding fracture locations; a design feature which truly represents the next generation of clavicle plating.

Within the world of Spine, the Cervical Spine Expert Group (CEEG) brings you Symphony Compartment 2. The Symphony Occipito-Cervico-Thoracic System aims to reduce the complexity of Posterior Cervical Fusion procedures and improve patient outcomes in a solution containing both Foundational (Compartment 1) and Enhancement (Compartment 2) elements. Comprising navigated instrumentation and a more sophisticated range of screws and rods, Symphony represents true innovation while successfully retaining the best features of Mountaineer and Synapse. The CEEG has recently been awarded the AO TC Innovation Prize for its efforts with Symphony which you can read more about here.

Updates from other areas of the AO ITC include exciting news from Technology Transfer as they continue to drive the development and valorization of innovative solutions in the advancement of patient care. Biphasic plating is a concept conceived by ARI, Queensland University of Technology and 41Medical. The Biphasic Plate for Distal Femur obtained CE certification as a class IIB medical device in April 2021; a significant achievement by all involved and one to be celebrated in this edition of the *Innovations* magazine.

Technology Transfer also introduces OSapp; an interactive virtual osteosynthesis software and learning tool which has been created through a collaboration between the AO Research Institute Davos and Chair of the UEGEC, Simon Lambert. The project was started in July 2020 and aims to solidify the

learner's understanding of biomechanical concepts underlying the principles of fracture fixation.

As an appropriate accompaniment to our lead article, ARI provides a detailed account of the patella plate biomechanical study which makes for an interesting read. It is evident that ARI is working extremely hard in the pursuit of evidence-based medicine and better patient outcomes following complex procedures as we delve into their articles on proximal humeral fractures, fatigue analysis in pancarpal plate arthrodesis, and fixation strength of re-orientation pelvic osteotomy. We congratulate them on their vision and scientific approach to medicine.

Clinical Science supports innovation translation at the AO with clinical evidence grounded in sound scientific methodology. In close collaboration with other AO ITC business units, Clinical Science is part of an efficient pathway to transform ideas into published clinical evidence. In June this year, Dr Michael Fehlings chaired the first meeting of the AO ITC Clinical Science Advisory Commission (CSAC) and we are glad to update you about the work of the group, its members and their future visions for clinical research in an information packed interview between Fehlings and the group's spine representative, Dr Philip Louie.

Finally, we celebrate a new collaboration between the AO Foundation and the Rimasys Group; a technology-driven health-tech start-up founded in 2016. The strategic partnership will be driven by a focus on enhancing surgical education and improving patient outcomes by advancing practical skill training through digital health, artifical intelligence, and virtual reality.

With all of this and more, the 2021 edition of the AO ITC *Innovations* magazine promises to be an informative issue. We hope that you enjoy it and welcome your feedback and involvement.



Maartin Spruit Chair AO Technical Commission Executive Board



Mad

**Michael Fehlings** Chair AO ITC Clinical Science Advisory Commission



Michael Schütz Chair Technology Transfer Board



Tim Pohlemann Member AO Foundation Board MedTech Development

# AO Foundation and Rimasys enter strategic partnership to advance surgical education

In March 2021, the AO Foundation and German-based education start-up Rimasys announced a strategic partnership to join forces in their efforts to develop high-fidelity solutions to educate surgeons. Rimasys technological capabilities and disruptive product portfolio complement the state-of-the-art expertise in orthopedics and trauma surgery that the AO has built with global impact over the past 60 years. The partnership focuses on advancing the technology used to train and engage practitioners worldwide in the surgical treatment of trauma and musculoskeletal disorders.

Going forward, the AO Foundation will be integrating Rimasys products and services in selected high-end surgical training formats globally and leverage Rimasys dynamic innovation force especially around novel online education, their 3D virtual interaction platform, and artificial intelligence (AI) powered support tools for surgeons.

The partnership is built on successful past collaborations with the long-term perspective to create synergies and use strengths of both organizations advancing innovation in a dynamic environment.

Christoph Lindenmeyer, CEO of the AO Foundation, and Marc Ebinger, CEO and Co-Founder of Rimasys, sat down for an interview with Dankward Höntzsch, MD, who was an early advocate of the synergies of a potential partnership, to provide more information about the future benefits of the collaboration for both the surgeon community and industry partners.

**Höntzsch:** I am pleased to learn of the partnership, and proud that my vision of a collaboration has materialized. Chris, what is the AO's motivation for and expectation of the strategic partnership with the Rimasys Group?

Lindenmeyer: Rimasys is an innovative group in the field of surgical education. They started with the systematic generation of lifelike fractures and developed totally new educational formats. Their Trauma Academy and the Cadlab in Cologne, Germany, generated a lot of attention quickly. We have been loosely in touch with the three founders, Marc Ebinger, Robert Holz and André Passon, over the past years and were impressed with their creative ideas and drive to both innovate and implement. Over time we concluded that a strategic partnership could add value to both organizations and last year we began to engage in more serious discussions. I am happy that the discussions and negotiations moved forward rapidly at the end of last year and resulted in this strategic partnership.

**Höntzsch:** I can imagine that this was a complex and inspiring process. What are the opportunities and benefits of the strategic partnership for the Rimasys Group and the AO? And how can the partners of both organizations benefit in this strategic collaboration?

**Ebinger:** We are delighted to contribute to the AO's mission of promoting excellence in patient care and outcomes in both trauma and musculoskeletal disorders with our innovative products and solutions. The partnership agreement feels like an accolade for our hard work over the last years. The AO is a global network of surgeons comprising over 215,000 healthcare professionals. The impact of this status and subsequently the partnership will help to provide our surgical training concepts to a broader audience worldwide. Our trusted and longstanding partners are also benefiting from this partnership through the capability of reaching more surgeons in upcoming digital and hybrid projects including our live World Surgery Tour.

**Lindenmeyer:** As mentioned before, we are impressed by the creativity of the three founders and their drive for innovation. They are not only creative but also fast in implementing innovative approaches for surgical education. We are looking forward to bringing their concepts or elements of them into AO's educational offerings. As we are moving toward more digital and hybrid formats, their innovations fit well into our organization.

**Höntzsch:** How does a startup company like Rimasys interact with a globally established organization like the AO Foundation? How can you ensure that the individual strengths and characteristics of each organization is leveraged?

**Lindenmeyer:** The last intensive negotiation with the founders were productive. They confirmed the chemistry that exists among all those involved in the collaboration which demonstrates that we can all benefit from the partnership quickly. We have set-up a small and agile structure which acts as both an interface and a catalyst for value creation in both organizations. Rimasys is a fast-moving company, and we are fully aware that they need a lot of autonomy to remain agile and innovative. We will ensure that this remains the case.

**Ebinger:** Without a doubt the AO is the biggest organization of its kind worldwide with an impressive history from which we can benefit and learn a lot. Our young and diverse team loves to challenge the status quo with new innovations and uncommon, sometimes controversial, approaches from time to time. Our formula for success is rapidly trial, improve and professionalize ideas within a brief timeframe without being afraid of making mistakes. It is mandatory that we remain independent in decision making and maintain our working style. We complement the partnership with our vision to address the surgical challenges of the future, our knowledge of the digital world and desire to meet the needs of a new generation of surgeons.

**Höntzsch:** This sounds promising and thrilling. What are the first joint initiatives and when will they be visible to the surgical community?

**Lindenmeyer:** We have plenty of ideas for bringing innovations into AO's educational programs, especially across the digital offerings. A specific idea is bringing the mobile lab "The Shard" to the next Davos Courses.

**Ebinger:** The Shard is a polarizing example of one of our latest innovations and we will be happy to stream in and out from Davos 2021 to the AO network. We have already initiated various strategic projects from video-based education platforms to AI algorithm-based medical image recognition and gamification. Bringing all this together, we are now looking forward to accelerate on a global level.

# **AO ITC welcomes new staff**

The AO ITC team is growing. Ten new employees joined us in 2021.

#### **AO Innovation Translation Center**

In April, the AO ITC team welcomed Sarah Kempf (Fig 1) in her role as AO ITC Coordinator. Sarah has a degree in Business Administration and advanced training in Journalism and Leadership. She previously worked at a foundation for people with disabilities and gained further insight at corporate law firms. She enjoys the outdoors doing all types of sport and when indoors, Sarah likes to relax with a good book. Originally from Canton Uri, Sarah now lives in Davos.



**Fig 1** Sarah Kempf, AO ITC Coordinator

Sharon J Heller (Fig 2) joined the AO ITC team in May as AO ITC Coordinator. Sharon has a qualification in commercial education and spent many years working as a professional jockey, both in Switzerland and England. After retiring from horse-racing, Sharon moved to Davos to manage the Bolgenschanze and Rotliechtli Bar. She spends her free time on the snowboard or trail running.

Graziella Fopp was employed as AO ITC Assistant and started in her role in October. Graziella has a Bachelor's degree in International Hospitality Management and has worked in a number of hotels across Switzerland and abroad. She previously worked as an Event Manager at the Hotel Grischa in Davos and through her role as a meeting organizer, became very familiar with the AO Foundation.

She loves both downhill skiing and ski touring as well as mountain biking in the summer.

#### **Clinical Operations**

Felix Thomas started working for the AO ITC Clinical Operations team as a Clinical Research Associate in January. Felix has an MSc in Sport and Movement Science and a PhD in Neuroscience. For his PhD thesis he investigated the motor control of the upper limb and developed a novel therapy for stroke patients with upper limb impairments. Felix enjoys the outdoors regardless of the weather, doing sport, fishing, or just reading a book. He also likes cooking, especially Indian cuisine, and plays the guitar.

Also in January, the Clinical Operations team hired Viola Grünenfelder as a Clinical Research Associate. Viola has an MSc in Biomedical Sciences from the University of Bern. She enjoys traveling and practicing different outdoor sports and activities in her hometown of Balzers.



**Fig 2** Sharon J Heller, AO ITC Coordinator

Fig 3 Graziella Fopp, AO ITC



Assistant

**Fig 4** Felix Thomas, Clinical Research Analyst



**Fig 5** Viola Grünenfelder, Clinical Research Associate

In September, Aleksandra Vidakovic joined the Clinical Operations team as a Project Manager. Having previously worked as a Clinical Project Manager, Aleksandra has been exposed to all aspects of a clinical study from set-up to post-market evaluation. Her hobbies are traveling, hiking, reading, and scrapbooks.

#### **Clinical Science**

Robert Borotkanics joined the Clinical Science team in June as a Senior Project Manager in Medical Statistics. He has a PhD from the Johns Hopkins Bloomberg School of Public Health and is a former Informatics Research Fellow at the US National Institute of Health. He has over 40 peer-reviewed publications and recently moved to Davos from New Zealand where he was a Senior Research Fellow at the Auckland University of Technology. His hobbies are skiing, climbing, and hiking.

Also in June, Dimitri Hauri joined the team as Project Manager Medical Statistics. He is a statistician/data scientist with several years of experience in statistical analysis, data processing and data querying of large relational databases. Dimitri enjoys traveling, hiking, cultural activities, cooking, and eating out.

In August, Volker Timme started as Project Manager Statistical Programming. Volker has a PhD in Chemistry and more than a decade of experience working in this field, most recently for the Swiss Group for Clinical Cancer Research (SAKK) in Bern. His preferred hobby is cycling, especially in the mountains.

#### **AO Technical Commission**

In July 2021 Melissa Forster joined the AO Innovation Translation Center as a Project Manager with the AO Technical Commission. Melissa brings a wealth of knowledge and experience to the role, having previously worked for the AO Technical Commission and DePuy Synthes. She recently returned to live in Davos with her family and is happy to enjoy the mountain air once again. She is an accomplished athlete, having completed the Swiss Ironman in 2017, and loves to ride her bike. Fig 7 Robert Borotkanics, Senior Project Manager Medical Statistics

Fig 8 Dimitri Hauri, Project Manager Medical Statistics

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Programming











# The 2021 annual Chair's Innovation Fair goes digital

Throughout 2020 we all became familiar with virtual communication tools. The inability to travel and meet face-to-face certainly impacted our worlds in ways we could not have imagined, and yet we adapted well. Across the AO Innovation Translation Center (AO ITC) techniques were adopted to ensure that innovation continued; meetings were hosted, product testing was performed, and anatomy laboratories were scheduled. In February 2021, through the utilization of the Kaltura video platform, the Chairs of the AO Technical Commission joined the AO ITC first ever digital Innovation Fair to learn about development projects approaching approval and subsequent market release.

A total of 15 Intellectual Property protected projects were identified for virtual presentation by the AO Research Institute

Davos, Technology Transfer, and our industrial partner DePuy Synthes. Each project was allocated a dedicated breakout room and participants were able to preselect six project sessions to attend before the event. Project sessions were 15 minutes and included a structured presentation covering product features and benefits as well as an opportunity for Q&A. Two of the 15 projects that were covered in the sessions were the Variable Angle LCP Periprosthetic Proximal Femur Plating System and the Variable Angle LCP Clavicle Plate System, both of which are covered at length in this magazine.

The AO ITC digital Innovation Fair was a significant success, and we acknowledge those involved in the preparation of the event and are grateful to all participants (Figure). We look forward to potentially hosting another virtual Innovation Fair in the future.

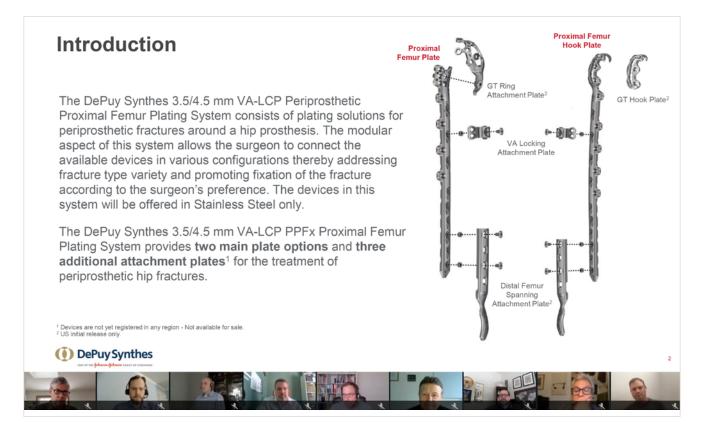


Figure Participants during the session about the new VA-LCP Periprosthetic Proximal Femur Plating System.

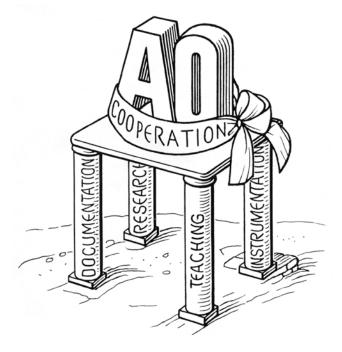
## 60 years AO Technical Commission— Four pillars concept for the success of the "revolution"

Despite the tradition of adopting a conservative approach in the management of fractures, the five founders of the 'AO Cooperation' envisaged better healing and patient outcomes with open reduction and internal fixation. While the idea of open reduction and internal fixation was not well accepted by the orthopedic surgeon community in the 1950s, Maurice E Müller, Hans Willenegger, Martin Allgöwer, Robert Schneider, and Walter Bandi identified four key concepts that would be integral in the adoption and success of this new 'revolution' in fracture treatment. The four 'pillars' were defined in 1959 as Teaching, Research, Documentation, and Instrumentation and provided a clear rationale for the adoption of internal fixation techniques (Fig 1).

Hardware is critical in the management of fractures when using an internal fixation technique. To ensure consistency in production and safety in usage, the founders recognized the need to work with a single partner in the development of both implants and instruments. Implants were offered in different sizes for fracture fixation in specific anatomical areas and tested to ensure that clinical needs would be successfully met. Instruments were used and approved by the founders and partner engineers to confirm indications for use as well as robustness of the material. In December 1960, Synthes AG Chur (currently known as AO Technology AG) was established to coordinate instrument production, market presentation, and profit distribution.

AO Technische Kommission (AOTK) established in 1961

In November 1961, the AO founders established the AO Technische Kommission that was simply known worldwide as the AOTK for many decades. The AO Technical Commission (AO TC) was the responsible department for the development and approval



**Fig 1** The Four Pillars of the AO Cooperation Agreement defined in 1959 by the five Founding Fathers.

of innovative surgical techniques, implants, and instruments. The AO TC controlled all "Synthes" catalogues and commercial material and guaranteed that the products offered were identical with those described in the AO textbooks. Only instruments and implants that were approved by the AO TC were promoted for sale with the registered trademark "Synthes."

The first meeting of the AO TC on December 16, 1961 was an informal gathering of the four AO founders and Synthes AG Chur shareholders together with producers Robert Mathys, Sr, and Fritz Straumann (Fig 2). The group continued to meet regularly, and decisions made by majority vote were equally binding for all AO TC members, surgeons, and producers. As the AO developed, the AO TC also grew to encompass a large group of surgeons.

To expand at a faster rate and allow for more flexibility, the AO TC established specialist subgroups in 1991 while remaining the exclusive approver of innovative techniques and technologies. In 2004, the birth of Trauma, Spine, and Craniomaxillofacial Surgery divisions further reflected the increasing demand for specialization, and the success of this structure remains today.

s s	ONTHES A.G.		Herrn F. Straumann					
	CHUR							
			chnischen Kommission anlässlich 16. Dezember 1961 in D a v o s					
		Anwesend waren die Her	ren Dr. Allgöwer, Karpf, Mathys, Dr. Miller, Dr. Schneider, Straumann, Vogt, Wettstein. Madame Moras.					
		infolge Zeitmangel nur	iste vom 16.12.61 vorgesehenen Traktenden konnten teilweise besprochen werden. Die Traktanden					
			i gesamthaft als eine Position behandelt. Die ern wurden aufgrund der neuen ab 1. Januar 1962 sprochen.					
	I. CORTI	CALIS - KASTEN						
Ma/I	A-3/2	Gewindeschneider lang:	Bei 52 mm ist eine Ringmarke anzubringen.					
I	A-5/2 A-5/1 A-6	Schraubenzieher:	Eine Metallanalyse soll vorgenommen werden um su wissen, ob der Schnubensicher sich mit den Schrauben werträgt. Die Spitse soll fernor härter sein und sich tief in den Konus der Schrauben einfügen lassen.					
Ma/I	A-9/1	Zielgerät mit Gewinde:	Unbefriedigend, soll neu konzipiert werdan. Es soll danach getrachtet werden die Vorteile der beiden Modelle herauszugreifen und zu verbinden.					
Ma/I	ohne Nr.	Gabel zur Entnahme der Schrauben aus dem Schraubenkasten:	Sollte sobald wie möglich hergestellt werden.					
Ma/I	A-11	Drahtumführungs- instrument:	Das frühere Modell erhält den Vorzug (muss vorne scharf sein). Eitte sich zu diesem Zwecke an die Herren Dr. Allgöwer und Dr. Schneider zu wenden.					
Te	A-14	Drahtschneidezange:	Wird etwas grösser und mit Uebersetzung gewünscht.					
			./.					

**Fig 2** Minutes taken from the inaugural meeting of the AO Technische Kommission in 1961.

Are you interested in the complete AO Technical Commission narrative? Then, check out the detailed timeline at (link to AO Technical Commission history).

# AO Technical Commission Executive Board welcomes a new Chair

The AO Technical Commission (AO TC) is delighted to welcome Maarten Spruit as the new Chair of the AO Technical Commission Executive Board (TCEB). Elected in June 2021 at the AO Foundation Board Meeting in Davos, Spruit takes up the position from the outgoing Chair Daniel Buchbinder, who will continue in his current role as Chair of the AO TC CMF. Buchbinder will also continue to lead the annual meetings of Chairs of the AO TC.

During his tenure as TCEB Chair, Buchbinder successfully steered the AO Technical Commission through a period of transformation and increased productivity. In March 2020, Buchbinder's longheld ambition for an AO "innovation clearing house" came to fruition with the launch of the new AO Innovation Translation Center (AO ITC). Comprising four business units (the AO TC, Clinical Operations, Clinical Science, and Technology Transfer), the AO ITC brings together AO teams engaged in innovation, streamlines workflows, and makes innovation translation at the AO Foundation more efficient and agile. Buchbinder's term of office as TCEB Chair also witnessed an acceleration in the development and launch of new solutions, with numerous innovative products receiving AO TC approval during his tenure.

Reflecting on his tenure as TCEB Chair, Buchbinder finds it especially rewarding to see the growth in interdisciplinary collaboration among the different clinical areas represented in the AO TC and values the close personal relationships he has formed with both medical and AO colleagues.

Buchbinder states "One particular highlight was seeing the AO Innovation Translation Center taking shape. Building on the AO's strong legacy of innovation and development, the AO ITC provides expertise and resources to foster an environment where ideas are translated into clinical solutions addressing the needs of modern healthcare in a rapidly evolving environment."

As incoming Chair, Spruit perceives several opportunities to further strengthen the innovative output of the AO TC and aims

to promote the AO TC as a Global Expert Think Tank that will drive disruptive innovation. A key goal will be to deepen the partnership with the AO TC's primary industrial partner DePuy Synthes (DPS), to grow the number of collaborative development projects that can be realized across all divisions of the AO TC (Trauma, Spine, and CMF) and to bring digital surgery solutions to the forefront. He also intends to build on the network of alternative industry partners to advance the development of technology and concepts categorized as off-ramp by DPS. Spruit will usher in a renewed focus to the creation of Clinical Evidence as a critical part of the modern healthcare environment via efficient processes that address the needs of all stakeholders.

Spruit takes over during a challenging phase for the AO TC, as travel restrictions imposed by the Covid-19 pandemic have forced the usual AO TC activities of international face-to-face meetings and anatomy labs to be conducted differently. During the last 18 months, the AO TC's expert medical members have continued to drive innovation forward via online meetings and anatomy labs attended by members regionally, with international members participating via live stream links. Notwithstanding the challenges, the AO TC has worked extremely productively throughout the pandemic period, with a record number of new product approvals, the kick-off of new off-ramp projects and the formation of several new task forces to support DPS with expert clinical guidance for new development projects. The formation of the new AO ITC in spring 2020 has enhanced the AO TC's capacity to drive innovation via the rapid allocation of innovative concepts to the appropriate development pathway with appropriate funding streams.

Maarten Spruit says: "I am honored to take over as Chair of the AO Technical Commission Executive Board and value the opportunity to consolidate the work done by my predecessor, Daniel Buchbinder. I look forward to leading the AO Technical Commission to develop an ever-broader range of innovative solutions to improve surgical outcomes for patients across the globe."



**Figure** From left to right: former TCEB Chair Tim Pohlemann, incoming TCEB Chair Maarten Spruit, and outgoing TCEB Chair Daniel Buchbinder.

Eladio Saura-Sanchez, Karl Stoffel, Mark Lee, Cong-Feng Luo, Rodrigo Pesantez, Dean Lorich, David Helfet, Stephen Warner, Christoph Sommer

# Variable Angle Locking Patella Plating System

#### **Clinical problem**

Patella fractures account for about 1% of all skeletal fractures [1] with an incidence of approximately 21 per 100,000 per year [2]. Despite the low incidence, the consequences of inadequate treatment are potentially disabling, with possible development of knee stiffness, loss of extension or patellofemoral osteoarthritis. Most patella fractures occur due to direct blunt trauma. The resulting fracture type depends on the trauma mechanism, the energy transmitted to the bone and the bone quality.

Undisplaced or minimally displaced fractures with an intact extensor apparatus can be managed conservatively. In 20-30% of cases surgical treatment is required because the fracture is displaced (displacement of more than 2-3 mm) and/or the extensor mechanism is disrupted. A cohort study [2] with 22,689 patella fractures reported that 26% of the fractures were surgically treated.

Aim of every surgical intervention is to achieve anatomical reduction with joint congruity and to provide high stability for early active range-of-motion exercises [1]. Because of the subcutaneous anterior location, the biomechanical function, and the high level of force transmission (extensor force of up to 3200 N in the quadriceps tendon and up to 2800 N in the ligamentum patellae) [3], stable reconstruction of patellar fractures continues to represent a major surgical challenge [4].

Tension band wiring (TBW) is the most common fixation method. It is performed with two parallel K-wires and a figure-of-8 cerclage wire which is intended to convert tension forces acting on the anterior surface into compression forces at the articular surface. Additional K-wires and cerclage wires or cable configurations can be used to address complex patella fractures. As a low-cost implant solution TBW has proven to be successful if performed with the proper surgical technique. Accurate K-wire placement as well as proper cerclage application and tightening are essential for achieving good clinical results. Limited cerclage-bone contact due to soft-tissue interposition and insufficient cerclage tightening, as well as cerclage migration through osteoporotic bone compromise construct stability and may lead to fixation failure. Cannulated screws (as lag or positioning screws), instead of the two K-wires, with TBW (CSTBW) through the screws has been proposed as an alternative fixation technique to increase and maintain primary stability. However, osteoporotic bone often lacks the strength to support a TBW construct and can compromise screw function, which may result in fixation failure before bone union [5].

High rates of symptomatic hardware are reported for TBW and CSTBW. According to a prospective randomized study [6] on transverse patella fractures, the percentage of patients complaining of implant prominence was 5.8% in the CSTBW group and 17.6% in the TBW group. In a retrospective cohort study [7] on comminuted patella fractures 22.9% of patients in the CSTBW group and 40.5% in the TBW group underwent implant removal due to symptomatic hardware. There is a demand for alternative fixation methods to reduce these complication rates.

Patella fracture fixation becomes increasingly challenging with the degree of fracture comminution which can be difficult to assess based on plain x-rays. Lazaro et al [8] investigated the effect of computed tomography (CT) on the classification and treatment plan for patellar fractures. With a CT scan, there was a change in the AO/OTA classification in 66% of cases and a modification of the surgical strategy for 49% of patients. Severely comminuted distal pole fractures were missed on nearly half of the standard images. The study findings underline the importance of a CT scan to realize the complexity of the fracture. Furthermore, it suggests that the occurrence of complex patella fractures is much higher than expected, thus emphasizing the need for better fixation strategies.

Preservation of the patella blood supply must be considered when developing new fixation concepts (implants as well as surgical technique). It has been shown that large blood vessels enter in the lower pole of the patella behind the ligamentum patellae [9]. According to a study [10] about the vascular anatomy of the patella, the medial-sided vessels seem to contribute more significantly to the peripatellar anastomotic ring compared with the lateral-sided vessels [10]. Approach and osteosynthesis should not compromise the dominant blood supply through the inferomedial aspect of the distal pole of the patella. Avoiding inferior pole patellectomy to preserve vascularized bone presents further demands on the fixation concept.

