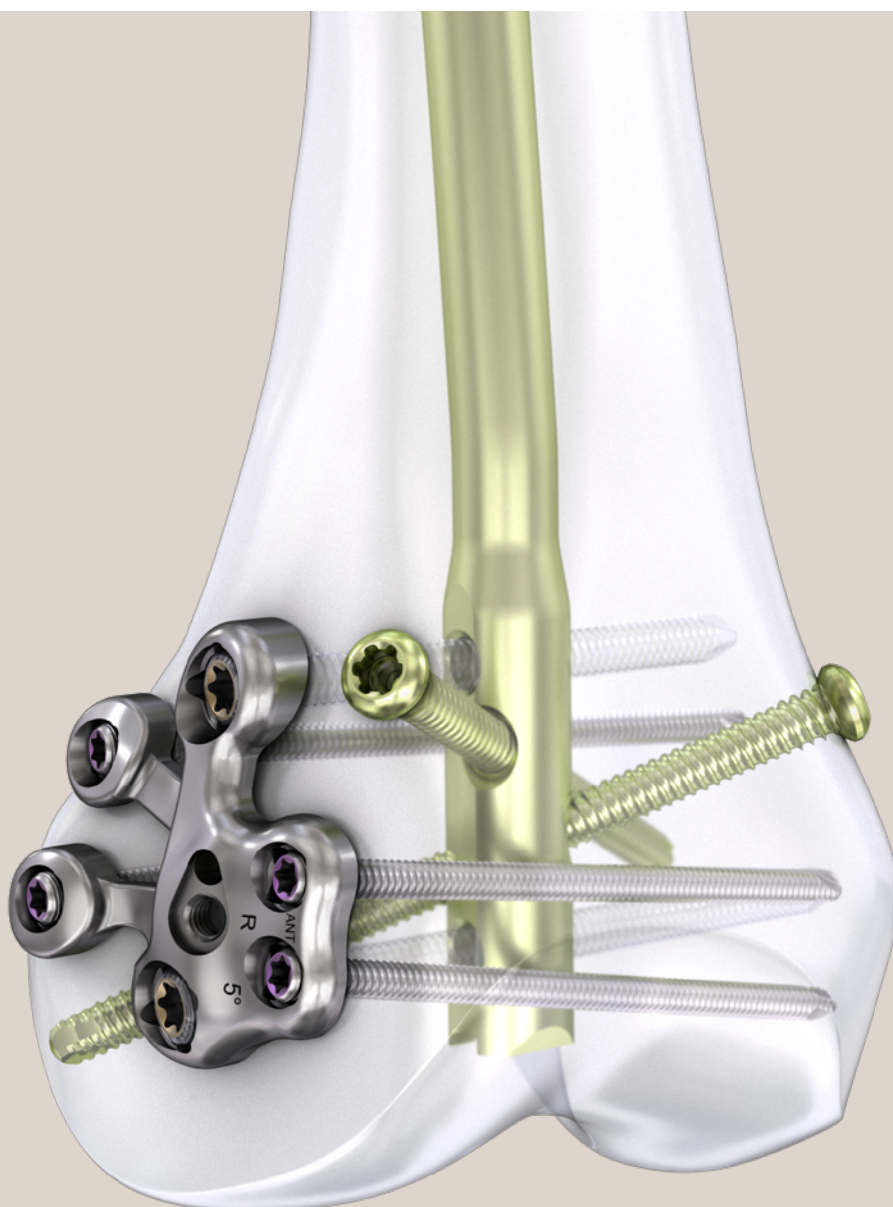


Innovations 2020





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Editorial

Dear reader,

Welcome to the 2020 edition of *Innovations* magazine. Following the successful launch of the AO Innovation Translation Center (AO ITC) in March 2020, this magazine now covers not only the new developments from the AO Technical Commission (AO TC) but also the innovation activities of the Technology Transfer, Clinical Operations, and Clinical Science units.