Considering all these aspects, the Patella Task Force (PTF) (medical members: Dankward Höntzsch, David Helfet, Dean Lorich, Sean Nork, Pol Rommens, and Eladio Saura-Sanchez) and the Lower Extremity Expert Group (LEEG) (medical members: Christoph Sommer, Karl Stoffel, Cong-Feng Luo, Rodrigo Pesantez and Mark Lee) of the AO Technical Commission defined as main requirements for the development of a better osteosynthesis solution for the patella:

- Low prominence solution to avoid soft-tissue irritations
- · High osteosynthesis stability to withstand tensile forces
- Usability for many different fracture patterns (simple and complex fractures) as well as patella morphologies
- Preservation of blood supply at the inferomedial aspect
   of the distal pole
- Surgical technique with quick learning curve to achieve consistent stability and reproducible results

#### Solutions

The Variable Angle Locking Patella Plating System addresses these identified requirements with two new plating solutions:

• 2.7 Variable Angle Locking Anterior Patella Plates

• 2.4/2.7 Variable Angle Locking Lateral Rim Patella Plates Surgeons have the option to choose the most appropriate plating solution based on fracture pattern, soft-tissue conditions and individual preferences.

#### 2.7 Variable Angle Locking Anterior Patella Plates

At the onset of the development of this plating solution Saura-Sanchez reported about his good clinical results using the Locking Calcaneal Plate from DePuy Synthes in an off-label manner for comminuted patella fractures. His fixation concept was to place the calcaneal plate on the anterior surface of the reduced patella and to bend plate arms around the distal patella pole for the insertion of longitudinal locking screws from distal to proximal. In a subsequent step, the patella fracture could be fixed with locking screws from anterior to posterior. Although this fixation concept resulted in stable osteosynthesis, there were usability challenges: the plate required frequent cutting and cumbersome bending to adapt the flat plate to the shape of the patella. Furthermore, the intended bending directions could often not be achieved without cutting selected plate arms compromising construct strength. To address these issues Saura-Sanchez envisioned a dedicated, preformed anterior patella plate mimicking the structure of an ice crystal with well distributed locking hole options. In addition to a basic plate, he proposed a patella plate version with some extended plate legs that can be bent around the patella to basket and stabilize fracture fragments

as required. Inspired by this vision, the 2.7 Variable Angle Locking Anterior Patella Plates (Fig 1) and instruments were developed by the PTF and LEEG in collaboration with DePuy Synthes under the medical lead of Saura-Sanchez.

#### Plate design and plate features

The 2.7 Variable Angle Locking Anterior Patella Plates comprise six plate types (Fig 2) in stainless steel (with 1.8 mm plate thickness) and titanium (with 2.0 mm plate thickness) to

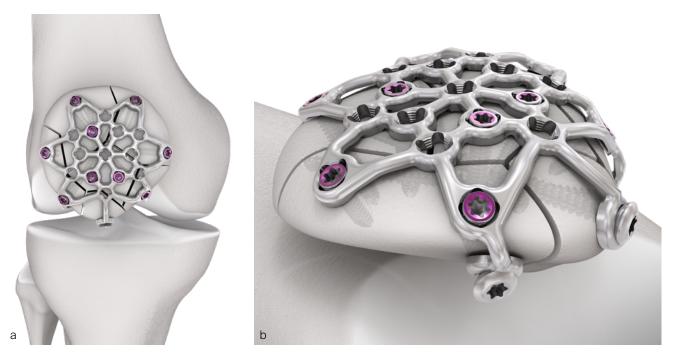
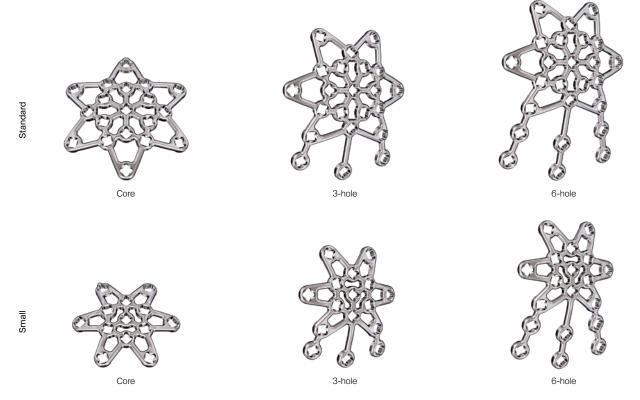


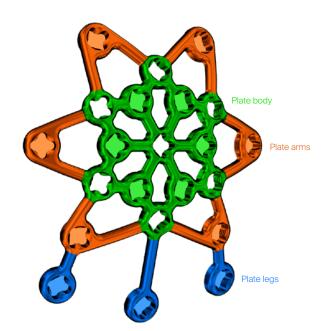
Fig 1a-b Low profile anterior VA locking patella plate with various screw fixation options.



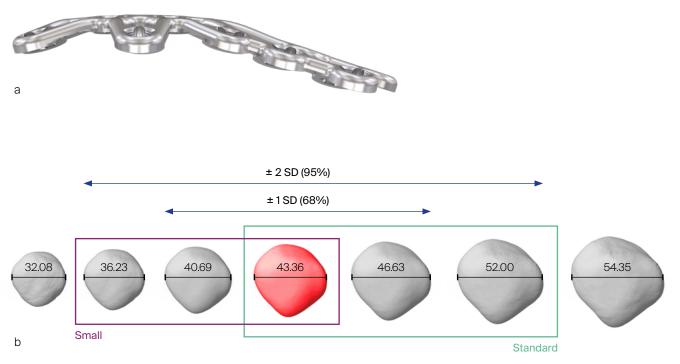
**Fig 2** Small and standard size patella plates with 13 to 25 VA locking holes (depending on plate size). While the core plates are intended to be used for simple fractures, the three-hole and six-hole plate versions can be chosen to treat more complex fracture patterns.

address a large variety of fractures in large and small patellae. The plates leverage a smooth, low-profile mesh design to minimize soft-tissue irritations, preserve blood supply and facilitate plate adaptation to the bone. The plate consists of three plate sections (body, arms, and legs) to allow versatile plate use (Fig 3). All plates are precontoured to minimize intraoperative bending and contouring (Fig 4). The arms and legs can be cut to meet the needs for the specific fracture pattern and patient anatomy.

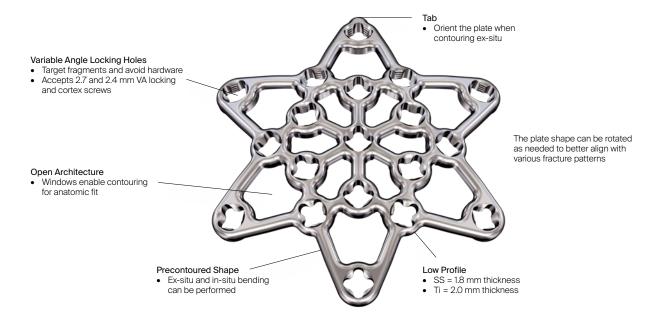
There are several plate features to ease and improve patella fracture fixation (Fig 5): variable angle (VA) locking holes enable up to 15° of screw angulation to target small bone fragments and to avoid fracture lines as well as other hardware. The screw holes accept 2.4 mm and 2.7 mm VA locking and cortex screws (2.4 mm screws are only for use in small, non-load bearing fragments). There are two sterile plate templates available (small and standard six-hole plate sizes) to help determine proper sizing and contouring of the implant (Fig 6).



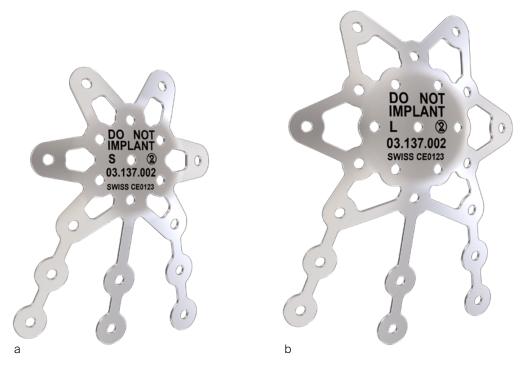
**Fig 3** Plate arms originate from a rigid plate body to achieve the required anterior bone coverage. The arms can be bent to adapt to the anterior patella surface. Three legs extend from the arms/body of the three-hole and six-hole plate versions. They can be oriented and bent around the patella to secure fracture fragments.



**Fig 4a-b** The plate body and arms are precontoured based on statistical CT bone model data from 83 adults (45 Europeans and 38 Asians; 48 women and 35 men; age: 23–88 years) provided by the AO Research Institute Davos. The small and standard plates were designed to cover ± 2 standard deviations (SD) of the patella sizes (patella width is given in millimeters). Following plate features were optimized: plate contour and footprint, hole spacing, plate leg design for pole fragment and soft-tissue management.



**Fig 5** Plate features of the core plate which is available in stainless steel (SS) and titanium (Ti). There is a tab on one of the plate arms for orientation purposes when the plate is contoured ex-situ. The tab is not required in the three-hole and six-hole plate versions since the plate legs help with proper plate orientation. The plate windows in the open architecture plate can be used to attach soft tissues with sutures.

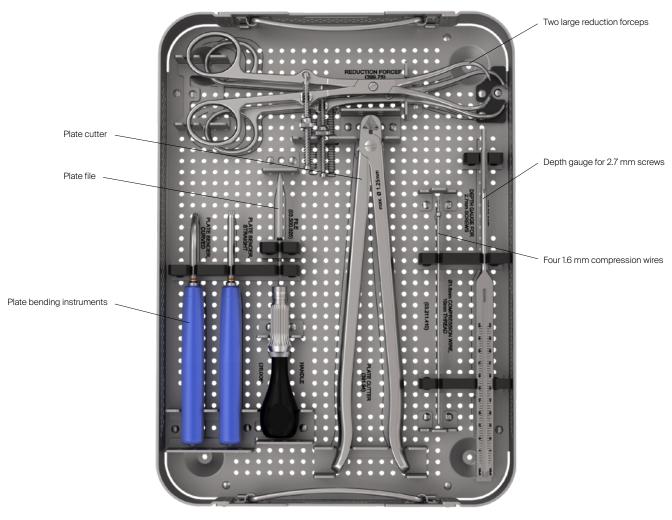


**Fig 6a-b** Small (a) and standard (b) preformed templates are provided in the six-hole configuration only, which can be used to approximate sizing and contouring for core, three-hole and six-hole implants. They are malleable and include holes for K-wire fixation.

#### Instrument tray

A patella specific instrument tray is provided to facilitate fracture reduction, plate bending, plate application, and it includes the following instrumentation (Fig 7):

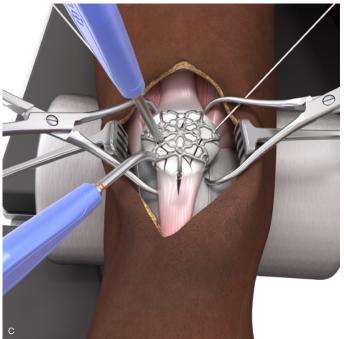
- Two large reduction forceps for reducing fragments of small and large patellae in simple and complex cases.
- Four 1.6 mm compression wires with 10 mm thread and sphere for compressing the plate to the bone for provisional fixation. The sphere is self-seating in the recess of the VA hole.
- One straight and one curved plate bending instrument for appropriate in-situ and ex-situ bending of the plate (Fig 8).
- Plate cutter with small cutting jaws for plate cutting close to the VA holes.
- Plate file for smoothing the plate edges after cutting.
- Depth gauge for 2.7 mm screws for directly reading the required screw length.



**Fig 7** Instrument tray containing reduction forceps, 1.6 mm compression wires, plate bending instruments, plate cutter, plate file and depth gauge for 2.7 mm screws.







**Fig 8a-c** The straight and curved plate bending instruments (**a**) should be inserted in adjacent plate holes to bend the plate between the VA locking holes (**b**). The instruments have a tip with a special cloverleaf design which maintains the integrity of the VA locking holes during bending. The cloverleaf shape allows the bender orientation to be rotated in 90° increments to obtain appropriate leverage for bending (**b**). The instruments can be used for ex-situ and in-situ (**c**) bending to ensure that the plate closely fits the specific anatomy.

#### **Surgical technique**

The surgical technique which was refined throughout several anatomy labs (Fig 9) comprises the following steps:

- Position the patient supine with the knee in slight flexion.
   Create midline or parapatellar incision (lateral parapatellar is
- recommended to preserve the inferomedial blood supply).
  Reduce the fracture fragments (with reduction forceps and K-wires). It can be beneficial to evert the patella to achieve accurate fracture reduction and joint congruency under direct vision (Fig 10).
- 4. Use the templates to determine the appropriate plate size, configuration, and orientation.
- 5. Cut the plate legs and file cutting edges (as needed).
- 6. Contour the plate with the plate bending instruments (as needed). Avoid bending the plate beyond what is required to match the anatomy. Repeated reverse bending may weaken the plate and lead to premature plate failure, especially in titanium plates.

- 7. Position the plate according to the fracture pattern and patient anatomy with provisional plate fixation using the 1.6 mm threaded compression wires.
- Insert screws (VA locking screws and cortex screws).
   a. Place the distal to proximal screw(s) first when using the three-hole or six-hole plates.
  - b. Drill, measure, and place the anterior to posterior monocortical locking screws.
  - c. Final tigthening of the VA locking screws with 1.2 Nm torque limiter.
- 9. Use sutures through the plate windows to anchor soft tissues (as needed). Sutures must not be placed through the locking holes.

In most complex fractures a three-hole or six-hole plate is useful for bending the plate legs around the rim of the patella to basket and fix bone fragments. The plate can be oriented on the patella as needed to utilize the plate legs for fracture fixation. For distal to proximal screw placement through the distal patella pole (with a pole screw) a longitudinal split in the patellar tendon is required to insert the plate leg. Sometimes proximal to distal screw placement through the quadriceps tendon might be preferred. The VA locking or cortex screws can be used as pole screws (Fig 11). It is important to place the pole screw(s) before the insertion of the anterior to posterior locking screws.

A minimum of two screws per fragment are recommended. If this is not possible, augmentation techniques (eg, sutures) can be applied. The 2.4 mm anterior-posterior locking screws may only be used in small, non-load bearing fragments. For the complete surgical technique, refer to the DePuy Synthes Surgical Technique Guide.

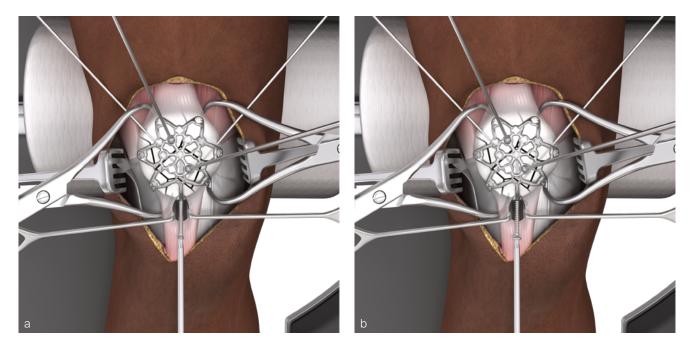
The performance of the plate was explored in a biomechanical test at the AO Research Institute Davos. The anterior patella plate provided significantly higher stability in simple and complex fractures compared with modified TBW (more detailed information is provided in the corresponding article in this magazine).



**Fig 9** Anatomy lab to determine the optimal surgical technique. From left to right: Mark Lee, Christoph Sommer, Eladio Saura-Sanchez, and Rodrigo Pesantez.



**Fig 10** Lateral parapatellar arthrotomy and patella eversion for direct visual reduction of the articular surface (courtesy of Mark Lee).



**Fig 11a-b** Placing a VA locking screw as pole screw (**a**) prevents screw head prominence and provides angular stable fixation. A cortex screw can be used as pole screw (**b**) to bring the plate down to the bone and to achieve interfragmentary compression with a lag screw technique.

#### **Clinical cases**

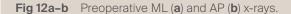
#### Case 1

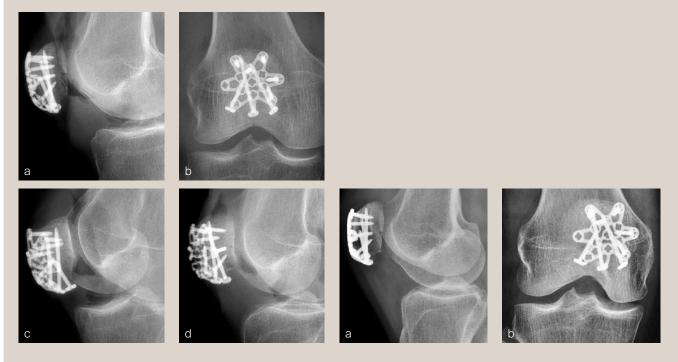
Treatment of a fragmented distal pole patella fracture with a three-hole patella plate (by Christoph Sommer, Kantonsspital Chur, Switzerland).

A 73-year-old woman sustained a right 34-C3.1 patella fracture during a hiking injury (Fig 12). X-ray analysis revealed that the distal pole was fractured in four fragments (Fig 13). After fracture reduction, a three-hole plate was used with three inferior to superior locking screws in the coronal plane through the holes of the plate legs and five anterior to posterior locking screws (Fig 14 and Fig 15).



**Fig 13** Enlarged preoperative ML x-ray with four distal pole fragments including a coronal fracture line.





**Fig 14a–d** Intraoperative x-rays. True ML (**a**), true AP (**b**), oblique lateral facet (**c**), and oblique medial facet (**d**).

Fig 15a-b ML (a) and AP (b) x-rays 2 days postoperatively.

#### Case 2

Treatment of a complex patella fracture with a three-hole patella plate (by Eladio Saura-Sanchez, University Hospital of Elche, Spain).

A 71-year-old obese woman with osteoporosis sustained a fall from standing height with a direct blunt trauma on the left knee. It was impossible for her to walk or extend the knee. X-rays revealed a complex patella fracture with a comminuted distal pole (Fig 16). A CT scan was performed to assess the complexity of the fracture pattern (Fig 17).

A direct anterior approach was chosen (Fig 18a). The extensor mechanism was completely ruptured (Fig 18b). After intrafocal

identification of the fracture fragments, bone anchors with augmentation sutures were placed in the proximal pole (Fig 19a). The sutures passed intraosseous toward the patellar tendon. A lateral parapatellar incision was performed for eversion of the patella to achieve articular reduction of the main fragments under direct vision (Fig 19b). K-wires were used for temporary fixation of the fracture fragments. A headless screw was inserted as lag screw to compress the two main articular fragments. After fracture reduction and temporary fixation, the plate template was used on the patella to select the appropriate plate size and to determine the best plate position with the desired location for the inferior to superior locking pole screw through the central plate leg (Fig 20).

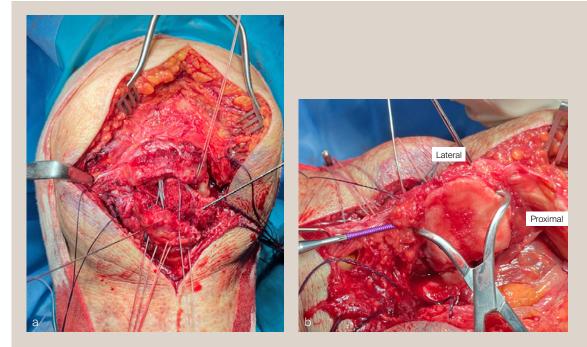


**Fig 16a-b** Preoperative ML (**a**) and AP (**b**) x-rays: complex patella fracture with inferior pole avulsion and severe displacement.



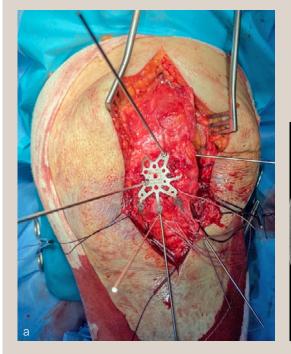
**Fig 17** The CT scan revealed the complexity of the fracture.

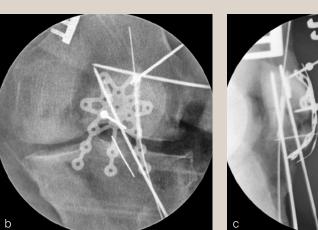
**Fig 18a-b** Surgical approach (**a**) and initial exposure of the fracture with complete, transverse disruption of the extensor mechanism (**b**).



#### Fig 19a-b

- a Reduction and temporary fixation of the fracture fragments. Insertion of two bone anchors in the
- proximal pole with intraosseous sutures passing toward the patellar tendon to augment the fixation.
- ${\boldsymbol b}$   $\,$  Articular reduction of the everted patella and placement of a headless screw as lag screw.





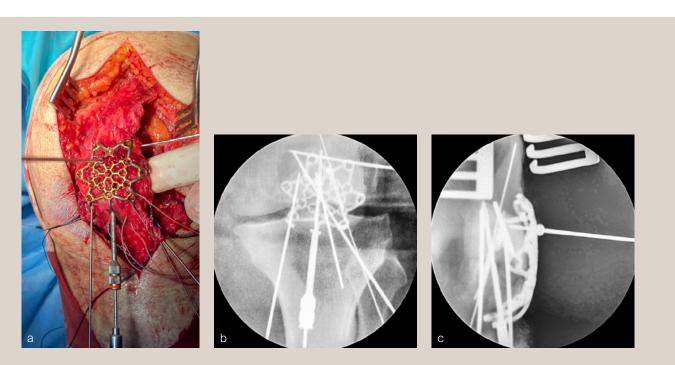
#### Fig 20a-c Templating.

**a** The plate template was pinned to the patella with the help of threaded compression wires. AP (**b**) and ML x-ray (**c**) of the template position.

A standard three-hole patella plate was chosen and bent according to the template. A central trans-patellar tendon stab incision was made to insert the middle plate leg when positioning the plate (Fig 21). The plate was provisionally fixed to the proximal patella fragment. The inferior to superior pole screw was inserted first as the 'primary' screw through the preselected plate hole of the middle plate leg to prevent collision with subsequent 'secondary' anteroposterior screws.

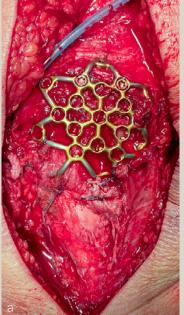
Bicortical pole screw placement increases the stability of the construct. In this plate configuration the plate was used as a "basket plate" to stabilize the fracture. A second pole screw was inserted through the lateral plate leg.

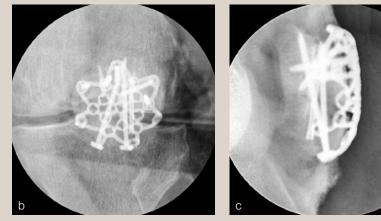
The plate fixation was finalized by placing the monocortical AP locking screws. Subsequently, the sutures were tightened to the patellar tendon and the extensor mechanism (Fig 22).

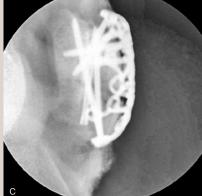


#### Fig 21a-c

a Plate application and drilling of the hole for the pole screw through the drill sleeve placed in the central plate leg. AP (b) and ML x-ray (c) during drilling.



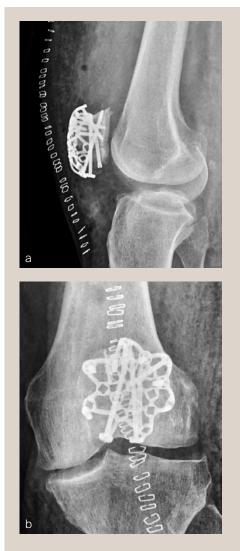




#### Fig 22a-c

**a** Final plate fixation and suture augmentation. Intraoperative AP (b) and ML x-ray (c) of the fixation construct. The plate may help to enhance the suture fixation. Figure 23 illustrates the final fixation construct.

The patient was allowed to perform early active knee movement at 2 weeks (Fig 24).



**Fig 23a-b** Postoperative ML (**a**) and AP (**b**) x-rays.





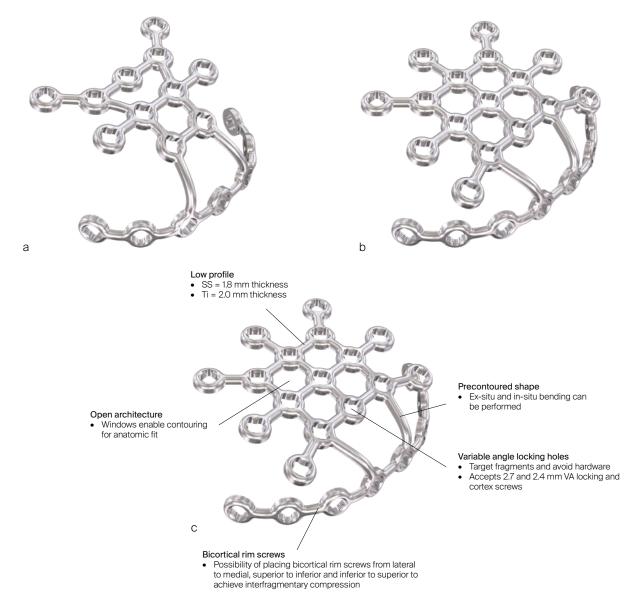
Fig 24a-b Pain free early active knee movement.

**2.4/2.7 Variable Angle Locking Lateral Rim Patella Plates** The development of the 2.4/2.7 Variable Angle Locking Lateral Rim Patella Plates was based on the fixation concept published by Dean Lorich, Stephen Warner, and David Helfet in 2015 [11]. The authors used the Variable Angle LCP Mesh Plate 2.4/2.7 (part of the Variable Angle LCP Forefoot/Midfoot System 2.4/2.7) for multiplanar fixation of patella fractures. The surgical technique included a lateral parapatellar arthrotomy to avoid the predominant vascularity to the patella coming in inferomedially and to allow for eversion of the patella to directly visualize the articular surface during reduction and plate fixation. The mesh plate had to be cut to size and contoured to fit around the lateral rim of the reduced patella and the anterior cortical surface.

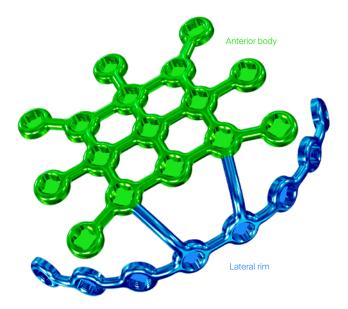
#### Plate design and plate features

The 2.4/2.7 Variable Angle Locking Lateral Rim Patella Plates

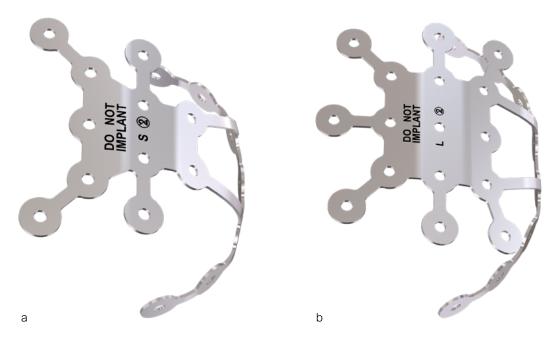
are offered in both a small and a standard size with various screw hole options for each size to provide fixation for various patella fracture patterns (Fig 25). These plates are an evolution of the mesh plate to ease plate application and to optimize plate function in patella fracture treatment. The plates are offered in stainless steel (with 1.8 mm plate thickness) and titanium (with 2.0 mm plate thickness) and contain the same smooth, low-profile mesh design and VA locking hole technology as the 2.7 Variable Angle Locking Anterior Patella Plates. The 2.4/2.7 Variable Angle Locking Lateral Rim Patella Plate consists of two plate sections: anterior body and lateral rim (Fig 26). There are two sterile plate templates (Fig 27) available (small and standard) to help determine proper sizing and contouring of the implant. The same screws and instruments are used for plate application as for the 2.7 Variable Angle Locking Anterior Patella Plates.



**Fig 25a-c** The 2.4/2.7 Variable Angle Locking Lateral Rim Patella Plates are precontoured and can be cut as needed with the plate cutter in the instrument tray. They are available in a small plate version with 18 VA locking holes (**a**) and a standard plate version with 24 VA locking holes (**b**) in stainless steel and titanium. The plates have specific plate features (**c**).



**Fig 26** Anterior body and lateral rim of the standard 2.4/2.7 Variable Angle Locking Lateral Rim Patella Plate.



**Fig 27a-b** Small (a) and standard (b) preformed templates are provided which can be used to approximate sizing and contouring. They are malleable and include holes for K-wire fixation.

#### **Surgical technique**

The 2.4/2.7 Variable Angle Locking Lateral Rim Patella Plate utilizes the same surgical steps as the 2.7 Variable Angle Locking Anterior Patella Plates; however, the plate is placed along the lateral rim of the patella instead of the anterior surface. To apply the plate on the rim a lateral peripatellar retinacular release is necessary. This assures a perfect rim fit for the plate but also facilitates patella eversion for an anatomical reduction of the articular surface. Often the retinaculum needs to be repaired to the plate.

The lateral rim of the plate is contoured to sit beneath the patellar ligament and the quadriceps tendon (Fig 28). The plate is placed so that it does not interfere with the articular surface.



Subsequently, the bridges connecting the lateral rim to the anterior body can be bent such that the latter sits against the anterior surface of the patella. Additional contouring of the anterior body is performed from the center outward.

Avoid bending the plate beyond what is required to match the anatomy. **Repeated reverse bending may weaken the plate and lead to premature plate failure, especially in titanium plates.** 

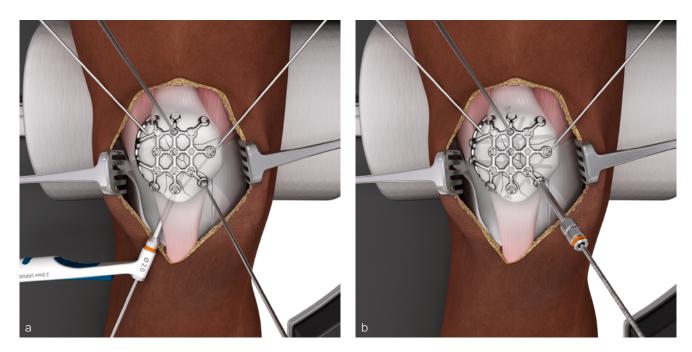
First place bicortical cortex screws in the rim portion of the plate (Fig 29). Once these are secured, insert the unicortical anterior to posterior variable angle locking screws. A minimum of four bicortical rim screws per construct is recommended; however, if this is not possible consider an additional augmentation technique. For the complete surgical technique, refer to the DePuy Synthes Surgical Technique Guide.

#### Intended use and indications

Both plating solutions have the same intended use and indications:

- Intended use: The DePuy Synthes VA Locking Patella Plating System is intended to provide internal bone fixation for simple, complex, and comminuted patellar fractures.
- Indications: The DePuy Synthes VA Locking Patella Plating System is indicated for the fixation and stabilization of patellar fractures in normal and osteopenic bone in skeletally mature patients.

**Fig 28** Everted patella indicating the placement of the lateral plate rim beneath the patellar ligament and the quadriceps tendon.



**Fig 29a-b** Placing the bicortical cortex rim screws first (**a**) optimizes screw purchase, ensures the plate is compressed to the bone and minimizes the likelihood of screw interference when placing the anterior to posterior locking screws (**b**).

#### Summary

The VA Locking Patella Plating System offers various low-profile plates that allow surgeons to achieve stable fixation in simple and complex patella fractures while minimizing soft-tissue irritation, aimed to reduce unplanned reoperation rates. The plates can be cut and contoured with dedicated instruments to meet the patient anatomy and to address various fracture patterns.

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# FIBULINK<sup>™</sup> Syndesmosis Repair System

#### **Clinical problem**

The ligaments around the syndesmosis maintain the proper relationship between the distal fibula and tibia. As such, they provide strong stabilization and dynamic support to the ankle mortise. Syndesmotic injuries occur in 1–18% of all ankle sprains, and 13–50% of all ankle fractures [1]. Based on data obtained from eight US states in 2009, Vosseler et al [2] reported an incidence rate of 2.09 syndesmotic injuries per 100,000 person-years. This incidence would correlate to about 7000 such injuries in the US in 2020. Syndesmotic injuries tend to occur in younger patients (between 18 and 34 years), which adds to the burden of disease because of the potential of productive years of life lost secondary to disability from this injury [2].

Proactive recognition and adequate treatment of syndesmotic injuries are important to restore ankle function and prevent poor clinical outcomes including degenerative ankle disease. Unstable syndesmotic injuries typically require surgical stabilization [3, 4]. Accuracy and maintenance of syndesmosis reduction are considered key factors for a successful treatment. If an associated fracture is present, the length, alignment, and the rotation of the fibula must be restored before syndesmotic reduction and fixation.

Historically, the most common operative treatment method is syndesmotic screw fixation. Syndesmotic screws provide rigid fixation but inhibit the natural physiological tibiofibular movement. Screw breakages are frequently observed [5, 6]. A second operation might be required for screw removal which is associated with substantial costs [7]. Lalli et al [8] stated that their institution billed a total of \$188,271 for elective syndesmosis hardware removal in 56 patients. In 2012 a national survey [9] including 86 hospitals in the Netherlands revealed that syndesmotic screw removal was routinely done by 87% of the surgeons. There has been disagreement in the literature whether syndesmotic screws should be retained or removed. Timing of removal is also debated [4]. An argument in favor of screw removal is the restoration of the physiological syndesmosis function and the normal load transfer in the ankle joint.

Suture button devices have been developed for "dynamic" syndesmosis fixation with the claimed benefits of allowing physiological motion of the distal tibiofibular joint, reducing the implant breakage rate observed in rigid screw fixation and avoiding routine implant removal. Their use has become increasingly popular due to these appealing device features. Sanders et al [10] in a randomized controlled study compared two 3.5 mm 3-cortex screws with a frequently used suture button device (Syndesmosis TightRope®, Arthrex, Naples, Fla) for syndesmosis fixation. The reoperation rate was significantly higher in the group with screws (30%) than in the TightRope group (4%), largely due to elective removal of screw fixation [10]. Additionally, malreduction rate (2 mm translation or 10° rotation threshold) was 39% in the group with screws compared with 15% in the TightRope group [10]. A randomized trial [11] compared suture button fixation (48 patients) and fixation with a single quadricortical syndesmotic screw (49 patients) for syndesmosis injury. At 2 years, the median American Orthopedic Foot and Ankle Society (AOFAS) score was higher in the suture button group than in the syndesmotic screw group (96

vs 86), as was the median Olerud-Molander Ankle score (100 vs 90) [11]. In a randomized controlled trial Ræder et al [12] found no differences in the AOFAS score at 2 years (median AOFAS score was 97 in both groups) after treatment with single tricortical 3.5 mm syndesmotic screw fixation (n = 47) and suture button fixation (n = 48). A systematic review [13] of the treatment for acute syndesmotic injuries found that the implant removal rate of TightRope was lower compared with that of syndesmotic screws, but still amounted to 10% (in 220 patients). Several drawbacks have been reported for TightRope fixation: superficial wound infection, chronic osteomyelitis, irritation from the suture knots, and creeping button migration/ bony subsidence [4]. A study from Pirozzi et al [14] showed that there is a considerable risk of entrapment of superficial medial neurovascular structures. The authors advised that a medial incision should be used to ensure that these structures are not entrapped. LaMothe et al [15] concluded that in simulated highly unstable injuries a single suture button placed from the lateral fibula to the anterior medial malleolus allowed significantly more posterior motion of the fibula (and sagittal plane instability) than a syndesmotic screw. Additionally, Tight-Rope devices are not indicated as sole fixation in length unstable patterns as they do not reliably prevent shortening from occurring [16]. A technical drawback of suture button instrumentation is the limited capability to reverse or fine tune the amount of tensioning in the system which may cause inadequate syndesmosis reconstruction.

The Foot and Ankle Expert Group (FAEG) and DePuy Synthes (DPS) investigated alternative concepts for syndesmosis repair to address the issues of syndesmotic screw and suture button fixation for treatment of syndesmotic injuries.

#### Solution

The FIBULINK<sup>™</sup> Syndesmosis Repair System (Fig 1) combines the benefits of fixation of a screw and the flexibility of a suture. It is the first adjustable syndesmotic repair system to enable precise, anatomical syndesmotic fixation. A short, high-strength suture bridge helps to restore the physiologic ankle motion. The fixation concept addresses limitations of suture button constructs including lack of tension control and medial soft-tissue disruption.

#### Implant features

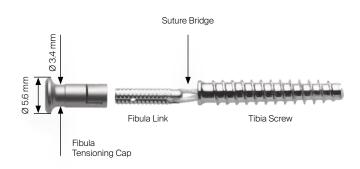
The implant is a multicomponent anchor system consisting of four main components (Fig 2):

- Fibula Tensioning Cap: interfaces with the Fibula Link. A rotation of the Tensioning Cap applies tension to the construct.
- 2. Fibula Link: transfers the tension applied by the Fibula Tensioning Cap to the Suture Bridge. As such, it functions as an interface in the primary tension mechanism.
- Suture Bridge: applies compression between the fibula and the tibia via transferring the tension between the Fibula Link and the Tibia Screw.
- 4. Tibia Screw: functions as an anchor in the tibia.

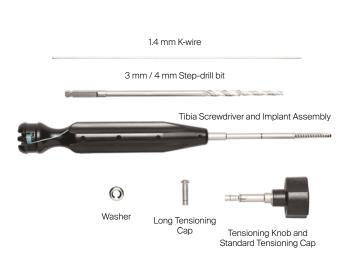
The implant components and instruments are provided in sterile, single-use kits (Fig 3). The Tensioning Knob is used to fine tune and readjust the tension in the Suture Bridge intraoperatively (Fig 4).



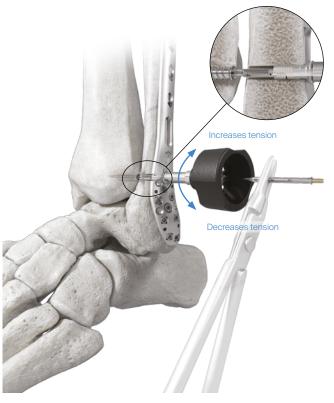
**Fig 1** The FIBULINK Syndesmosis Repair System is available in stainless steel and titanium. It can be used in combination with a fibula plate. The system is compatible with the following DPS plate holes: 1/3 tubular plate holes (LCP and non-locking), non-threaded portion of a combi hole in a 2.7 mm/3.5 mm LCP Distal Fibula Plate and the syndesmotic slots of a 2.7 mm VA-LCP Lateral Distal Fibula Plate. Additionally, the FIBULINK Implant is compatible with any distal fibula plate hole which accepts a 4 mm non-locking cortex screw.



**Fig 2** FIBULINK Implant components. The Fibula Tensioning Cap is provided in two lengths (standard: 10 mm; long: 15 mm). The Fibula Link has an outer diameter of 2.8 mm and is 10.7 mm long. The 4 mm long Suture Bridge consists of four strands of #1 Ultra High Molecular Weight Polyethylene. The 22 mm long Tibia Screw has a 4.0 mm cortical threadform at the proximal end, transitioning to a 4.0 mm cancellous threadform at the distal end.



**Fig 3** FIBULINK Syndesmosis Repair System components. The standard Fibula Tensioning Cap is preattached to the Tensioning Knob. The self-tapping Tibia Screw is preloaded to the Tibia Screwdriver. During drilling it is important that the larger diameter portion of the step-drill bit does not penetrate the tibial cortex.



**Fig 4** Clockwise or counterclockwise rotation of the Tensioning Knob will advance or reverse the Fibula Tensioning Cap, thereby adjusting the tension in the suture bridge in a two-way tension control to achieve the desired level of correction.

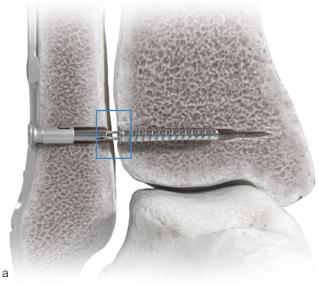
The FIBULINK fixation concept does not require medial soft-tissue disruption and helps improve procedural efficiency by delivering fixation through a single lateral incision. Since it does not rely on hardware placement on the medial tibia it eliminates medial side complications, such as damage to neurovascular structures and soft-tissue entrapment associated with suture button constructs. It also limits interference with the placement of additional hardware on the medial side (eg, medial malleolar screws), which might be required because of the injury (eg, high-energy injury).

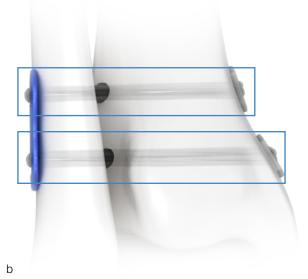
The short, high-strength suture bridge (Fig 5) enables physiological motion by spanning the distance between the medial side of the fibula and the lateral side of the tibia. Suture button constructs typically rely on long suture bridges between the lateral side of the fibula and the medial side of the tibia. The long suture distance can lead to suture toggling and tunnel widening compromising the fixation stability and changing the syndesmosis gap.

#### **Biomechanical testing**

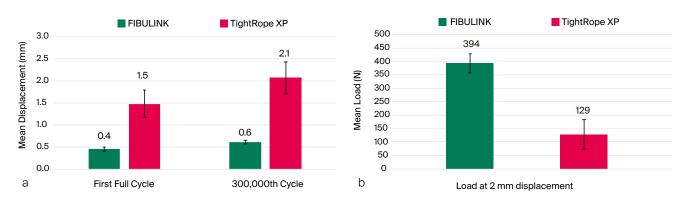
Bench testing was performed in a poor-quality bone model to compare the fixation strength provided by the FIBULINK<sup>™</sup> Syndesmosis Repair System and Arthrex Syndesmosis Tight-Rope<sup>®</sup> XP Implant System. Eight samples in each group were cyclically loaded in the direction of the fixation from 20 N to 113 N for 300,000 cycles. Displacements in load direction (elongation of the device) were recorded. After cyclic loading, a static load to failure test was executed. The load at 2 mm displacement was determined as measure for the fixation strength because the fibula displacement difference of 2 mm or more medial to lateral is pathological [17–21].

The FIBULINK Syndesmosis Repair System provided three times higher fixation strength (load at 2 mm displacement) than TightRope XP (Fig 6b). The elongation of the TightRope XP at 300,000 cycles was 3.5 times higher compared with the one of the FIBULINK Syndesmosis Repair System (Fig 6a).





- Fig 5a-b
- **a** Short, flexible suture bridge for physiological motion.
- **b** Long sutures of suture button constructs.



#### Fig 6a-b

- a Mean displacements (±1SD) at the first cycle and at 300,000 cycles for the FIBULINK Implant System and TightRope XP.
- **b** Mean loads at 2 mm displacement ( $\pm$  1 SD) for the FIBULINK Syndesmosis Repair System and TightRope XP.

#### Removal

There is a dedicated removal kit available for implant removal (Fig 7). Removal of the implant is completed by reversing the installation steps.



Fig 7 FIBULINK Removal Kit.

#### Indications

The FIBULINK Syndesmosis Repair System is currently only available in the US with the following indication statement:

The FIBULINK Syndesmosis Repair System is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated and as an adjunct to fixation systems involving plates, with fracture braces and casting. Specifically, the

FIBULINK Syndesmosis Repair System is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.

The plan is to introduce the FIBULINK Syndesmosis Repair System in Europe in the third guarter of 2022.

#### **Clinical case series**

In a case series of 14 patients (mean age: 48 years; age range: 26-77 years; eight men and six women) the FIBULINK Implant was used to treat nine supination external rotation; two pronation external rotation; one Maisonneuve; and two isolated syndesmotic injuries [1]. The mean AOFAS score at follow-up (average: 9.5 months) was 94. It varied slightly by type of injury, gender, and age (range: 87-100 years). Isolated syndesmosis and Maisonneuve injuries had the highest AOFAS scores. There were no instances of loss of reduction, hardware removal, repeat surgeries, wound issues, or other complications.

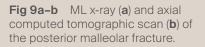
#### Clinical cases from Michael Swords (Michigan Orthopedic Center, Lansing, Mich, US)

#### Case 1

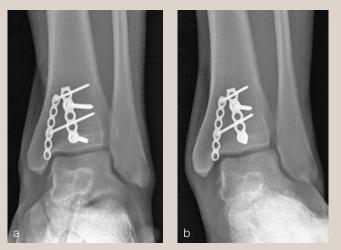
A 27-year-old man fell from a ladder sustaining a proximal fibula fracture (Fig 8) with a multipart posterior malleolar fracture (Fig 9).



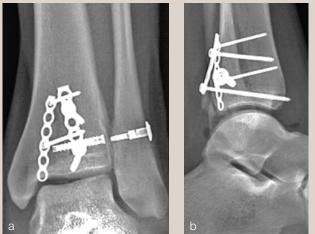
AP (a) and ML x-rays (b) of the proximal fibula fracture.



The patient was treated operatively with direct reduction and plate fixation of the posterior malleolar components. Intraoperative testing demonstrated continued syndesmotic instability requiring fixation (Fig 10). The syndesmosis was reduced in direct fashion and stabilized with a provisional K-wire and clamp before insertion of a FIBULINK Implant (Fig 11). The patient healed (Fig 12) and returned to preoperative function.



**Fig 10a-b** AP mortise views revealed continued syndesmotic instability after malleolar fracture fixation.



**Fig 11a-b** AP mortise view (**a**) and ML view (**b**) after syndesmotic fixation with the FIBULINK Implant System.

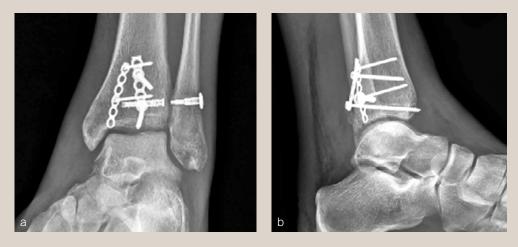


Fig 12a-b AP mortise x-ray (a) and ML x-ray (b) after healing.

#### Case 2

A 34-year-old woman was injured while riding a motor scooter sustaining an ankle fracture with associated syndesmotic injury (Fig 13a). The fibula was reduced anatomically and stabilized with a 1/3 tubular plate (Fig 13b). The unstable syndesmosis was reduced and provisionally stabilized with a K-wire and clamp (Fig 14) before FIBULINK Implant System implantation (Fig 15). The patient had an uneventful recovery (Fig 16).

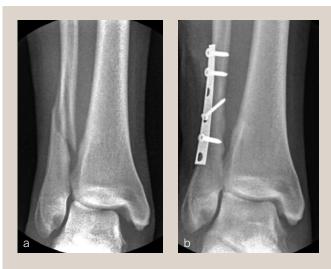


Fig 13a-b AP mortise views. The fibula fracture (a) was stabilized with a 1/3 tubular plate (b).

view (b) after FIBULINK Instrumentation.

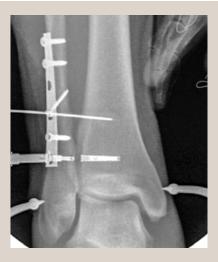


Fig 14 Intraoperative AP mortise view. Reduction of the syndesmosis with K-wire and clamp before FIBU-LINK Instrumentation.



Fig 16a-b AP mortise x-ray (a) and ML x-ray (b) after healing.

#### Key points of insertion

The 1.4 mm K-wire must be placed in appropriate position. Either in the center of the fibula and directed slightly anterior into the tibia, or–if used with a plate–through the center of the plate hole to allow free passage of the device.

The step-drill bit should be advanced with caution to avoid penetration into the tibia. The tibia screw must be inserted until just flush with the lateral cortex of the tibia. Internal and external oblique imaging with the C-arm may be necessary to confirm appropriate depth of insertion.

As with any new implant, there are clinical questions that require clarification: Is there any clinical indication for using two FIBULINK implants? If there is an indication, how will appropriate tightening be performed to achieve equal tensioning of the two devices? These questions will be addressed by the FAEG.

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# VA-LCP Distal Fibula Plates in titanium and associated anatomic tray for the Universal Small Fragment System

In 2013 the Variable Angle LCP Ankle Trauma 2.7/3.5 system was approved by the AO TC Trauma. So far, the plates of this low-profile plating system with variable angle locking screw technology have been available in stainless steel only. As part of a new line extension, the VA-LCP Lateral Distal Fibula Plate will also be available for surgeons in titanium after a sequential market introduction which started at the end of 2020 (Fig 1). The plate is provided in sterile and non-sterile packaging. It can be used in combination with the FIBULINK<sup>™</sup> Syndesmosis Repair System. Further information is provided on the design features of the lateral distal fibula plate in the article titled Variable Angle LCP Ankle Trauma 2.7/3.5 system.

In addition, a new anatomic tray is introduced for the Universal Small Fragment (USF) System, which can be stocked with stainless steel or titanium VA-LCP Lateral Distal Fibula Plates (Fig 2). The tray contains 4.0 mm cortex screws up to 80 mm in length as well as instruments for syndesmotic fixation. It can be used in combination with the original Universal Small Fragment Core Set or with a modified core set specifically designed to treat ankle fractures.

**Fig 1a-b** VA-LCP Lateral Distal Fibula Plate in titanium. Right plate version (a) and instrumented left plate version including FIBULINK<sup>™</sup> (b).



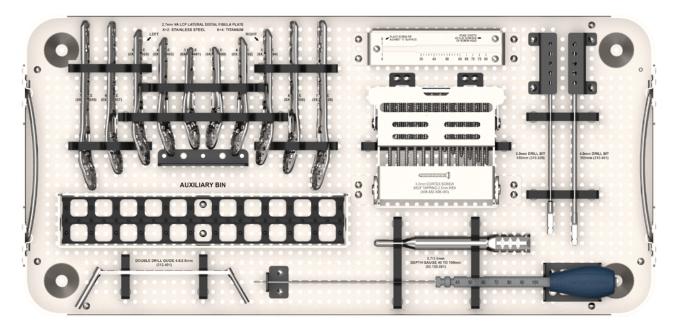


Fig 2 VA-LCP Lateral Distal Fibula Anatomic Tray for the Universal Small Fragment System.

# Variable Angle LCP<sup>®</sup> Periprosthetic Proximal Femur Plating System

#### **Clinical problem**

## Incidence of periprosthetic and peri-implant femoral fractures

Hip arthroplasty is a commonly performed procedure to treat various hip pathologies. Due to the general aging of the population and increased lifestyle demands, the number of people receiving hip replacements is expected to rise [1]. The demand for primary total hip arthroplasties (THAs) in the United States is estimated to grow by 174% from 2005 to 2030 [2]. Total hip revisions are projected to grow by 137% in this time span [2].

As the number of THAs increase, the number of periprosthetic femoral fractures (PFFs) that occur intraoperatively and postoperatively is also expected to rise. Although rare, PFF is a severe complication of THA. Following primary THA the 20-year probability of sustaining a postoperative PFF is reported to be 7.7% after placement of an uncemented stem and 2.1% after placement of a cemented stem [3]. The cumulative 20-year postoperative PFF risk increased to 11% [4] for revision THA. Most PFFs are caused by low-energy trauma events [5, 6]. A meta-analysis suggested that female gender, rheumatoid arthritis, and revision arthroplasty are major risk factors for the development of PFF after THA [7].

A non-prosthetic peri-implant fracture is a challenging clinical problem with a high rate of postoperative complications [8]. Chan et al [8] concluded that these fractures are distinct from periprosthetic fractures and should be understood as a separate entity. Ipsilateral refracture of the femur after intramedullary nail fixation is a sub-entity of femoral peri-implant fractures. A study [9] of 609 patients with pertrochanteric hip fracture treated with short and long intramedullary nails described an ipsilateral fracture rate between 1.6% at 1 year and 8.9% at 5 years. A retrospective study [10] noted 15 peri-implant fractures in a series of 705 proximal femoral nails inserted between 2006 and 2015 (fracture rate, 2.1%). If nail revision is not indicated and if the nail is short, fracture fixation could be achieved with a proximal femoral plate bridging the fracture. Such a plate will benefit from plate features, which facilitate plate anchorage around the nail.

# Fracture classification of periprosthetic femoral fractures

The Unified Classification System for Periprosthetic Fractures was introduced in 2013 [11]. It also classifies fractures about or in a bone with a non-arthroplasty implant. Since many publications on PFFs use the Vancouver classification [1] system we refer to it in this article. The Vancouver classification system is based on fracture location, the stability of the femoral component, and the quality of the bone stock. Type A fractures are confined to the greater  $(A_G)$  or lesser  $(A_I)$  trochanter. Type B fractures are diaphyseal, around the prosthesis or immediately distal to it, and are divided into three subtypes: B1, B2, and B3, characterized by a well-fixed stem, an unstable or loose stem with good quality of the surrounding bone stock, and an unstable or loose stem with inadequate surrounding bone stock, respectively [1]. Stoffel et al [12] presented an algorithmic approach to identifying loose stems around proximal femoral periprosthetic fractures, taking patient history, stem design, and plain x-rays into consideration. Type C fractures occur

below the tip of the prosthesis. Based on 1049 PFFs that were reported to the Swedish National Hip Arthroplasty between 1979 and 2000, Lindahl et al [13] found that more than 80% of the fractures were type B fractures (type A: 4%, type B1: 29%, type B2: 53%, type B3: 4%, and type C: 10%). Some studies [3, 4] report a higher percentage of type A fractures after primary and revision THA (Table 1).

Fracture type		A <sub>G</sub>	AL	<b>B1</b>	<b>B2</b>	<b>B</b> 3	C
Primary THA (n = 421)	n	135	11	61	103	39	72
	⁰⁄₀	32.1	2.6	14.5	24.5	9.2	17.1
Revision THA (n = 174)	n	49	5	53	24	19	24
	⁰⁄₀	28.1	2.9	30.5	13.8	10.9	13.8

**Table 1**Number and percentage of postoperative fracturesaccording to the Vancouver classification after primary andrevision THA [3, 4].