The AO ITC is the AO's new innovation hub. By bringing different AO innovation units under one roof, silos are broken down and ideas flow more freely. Under the leadership of Claas Albers, the AO ITC explores and channels innovative ideas from the AO global network to realize their full potential, thus generating value according to the AO's core mission. Innovation translation at the AO ITC encompasses the conception and development of clinical solutions and the creation of scientific evidence to prove the added value of new solutions. Full details on the goals and key activities of the AO ITC can be found in the article "The AO Innovation Translation Center: strengthening innovation within the AO". The information therein also contains an overview of the various opportunities to transform your ideas into clinical reality in collaboration with the AO ITC.

AO Technical Commission

The AO TC is delighted to inform you that despite the COVID-19 pandemic, the development of several new products has been finalized. We are profoundly grateful to all our AO TC members for their dedication and flexibility to drive projects forward through numerous videoconferences—time zone differences notwithstanding. Anatomy Labs, which are so fundamental for our development work, were organized at short notice by finding regional solutions under the constraints of ever-changing travel restrictions. We are also grateful to the AO Research Institute Davos for providing the environment to realize such labs. The challenges we face during this pandemic have once more demonstrated how strong the AO family is.

Do familiarize yourself with the various innovations in Trauma, Spine, CMF, and Vet in this magazine; they are the results of the dedicated work of our AO TC surgeons. We would like to draw your attention to the new retrograde femoral nail, which offers for the first time the unique possibility to connect a washer-like locking plate to a nail in an angular stable manner for enhanced fixation at the distal femur. The new tibia nail with inlays for angular stable locking and new interlocking screws for reduced soft-tissue irritation are further innovations to advance fracture treatment by intramedullary nailing. This magazine also contains several articles from the AO Research Institute Davos, our close partner in generating preclinical evidence for treatment solutions.

Clinical Operations

With the ultimate goal to provide our clients with clinical data of the highest quality, the clinical evidence at AO ITC is generated in accordance with the industrial standards for clinical studies (ISO14155 and International Council for Harmonisation, Good Clinical Practice).

Clinical Operations on one hand investigates, selects, trains, and monitors the participating study sites, and on the other communicates frequently with regulatory authorities to secure ethics approvals and ensures the adherence of their guidelines. The team of clinical research specialists at the Clinical Operations conducts clinical studies following the standard operation procedure dictated in our Process Management System. Clinical Operations routinely conducts multicenter studies involving clinics around the world, while ensuring consistent adherence to the study protocols. With the implementation of a new digital clinical trial management system (CTM) system in 2020, Clinical Operations looks forward to further improving its efficiency in conducting clinical studies.

Clinical Operations currently has 54 ongoing clinical studies in collaboration with both internal and external clients.

Clinical Science

With a team of data managers, physicians, medical statisticians and statistical programmers, and medical writers, 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.

Aside from providing internal services in methodological, statistical, literature, and regulatory support of clinical studies, Clinical Science has been the driving force behind the newly launched AO Global Data initiative. With AO Global Data, AO offers surgeons an innovative approach to gather valuable patient insights. By doing so, AO Global Data enhances the clinician-to-patient dialog, provides real-time feedback on patient recovery, and allows comparison of patient outcomes. Additionally, it enables the collection of device-related data (eg, data about implants), which, together with patient outcomes data, can support and drive innovation. For additional information see also the interview with Simon Lambert about AO Global Data.

Technology Transfer

As part of the AO ITC, Technology Transfer helps drive the development and acquisition of innovative solutions to advance patient care in trauma and musculoskeletal disorders. The AO offers inventors and product developers a pathway to transform

their ideas from benchtop to bedside through funding, expert knowledge, proof-of-concept, clinical validation, and valorization.