# Complications after surgical treatment of periprosthetic femoral fractures

Most PFFs are treated surgically including open reduction and internal fixation (ORIF), revision THA, and revision THA in combination with ORIF [12]. Most treatment protocols are based on the Vancouver classification. Type A fractures may be treated either conservatively or surgically, depending on the stability of the fracture [12]. In general, it is accepted that types B1 and C fractures should be treated with ORIF. Type B2 fractures typically require revision THA with a longer stem (and additional ORIF as needed). In selected cases with B2 fractures, internal fixation with plate, screws and cerclage can be a viable alternative option [14]. Revision THA with more complex reconstruction procedures are usually used for type B3 fractures. Since many PFFs require ORIF as part of their treatment there is a need for adequate implants including plates, screws, cerclage wires and cables. Their use is challenging because patients often have diminished bone quality and the physical presence of the THA, and possibly a cement mantle, obstruct adequate proximal fixation. High failure rates have been reported for plate fixation of PFFs (Table 2) [13]. Advances in plating techniques and technology have improved the outcomes of PFF treatment [15].

	Revision and ORIF n = 440	Plate fixation n = 256	Cerclage n = 41
Loosening	3.1%	14.4%	19.6%
Refracture	5.2%	6.6%	9.8%
Dislocation	4.3%	0.8%	9.8%
Nonunion	2.7%	5.8%	0%
Infection	1.6%	4.2%	0%
Miscellaneous	1.8%	1.9%	4.9%

**Table 2**Reason for failure in each treatment group bynumber and percentage [13].

Internal fixation is frequently achieved with locking plates, using minimally invasive surgery and indirect fracture reduction techniques leading to favorable results [15]. In a series of 60 consecutive type B1 and type C fractures treated with locked plating three fractures had to be reoperated due to failure of fixation (failure rate 5%) [16]. A retrospective review [17] of 14 patients (11 patients with revision arthroplasties) led to less favorable results. In nine fractures that were only treated with locked plating there were five failures because of plate breakage or plate pullout (failure rate, 56%) leading the authors to recommend the use of additional struts to treat these fractures. Another study [18] reported that in case of transverse type B1 fractures around the stem tip locked plating alone has a high failure rate, which emphasizes the importance of using additional fixation for the treatment of this fracture pattern. These studies imply that better implants are required for the treatment of PFFs.

There are concerns that stress risers at the end of a locking plate construct may lead to complications like refracture of the femur [19, 20]. A strategy to avoid potential complications is to protect the femur with femoral-spanning plates. Moloney et al [21] concluded that for treatment of type B1 fractures a plate fixation that spans the length of the femur to the level of the femoral condyles is associated with a decreased rate of nonunion and refracture compared with short plate fixation.

The rate and strength of healing is intimately linked to the integrity of surrounding soft tissues [22]. A loss of periosteal blood supply and soft-tissue stripping increase the risk of

nonunion, failure, and refracture [15]. The use of more streamlined implants may better preserve the periosteal blood supply and facilitate bone perfusion and biological response and may reduce the likelihood of implant removal due to irritation [23, 24].

### Approach to develop better treatment solutions

Realizing the deficiencies in the treatment of PFFs and peri-implant femoral fractures, the AO Technical Commission formed a dedicated Periprosthetic Fracture Task Force (PFTF) which was mandated to develop better osteosynthesis solutions for these challenging fractures in cooperation with DePuy Synthes (DPS). Medical members of the PFTF were Karl Stoffel (chair), Mark Lee, Christopher Finkemeier, Michael Blauth, Steve Velkes, George Haidukewych, Cory Collinge, Frank Liporace, and Bruce Ziran (Fig 1).

The PFTF identified following main requirements for the development of a state-of-the-art proximal femoral plating system (focusing on types A and B fractures):

- Modular implant configuration to address a wide variety of PFFs.
- Implant system with many fixation options to achieve high osteosynthesis stability in poor bone quality.
- Implant design to facilitate fracture fixation in presence of THAs and other intramedullary implants (eg, short proximal nails).
- Soft-tissue friendly solution that minimizes damage to the blood supply.
- Implant that allows to span and protect the whole femur.



Fig1 Medical members of the PFTF with the DPS development team at the first meeting in West Chester, Penn, USA, 2014.

The medical members of the Lower Extremity Expert Group (Christoph Sommer, Rodrigo Pesantez, and Cong-Feng Luo) accompanied the development to refine the implant design. Various Anatomy Labs were performed to optimize the surgical technique (Fig 2).

In addition to a proximal plating system, the PFTF and the Intramedullary Nailing Expert Group developed a new retrograde femoral nail with an innovative locking attachment plate (RFN-Advanced Retrograde Femoral Nailing System) for native and periprosthetic distal femoral fractures associated with total knee arthroplasties which was launched in 2020.

### Solutions

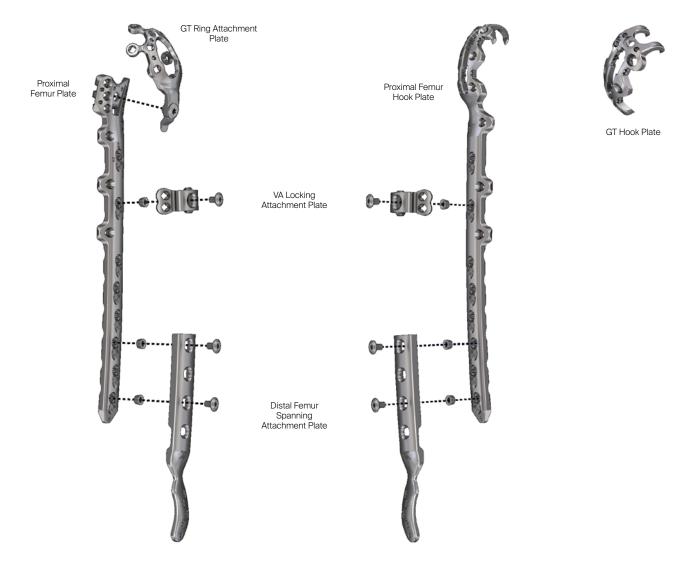
The 3.5/4.5 Variable Angle LCP® Periprosthetic Proximal Femur Plating System addresses the identified clinical needs by providing two main proximal plate options and three additional attachment plates with dedicated plate features (Fig 3 and



**Fig 2** Medical members of the PFTF during Anatomy Lab activities (from left to right: George Haidukewych, Mark Lee, and Karl Stoffel).



**Fig 3** The 3.5/4.5 Variable Angle LCP® Periprosthetic Proximal Femur Plating System is offered in stainless steel. The plate configuration shown: Proximal Femur Plate with GT Ring Attachment Plate, VA Locking Attachment Plate, and Distal Femur Spanning Attachment Plate. Fig 4). The anatomically shaped plate variations and compact plate connections were designed to minimize soft-tissue irritations. The modular aspect of this system allows the surgeon to connect the available devices in various configurations, thereby focusing on the variety of fracture type and promoting fixation of the fracture according to the surgeon's preference (Fig 4). All plates are equipped with Variable Angle (VA) Locking Screw holes, allowing angulation possibilities of up to 15° in each direction around the central axis of the plate hole to bypass intramedullary implants.



**Fig 4** The Proximal Femur Plate and the Proximal Femur Hook Plate are the two main plates. The Greater Trochanter (GT) Ring Attachment Plate, VA Locking Attachment Plate and Distal Femur Spanning Attachment Plate can be assembled to the two main plates with threaded inserts and upper screws. A dedicated Greater Trochanter (GT) Hook Plate without plate shaft is available as standalone device for fixation of simple type  $A_{\rm g}$  fractures as well as greater trochanter osteotomies. (At the time of publication of this magazine [November 2021] the GT Hook Plate, GT Ring Attachment Plate and the Distal Femur Spanning Attachment Plate were not available outside the United States.)

### **Plate features**

3.5/4.5 VA-LCP PPFx Proximal Femur Plates (VA-PFP) The VA-PFP (Fig 5 and Fig 6) has an anatomically shaped plate head and shaft. It includes 3.5 VA locking holes in the plate head and proximal plate shaft to provide fixation points around an intramedullary implant. There are 4.5 VA-LCP combi-holes in the plate shaft accepting 4.5 mm cortex screws, 5.0 mm VA Locking Screws and monocortical 5.0 mm VA PPFx Locking Screws. The plate was specifically designed to address type B or combined types  $A_{\rm g}$  and B fractures.

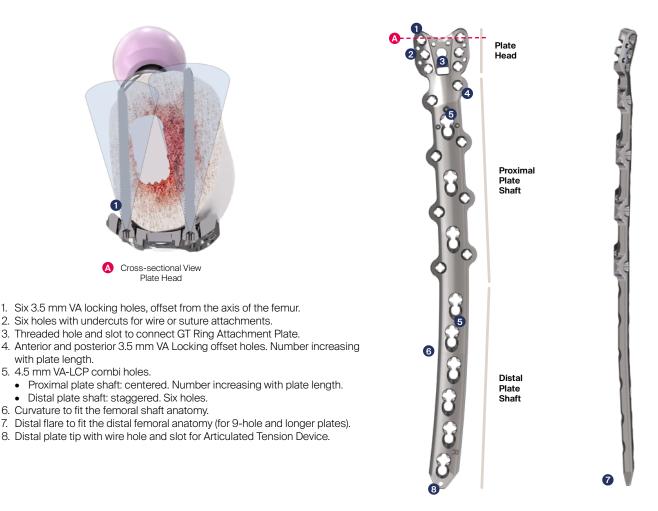


Fig 5 Plate features of the VA-PFP. The plate head and proximal plate shaft must not be bent.

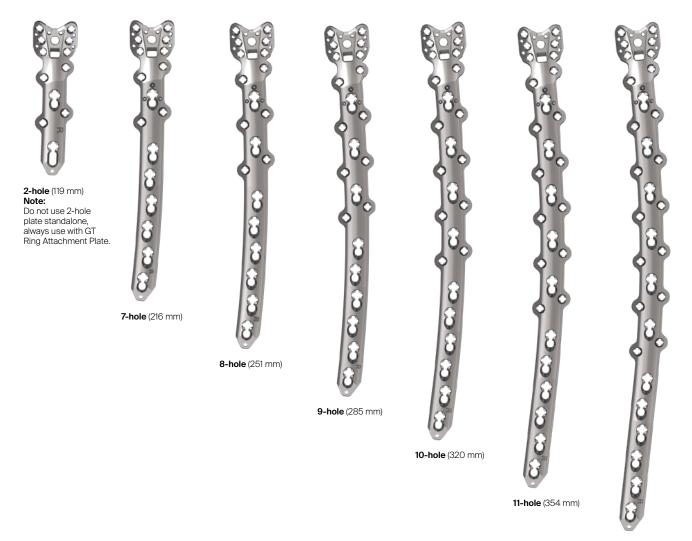


Fig 6 Plate portfolio of the VA-PFP. The plates are side specific (left and right versions).

12-hole (388 mm)

# 3.5/4.5 VA-LCP PPFx Proximal Femur Hook Plates (VA-PFHP)

The VA-PFHP (Fig 7 and Fig 8) has an anatomically shaped plate head and shaft. It has two proximal hooks as well as cable slots to reduce the greater trochanter. There are 3.5 VA locking holes in the plate head and proximal plate shaft to provide fixation points around an intramedullary implant. The VA-PFHP contains 4.5 VA-LCP combi holes in the plate shaft accepting 4.5 mm Cortex Screws, 5.0 mm VA Locking Screws and monocortical 5.0 mm VA PPFx Locking Screws. The plate was specifically designed to treat types  $\rm A_{g}$  and B fractures.

# 3.5 VA Locking PPFx Greater Trochanter Hook Plates (VA-GTHP)

The VA-GTHP (Fig 9 and Fig 10) is a short implant without plate shaft. It is indicated for fixation or re-attachment of the greater trochanter following fracture or osteotomy.

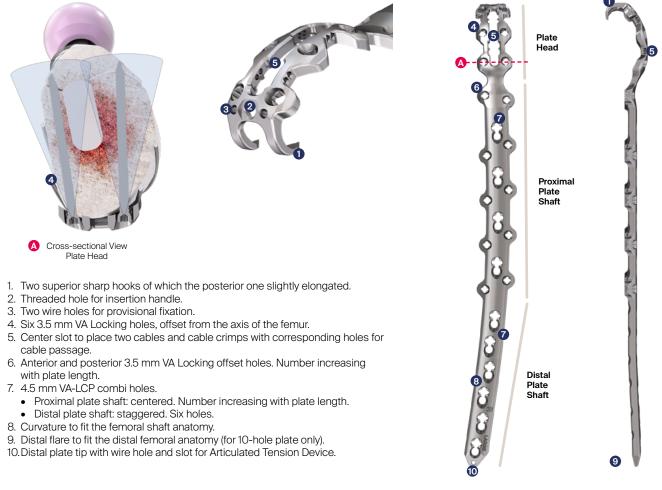


Fig 7 Plate features of the VA-PFHP. The plate head and proximal plate shaft must not be bent.

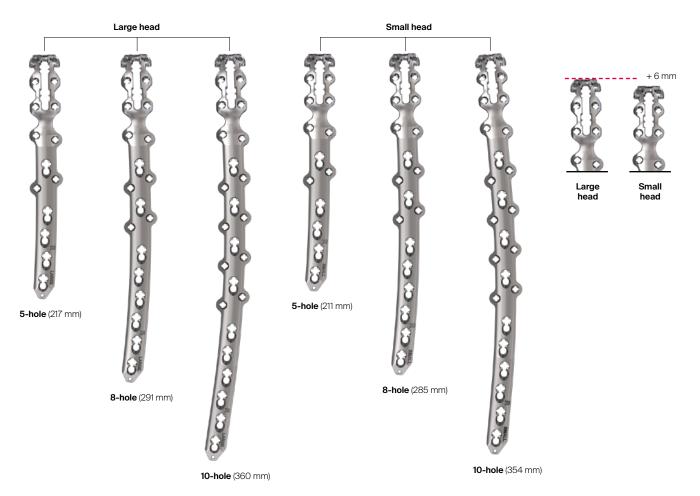


Fig 8 Plate portfolio of the VA-PFHP with large and small plate head. The plates are side specific (left and right versions).

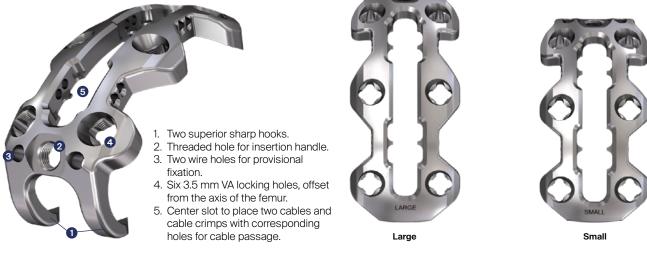


Fig 9 Plate features of the VA-GTHP.

**Fig 10** The VA-GTHP is available in two sizes (large and small). The plate profile is universal for left and right application.

+ 6 mm

\_ \_ \_ \_ \_ \_ \_ \_ \_ \_

# 3.5 VA Locking PPFx Greater Trochanter Ring Attachment Plates (VA-GTRAP)

The VA-GTRAP (Fig 11 and Fig 12) must be used with the VA-PFP and not as a standalone device. The assembly is shown in Fig 13. In combination with the VA-PFP the plate is indicated for fixation or re-attachment of the greater trochanter following a fracture or osteotomy.

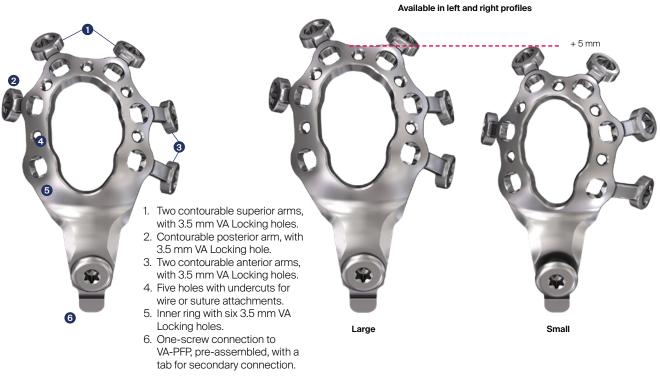
### 3.5 VA Locking Attachment Plate (VA-LAP)

The VA-LAP (Fig 14) attaches to both main plates (VA-PFP and VA-PFHP) and serves as an alternative to cables for added

fixation around intramedullary implants. The VA-LAP is indicated to augment the stabilization of fractures, including type B fractures when used with either the VA-PFP or the VA-PFHP, types B and C fractures when used with other LCP plates and VA-LCP plates and fractures in the presence of intramedullary implants in the femur, tibia, and humerus.

### 3.5 VA Locking PPFx Distal Femur Spanning Attachment Plate (VA-DSAP)

The VA-DSAP (Fig 15 and Fig 16) attaches to both main plates (VA-PFP and VA-PFHP) to extend the fixation construct over the



**Fig 11** Plate features of the VA-GTRAP. The inner ring must not be bent.

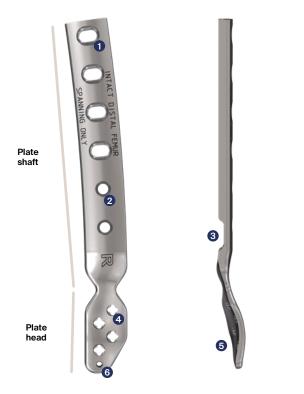
**Fig 12** The VA-GTRAP is available in two sizes (large and small). The plates are side specific (left and right versions).

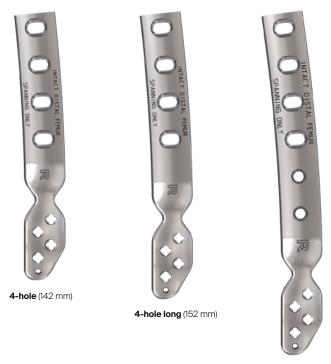


**Fig 13** The VA-GTRAP must be attached before the VA-PFP is in situ. The assembly is performed by inserting the tab of the VA-GTRAP in the slot of the VA-PFP and by tightening the connecting screw with the 6 Nm torque limiting handle.









6-hole (182 mm)

- 1. Four slots in the plate shaft for two-point connection with the main plate.
- 2. The 6-hole plate version includes two 4.5 mm cortex screw holes.
- 3. Bending Iron slot.
- 4. Four 3.5 mm VA locking holes in the plate head.
- 5. Pre-shaped plate head to fit the intact distal femur and lateral femoral condyle.
- 6. Wire hole for provisional fixation.

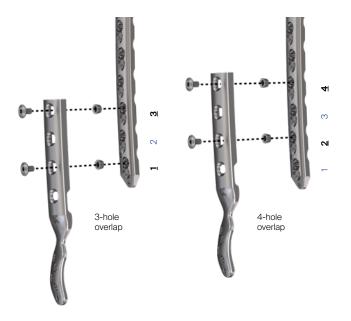
**Fig 15** Plate features of the VA-DSAP. The VA-DSAP must not be used as a standalone device and not in combination with the 2-hole VA-PFP or the 5-hole VA-PFHP.

**Fig 16** Plate portfolio of the VA-DSAP. The plates are side specific (left and right versions).

intact distal femur to the lateral femoral condyle. The plate overlap for the assembly must be either three or four holes (Fig 17). Two connecting screws are required to attach the VA-DSAP to two non-adjacent holes of the main plate. The VA-DSAP must not be used to span a fracture as this could lead to implant failure. The plate distributes stress among multiple points of fixation and is designed to avoid abrupt stiffness changes, thereby supporting the distal bone to protect it from further fractures.

There are sizing templates available for all plates which help to select the proper plate(s) for the best plating combination and assembly.

The surgical technique guide provides guidance on implant selection depending on fracture pattern and fixation recommendations (minimum number of screws and cortices).



**Fig 17** Assembly of the VA-DSAP to the main plate using a 3-hole and 4-hole overlap with two connecting screws (threaded inserts and upper screws) in non-adjacent holes of the main plate.

### **Availability**

The 3.5 mm/4.5 mm Variable Angle LCP<sup>®</sup> Periprosthetic Proximal Femur Plating System with all implants and instruments is available in the US since September 2021.

In Europe, the Proximal Femoral Plate, the Proximal Femoral Hook Plate and the VA Locking Attachment Plate are available since November 2021. Due to the new Medical Device Regulations in Europe, the GT Ring Attachment Plate, the GT Hook Plate, and the Distal Spanning Attachment Plate will be launched after CE mark based on post-market clinical data from the US release has been obtained.

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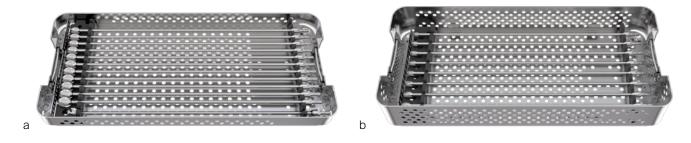
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### **Flexible Monobloc Reamers**

During the design of Gerhard Küntscher's cloverleaf nail intended for the intramedullary internal fixation of femoral shaft fractures in the late 1930s, it became apparent that a device that is too large for the isthmus impeded insertion and resulted in jamming or iatrogenic fracture. To avoid such problems, Küntscher proposed reaming of the medullary cavity before nail insertion. He also suggested that this will enable use of a larger diameter implant, thereby providing better stability and a reduced risk of postoperative implant breakage.

Since the introduction of reaming, instruments used for the adoption of this pre-nailing procedure have evolved significantly. In response to various clinical demands specific to intramedullary reaming (cutting performance, usability), the Intramedullary Nailing Expert Group (INEG) is honored to announce the approval and subsequent launch of the new Flexible Monobloc Reamers that are intended to ream an intramedullary bone canal (femur/tibia) in preparation for the insertion of implants.

The new monobloc reamers are provided in reamer diameters from 8 mm to 18 mm in 0.5 mm increments and in reamer lengths of 480 and 620 mm (Fig 1). Each reamer has a onepiece design with a flexible shaft manufactured from laser-cut stainless steel (Fig 2). Compared with modular reamers there is no need for intraoperative reamer head exchange, which improves usability and streamlines the workflow with the potential to reduce surgery time. All reamers have a hybrid reamer head design that incorporates both front- and side-cutting features (Fig 3). Consequently, surgeons can reduce the rate of reamer passes per procedure through having the freedom to initiate reaming with a larger reamer diameter compared with the SynReam system which contains only one diameter of reamer head (8.5 mm) with a front-cutting design.



**Fig 1a-b** The flexible monobloc reamers are provided in an efficiency set (**a**) for the reamer diameters 8 to 14 mm (which can support about 90% of the clinical cases) and in an outlier set (**b**) for the reamer diameters 14.5 mm to 18 mm for the reamer. Both sets are available for the 480 and 620 mm reamer lengths. The outlier trays have an instrument tray above them, which can store a Reaming Rod Pusher and a Universal Chuck. It also has bracketing for 6 mm and 7 mm hand reamers, and a spare space for one reamer, as needed. The instrument tray is useful if only an outlier tray is being taken into the operating room for a particular case.





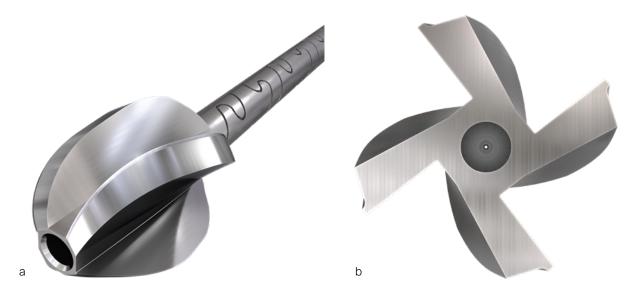


Fig 3a-b Acorn shape reamer head with deep flutes.

The flexible shafts and deeply fluted reamer heads (Fig 3) function to reduce intramedullary pressure and increase the flow of bone chips and marrow during reaming, which is important to reduce the risk of intravasation of bone marrow or fat into the vascular system potentially leading to pulmonary dysfunction.

The smooth reamer head to shaft transition (Fig 2) eradicates the potential for interference with the distal end of the soft-tissue protection sleeve during reamer retraction that was sometimes reported as an issue when using the SynReam reamers. The new reamers are supposed to be used with the new Ø 3 mm Advanced Nailing System reaming rod with Ø 3.8 mm ball tip (available in 950 and 1150 mm lengths), which is beneficial for reducing fractures and controlled reaming. The modified-trinkle (Hudson) connection of the new reamers eases the assembly to the power tool and thereby improves the overall usability (Fig 4).



**Fig 4** Modified-trinkle connection to facilitate assembly to the power tool.

A wear indicator in the Graphic Case allows surgeons to understand the extent of reamer wear (Fig 5). This feature will indicate if the reamer is worn more or less than  $\emptyset$  0.25 mm.

With the new Flexible Monobloc Reamers, surgeons can choose simplicity and enhanced usability for the reaming procedure that has the potential to be challenging and time consuming when using a modular reamer system.

In addition to the new reamers, the following DePuy Synthes reaming systems continue to be available:

### Monobloc Flexible Reamers-small:

- From sizes Ø 6 mm to 10.5 in 0.5 mm increments
- Flexible shaft of 385 mm
- Front-cutting
- Ø 2.5 mm reaming rod

Hand Reamers:

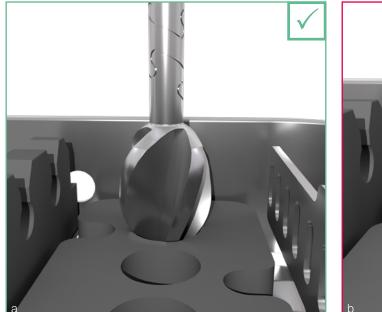
- Ø 6.0 mm, Ø 7.0 mm, Ø 8.0 mm
- 450 mm long

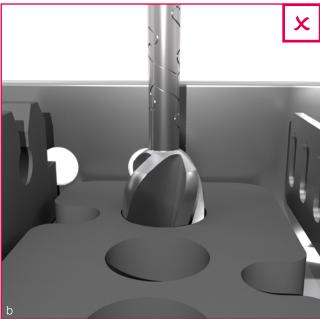
### SynReam System:

- From sizes Ø 8.5 to 19 mm in 0.5 mm increments
- Flexible shaft of 470 mm (in the US system a 620 mm shaft is also available)
- Side-cutting, Ø 8.5 mm: front-cutting
- Ø 2.5 mm reaming rod

#### RIA 2 System:

- Reamer heads from Ø 10 to 18 in 0.5 mm increments
- Drive shaft length: 520 mm
- Ø 2.5 mm reaming rod
- Front-cutting





- Fig 5a-b A wear indicator is incorporated into the trays to help identify worn reamers.
- $\mathbf{a}$  Reamer interfering with the hole means that it has worn less than Ø 0.25 mm of the initial diameter.
- ${\bf b}$  Reamer passing through the hole means that it has worn at least Ø 0.25 mm of the initial diameter.

# UNIUM<sup>™</sup> Small Bone and Trauma Power Tool

### **Clinical problem**

The use of power tools is closely associated with modern orthopedic surgery. These tools have advanced surgery by allowing surgeons to work efficiently and accurately. Pneumatic and electric power tools which require cords have been largely replaced by battery-operated devices because of their unconstrained and more comfortable use.

The battery-driven power tool Colibri II/Small Battery Drive II manufactured by DePuy Synthes has been available since 2012. Surgeons have long appreciated its ergonomic design, ease of use, and the high capacity delivered by the 14.4V Lithium-Ion battery pack. (The power tool is sold under the brand name Colibri II in Europe, Middle East, Africa, Asia Pacific, and Latin America. In the US and Canada, it is sold under the brand name Small Battery Drive II).

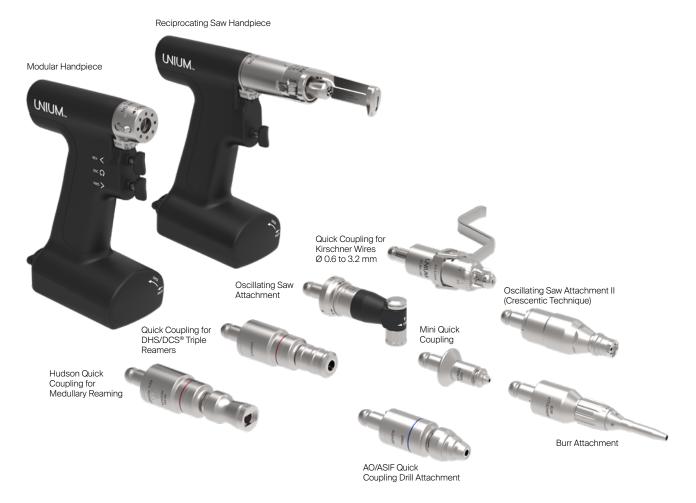
Since the initial launch of the Colibri II/Small Battery Drive II, the small bone surgery requirements have been evolving and increasing in complexity. In response, there is a need for improved devices which address the following essential demands:

- Lightweight and compact design for precise handling and low hand fatigue.
- Power, torque, and speed to match the broad range of applications in the small bone segment as well as heavy duty surgery.
- The battery capacity should be sufficient to cover the whole surgery to avoid intraoperative battery change. The battery must deliver consistent performance.
- Long lifetime and reliability of the system.

The Foot and Ankle Expert Group together with DePuy Synthes have developed an innovative power tool system that takes advantage of the latest technologies to fulfill these demands.

### Solution

The UNIUM<sup>™</sup> Power Tool was designed for increased reliability, efficiency, and comfort of use for an enhanced surgical experience and improved outcomes (Fig 1). It is intended for use in traumatology and orthopedic surgery that may include drilling, reaming, burring, screwing, tapping, sawing, and setting pins and wires. The UNIUM Power Tool replaces the Colibri II/Small Battery Drive II.



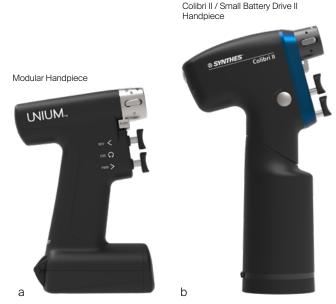
**Fig 1** The UNIUM Small Bone Power Tool consists of a modular handpiece for general use and a standalone reciprocating saw handpiece for cardiothoracic surgery (specifically for sternotomies). The system covers the following surgical areas: lower extremities (including intramedullary reaming but excluding acetabular reaming), pelvic, upper extremities, spine, sports medicine, and cardiothoracic.

The UNIUM Handpiece is more powerful (100 W) than the Colibri II/Small Battery Drive II (85 W), although it weighs 175 g/0.39 lbs less (Fig 2). The increased power is expected to be beneficial for the performance in dense bone conditions (eg, in hindfoot arthritic bone and dense subtalar bone) and for reaming of long bones.

The trigger mechanism of the modular handpiece is different to that of the Colibri II/Small Battery Drive II and is in line with current industry standards. The lower trigger is for forward operation and the upper trigger for reverse operation. The oscillation mode is activated by pressing both triggers simultaneously. Additionally, the handpiece can be put in "forward only mode."

The strength and durability of both UNIUM Handpieces is enhanced by a high-quality PEEK housing and a stainless-steel coupling. It is powered by an innovative Power Unit technology that incorporates the Electronic Control Unit and Li-Ion battery. These temperature sensitive parts are not exposed to steam sterilization, which extends the lifetime, reliability, and sustainability of the platform. **Figure 3** describes the benefits and features of the UNIUM Modular Handpiece.

The UNIUM Modular Handpiece is compatible with all existing Colibri II/Small Battery Drive II attachments (except for the K-wire attachment which has been updated as noted below), UBC II charger, and cutting tools for versatile use. UNIUM has a K-wire attachment with a range of  $\emptyset$  0.6–3.2 mm. There is an increased output speed of up to a maximum of 1700 rpm.



**Fig 2a-b** Although the UNIUM Modular Handpiece (**a**) is considerably smaller and 19% lighter, leading to improved handling, it provides 18% more bone penetrating power than the Colibri II/Small Battery Drive II (**b**).

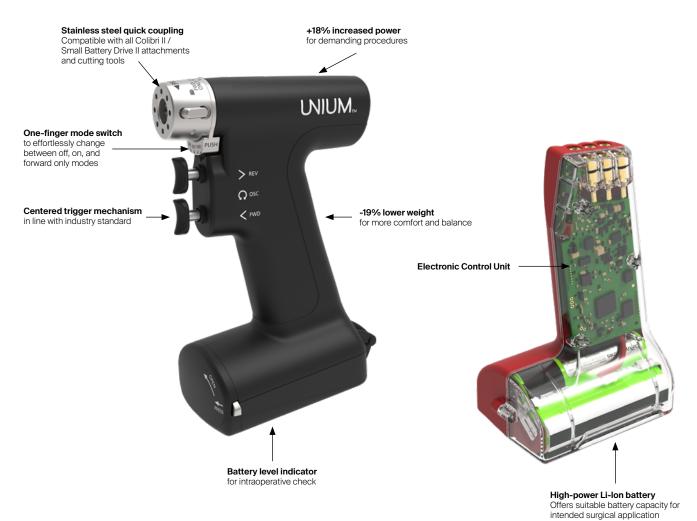


Fig 3 Benefits and features of the UNIUM Modular Handpiece and UNIUM Power Unit.

The standalone UNIUM Reciprocating Saw Handpiece was developed as a power tool for cardiothoracic applications (Fig 4). It was thoroughly tested and approved by the Thoracic Expert Group.

In conclusion, UNIUM is a next generation small bone power tool that is approved by the AO Technical Commission and complies with the required standards for operating room use and addresses the needs of today's healthcare professionals.



**Fig 4** While the standalone reciprocating saw handpiece is beneficial for primary sternum opening, the modular handpiece with the saw attachment and oscillating saw blades can be used for sternum re-openings.

# **MAXFRAME Update**

The MAXFRAME™ Multi-Axial Correction System is a computer-assisted circular ring fixation system based on two rings connected with six adjustable struts configured as a hexapod. The modular nature of MAXFRAME System enables surgeons to customize each frame to meet individual patient needs. The MAXFRAME System is designed to reduce procedure complexity by streamlining the surgical and software workflows. A simplified surgical workflow and streamlined set configuration can optimize time in the operating room.

The MAXFRAME System has now been updated with a new Software release and additional Hardware. The MAXFRAME 3D Software 2.0 assists with the creation of treatment planning when applying the MAXFRAME System.

New Hardware has been added to the MAXFRAME System to enhance versatility specifically in relation to the linear struts. Surgeons can transition from a moving to a stable frame without changing the components used for mounting the rings to bone.

### What is new in MAXFRAME 3D Software 2.0?

A more efficient logic makes data management easier with the new MAXFRAME 3D Software 2.0. Surgeons can view patient case information directly in the overview without the need to search and navigate through stored data.

Entering patient- and case-related data into MAXFRAME 3D Software 2.0 provides surgeons with a more logical workflow. The planning process is intuitive and unlike the previous system (Fig 1), all data entries are saved and remain in the dataset if they are not affected by a change of predefining data in the workflow. It is easy to revise plans and make changes based on clinical decisions. The stored data is easy to retrieve, and the display of information is clear. The data for each component in the frame's configuration is structured in a table format allowing a clear overview of all parameters.

The improvements in the visualization of the frame allow the user to see all parts as they appear in real life (Fig 2). Struts can be viewed from all angles so the entire construct can be fully appreciated.

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Fig 1 Case data overview.

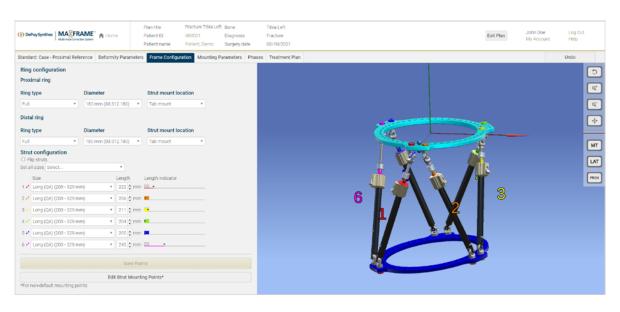


Fig 2 Frame configuration and simulation of the frame in 3D visualization.

The possibility to define up to five phases during the preoperative planning process is a useful new feature of the MAX-FRAME 3D Software 2.0. Surgeons can define phases according to specific procedural steps and ensure safety throughout. Phases allow for a clear overview of the procedure and assist with the avoidance of interference of bone segments and/or frame components (Fig 3).

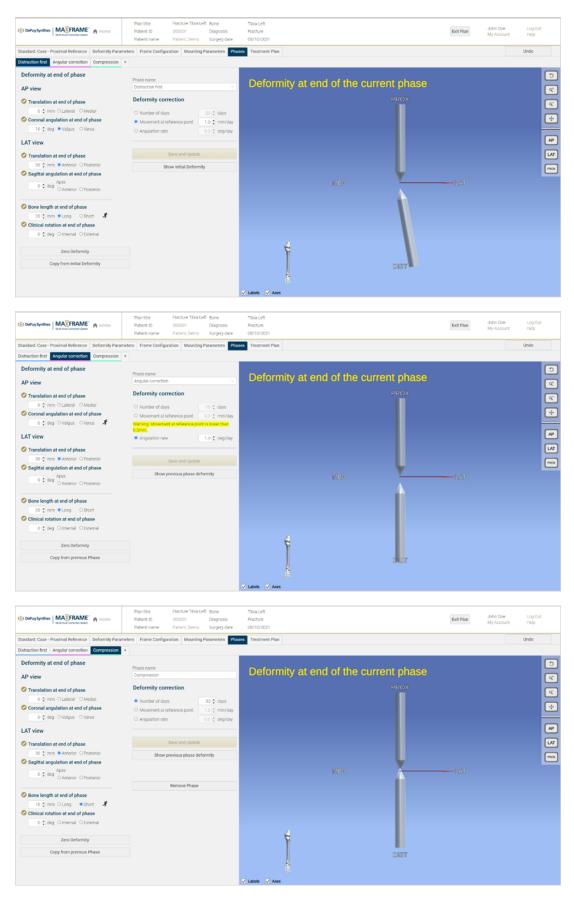


Fig 3 Planning of phases by defining the end status for the phase.

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The treatment plan has been adapted to display each phase in a different color making the new MAXFRAME 3D Software 2.0 extremely user friendly. If the entered data may be incorrect, the system now alerts users to check the data and adapt their planning if necessary (Fig 4). This is a significant update from the first release.



Fig 4 Simulation of the movements during the planned phases.

### New MAXFRAME Hardware The new Linear Struts

The original MAXFRAME Hardware is a hexapod consisting of two rings and six struts. New linear versions of the latter with variable joints enable intraoperative alterations to the frame configuration without risking construct instability (Fig 5). Before the new linear struts, hardware from the Distraction Osteogenesis (DO) Ring System was required to enable strut exchange.

There are several options for adjusting the length of the linear struts depending on surgeon preference.

At the end of a patient's deformity correction with the MAX-FRAME, it is possible to opt for definitive treatment using the MAXFRAME rather than potentially resorting to open reduction and internal fixation. Traditional MAXFRAME struts can be exchanged for a lesser number of linear struts and provide a stable construct for final healing.

In some scenarios, linear struts can also replace threaded rods in a normal ring fixator construct. This may be a preference for surgeons who prefer the ease of use presented by the linear struts compared with threaded rods. Linear struts also provide superior stability and enhanced versatility of the ring frame construct.



Fig 5 MAXFRAME rings stably connected with three variable angle linear struts.

### The new connecting elements

The improved connecting elements provide new Schanz Screw Connectors with fixed angles for positioning of the Schanz screws. When using slotted posts, stability is dependent on friction (Fig 6). The new Schanz Screw Connectors offer only one angle of connection, thereby providing increased stability in the frame construct.

The new third and half rings in the system provide versatility in the type of frame selected and strengthen the construction of the bone segments.

### The new Schanz screws with blunt tip

Looking forward, only two versions of Schanz screw will be

available: a Seldrill (self-drilling, self-tapping) Schanz screw and a blunt-tipped Schanz screw (Fig 7).

Seldrill Schanz screws will largely remain the same but with alterations to the available range of thread lengths.

Schanz screws with blunt tip will be offered in the same range as their Seldrill counterparts but will also possess a blunt tip allowing better purchase in the far cortex and a subsequent decreased risk of soft-tissue irritation. The blunt-tipped Schanz screws also react differently when exposed to the magnetic field of a magnetic resonance imaging, becoming less affected by the heat, and thereby acting to further protect the surrounding soft tissue.

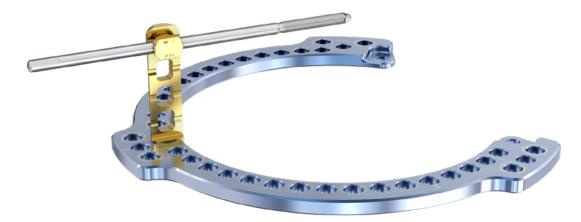


Fig 6 New connection element for the angle stable fixation of a Schanz screw in a MAXFRAME ring.

Fig 7 New Schanz screw with blunt tip and new Seldrill Schanz screw.

# VA-LCP<sup>®</sup> Clavicle Plate 2.7 System

The Variable Angle (VA) LCP Clavicle Plate 2.7 System is the next generation of internal fixation for the clavicle designed to treat medial, lateral, and shaft fractures (Fig 1). The system was created in response to clinical challenges in the current treatment of fractures of the clavicle and is available in both stainless steel and titanium alloy.

One of the most common complications when treating clavicular fractures operatively is the need for hardware removal due to irritation caused by prominent plates. The VA-LCP Clavicle Plate 2.7 System was subsequently designed to treat lateral, shaft, and medial fractures in different size clavicles for patients of small, medium, and large stature. Based on extensive analysis of 15 anatomical parameters on more than 600 clavicle CT scans, the shapes of the VA-LCP Clavicle Plate 2.7 are designed to match the bow and contour of the clavicle for low construct prominence and enhanced plate-to-bone fit compared with other systems (Stryker VariAx 2 and Acumed Clavicle Systems).

The clinical challenges of clavicular fracture fixation are noted in the year 2020 Innovations magazine (Simplicity derived from Complexity) and several key reasons for initiating changes to the already existing internal fixation system for clavicular fractures were cited. The reasons were poor plate fit, mainly due to the incompatibility between implant design and anatomical variability in the clavicle, hardware prominence, and reoperation rates. It is important to concede that the new VA-LCP Clavicle Plate 2.7 System was developed following extensive investigation of the implant-preferred pathway on the clavicle. A research project on the implant-preferred pathway by the AO Research Institute Davos (ARI) initiated a morphology study of the clavicle [1]. This study [1] conducted by DePuy Synthes in collaboration with the medical members of the UEEG proved a strong correlation between a patient's height and clavicle length as well as clavicle length and specific shape parameters, such as curvature radii.

The VA-LCP Clavicle Plate 2.7 System comprises a selection of plates to address fractures in specific segmental regions

of the clavicle (Fig 2). Lateral and shaft plates are available in three sizes corresponding to a patient's height and clavicle length.

Additional plate options are also offered to address alternative clinical settings. The VA-LCP Clavicle Plate 2.7 System is the first system to include a dedicated medial plate designed to treat medial clavicular fractures (Fig 3). The XL shaft plate is designed for extended shaft fractures in larger patients' anatomies (Fig 4).

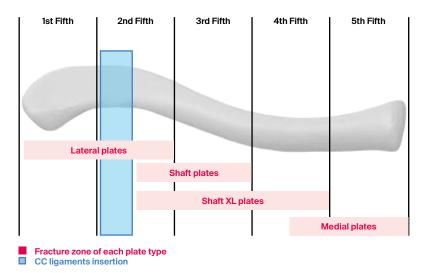
Each plate in the system is designed to reduce procedural complexity. The plate shapes match the bow and contour of the clavicle for low prominence and enhanced plate-to-bone fit. By improving overall plate fit, intraoperative plate placement is less challenging and the need for hardware removal due to irritation caused by prominent plates is reduced.

All screw holes in the VA-LCP Clavicle Plates accept 2.7 mm screws which presents an important adaptation to the previous LCP 2.7/3.5 mm Clavicle Systems. The decision to utilize only one screw size enhances usability through use of a single drill diameter for all screws. Metaphyseal screws with a low-profile head have also been included in the system to provide compression when needed. Staggered screw hole positioning with pre-defined hole angulation increases screw density (compared with a plate of the same length with in-line screw holes) and is designed to achieve the required construct stability (see white paper on the Mechanical Performance of the DePuy Synthes 2.7 mm VA-LCP Clavicle Plate System).

The VA Combi holes combine a dynamic compression unit with a VA locking hole. The VA Combi hole allows fixation with VA locking screws in the threaded section for angular stability and cortex screws in the non-threaded section for compression. The thread profile of the VA locking hole also allows for the angulation of the VA locking screw when needed by specific fracture patterns for fragment capture (Fig 5).



**Fig 1** The VA-LCP<sup>®</sup> Clavicle Plate 2.7 System comprises three dedicated plate shapes for the treatment of lateral, shaft, and medial clavicular fractures.



**Fig 2** The clavicle divided into fifths. The VA-LCP® Clavicle Plate 2.7 System provides fracture zone specific fixation.



**Fig 3** VA-LCP<sup>®</sup> Clavicle Medial Plate 2.7 designed for fractures located at the medial end of the clavicle.



**Fig 4** Image shows VA-LCP<sup>®</sup> Clavicle XL Shaft Plate 2.7 designed for the treatment of shaft fractures in larger patients' anatomies.



**Fig 5** All potential insertion angulations for the VA screw in the VA-LCP<sup>®</sup> Clavicle Plate 2.7 System.

Smooth plate surface, tapered edges, and low-profile design with reduced thickness (compared with other clavicle systems) serve to further enhance the intraoperative experience and are features of the DePuy Synthes plate systems that are valued by surgeons during plate insertion.

The VA-LCP Clavicle Plate 2.7 System has undergone various mechanical tests throughout its development to assess plate construct and the performance of isolated design features, such as bending notch and suture holes. In the final validation of the system, surgeons provided their ratings based on key procedural elements and high scores were awarded for plate fit and ease of plate adaptability during usability labs which occurred in the United States and Europe. Further to System

launch earlier this year, it is exciting to share some early reallife case reports with our readers.

### **Cases using VA-LCP Clavicle Plate 2.7 System** (by Martin Jaeger, Universitätsklinikum Freiburg, Germany)

#### **Case 1: lateral plate**

A 30-year-old man sustained a lateral fracture to his left clavicle following a fall from his bike (Fig 6). Intraoperative images indicate plate placement and screw insertion (Fig 7). Intraoperative image revealing usage of sutures through the plate for soft-tissue fixation (Fig 8). Image shows the fracture healing at 8 weeks' follow-up (Fig 9).





Fig 6 Injury x-rays.

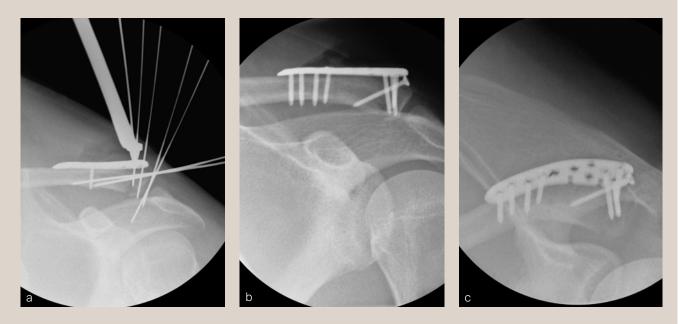


Fig 7a-c Intraoperative x-rays indicate plate placement and screw insertion.

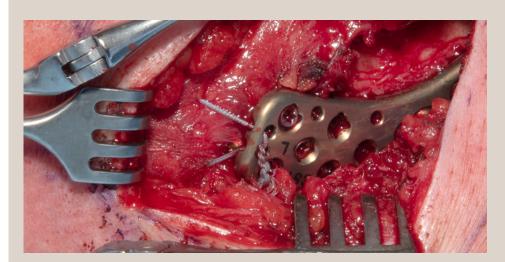
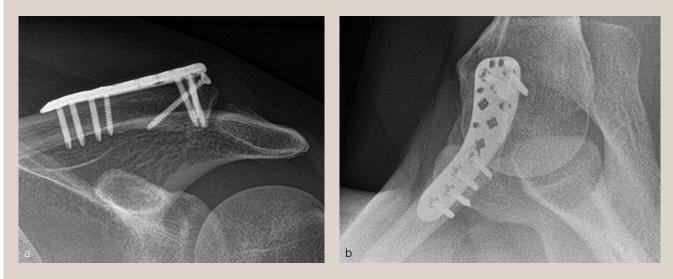


Fig 8 Sutures through the plate for soft-tissue fixation.



**Fig 9a-b** X-rays at 8 weeks' follow-up.

### Case 2: shaft plate

A 54-year-old man sustained a mid-shaft fracture to his right clavicle following a 2 m fall from a ladder (Fig 10). Intraoperative images show plate placement and screw insertion (Fig 11).

Postoperative image depicting minimal incision size for plate insertion before wound closure (Fig 12). Image shows the fracture healing at 6 weeks' follow-up (Fig 13).

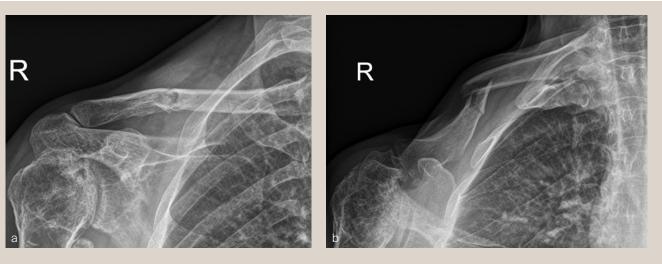


Fig 10a-b Injury x-rays.

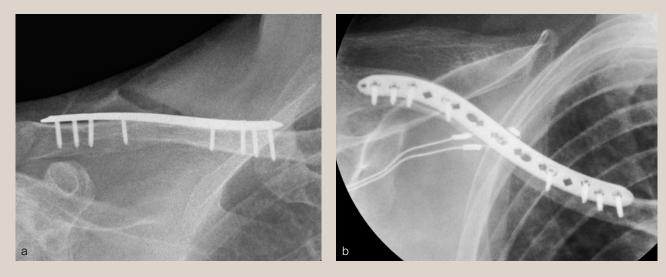


Fig 11a-b Intraoperative x-rays of plate application.



Fig 12 Minimal incision size for plate insertion before wound closure.

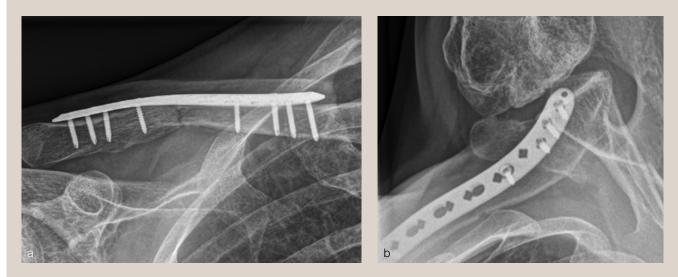


Fig 13a-b X-rays at 6 weeks' follow-up.

### Case 3: medial plate

A 60-year-old woman sustained a medial fracture to the left clavicle following a car crash. A computed tomographic (CT) scan was performed 8 weeks after the incident (Fig 14). Intraoperative images reveal plate placement and screw insertion (Fig 15). Image shows the fracture healing at 4 weeks' follow-up (Fig 16).

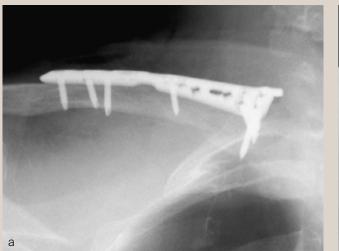
### VA-LCP® Clavicle Hook Plate 2.7 System

As an addition to the VA-LCP Clavicle Plate 2.7 System, the VA-LCP Clavicle Hook Plate System 2.7 was launched in August 2021.

As previously emphasized, the most significant clinical challenge associated with clavicle plating is the high reoperation



Fig 14 Computed tomographic scan 8 weeks after injury.



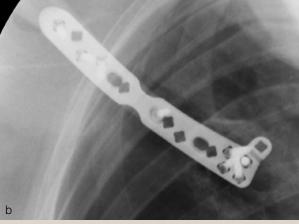


Fig 15a-b Intraoperative x-rays of plate application.





Fig 16a-b X-rays at 4 weeks' follow-up.

rate. Poor plate fit and high construct prominence in clavicular fracture fixation causes tissue irritation that can result in patient pain, discomfort, and additional surgery to remove hardware. Specific clinical challenges associated with clavicle hook plates are hook impingement and acromial osteolysis.

The VA-LCP Clavicle Hook Plate 2.7 System provides a solution for both lateral clavicular fractures with associated acromioclavicular ligament and coracoclavicular ligament injuries and ligamentous injuries of the acromioclavicular joint. Higher grade acromioclavicular joint dislocations require surgical fixation. One option for surgical treatment is the hook plate although its use has historically been associated with pain and impingement causing some patients to request implant removal before complete healing. The VA-LCP Clavicle Hook Plate 2.7 System has enhanced hook geometry designed to reduce pin-point contact of the hook on the underside of the acromion (3D morphometric analysis of the acromioclavicular joint–implications for surgical treatment using subacromial support, unpublished data).