The Technology Transfer Board evaluates close to 100 project proposals annually, and the Strategy Fund Committee received more than 70 applications in the last call for proposals. Currently, the Development Incubator supports a portfolio of six projects, and Strategy Fund supports eight projects. These projects cover a broad scope, ranging from topics such as smart implants, robotics, and tissue engineering. In this magazine two innovative approaches to improve patient treatment are presented: a new implant concept which provides controlled fracture motion (Biphase Plate) and a robotic system for sacroiliac luxation/fracture reduction and fixation.

The newly created AO ITC strengthens the AO's position as the premier institution to advance orthopedic surgery by integrating solution development, evaluation by clinical experts, innovation valorization, and evidence creation. The formation of the AO ITC ushers in a new chapter of the AO's aspiration in the patient-centric innovation translation of musculoskeletal treatments. We invite you to dive into this issue of *Innovations* magazine and we look forward to your feedback and further partnership in improving treatments in orthopedics and traumatology.

Yours sincerely,



Daniel Buchbinder
Chair AO TC Executive Board



Michael Fehlings
Chair AO Clinical Research Review
Commission



Michael Schütz
Chair Technology Transfer Board



Tim Pohlmann
Member AO Foundation Board
MedTech Development

The AO Innovation Translation Center: strengthening innovation within the AO

2020 saw the realization of a new approach to foster innovation within the AO by the creation of a new AO innovation hub—the AO Innovation Translation Center (AO ITC), which comprises four business units: the AO Technical Commission, Clinical Operations, Clinical Science, and Technology Transfer. The AO ITC brings together AO teams engaged in innovation, streamlines the process, and makes innovation translation at AO more efficient and agile.

Innovation translation at AO encompasses the conception, strategic evaluation, and development of clinical solutions in collaboration with industrial partners. It includes proof-of-concept work with innovators, valorization of new technologies and techniques and clinical evidence creation to prove the added value of new solutions. Strategic investments in intellectual property, technology, and companies are also part of AO ITC’s mandate. At the center of all innovation is AO’s global network of surgeons and other healthcare providers who contribute ideas and expert guidance at all stages of development. Throughout the process, the AO ITC provides the 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.

Structure of the AO ITC

Four complementary competence areas (innovation clearing, clinical expertise, clinical evidence, and innovation valorization)

are embedded in a process-driven matrix under four business units (Fig 1) which are responsible for the realization of innovation projects and serving internal and external partners. The creation of the AO ITC allows quicker evaluation of new concepts from innovators, harmonizes budgeting processes, and reduces administrative hurdles.

Key activities according to competence areas

1. Clinical expertise

The AO ITC places expert clinical guidance from leading surgeons at the center of the innovation translation process, covering all relevant areas of trauma, spine, craniomaxillofacial, veterinary, and other surgical fields as required (Fig 2). Dedicated groups of key opinion leaders define unmet clinical needs and identify the best solutions to address these needs in line with the overall AO strategy. The development of clinical solutions is executed by close collaboration between expert surgeons and selected industrial partners.

Surgeons engaged in the AO ITC also support the AO’s endeavor to provide education for new surgical techniques through the creation of educational materials and may participate as course faculty. Approval by the AO Technical Commission serves as a prerequisite for new technologies to be taught in surgical courses organized by the AO’s clinical divisions.