**Fig 17** Available plates in the VA-LCP<sup>®</sup> Clavicle Hook Plate 2.7 System.

The system includes three low profile plate types (Fig 17); Button, Short and Long, with better anatomical fit and lower construct prominence intended to reduce soft-tissue irritation and related pain. Each plate type is available in left and right with three hook depths (9 mm, 12 mm, and 15 mm) to fit the angulation of the subacromial space in a wide variety of patients. The hook depth and angulation has been enhanced on all three plate designs following analysis of more than 120 shoulder CT scans (compared with Stryker VariAx 2 Clavicle System and Globus Anthem Clavicle Hook System).

The dedicated plate shapes not only possess an enhanced fit but also are designed to accommodate the bow and curvature of the clavicle at corresponding fracture locations. To achieve an optimal fit, a database of more than 600 CT clavicle scans was used to influence the design of the plate shapes while taking clavicle size as well as gender and ethnicity into consideration. For outlying anatomical variation, plates are designed to facilitate 3D bending.

The VA-LCP Clavicle Button Hook Plate 2.7 is the smallest hook plate on the market (compared with Stryker VariAx 2 Clavicle System and Globus Anthem Clavicle Hook System) and has been specifically designed for the treatment of acromioclavicular joint separations. The shortened and rounded plate body allows the hook to be targeted at the optimal contact location under the acromion with minimal incision size (Fig 18). The 2.7 mm single screw (as seen in the VA-LCP Clavicle Plate 2.7 System) reduces system complexity and facilitates ease of surgical procedure.

The VA-LCP Clavicle Hook Plate 2.7 System has undergone several mechanical tests throughout development to assess plate construct and the performance of isolated design features, such as suture holes. The construct pull-out strength is non-inferior in comparison with the DPS 3.5 mm LCP Clavicle Hook Plate System. Load testing was also completed to evaluate the performance of the system during plate contouring and hook bending.

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# SYMPHONY OCT System–Compartment 2

Occipital-Cervical-Thoracic (OCT) Systems have been developed to provide posterior correction and stabilization of spinal segments as an adjunct to fusion from the occiput to the thoracic spine. The current generation of OCT systems address the clinical needs for open posterior approach for numerous pathologies to include degenerative conditions, trauma, tumors, deformities, and infections.

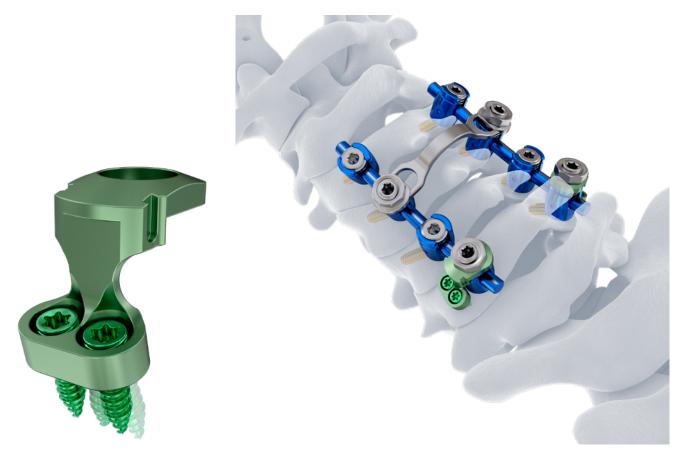
The SYMPHONY<sup>™</sup> OCT System is an enhanced set of instruments and implants for posterior fixation of the occipital-cervical junction, subaxial spine, and cervico-thoracic junction. Compartment 1 of the SYMPHONY OCT system was launched in November 2019, and was described in the 2019 issue of the *Innovations* magazine (*Innovations* magazine; 2019). A complex cervical case was presented in the 2020 issue of the *Innovations* magazine demonstrating the utility of Compartment 1 (*Innovations* magazine; 2020).

SYMPHONY Compartment 1 has recently been supplemented by enhanced and innovative elements (Compartment 2) to further address surgical needs and avoid pitfalls in a complex cervical surgery. Launched in early 2021, the Compartment 2 components include MULTIPOINT SECURE™ to augment lateral mass screws, reduction screws, advanced connector and various rod designs, a short drill guide, and polydriver. This additional feature builds on the advanced features already found in Compartment 1, which took the best of Synthes Synapse and DePuy Mountaineer.

#### **Fixation**

By optimizing and improving instruments and implants for posterior cervical fusion (PCF) following FATE principle (fixation, alignment, targeting, and extension), Compartment 2 further addresses surgical and technical concerns in an aging population with suboptimal bone quality and in patients who may require stronger constructs meeting the indications for spinal fusion [1–3]. There is also an increasing number of patients requiring extensions from prior posterior instrumented fusions. Screw fixation failure is another frequently reported issue (up to 5.2%) in PCF, and patients with suboptimal bone quality may be at a greater risk [3, 4]. More robust fixation of lateral mass screws (C3-C7) is now provided with MULTIPOINT SECURE (Fig 1).

A significant potential complication associated with lateral mass screws is loss of fixation. Market research reveals that 95% of surgeons have observed a lateral mass screw pullout or screw loosening [5]. The supplemental use of MULTIPOINT SECURE adds additional points of fixation, as the load can be shared across additional points of fixation via a locking plate. Reinforcing a lateral mass screw with MULTIPOINT SECURE with additional screws, increases the resistance to screw pullout by an average of 48.2% compared with standalone lateral mass screws [5].



**Fig 1** MULTIPOINT SECURE adapter with a two-screw fixation. It has variable angle locking technology. Screw tips are self-drilling. The adapter allows up to 25° cone of angulation.

### Alignment

Improvements in cervical alignment after deformity correction are correlated with improvement in HRQoL [6]. Market research indicates limited surgeon satisfaction in the ability to achieve alignment targets with the current instrumentation systems [5].

A single 4.0 mm SYMPHONY OCT System rod achieves biomechanical equivalence to a 3.5–5.5 mm construct in rangeof-motion testing. Utilizing a single system for long cervico-thoracic constructs may reduce procedure complexity and facilitate alignment correction. The SYMPHONY OCT System offers 3.5 mm and 4.0 mm CoCr rods, both demonstrated to be stiffer and stronger than titanium equivalents [5]. Stronger and stiffer constructs may support surgeons in achieving regional cervical alignment targets.

Besides the Reduction Towers and the Kerrison Reducer, cannulated Reduction Screws are now offered in the system with Compartment 2 (Fig 2). Reduction Screws and Reduction Towers were designed to simplify rod capture in complex deformity surgeries and allow for a more harmonious spinal force distribution and prevention of screw pullout [5].



### Fig 2a-c

- a Reduction Screws to address the growing number of deformity cases.
- **b** Reduction Tower designed to simplify rod capture in complex deformity surgeries.
- c Kerrison Reducer with an improved interface to aid with rotational alignment and engagement with implant to reduce the rod into the polyaxial head of the screw.

### **Targeting and navigation**

According to DePuy Synthes data [5] 91% of surgeons have reported feeling less than satisfied with their screw placement's initial trajectory. Cannulated screws provide a less invasive technique for the insertion of cervical pedicle screws. The use of cannulated screws has been shown to decrease perforation and complication rates in adolescent idiopathic scoliosis spine surgery [7].

The SYMPHONY OCT System instruments are navigation compatible and are offered to reduce the risk of screw breach and malpositioning.

Rates of pedicle perforations in the cervical spine have been shown to be lower with computer-assisted surgery compared with conventional techniques (3.0% vs 8.6%) [8]. Furthermore, navigated instrumentation may reduce radiation exposure to the user, providing a safer environment for surgeons [9–11].

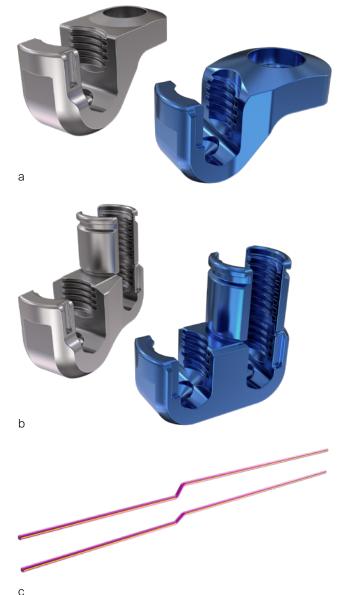
With Compartment 2, key instruments can now be navigated with navigation arrays and adaptors (Fig 3). There are two Universal Navigation Adaptor Sets (UNAS)—one set that can be used with a Medtronic SureTrak(R) II array and be manually calibrated to the Medtronic StealthStation navigation system. The other set works directly with Brainlab, and includes pre-calibrated instruments and new, aligned Brainlab Software that can substantially improve the surgical workflow. The cannulated screws provide a potentially less invasive technique for the insertion of cervical pedicle screws.

### **Extension and revision**

Posterior cervical fusion revisions may involve the removal, replacement, and extension of existing constructs that can undeniably drive-up revision cost and time. Extending rather than replacing existing constructs may help to save revision-related costs. Market research has shown limited surgeon satisfaction with the ability to extend constructs, and roughly 56% of surgeons state that they currently have difficulty inserting connectors [5].

The SYMPHONY OCT System offers comprehensive rod and connector options that were designed to match patient anatomy and accept multiple rod sizes (3.5–6.35 mm) providing the ability to connect to existing systems.

Compartment 2 now has been supplemented with Advanced Connectors designed to accept multiple rod sizes, accommodate multiple systems, and reduce procedure complexity. Currently it also offers Offset Rods (Fig 4).





**Fig 3** Polyaxial Screw Driver with the SureTrak II array and adaptor attached. SYMPHONY OCT System instruments are navigation compatible and are designed to reduce the risk of screw breach and malpositioning.

**Fig 4a-c** SYMPHONY Advanced Connectors to extend and connect constructs:

- a Top-Loading Rod Connectors.
- **b** Reduction Connectors.
- c Offset Rods.

The SYMPHONY OCT System instruments have been enhanced with ergonomic instruments which facilitate the new features of Polyscrew, percutaneous and interconnecting implants (MULTIPOINT SECURE, Reduction Connector, Top-Loading Rod Connector and Hooks) (Fig 5).

For more information and insight on the instruments and other features check the Surgical Technique Guide (SYMPHONY™ OCT System).

### Conclusion

Compartment 2 of the SYMPHONY OCT System is an AO TC

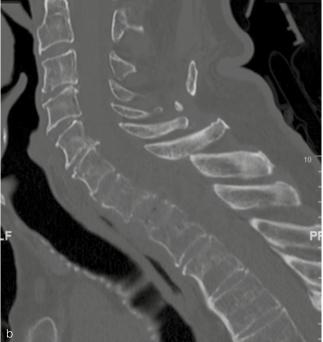


**Fig 5** Unilateral Inserter to connect and place MULTI-POINT adapter, Advanced Connectors and Laminar Hooks (shown with a Top-Loading Rod Connector). approved extension of Compartment 1, resulting in a state-ofthe-art posterior cervical instrumentation system with features that address surgical needs and promote improved patient outcomes.

### **Clinical case using MULTIPOINT SECURE** (by Richard Bransford, Harborview Medical Center, Seattle, Washington, USA)

A 73-year-old man with a history of renal cell carcinoma presented with progressive bilateral upper extremity paresthesia/ numbness, left upper extremity weakness, and upper back pain with a newly identified T1 pathological fracture (Fig 6).





**Fig 6a-b** Preoperative sagittal T2 magnetic resonance imaging and sagittal computed tomographic reformat demonstrating destructive lesion at T1.

The patient was taken to the operating room and underwent:

- Anterior T1 corpectomy and decompression of tumor and compressive material.
- Surgical reconstruction with DePuy Synthes SYNMESH cage and restoration of height. Given manubrium and angle of access, an anterior plate was not applied.
- C5-T3 posterior instrumentation with the DePuy Synthes SYMPHONY OCT System. Given the patient's suboptimal bone quality, C5 and C6 lateral mass screws were reinforced with two MULTIPOINT SECURE screws placed bilaterally for an additional eight screws (Fig 7).

The patient had immediate relief of the radicular symptoms postoperatively. Three months postoperatively (Fig 8), he had no neck pain and was anxious to return to daily exercise at the gym. He had maintained resolution of his radiculopathy and was satisfied with the outcome.

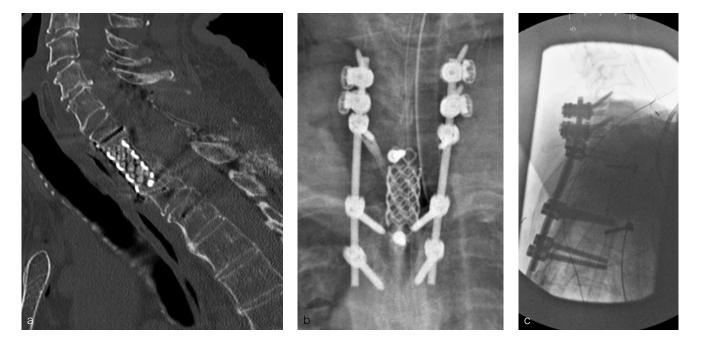


Fig 7a-c Postoperative sagittal computed tomography and intraoperative AP and lateral image intensifier images.

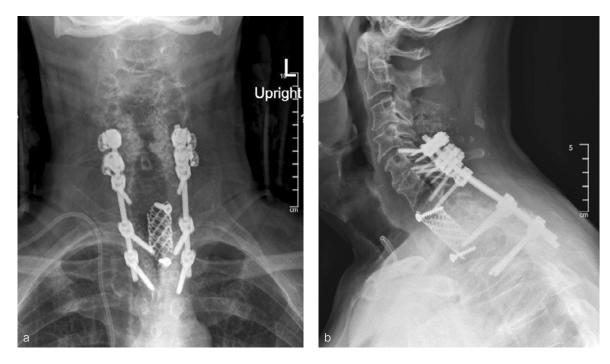


Fig 8a-b AP and lateral plain x-rays at 3-month follow-up.

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### MatrixMIDFACE 1.3 Line Extension

### MatrixMIDFACE System expanded with new 1.3 plates and 1.3 mm screws

The new 1.3 plates and 1.3 mm screws are aligned with the Matrix concept, providing low-profile plates and screws in a modular system with a wide range of plate shapes and screw options for fracture fixation. The new 1.3 mm screws (existing Matrix screws are 1.55 mm in thread diameter) have allowed the distance between the screw holes in the 1.3 plates to be significantly reduced, providing more fixation options in the

smaller plates. The 1.3 mm screws are not compatible with the existing Matrix 1.5 plates designed for 1.55 mm screws and vice versa. The instrumentation for both Matrix Systems is identical. A smaller 1.0 mm drill bit required for the 1.3 mm screws has been included from the COMPACT Midface System. With the inclusion of new plates and screws, the MatrixMID-FACE System supersedes the COMPACT Midface System and offers implants in a range of sizes and shapes suitable for various applications.

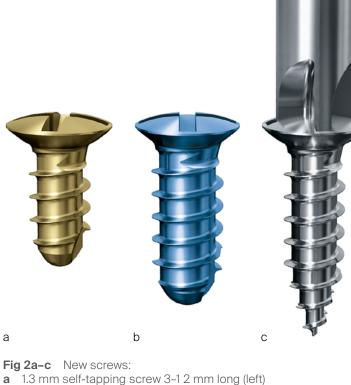
### 





**Fig 1a-c** New plates:

- a 1.3 Adaption plate (straight), 24 holes
- **b** 1.3 Orbital rim plate, 9 holes
- c 1.3 Adaption plate (straight), 8 holes



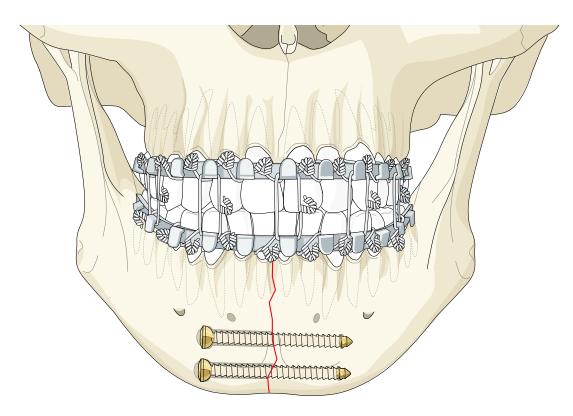
- b 1.7 mm emergency screw 3–12 mm long (middle)
- **c** 1.3 mm self-drilling screw 3–6 mm long (right)

# MatrixMANDIBLE 2.4 mm Cortex Screw Line Extension

### MatrixMANDIBLE System expanded with the new 2.4 mm Titanium Cortex Screw in lengths of 20–40 mm

The new 2.4 mm Titanium MatrixMANDIBLE Cortex Screw offers better flexibility for craniomaxillofacial surgeons in the treatment of mandibular fractures. Available in lengths of 20-40 mm, the new screw has the same design as the existing 2.4 mm Titanium MatrixMANDIBLE Cortex Screw (available in lengths of 5-18 mm) (Figure). The existing 2.4 mm Matrix-

MANDIBLE Cortex Screw was too short in certain surgical situations, for example when applied as a lag screw in the anterior mandible, or when used in oblique mandibular body fractures. In such situations, screws from the COMPACT System were often used instead. With the new additional screw lengths, all applications can be covered by one System. The COMPACT Mandible System will be withdrawn and superseded by the MatrixMANDIBLE System.

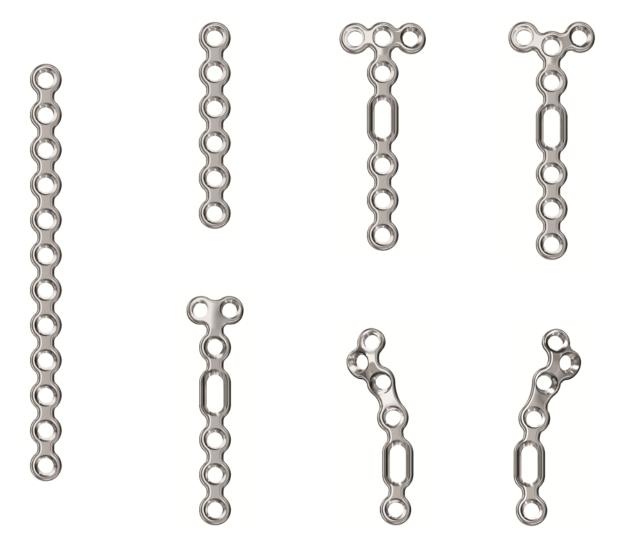


#### Figure

New screws: 2.4 mm MatrixMANDIBLE Cortex Screws 20–40 mm long

## **1.3 Locking System**

The 1.3 Locking System is intended for the treatment of fracture and arthrodesis in canines and felines. This recently approved system developed by our industrial partner DePuy Synthes in collaboration with the Small Animal Expert Group (SAEG) is a solution for fracture management in the smaller breed canine and feline population for which the 1.5 LCP System is too large. The 1.3 Locking System consists of stainless steel 1.3 mm screws, locking plates, instruments, and an implant module set. The set contains an extensive range of implant options (Fig 1) to accommodate various fracture types and locations. The plates are low profile to minimize soft-tissue irritation (Fig 2). Stacked combi holes allow the use of a locking screw



**Fig 1** The 1.3 Locking System consists of stainless steel locking plates in different sizes and with different shapes to fit specific fracture types.



Fig 2 Plates are low profile to minimize soft-tissue irritation.

or a cortex screw in the same round conical plate hole (Fig 3) and the cut-to-length feature (Fig 4) minimizes inventory. Screws are self-tapping and possess a self-retaining Star Drive recess which allows improved torque transmission and an increased resistance to stripping (Fig 5). The threaded head profile creates a fixed angle construct, and its low profile means that it sits flush with the surface of the plate.

The following two cases provided by SAEG member Erik Asimus illustrate common canine fractures in miniature breed dogs. Each fracture is treated with a different option dependent on the size of the radius and the ulna, the weight of the dog, and the type of fracture.



**Fig 3** Round conical hole can accept both locking and cortex screws depending on fixation principle required.



Fig 4 Plate cutter demonstrates the cut-to-length feature available in all plates across the system.



**Fig 5** Stardrive recess allows improved torque transmission and an increased resistance to stripping.

# **Clinical cases** (by Erik Asimus, Ecole Nationale Vétérinaire, Toulouse, France)

**Case 1:** Open reduction and internal fixation of distal radial and ulna fractures with a single 1.3 radial plate (Fig 6).

The patient was a 6-month-old, 1 kg (exactly 0.950 kg) Pomeranian dog presenting with a radial fracture of the left thoracic limb after a jump from  $\approx$  50 cm. The 1.5 mm System was too large for the width of the radius (2.2 mm) and the width of the radial medullary canal (0.5 mm) (Fig 7). The 1.3 mm adaptation plate was a perfect plate for this fracture. This plate option permitted the use of cortex and locking screws.

An open but do-not-touch approach was performed, and the plate was fixed with one proximal and one distal cortex screws and one proximal and one distal locking screws (Fig 8). After 1 month the fracture of the radius was healed, and the dog had a complete functional recovery (Fig 9).



**Fig 6a-b** Preoperative AP and lateral x-rays. Complete transverse fractures of the distal diaphysis of the left radius with a lateroproximal displacement of the radial fracture. Ulnar fracture is subperiosteal.



**Fig 7a-b** AP and lateral x-rays of the right radiusus-ulna showing the width of the radius and the width of the radial medullary canal.



**Fig 8a-b** Postoperative craniocaudal and lateral x-rays. Good apposition and alignment of the radial fractures were achieved.



**Fig 9a-b** Postoperative craniocaudal and mediolateral x-rays at 1 month.

**Case 2:** Open reduction and internal fixation of distal radial and ulna fractures with a 1.3 radial plate and a 1.3 ulnar plate (Fig 10).

The patient was a 2.5-month-old, 1 kg Japanese Spitz dog presenting with a radial-ulna fracture of the left thoracic limb after a jump from the sofa. The LCP 1.3 T-plate was perfectly adapted for the distal radial fracture. As the dog was "active"

and as the ulna was about the same size as the radius (Fig 11), a four-hole LCP 1.3 adaptation plate was used on the ulna.

An open but do-not-touch approach was performed, and the plate was fixed with both cortex screws and locking screws for both plates (Fig 12). After 4 months, the fractures were totally healed with normal bone growth and the dog had a complete functional recovery (Fig 13).



**Fig 10a-b** Preoperative AP and lateral x-rays. Complete transverse fractures of the distal diaphysis of the left radius/ulna with a lateral displacement of the radial and ulnar fractures.



**Fig 11a-b** AP and lateral x-rays of the right radiusus-ulna showing the relative size of the two bones.



**Fig 12a-b** Postoperative craniocaudal and lateral x-rays. Good apposition and alignment of the radial and ulnar fractures were achieved.

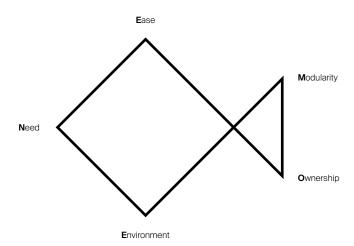


**Fig 13a-b** Postoperative craniocaudal and mediolateral x-rays at 4 months.

# **Update from the Smart Digital Solutions Task Force**

Having identified how current digital solutions can meet the demands of orthopedic trauma surgery and further the development of the NEEMO approach to guide the use of new digital technologies (Fig 1), the Smart Digital Solutions Task Force (SDSTF) is continuing to assess available technologies and their potential applications in orthopedic trauma surgery.

Although limited to digital meetings and restricted research capabilities with our affiliated hospitals during the Covid-19 pandemic, the initial aim of the SDSTF was to provide a systematic review of all studies on wearable activity monitors for fracture management published in the last decade. From more than 2000 identified studies, 136 reports were analyzed focusing on technology, treatment, assessed outcome, and general usability

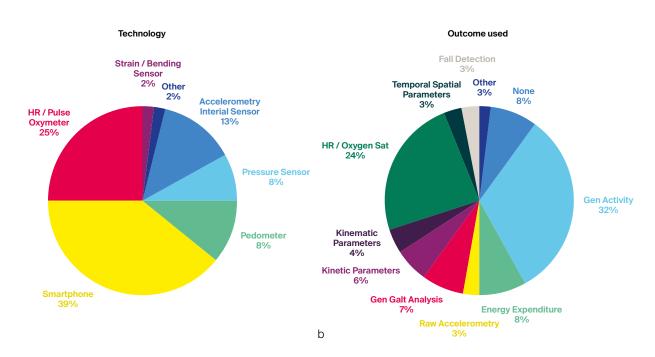


features. The study was accepted at the DKOU and SICOT annual meetings and is currently under review for publication (PROSPERO ID:210344). As soon as an accepted version of the manuscript is available it will be published on the AO website.

To provide a clinical perspective on the current state of wearable technology and determine future needs relating to this field, SDSTF and AO Trauma conducted a survey analysis derived from more than 400 respondents (Fig 2). Not only were we able to determine the current characteristics of these tools but we were also able to assess the additional developmental needs of trauma surgeons. The analysis is now finalized and will be prepared for publication.

In addition to these projects and alongside the collaboration with DePuy Synthes on emerging digital projects SDSTF members are presently overseeing an investigator-initiated clinical study to assess the direct impact of new wearable monitors on clinical trauma treatment and determine how digital technologies can enhance the patient journey. The first patients are already enrolled in this new trial to track the healing progress and subsequently provide objective patient outcome data. Together with the systematic review, survey, and study, the ambitious goal is to provide comprehensive recommendations on the best evidence-based practices for using wearable devices to measure activity, and then advise on clinically relevant outcome parameters.

**Fig 1** Need Ease Environment Modularity Ownership (NEEMO) is a guiding framework to aid developers, researchers, and clinicians when using digital solutions to address their needs (Finding NEEMO).



**Fig 2a-b** Preliminary survey analysis. Technologies (a) and outcomes (b) used by surgeons already utilizing wearable technologies.

а

# AO TC Meet the Experts sessions 2020

The annual AO TC Meet the Experts event at the AO Davos Courses presents an opportunity for world renowned surgeons to present the latest innovative technology designed to treat fractures and musculoskeletal disorders across CMF, Spine, Trauma and Vet. As a result of disruption to both travel and face-to-face events in 2020, the AO TC was forced to consider an alternative approach to hosting the Meet the Experts event. One offering included the preparation of a selection of videos showcasing the best innovations from the last 10 years. The following recordings (all available on the AO Approved Solutions website) were offered to participants of the AO Davos Courses during last year's digital event.

Торіс	Presenter/s	Released year
Innovations in femoral nailing	Christopher Finkemeier	2015
RIA 2 System: The next generation reamer irrigator aspirator	Brent Norris Martijin Poeze	2019
Complex deformity corrections in long bones using external fixation	Theddy Slongo Spence Reid Christoph Nötzli	2017
Femoral neck system—a new technique for minimal invasive fixation of femoral neck fractures	Karl Stoffel Christoph Sommer	2018
Advances in femoral nailing with special focus on the femoral Recon Nail System	Paulo Barbosa Christopher Finkemeier	2018
Patient specific procedures in CMF—state of the art	Daniel Buchbinder Damir Matic	2019
Planning and performing maxillo-mandibular distraction osteogenesis	Alberto Rocha	2019
Overview of MIS pedicle screw insertion and Viper Prime Technique	Andreas Korge Pujan Kavakebi	2017

A second AO TC Meet the Experts offering to AO Davos Courses participants was a LIVE webinar hosted by Michael Kowaleski and Erik Asimus from the Small Animal Expert Group. Having pre-recorded the surgical technique for the 3.5 LCP Distal Femoral Osteotomy Plates, both Veterinary experts could remotely showcase this new system during the Meet the Experts webinar alongside their virtual presentation and live Q&A (Fig 1).



**Fig 1** Michael Kowaleski (top) and Erik Asimus (bottom) hosting a live session to present the 3.5 LCP Plate during the 2020 digital Davos Courses.

#### 3.5 LCP Distal Femoral Osteotomy Plates for distal femoral fractures and osteotomies in medium and large dogs

Patellar luxation is a common cause of pelvic limb lameness in dogs. Although patella luxation can occur because of trauma, most canine cases of patellar luxation occur because of abnormal femoral and tibial modeling during skeletal development. The 3.5 LCP Distal Femoral Osteotomy Plate system has been designed to accommodate femoral pro-curvatum and addresses condylar morphology. The trajectories of the three distal locking screws have been designed to avoid the intercondylar notch and maximize screw purchase in the caudal portion of the femoral condyle while avoiding cranial screw placement to preserve bone for concurrent sulcoplasty.

Two important Meet the Experts sessions that should have been part of the 2020 event have since been recorded in collaboration with Rimasys. The sessions present recent innovations in intramedullary nailing of the femur and tibia (Fig 2).

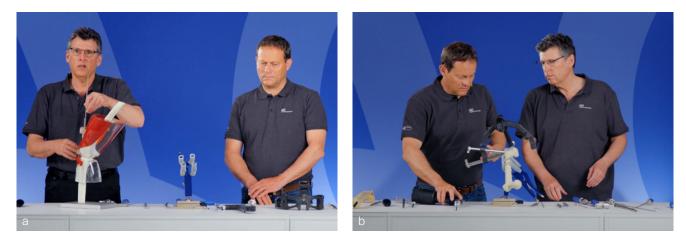
#### **Retrograde Femoral Nail Advanced**

Retrograde nailing of native and periprosthetic distal femoral fractures can be challenging due to limited implant anchorage

in very distal femoral fractures and in the presence of prostheses. Insufficient implant fixation may result in complications requiring revision surgery. The new RFN-Advanced (RFN-A) Retrograde Femoral Nailing System was developed to address this issue and offers an anatomically shaped six-hole plate (the locking attachment washer) that can be placed at the lateral femoral epicondyle to connect it to the retrograde nail in an angular stable manner. The enhanced fixation options of the RFN-A (also including a nut and washer system for interlocking screws) are intended to expand the retrograde nailing indications and to support early patient mobilization.

#### **Tibial Nail Advanced**

Intramedullary nailing of both proximal and distal tibial fractures has been a popular surgical option for some time. Expanding the indications to include metaphyseal fracture raises the question of stability regarding the fixation of short bone fragments. The new TN-Advanced (TN-A) Tibial Nailing System was specifically designed to address this issue. The new nail has preassembled inlays both proximally and distally to provide angular stability when interlocking screws are inserted. Furthermore, the new nail system provides instruments for the



#### Fig 2a-b

- **a** Martin Hessmann (left) and Karl Stoffel (right) present the new TN-Advanced including the instruments for the suprapatellar approach.
- b Karl Stoffel (left) and Martin Hessman (right) explain the benefits of the new RFN-A system.

infrapatellar, intraarticular suprapatellar, and extraarticular parapatellar approaches. The suprapatellar instrumentation features a compressible suprapatellar sleeve designed to reduce the pressure on the patellofemoral joint. The AO TC will bring new AO TC approved solutions to the AO ITC stage during the Davos Courses 2021. We are prepared for the live demonstrations and online sessions (Fig 3). Stay tuned on our web, where you will find the latest videos released.



#### Fig 3a-d

- a The Rimasys studio in Cologne, Germany, will feature AO TC Meet the Experts sessions in 2021.
- **b** Christoph Sommer and Eladio Saura-Sanchez prepare to host their Meet the Experts session on the new VA Locking Patella Plating System.
- c Set up of the Rimasys studio for filming of human anatomical specimen procedures.
- d Martin Jaeger of the Upper Extremity Global Expert Committee scrubs for a demonstration of the new VA Clavicle Plating System at the Rimasys studio with Chair Simon Lambert joining remotely.

## AO Technical Commission Innovation Prize awarded to the Cervical Spine Expert Group

The AO Technical Commission is proud to announce the Cervical Spine Expert Group as well-deserved winner of the 2021 Innovation Prize. Awarded for advancements in Posterior Cervical Fusion (PCF) and development of the Symphony Occipito-Cervico-Thoracic System, the prize acknowledges clinical innovation apparent in a solution that successfully addresses deformity correction, revision surgery and fixation in poor quality bone (Fig 1).

Fig 1 Symphony Occipito-Cervico-Thoracic System.

Symphony aims to reduce the complexity of PCF procedures and improve patient outcomes in a system containing Foundational (Compartment 1) and Enhancement (Compartment 2) elements. Comprising navigation instrumentation and a more sophisticated range of screws and rods, Symphony represents true innovation while successfully retaining the best features of Mountaineer and Synapse. Discussions about the need for such a system were initiated during a 2014 Cervical Spine Expert Group meeting. After years of development Symphony was introduced in a teaching capacity during the 2019 Complex Cervical Course in Davos (Fig 2).

The Cervical Spine Expert Group is an international group of expert spine surgeons, and the AO Technical Commission congratulates them for their achievements in advancing the care of patients requiring fixation of the cervical spine.

At the time of Symphony release, the CEEG members were: (Fig 3)

- Frank Kandziora (Germany)–CEEG Chair
- Rick Bransford (US)
- Osmar JS Moraes (Brazil)
- Chung Chek Wong (Malaysia)
- Abdulrazzaq Alobaid (Kuwait)



**Fig 2** Osmar Moraes delivers instructional tips for the use of Symphony during a dry bone laboratory in Davos, 2019.



**Fig 3** CEEG members at the time of Symphony release. Left to right: Rick Bransford, Frank Kandziora, Lois Wallach (AO TC), Chung Chek Wong, Abdulrazzaq Alobaid, and Osmar Moraes.

## **Clinical Science Advisory Commission Interview with Michael Fehlings and Philip Louie**

Clinical Science supports innovation translation at the AO with clinical evidence grounded in sound scientific methodology. In close collaboration with other AO ITC business units, Clinical Science is part of an efficient pathway to transform ideas into published clinical evidence. In June this year, Michael Fehlings, MD, chaired the first meeting of the AO ITC Clinical Science Advisory Commission (CSAC) and we are pleased to update you about the work of the group, its members, and their future visions for clinical research via an interview with Fehlings and the group's spine representative, Philip Louie, MD.

**Interviewer:** Thank you for scheduling this time to talk about your involvement with the newly formed Clinical Science Advisory Commission.

As Chairperson of the commission, Dr Fehlings, could you tell us the purpose of the group and your role and responsibility as Chair.

**Dr Fehlings:** The CSAC is a critical part of the AO Innovation Translation Center and is predated by an advisory committee that was formed to offer guidance to AO CID—one of the original critical pillars of the AO Foundation. I was the Chairperson of that advisory group for CID and some of my responsibilities subsequently overlap in my new role with the CSAC. Not only do we offer study feedback to Clinical Science and Clinical Operations we are also intrinsically involved with the AO Technical Commission (formerly known as the AOTK) and provide strategic advice around clinical science related to the work of the AO Innovation Translation Center and the whole concept of the recently formed AO Global Network.

Interviewer: What are the criteria to be elected to the CSAC?

**Dr Fehlings:** The membership on the commission includes representation from all clinical divisions. We are looking for people who have a strong engagement and are motivated by the opportunities around innovation and translation. We require practical people who think 'outside the box.' We aim to embrace the concept of globalization, equity, diversity, and inclusion, bringing on younger faculty to prepare for the future.

**Interviewer:** Turning now to the group's spine representative, Dr Philip Louie, what are your first impressions of AO ITC Clinical Evidence and specifically the recently formed CSAC?

**Dr Louie:** Despite being an AO Fellow, this is early exposure for me as Faculty to the AO Foundation and the workings of this new group. I was very impressed by the first CSAC meeting and by the goals of the AO ITC in general. I am delighted to collaborate with individuals from around the globe, and passionate about being involved with innovation. I am interested to see how ideas are translated into practical solutions and how such solutions can be integrated into a clinical workflow.

**Interviewer:** How do you plan to contribute to the CSAC during your 3-year term, and can you share some thoughts about future opportunities in spine research?

**Dr Louie:** I have a strong passion for the academic side of spine and for innovation and the translation of ideas. I appre-

ciate that I am younger than other group members but hopeful that my recent training from various parts of the world will bring a valued new perspective. I am keen to get involved in brainstorming sessions and evidence-based activities to truly understand the nuts and bolts of a clinical study. In terms of future opportunities, we are certainly moving into an age of Big Data, and I am enthusiastic about contributing to a global database with the initiation of global partnerships. We should be asking each other about clinical problems that we all face on a global scale and approach them together. Through the increased application of Artificial Intelligence and Machine Learning we really can begin to personalize the care of our patients. I am fascinated by the potential for an integrated platform to assist with patient care across the entire continuum. We are all aware of the intraoperative technologies that currently exist, but the future relies on an amalgamation of new developing technologies such as navigation, robotics, Augmented Reality across all phases of the patient journey. When we have the capacity to integrate such technologies from preoperative planning to postoperative data collation, we really will be in the position of having a centralized comprehensive treatment outcome database.

**Interviewer:** You are both familiar with the AO Foundation's Mission: **'Promoting excellence in patient care and outcomes in trauma and musculoskeletal disorders.'** How does the clinical research at the AO help to support and sustain that mission?

Dr Fehlings: The fundamental aspect of the AO relates to Knowledge Creation and Knowledge Translation. The AO was originally created to solve problems related to orthopedic fracture care, which was largely nonoperative before novel implants and technologies were developed. The AO has evolved significantly which is why we see the evolution of departments like CID, the AO TC (formerly AOTK) and Education. The AO Clinical Investigation Department, now the business units AO ITC Clinical Operations and Clinical Science form the Clinical Evidence competence area within AO ITC, became a required pillar of the AO tasked with studying and documenting patient treatment outcomes. The AOTK or AO TC (AO Technical Commission) as it is now known was developed as a collaborative function designed to work with industry engineers toward the development of implants, and the AO Education Institute was a natural follow on to ensure that procedure and product-based teaching could be performed consistently. This is a perfect example of knowledge translation and represents how the core functions of the AO work effectively together. When innovation occurs through surgeon collaboration, the clinical research infrastructure of the AO via the work of AO ITC Clinical Evidence and CSAC, ensures that studies performed by ARI (assessing basic and fundamental science) and the AO TC (performing device-oriented research) adopt the correct approach and interpret outcomes accurately. The CSAC is an objective committee created to assess all elements of a study and work in partnership across the AO ITC to drive innovation and translation. CSAC is intrinsically involved in knowledge creation, which is critical to the mission of the AO.

**Interviewer:** What was the goal of the CSAC kick-off meeting in June?

**Dr Fehlings:** The meeting was very successful and accomplished critical objectives. The CSAC was again defined as a group created to provide strategic advice related to clinical science and clinical studies affiliated with the AO ITC mission. During the meeting, we were able to effectively position ourselves within the broader AO ITC and confirm our understanding of the global network approach being adopted by the AO Foundation.

**Dr Louie:** My goal for the meeting was to work out where the CSAC sits in the big picture; understand the group's value and where it sits in the AO ITC. The CSAC is not alone on its mission to improve patient outcomes and it was good to see how we will be collaborating with many others across the AO Foundation in pursuit of this goal.

**Dr Fehlings:** I think we have a great opportunity within the CSAC and the wider AO Foundation to recognize areas that will impact how we treat patients going forward. The world is changing at a rapid rate, and we really need to embrace what is happening. The pandemic has shown us the capability and value inherent in virtual technologies; there is no doubt that this will influence the way we work, from participating in Zoom meetings with colleagues to clinically assisting communities that can't receive basic care. Virtual technologies enable the ability to network in many ways and this won't change. With the increased use of virtual technologies over the previous 18 months, it is also now possible to conceive how studies could be performed electronically without compromising safety or quality.

As clinicians operating in a world of complex disease, we need to define how we use technologies like Artificial

Intelligence and Machine Learning to obtain Big Data. The collation of real time data as a means of looking at outcomes is the future of clinical research. I also believe that precision-based medicine (robotics, image guidance solutions) is gaining importance in the complex procedures that we perform. Regenerative medicine is another big growth area and represents an opportunity for more collaboration with the AO Research Institute Davos. We have become masters of fracture fixation, but we need to learn more about replacing tissue defects across the entire anatomy. I am thrilled about the many research opportunities that await all current members in the Clinical Science Advisory Commission over the next 3 years.

Dr Michael Fehlings is a neurosurgeon at the Toronto Western Hospital and Vice Chair of Research for the Department of Surgery at the University of Toronto. Dr Fehlings combines an active clinical practice in complex spinal surgery with a translationally oriented research program and has been a long-time member of AO Spine.

Dr Philip Louie graduated from the University of Washington School of Medicine in 2014 and works as a spine surgeon in the Department of Neurosurgery at Virginia Mason Franciscan Health in Seattle. Dr Louie is the recipient of multiple academic awards including the Orthopaedic Innovator Award from the American Academy of Orthopaedic Surgeons (AAOS).

The AO ITC acknowledges Michael Fehlings and Philip Louie for their contribution to this article and all members of the Clinical Science Advisory Commission.



**Osama Farouk, MD** (Trauma Representative) Prof of Orthopedic Surgery and Chief of Orthopedic Trauma Unit, Assiut University Hospitals, Egypt



Prof Risto Kontio, MD, DDS, PhD (CMF Representative) Prof and Chair of Department of Oral and MaxFac Surgery, Helsinki University Hospital, Finland



Prof Michael G Fehlings, PhD, MD, FACS, FRCSC (Chair and Neuro Representative) Prof of Neurosurgery at University of Toronto, Canada



Philip Louie, MD (Spine Representative) Spine Surgeon, Department of Neurosurgery, Virginia Mason Medical Center, Seattle, USA Chief Operating Officer and Co-Founder of STREAMD

# Technology Transfer in AO fireside chat: the power of innovation, mentorship, and diversity

During this first ever video fireside chat to be published in the AO Innovation Translation Center (AO ITC) *Innovations* magazine, two Technology Transfer Board (TTB) members discuss the prerequisites for meaningful innovation. Renowned researchers, innovators, and longtime AO faculty members, Prof Jill Helms (Fig 1) and Prof Michael Schütz (Fig 2), agree that the AO's multidisciplinary nature, global network, and leadership in research, as well as the TTB's demonstrable commitment to mentorship and both gender and cultural diversity, establish a solid foundation for innovation.

In the past 2 years, the TTB has reached gender equality and today represents a diversity of cultural backgrounds, says TTB Chairperson Schütz, also director of the Jamieson Trauma Institute and chair of Trauma at Queensland University of Technology (QUT), Australia.

"We are a global organization at the AO" and subsequently "looking for global solutions," he asserts. "I'm very proud to facilitate this gender and cultural equality for real innovation."

Helms, a clinician scientist, cofounder of Ankasa Regenerative Therapeutics, and a professor of plastic and reconstructive surgery at Stanford University in the United States, emphasizes that the most promising areas for innovation lie at the intersection of disciplines.

"I think we have to create the concept of team science, where individuals with complementary skill sets can work together," she says. "This challenges how we think about problems, but it also challenges us to think about our identity."

Schütz believes challenges "are the perfect place to look for innovation," citing the example of Australia's Royal Flying Doctor Service, established in the 1920s to provide medical services to patients in the nation's outback.

"Nowadays we use augmented reality to overcome those distances and provide for those who are disadvantaged," he says. For example, the development incubator resources support projects like the AO Fracture Monitor, which enables

remote fracture healing monitoring by the clinician. True innovation can be realized when there is pressure to find a solution.

Meeting such challenges also requires talent, and Helms reveals there is a direct connection between diversity and innovation.

"The data shows that creating teams with gender diversity leads to radical innovation. It's abundantly clear that the environments that are fostering radical innovation also attract top talent. I'm not just talking about gender diversity," she says. "There's diversity in race, ethnic background, career path, age, experience, social background."

In addition to offering an inclusive environment for collaboration, Schütz says the Technology Transfer embraces a wide range of proposals for development incubator support.

"We get applications from clinicians, from researchers, from start-up companies who want to partner with us," he explains, adding that the AO's global network of trauma, spine, craniomaxillofacial, veterinary, and reconstructive surgeons brings vast expertise to every project team. "The cooperation with the applicants is tailored to their demands. We have a trustworthy team that offers advice on business development, research, and exit strategies. Once we accept a proposal and support a group, we don't let them down."

Helms sees TTB members as mentors to project leaders.

"We're collectively interested in furthering the success of a project and can provide them not only experience and expertise but also function as bridge builders, introducing innovators to people outside their core group," she says.

Watch the complete interview during which Helms and Schütz offer advice to junior surgeons and researchers with excellent ideas for improving patient outcomes.

Can your idea improve patient care or surgeon education? Apply for AO ITC funding!



**Fig 1** Prof Jill Helms, DDS, PhD: "Data clearly shows that creating teams with diversity leads to radical innovation."



**Fig 2** Prof Michael Schütz, MD: "A perfect place to look for innovation is where you see challenges."

# **AO Small External Fixator**

The AO Small External Fixator (Figure), developed toward proof of concept and valorization with AO development incubator resources made accessible by the AO Innovation Translation Center (AO ITC) Technology Transfer, was set for clinical documentation in summer 2021 in Germany, Austria, and Switzerland. The system which received Conformité Européene (CE) mark in early 2021 represents a soft-tissue protecting, less bulky, and more efficient solution for treating bruised, fractured, or broken small bones compared with existing solutions.

With support from the AO ITC Technology Transfer, the AO Small External Fixator–invented by Austria-based surgeon Karl Heinz Bürger, MD–has been technically optimized regarding material choices, tolerances, and portfolio definitions, and received enthusiastic feedback from AO experts who tested it in AO Research Institute Davos (ARI) wet labs. With a first production run of 200 pieces completed, the solution is now ready for clinical application.

#### The clinical problem

Over the course of his career, one of the setbacks consistently experienced by Bürger was the instability of K-wire fixation for fractures of the phalanx. Titanium plates—another fixation option—present additional challenges: "It's not always possible in an acute trauma situation to open the soft-tissue sufficiently to achieve fixation with a plate" says Bürger. Bone cement is also an alternative, but usage is expensive, time-consuming, and challenging because once it dries the fixation cannot immediately be corrected.

#### The clinical solution

Regularly faced with these constraints, Bürger set about to develop a solution: the AO Small External Fixator, which utilizes snap-on brackets to hold the horizontal rods of a fixation brace in place. With this concept in mind, he partnered with a product design expert who helped to create a prototype of a quick, affordable, stable, and tissue-preserving means of fixing fractures in small bones.

Development incubator resources made available through the AO ITC Technology Transfer have played a key role in the development of the AO Small External Fixator. Resources include investments granted by an independent board that approves proposals and consults extensively with experts in relevant fields. The board also offers knowledge about securing intellectual property, medical device development, enabling first clinical cases, and planning valorization of the proof of concept.

By late 2021, the AO Small External Fixator development team expects to seek a commercial partner to bring the system to market.



Figure AO Small External Fixator.

# Sound-Wave Induced Morphogenesis (3D SIM)

A new technology developed by an AO Research Institute Davos (ARI) research scientist has been licensed to a Switzerland-based start-up and is poised to transform tissue engineering. The result is mimiX Biotherapeutics CymatiX (Fig 1), the world's first acoustic bioprinter, making it possible to create biological architectures with sound.

Sound-Wave Induced Morphogenesis (3D SIM), significantly advanced by ARI research scientist Tiziano Serra, PhD, uses sound waves to generate a network of cells within seconds, providing a self-assembled substrate for vascularization (Fig 2). This has the potential to make tissue-engineered constructs based on autogenous materials widely available in operating rooms. In 2020, the technology was licensed to newly created mimiX Biotherapeutics in Switzerland.

Serra's project was supported by AO resources, including funding and know-how, through the Technology Transfer office at the AO Innovation Translation Center (AO ITC), which partners with inventors to achieve proof of concept and to make solutions clinically available.

#### **Clinical problem**

3D SIM technology resolves various challenges, for instance difficulties in rapid and mild recreation of the natural complex morphology of tissues and organs during surgery presented by other promising tissue-engineering technologies, such as 3D printing.

#### **Clinical solution**

The 3D SIM is a gentle, fast, and easy method used to generate multicellular, spatially orchestrated tissue constructs utilizing sound waves. It has excellent potential for use in operating rooms in the future due to its speed. Moreover, as no needles are involved in the printing process, there is no fluid stress on the cells printed and consequently no cell damage or death.

Vascular tissue engineering, the generation of tissue that includes vessels, has the potential to significantly impact the treatment of numerous medical conditions. It could provide in vitro generated, vascularized tissue and be useful for in vitro models for diagnostic and drug discovery indications. However, developing a large-scale, functional, vascularized construct is still a major challenge and an unsolved clinical problem.

The 3D SIM technology aims to make artificial tissues a true therapeutic option by providing affordable, life-transforming treatment for patients. This intraoperative method for generating vascularized constructs can disrupt and trigger development across the entire field of regenerative, personalized, and precision medicine. Serra began working on the 3D SIM project when he joined ARI in October 2016 and went on to earn CHF 180,000 in support from BRIDGE, a joint program with the Swiss National Science Foundation and Innosuisse–Swiss Innovation Agency.

In less than 1 minute, the system generates large-size, cell-patterned constructs (from a few millimeters to 150 square centimeters) to guide the formation of vascularized tissues-a real breakthrough. The technology can pattern cells and build tissue layer upon layer, meaning that it can be used to generate and in creating specially orchestrated tissue models for use in screening drugs, creating patient-specific tissue and disease models. This means scientists, pharma companies, and clinicians can simply use a pipette to put cells into the mimiX system's labware and then apply sound for a few seconds, leading to the formation of a pattern of cells that can then be extracted and used to treat the patient. In principle, this technology can be used to produce skin, bone, cartilage, and even organs. The system, Serra said, could revolutionize the way 3D organs and tissues are generated and the way of working in the operating room by offering a cost-efficient, point-of-care tissue-engineering approach to regenerative, patient-tailored precision medicine.

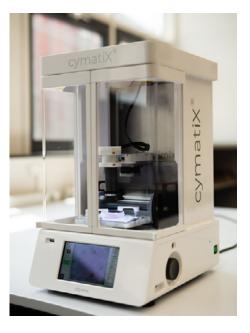
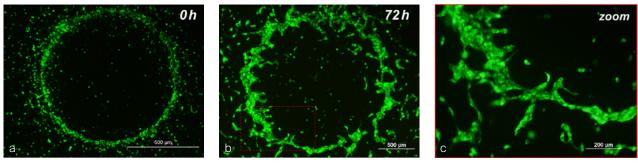


Fig 1 CymatiX<sup>™</sup>: the first acoustic bioprinter.



Cell patterning

Vasculature assembly

**Fig 2a-c** Human umbilical vein endothelial cells (HUVEC) patterned within fibrin gel in a circle shape to assemble a proto-vessel structure after 72 hours.

# **Biphasic Plate is now a CE marked medical device**

#### Introduction

On April 21, 2021, the Biphasic Plate DF (Distal Femur) obtained the CE certification as a class IIB medical device. This achievement represents a formidable team effort, made possible by the AO Innovation Translation Center (AO ITC) Technology Transfer.

Biphasic Plating is a new solution conceived by the AO Research Institute Davos (ARI), Switzerland, Queensland University of Technology (QUT), Brisbane, Australia, and 41medical as a legal manufacturer. Due to the Development Incubator funding from the AO ITC, the expansion phase of the distal femur version started in 2018. Today the plate is in its first series of production in preparation for clinical application in the middle of 2021 in Europe.

#### **Clinical problem**

Severe trauma to the extremities is a leading cause of disability during the wage-earning period. The socioeconomic burden of fracture is substantial: loss of working capacity represents more than 60% of the total cost of fractures, while the direct cost of medical treatment is less than 20%. Optimal outcomes require not only solid union but also early and complete recovery of limb function. The current generation of fracture fixation plates focus on minimizing the impact of surgery and preserving biological healing potential. However, their design poorly controls a second critical component: the mechanical environment of the fracture. Furthermore, these plates are prone to failure, which limits function and delays return to work.

#### **Novel solution**

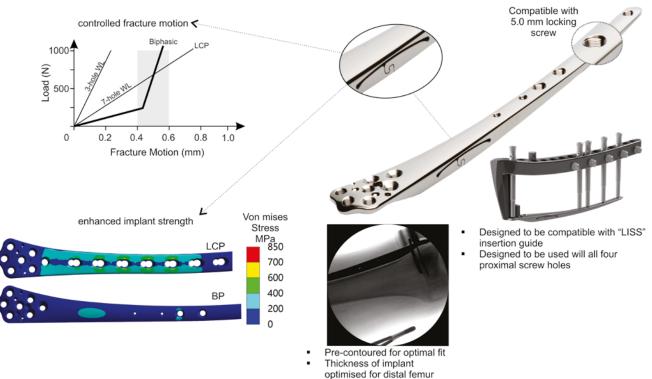
The Biphasic Plate with its novel plate fixation design: (Figure)

- Provides a beneficial mechanical environment at the fracture site for robust fracture healing
- Increases implant strength which carries potential to permit full, early weight bearing and prevent implant fatigue-related failure
- Standardizes and, therefore, simplifies the surgical procedure

Invented by Associate Professor Devakar Epari from QUT and ARI Focus Area Leader Markus Windolf (among others), the Biphasic Plating concept was proven by mechanical testing and preclinical experiments conducted at ARI between 2016 and 2018. Results of the large animal study were published in the August 2020 issue of the *Injury* journal [1] support in vivo feasibility of the Biphasic Plating concept. Additionally, computer simulations were performed at QUT [2] demonstrating its improved mechanical performance.