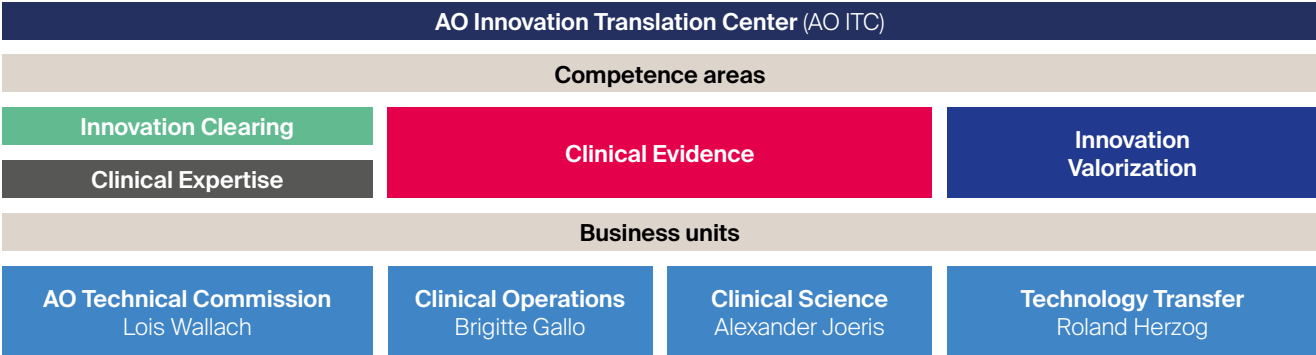


Fig 1 Organizational structure of the new AO Innovation Translation Center.

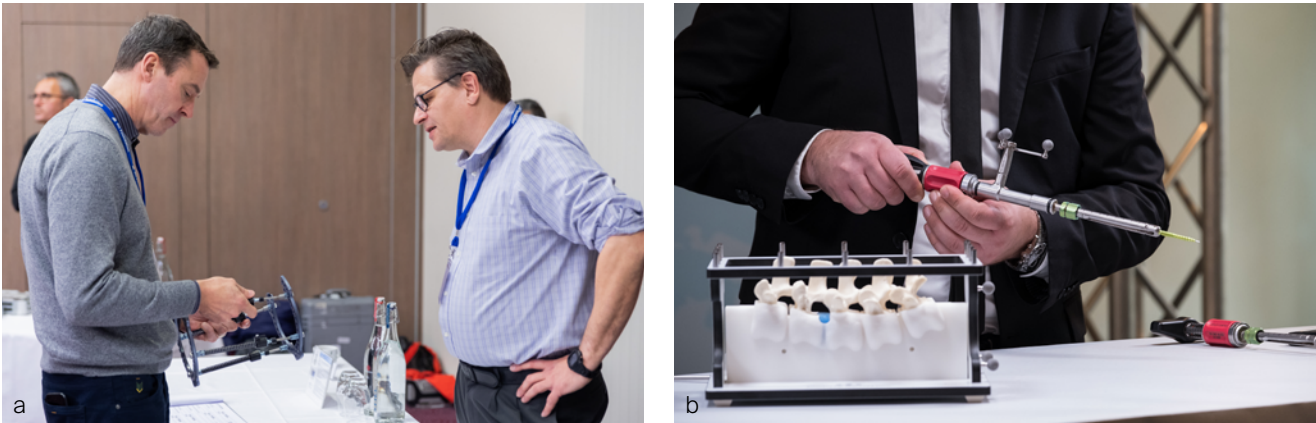


Fig 2a–b The AO Technical Commission at work: medical experts provide clinical guidance throughout the development process for new solutions.

2. Innovation clearing

The expert surgeons monitor major innovation activities within their areas of expertise, define the most feasible methods to realize new concepts, and determine the evidence creation strategy for each project at its inception (Fig 3). To ensure high-quality solutions to clinical problems, innovation clearing at the AO ITC follows a dedicated development process including the definition of clinical needs, assessment of new concepts, priority setting, implant and instrument design,

preclinical and clinical evaluation, and eventual approval. Regular communication between the AO Technical Commission and the AO's industrial partners allows effective sharing of opinions and alignment of priorities to realize new collaborative projects. Following market release, the clinical performance of new solutions is reported in Expert Symposia where groups of surgeons of all levels of experience meet regionally and review good and bad clinical cases using new technology.



Fig 3a–f Expert group meetings conducted by the AO Technical Commission: sharing opinions and strategies for new collaborative projects.

3. Clinical evidence

All AO ITC projects are firmly grounded in clinical needs and are compatible with AO's philosophy of evidence-based treatment development. Each new solution must provide measurable benefits for patients and physicians and improve the healthcare landscape. Aside from the exploration and validation of new technologies during product development, with the launch of the new European medical device regulation, high-quality clinical evidence becomes ever more essential in the development and post-market surveillance of medical devices.