#### References

- Hofmann-Fliri L, Epari DR, Schwyn R, et al. Biphasic Platingin vivo study of a novel fixation concept to enhance mechanobiological fracture healing. *Injury*. 2020 Aug;51(8):1751-1758.
- 2. Epari DR, Gurung R, Hofmann-Fliri L, et al. Biphasic plating improves the mechanical performance of locked plating for distal femur fractures. *J Biomech*. 2021 Jan 22;115:110192.



application

**Figure** Biphasic Plate DF (Distal Femur) features a transverse slot in a region of increased thickness that simultaneously provides controlled fracture motion and enhanced implant strength, as indicated by substantially lower stresses in the implant. Standard locking plates produce variable fracture motion depending on the working length, whereas the Biphasic Plate provides controlled fracture motion over a wide load range. The Biphasic Plate DF is designed to be compatible with existing 5.0 mm DePuySynthes locking screws and insertion instruments. The implant is precontoured for optimal fit with the region of increased thickness accommodated in the supracondylar region of the distal femur.

### OSapp fosters understanding of biomechanical concepts behind fracture fixation

Officially launched at the AO Davos Courses 2020, a new, interactive, and constantly expanding virtual osteosynthesis software tool and interactive online learning platform–OSapp– fosters understanding of the biomechanical concepts underlying the principles of fracture fixation. Initially supported by the AO Research Institute Davos, OSapp has been further developed with support from the AO Innovation Translation Center (AO ITC) strategy fund.

Since its public debut at the AO's flagship annual event in December 2020, the OSapp interactive osteosynthesis learning platform has achieved more than 1700 registered users and 4600 visitors from 121 countries. The platform's onboard survey tool indicates that 90% of respondents found OSapp useful, and more than 90% will highly recommend it to colleagues.

#### The problem

The OSapp project stems from a discussion between ARI Biomechanics and Modeling Focus Area Leader Peter Varga, PhD, and AO Technical Commission Upper Extremity Global Expert Group Committee member and longtime AO Trauma faculty Simon Lambert, MD. The discussion centered on a perceived gap in AO Davos Courses 2018 participants' understanding of the biomechanical concepts underlying the principles of fracture fixation.

#### The solution

Varga and Lambert suggested a solution: a tool that could act as an interactive reminder of those biomechanical concepts and illustrate the principles of fracture fixation. The resulting OSapp tool (Figure) is a virtual environment allowing users to experiment with various scenarios and immediately understand the outcomes of their decisions which in turn powers learning. Playing a valuable advisory role in aiding OSapp's development was Prof Stephan M Perren AO's fathers and senior scientific advisor until just a few days before his death in November 2019.

An offline version of OSapp was demonstrated at the AO Davos Courses 2019 and was met with positive feedback. The clinical relevance of OSapp's content is ensured by the supervision of renowned experts, Reto Babst, Florian Gebhard, Martin Jaeger, Michael Schütz, and Simon Lambert, who comprise the OSapp Medical Advisory Board.

The 30-month project that began in July 2020 is today an engaging online learning platform on which anyone can register and use OSapp. The platform's content is continuously being expanded and includes both a free configurator and a virtual clinical case discussion. Users can also access guided lessons through which they can view a selection of biomechanical principles via 3D computer simulations. When users successfully demonstrate knowledge of the principles underlying fixation, they can appreciate the positive impact it has on fracture healing.

The OSapp development team has established a collaboration with the ICUC medical research group to link ICUC cases to OSapp. Additionally, a series of new OSapp content extensions is planned for later this year based on input from users, the advisory board, and AO medical research fellows.

The latest OSapp content will be showcased at the AO Davos Courses 2021, and discussions are underway to gauge how the platform can best be used to support AO educational activities, such as the AO Trauma Competency-based Training and Assessment Program (CTAP) and AO Trauma Residents education program.

#### Reference

Lambert S, Mischler D, Windolf M, et al. From creative thinking to scientific principles in clinical practice. *Injury*. 2021Jan;52(1):32–36.

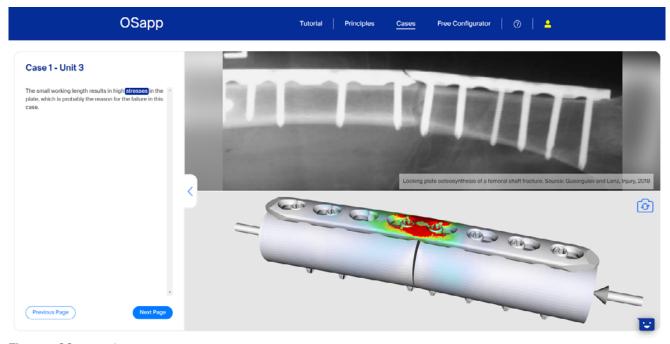


Figure OSapp tool.

### Digitally enhanced, hands-on surgical trainingdigital innovation in surgical skill training

With support from the AO Innovation Translation Center (AO ITC), AO Research Institute Davos (ARI) scientists are leveraging ARI's patented optical tracking technology to develop a cost-effective, transportable, and digitally augmented solution for hands-on surgical training.

Prototypes of a first module for surgical training on distal interlocking have received encouraging feedback from surgeons who have had the chance to test it. It is now in the product development stage and set for demonstration at the AO Davos Courses 2021. Supported by the AO Innovation Translation Center (AO ITC) strategy fund, the digitally enhanced hands-on surgical training (DEHST) solution supplements hands-on education with an extended training scope and collates data for comprehensive evaluation, assessment, and potential certification.

#### The problem

Surgeons' practical skill and the ability to improve their surgical capabilities are key to the attainment of successful orthopedic and trauma surgery outcomes. Hands-on, tactile exercises are crucial to an effective training concept. Conventional hands-on training for the distal interlocking of intramedullary nails tends to be cost-intensive; typically offered only in course events; limited to a specific number of applications and lacking substantial data collection to qualitatively evaluate and measure participant performance.

#### The solution

These limitations are solved by DEHST (Figure). It is a compact, cost-efficient, and mobile concept for hands-on training, offering a novel, mixed-reality training experience and enhanced training scope. A pilot module for distal interlocking of intramedullary nails

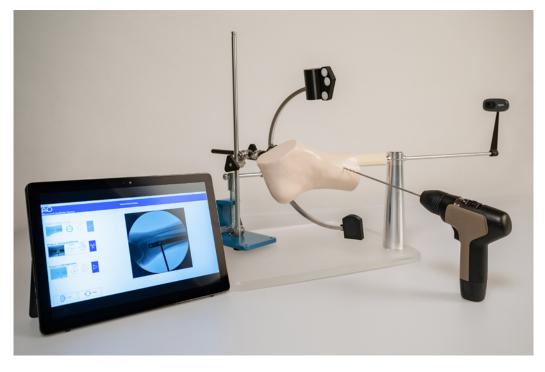
features an artificial x-ray imaging engine that generates radiation-free simulated x-rays for a realistic training experience. Training can be tracked, and data can be collected and uploaded to the cloud. Users can access the data to get comprehensive training analytics and personalized skill assessment.

AO Research Institute Davos scientist Jan Buschbaum, PhD, senior project leader in ARI's Concept Development Focus Area, is leading the 36-month project in collaboration with Markus Windolf, PhD, Focus Area Leader Concept Development.

The team aims to build a training station product line containing several modules for hands-on tutoring. For instance, the AO Skills Lab—an important hands-on surgical learning experience—can be complemented by a new education platform using digital technologies to enhance the scope and track the training to provide the user with feedback in the form of performance metrics.

Based on an optical tracking technology invented and developed by Buschbaum and Windolf at ARI, the DEHST concept originated at the AO Davos Courses 2019 with discussions also involving Synbone AG and other relevant parties on how the AO's training could best be digitalized. The concept so far has the support of AO's Competence-Based Training and Assessment Program (CTAP) committee and can potentially be integrated into the CTAP educational framework as an intermediate learning tool for basic skills during early-stage training. Test users have expressed a clear need for such a tool.

The development team looks forward to gathering comprehensive user feedback at the AO Davos Courses 2021.



**Figure** The digitally enhanced hands-on surgical training (DEHST) prototype will be demonstrated at the AO Davos Courses 2021.

Mark Lenz, Peter Varga, Dominic Mischler, Boyko Gueorguiev, Kajetan Klos, Alberto Fernandez dell'Oca, Pietro Regazzoni, Geoff Richards, Stephan Perren

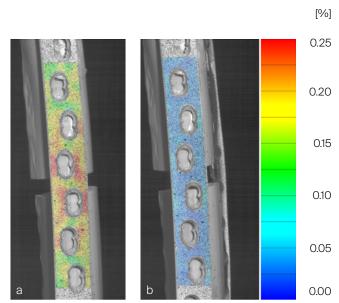
### Helical plating provides well-balanced load sharing in laterally plated femoral defect fractures

Single-plate fixation bridging bone defects provokes nonunion and risks plate-fatigue failure due to under dimensioned implants. Adding a helical plate to bridge the fracture increases stiffness and balances load sharing (Fig 1). The aim of this project was to compare stiffness and plate surface strain of different constructs in a transverse contact and gap femoral shaft fracture model.

Eight groups of six synthetic femora each were formed: intact femora; intact femora with lateral locking plate; contact and gap transverse shaft osteotomies each with lateral locking plate, lateral locking plate and helical locking plate, and long proximal femoral nail. Constructs underwent non-destructive quasi-static axial and torsional loading. Plate surface strain evaluation was performed under 200 N axial loading.

Constructs with both lateral and helical plates demonstrated similar axial and torsional stiffness, independent of the contact or gap situations, being significantly higher compared with lateral plating (P < .01). Torsional stiffness of the constructs, with both lateral and helical plates in the gap situation, was significantly higher compared with this situation stabilized by a nail (P < .01). Plate surface strain dropped from 0.3% in the gap situation with a lateral plate to < 0.1% in this situation with both a lateral and a helical plate (Fig 2).

Additional helical plating increases axial and torsional construct stiffness in synthetic bone and provides well-balanced load sharing. Its use should be considered in demanding situations for gap or defect fractures, where single-plate osteosynthesis provides inadequate stiffness for fracture healing and induces nonunion.



**Fig 1a-b** X-rays of a clinical case. Nonunion and lateral locking plate fatigue failure of a comminuted femoral shaft fracture with lacking medial cortical support (**a**). Bone healing with cortical reformation, following callus formation, after conversion to lateral locking plate plus helical plate, with absence of plate breakage 145 weeks postoperation (**b**) (Source: www.icuc.net).

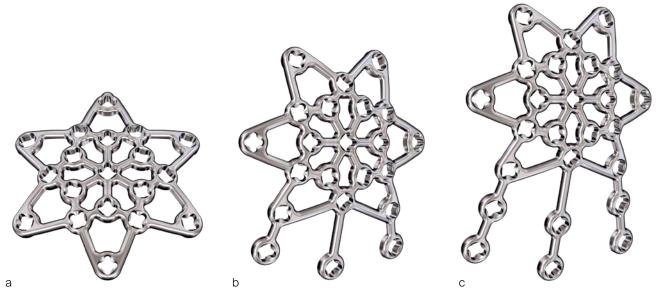
**Fig 2a-b** Maximum major principal strain on the surface of a single lateral locking plate spanning a gap and loaded at 200 N, with red color indicating a maximum surface strain above 0.3% (a). Adding an anteromedial helical plate to the lateral locking plate decreases the surface strain on the lateral plate to a level below 0.1% (b, blue color).



### Anterior variable angle locked plating vs tension band wiring of simple and complex patella fractures—a biomechanical investigation

Treatment of both simple and complex patella fractures represents a challenging clinical problem. It aims to restore the integrity of the extensor mechanism and the congruity of patellofemoral joint. Controversy exists regarding the most appropriate fixation method. Tension band wiring, aiming to convert the pulling forces on the anterior aspect of the patella into compression forces across the fracture site, is the standard of care; however, it is associated with high complication rates. Recently, anterior variable angle locking plates have been developed for treatment of both simple and comminuted patella fractures (Fig 1).

The aim of this project was to investigate the biomechanical performance of the recently developed anterior variable angle locking plates vs tension band wiring used for fixation of simple and complex patella fractures.

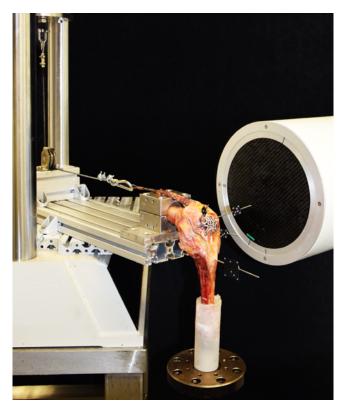


**Fig 1a-c** Core (a), three-hole (b), and six-hole (c) standard Variable Angle Locking Anterior Patella Plates 2.7 designed for treatment of simple and complex patella fractures.

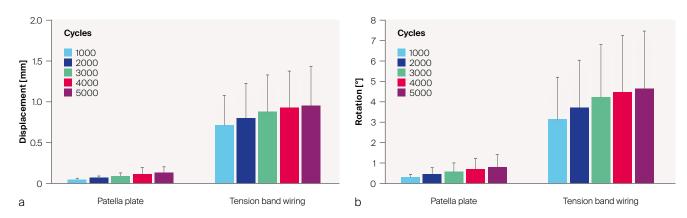
Sixteen pairs of human anatomical knee specimens were used to simulate either two-part transverse simple AO/OTA 34-C1 or five-part complex AO/OTA 34-C3 patella fractures by means of osteotomies, with each fracture model being created in eight pairs. The complex fracture pattern was characterized with a medial and a lateral proximal fragment, together with an inferomedial, an inferolateral, and an inferior fragment mimicking comminution around the distal patellar pole. The specimens with simple fractures were pairwise assigned for fixation with either tension band wiring through two parallel cannulated screws, or an anterior variable angle locking core plate. The knees with complex fractures were pairwise treated with either tension band wiring through two parallel cannulated screws plus circumferential cerclage wiring, or an anterior variable angle locking three-hole plate. Each specimen was tested over 5000 cycles by pulling on the quadriceps tendon, simulating active knee extension and passive knee flexion within the range from 90° flexion to full knee extension. Interfragmentary movements were captured by means of motion tracking (Fig 2).

For both fracture types, the articular displacements, measured between the proximal and distal fragments at the central aspect of the patella between 1000 and 5000 cycles, together with the relative rotations of these fragments around the mediolateral axis were all significantly smaller following the anterior variable angle locked plating compared with the tension band wiring, P < .01 (Fig 3).

From a biomechanical perspective, anterior locked plating of both simple and complex patella fractures provides superior construct stability vs tension band wiring.



**Fig 2** Test setup with a specimen implanted with an anterior variable angle three-hole locking plate, equipped with markers for motion tracking, and mounted for biomechanical testing.



**Fig 3a-b** Articular displacement at the central aspect of the patella (**a**) and rotation (**b**), both measured between the proximal and distal fragments after 1000, 2000, 3000, 4000, and 5000 cycles and featuring complex fractures fixed by either anterior variable angle locked plating or tension band wiring in terms of mean and standard deviation.

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# Statistical analysis of complex proximal humeral fractures

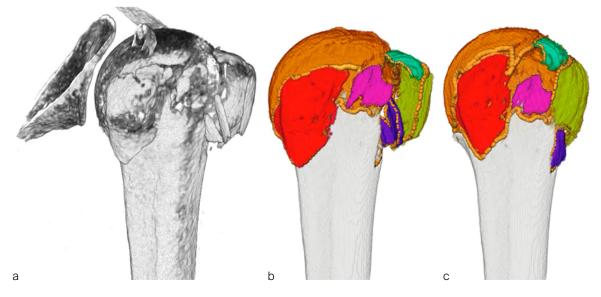
Fixation of complex proximal humeral fractures has remained challenging, partially due to the large variation in the number, shape, and displacement of fragments. Understanding the variability of fracture patterns could enhance surgical training and education and contribute to advanced implant development.

The aim of this project was to evaluate and statistically describe the pattern and spatial distribution of complex fractures at the proximal humerus.

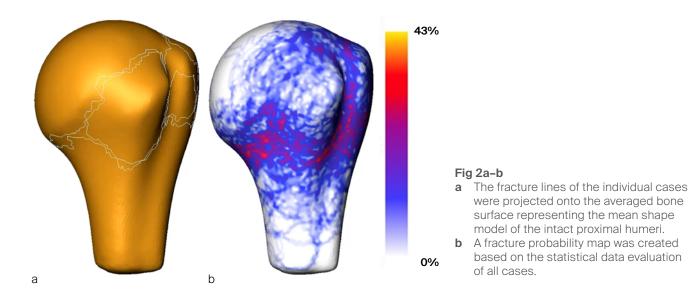
Preoperative clinical computed tomography (CT) datasets of 51 patients with three- or four-part proximal humeral fractures and intact contralateral side were collected retrospectively (Fig 1a). The fracture lines and fragments were identified semi-automatically on the CT images using advanced custom developed image

processing tools (Fig 1b). Following identification, the fragments were virtually reduced by solving the 3D puzzling problem and applying the mirrored intact contralateral side as template (Fig 1c). A statistical shape model of the proximal humerus was built for this cohort of patients utilizing homologous landmarks. All individual fracture lines were projected on the averaged bone surface (Fig 2a) and their spatial variability was evaluated to indicate the most probable locations of fracture patterns (Fig 2b).

The zones with highest fracture probability were identified, demonstrating a considerable scatter of the spatial distribution of fracture patterns. Enlarging the dataset with clustering of the cases is expected to provide further insights into the morphology of proximal humeral fractures that in turn can be used to design advanced implant fixation systems.



**Fig 1a-c** Clinical computed tomography images of complex proximal humeral fractures cases (a) were segmented to identify the fragments (b) that were virtually reduced to their respective anatomical locations (c).



Ivan Zderic, Peter Varga, Ursula Styger, Ludmil Drenchev, Boyko Gueorguiev, Erik Asimus, W Brian Saunders, Michael Kowaleski, Randy J Boudrieau, Loïc M Déjardin

# Mechanical evaluation of two hybrid locking plate designs for canine pancarpal arthrodesis

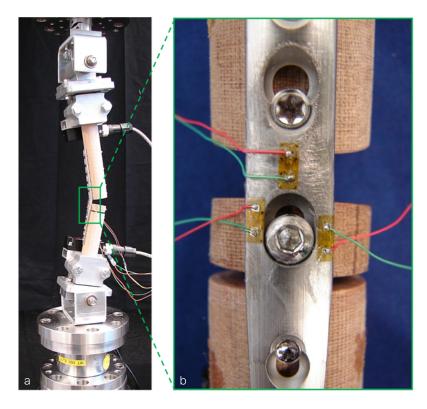
Pancarpal arthrodesis is a well-established procedure for treatment of canine carpal disorders including hyperextension injuries, severe fractures or luxations, end-stage osteoarthritis, and selected neurological deficits.

Two new hybrid locking pancarpal arthrodesis plates have recently been developed featuring a tapered profile and incorporating either a round (RH) or oval (OH) radiocarpal hole (Fig 1). The OH design was considered to facilitate both screw placement in the radiocarpal bone and plate positioning, but perhaps at the expense of mechanical strength. So far, neither mechanical comparisons between these plate designs have been performed nor the effect of an oval radiocarpal hole on the plate structural parameters investigated. The aim of this project was to compare the mechanical behavior of the two hybrid locking pancarpal arthrodesis plates under quasi-static and fatigue loading.

Plates with RH or OH design were prebent at 20° and assigned to three techniques for fixation of canine forelimb models with simulated radius, radiocarpal and third metacarpal bones. The OH plates were instrumented with the radiocarpal screw inserted either most proximally (OH-P) or most distally (OH-D) in the radiocarpal hole. Initially, all specimens were axially loaded to 300 N over 10 ramped cycles at 0.5 Hz (n = 6) and plate surface strains were measured with strain gauges placed at the areas of highest deformations as predicted by finite element analysis (Fig 2). The specimens were then subjected to cyclic axial loading at 8 Hz and 320 N peak load until failure to assess their fatigue life and mode of failure.

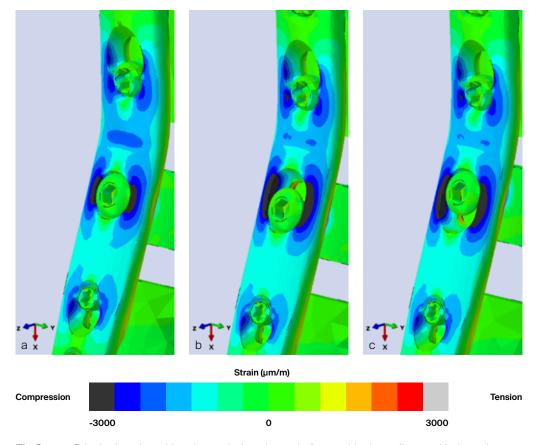


**Fig 1** Limited-contact hybrid locking pancarpal arthrodesis plates 2.7/3.5 with round (top) and oval (bottom) radiocarpal hole, 151 mm length.



**Fig 2a-b** Test setup with a specimen mounted for mechanical testing (**a**). Magnification (**b**) shows a construct with radiocarpal screw placed in the distal aspect of the oval plate hole (OH-D) and applied strain gauges at the weakest locations as predicted by finite element analysis—the plate bending point, and adjacent to the occupied and unoccupied radiocarpal hole regions. The finite element analysis predicted highest strains adjacent to the radiocarpal hole and the plate bending point (Fig 3). Experimentally, peak radiocarpal hole strains were not influenced by the OH screw position (P = .550) but were significantly higher compared with the RH design (P < .001). Peak strains at the bending point were significantly lower for both OH-P and OH-D versus RH configurations ( $P \le .006$ ). The OH plates demonstrated highest peak strains next to the radiocarpal hole and were associated with more heterogenous plate surface strain distribution. Cycles to failure were higher for RH plate fixation versus both OH-P and OH-D plate configurations, reaching significance versus OH-D (P = .030). No significant difference was detected between the OH-P and OH-D configurations (P = .090).

The radiocarpal oval hole design was associated with increased plate strains and lower cycles to failure compared with the round hole design. However, it can provide surgeons with more options regarding plate and screw positioning in dogs of smaller size.



**Fig 3a-c** Principal strains with color-coded strain-scale (bottom) in the radiocarpal hole region and at the bending point under 300 N axial compression, presented for round hole (RH) (**a**), screw insertion at distal margin of oval hole (OH-D) (**b**), and screw insertion at proximal margin of oval hole (OH-P) (**c**), indicating a lower strain magnitude next to the RH and a higher strain magnitude at the bending point, both compared with OH-D and OH-P.

### Design and implementation of the online AO Trauma Basic Principles Essentials course

The Covid-19 pandemic has changed the way we think about and deliver education. With the cancellation of faceto-face (F2F) courses, innovative ways to provide education to learners were required. The AO Education Institute (AO EI), together with the Residents Education Taskforce, stepped up to the challenge by creating AO Trauma's first completely online asynchronous course—the Basic Principles Essentials.

In a first step, the various teams within the AO EI (curriculum and faculty development, eLearning, video, and publishing) gathered to define the key elements and requirements for an online asynchronous course. The goal was to provide residents worldwide the possibility to continue learning and training at their own pace and place.

By combining the aspects of a competency (Fig 1) that can be delivered online with Miller's pyramid of educational outcomes (Fig 2), the decision was to focus on the core 'knows' and 'knows-how' components of the Basic Principles curriculum. Thus, we selected lectures, practical exercise videos, and Touch Surgery simulations for this course. The lecture recordings were produced by expert faculty using the Kaltura Capture software supplied by the AO El video team (Fig 3).

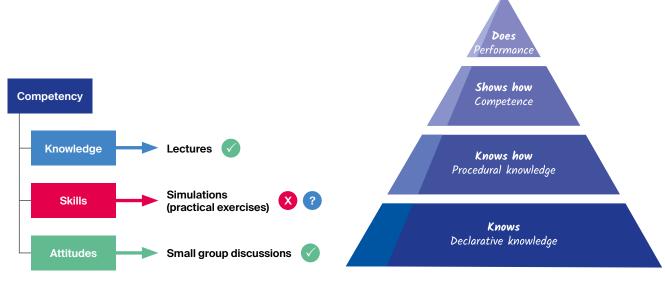


Fig1 Aspects of a competency that can be delivered online.



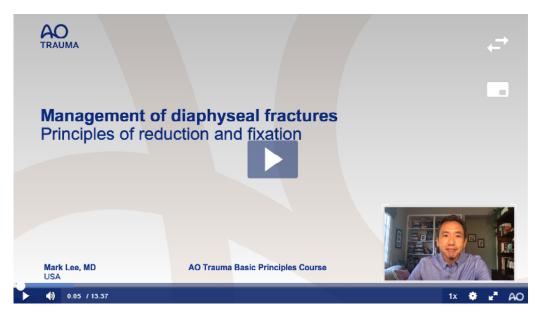


Fig 3 Example of a recorded lecture using Kaltura Capture.

This course was also an opportunity for the eLearning team of the AO EI to run a test-trial cycle of the new Learning Management System (LMS) of the AO Foundation, Totara–a Moodle-based LMS (Fig 4). The content of the course was organized in a modular approach, following a sequence like a F2F course. Participants were required to complete specific activities within a module before proceeding to the next. To successfully



complete the course, participants were expected to finish 80% of the course content.

To ensure interactivity within the course, a dedicated discussion forum was established for each module, as well as a general discussion forum for faculty and participant introductions and to exchange information outside of the course.

A pilot of the Essentials course was conducted in June 2020 with 100 participants from all AO Trauma regions. Participants had 4 weeks to complete the course, which was continuously monitored and evaluated, and feedback interviews with selected participants were conducted after the course. The success and demand for such an educational offering led to the first course in July/August 2020, with 250 participants. This course was fully booked within a few days of opening.

These two courses had a completion rate of about 80%. Postcourse evaluation and feedback data were collected from 230 participants. The course was well received and 91% of participants found the content to be very or extremely useful, and 100% would recommend this course to their colleagues. Although the learning objectives of the online and F2F course are slightly different, the overall evaluation results were similar, indicating a successful transfer to an online format (Fig 5).

This collaborative work of the AO EI, surgeon faculty, and AO Trauma is a classic example of disruptive innovation at work. The pandemic condition compelled us to 'think outside the box' and we come up with innovation education solutions that meet the current needs of residents. As of January 2021, this course is offered on a 6-weekly rolling basis by AO Trauma and was the stepping stone to building other online and blended educational offerings.

# To what degree were the stated objectives met?

(Pilot n=60, first course n=170)

Fig 4 Course structure in Totara.

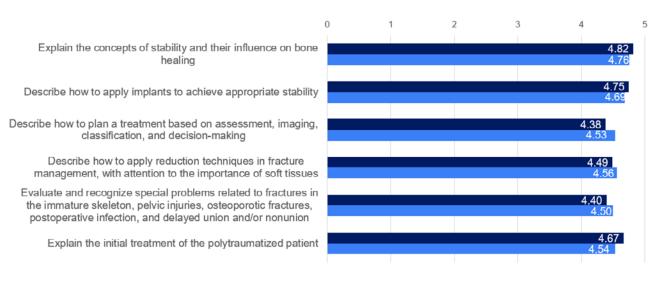


Fig 5 The course objective rating for pilot and first course were highly rated by participants.

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