The AO ITC's clinical evidence competence is based on the expertise of two in-house clinical research units, Clinical Operations and Clinical Science, which operate in compliance with a Process Management System based on the ICH GCP (Good Clinical Practice) and ISO 14155. At the outset of a clinical project, the Clinical Science team collaborates closely with the lead surgeon (and representatives of an external partner, if applicable) to generate an appropriate study protocol with optimal design and statistical considerations so as to lay a firm foundation for

high-quality clinical data. The Clinical Operations team ensures the faithful execution of study protocols through compliance with the state-of-the-art operational standards and applicable ethical guidelines to select, train, and monitor participating clinics. At the end of a clinical study, the Clinical Science team conducts data analysis, reporting, and publication in peer-reviewed journals to ensure dissemination of the knowledge. Close collaboration of these two units and their teams of specialists ensures that the AO ITC can support both internal and external partners with their regulatory and clinical research needs. Early involvement of Clinical Science and Clinical Operations ensures the delivery of high-quality clinical evidence with sound scientific methodology (Fig 4).

Aside from offering services in database management, statistical analyses, and medical journalism, Clinical Science and Clinical Operations also contribute toward the development of young surgeons into future clinical researchers. Team members of these two units host clinical research fellows in the Dübendorf office and conduct the GCP course under [AO PEER's](#) auspices.



Fig 4a–d Staff from Clinical Operations and Clinical Science at work, supporting evidence-based solution development.

4. Innovation valorization

Innovation valorization at the AO ITC encompasses business intelligence gathering, idea consolidation, and market research. On behalf of the AO Foundation Board, the Technology Transfer team performs these tasks and manages dedicated AO innovation funds, consisting currently of the Development Incubator and Strategy Fund, as well as projects derived from these funds. Headed by Michael Schütz, the Technology Transfer Board guides all innovation valorization activities and includes experts in areas such as business development, start-up companies, financing, and medical device research and marketing.

The Technology Transfer team aims to support inventors in product development through a well-structured pathway that transforms ideas from benchtop to bedside. Funding, knowledge leadership, expert insight, proof-of-concept, clinical validation, and valorization are all parts of this pathway, which ultimately leads to commercially viable products (Fig 5). Along this pathway, the team also helps to identify, attract, and negotiate with suitable commercial partners to ensure the eventual commercialization of the projects through either licensing or selling of assets derived from them.

In areas deemed strategically important to AO, the AO ITC may propose investment with partners needed to achieve the mission of the AO. These strategic goals may include innovation leadership in orthopedic technology to address unmet clinical needs, and leadership in education solutions for the global orthopedics community.

The Technology Transfer unit regularly publishes calls for proposals for the Strategy Fund and Development Incubator. Proposals are evaluated in cooperation with experts from the AO community to make sure that real clinical needs are covered. To see examples of current Technology Transfer projects, refer to the articles on the Biphasic Plate and the Robotics System.

Synergy at work

Since its launch in March 2020, the AO ITC has improved the efficiency of the innovation workflow within the AO. New concepts for surgical solutions are evaluated by expert surgeons and are allocated to the appropriate development pathway, whether with the AO's primary industrial partner DePuy Synthes (DPS), the Development Incubator, or with other carefully selected industrial partners. Importantly, evidence creation is

planned and initiated at the outset of every new project. This workflow crosses the previous boundaries of the AO Technical Commission, AO Clinical Investigation and Documentation, and the AO Development Incubator.

Since 2015, the AO Technical Commission has been able to realize development projects with alternative industrial partners in the event of a project proposal being declined by DPS and following approval by the AO Foundation Board. Expertise from the Technology Transfer unit in the areas of market evaluation and business planning has been invaluable in the development of robust business cases for these "off-ramp" projects. Additionally, selected project proposals declined by DPS are currently under evaluation by the Technology Transfer Board for potential development via the Development Incubator pathway. During the evaluation process, key opinion leaders from the AO Technical Commission's network provide expert insight to inform project shortlisting.

Voice of customer data is of increasing importance in the modern healthcare environment to support new product development. The creation of the AO ITC has enabled the AO Technical Commission to leverage the Clinical Evidence team's expertise in data gathering and analysis to create surveys for distribution to the surgeon network, both to evaluate market trends and clinical needs and to monitor the performance of newly launched products.

In keeping with the coming of the big data age, the AO ITC is the driving force behind the AO Global Data initiative. Transcending traditional registries, this initiative brings together advancements in computer science and the AO's leadership and integrity to incorporate clinical data from the AO's global network into benchmarked data sets. These are relevant to not only researchers and clinicians but also to healthcare providers and the medical device industry. Only the AO and the AO's network of surgeons can offer such unique, unbiased, evidence-based information for trauma and musculoskeletal disorders ([link to AO Global Data](#)). As a valued part of the AO network, our expert surgeons play a vital role in making the AO's voice heard globally.

The creation of the AO ITC has opened new pathways and opportunities for the development of cutting-edge surgical solutions and strengthens the AO's position as the premier institution to improve patient outcomes in the treatment of trauma and musculoskeletal disorders.

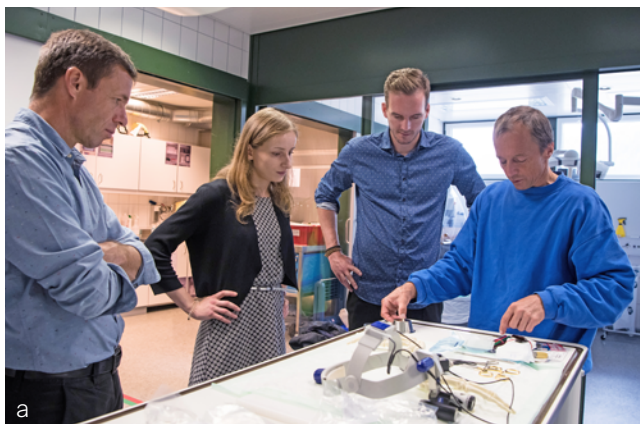


Fig 5a–b Technology Transfer supporting the proof-of-concept development of an innovative small external microfixator.

AO expertise coupled with SPI's innovative technology—potential to transform the future of surgery

Goal

Over decades, the AO and its members have developed vast knowledge concerning best practice in trauma and orthopedic surgery. Currently, this extensive knowledge is transferred to the community via educational events, publications, and AO Surgery Reference. Now, our partnership with the Surgical Process Institute (SPI) generates the unique opportunity to make this expertise available directly in the operating room (OR), supporting surgical teams to consistently achieve optimal results.

Background

SPI was established in 2008 in Leipzig, Germany, and is part of Johnson & Johnson Medical Devices Companies. SPI's purpose is to create a world where every patient has access to consistent high-quality care, no matter where, when, and by whom the surgery is performed. Reducing variability in surgery is considered crucial to achieve this vision. SPI offers a digital platform that is designed to reduce variability in the OR, supporting care teams during surgery, synchronizing workflows to enhance teamwork, coordination, and collaboration.

Combining synchronized workflows, real-life learning and real-time insights, SPI's platform supports care teams to operate in a synchronized way, aiming to help surgeons and hospitals to deliver consistent high-quality care and efficiency in their OR.

Synchronized workflows: choreograph the OR with digital surgical workflows

The step-by-step definition of what needs to be done bears a tremendous value for all team members in the OR. SPI provides an intuitive digital platform that allows care teams to design and implement their own step-by-step surgical workflows. These workflows are synchronized with adjacent processes and can be enhanced with important safety checks, surgeon notes, pictures, or videos. During surgery, the synchronized workflows are powered by SPI's digital platform and displayed on dedicated screens in the OR. The surgeon confirms when each step has been completed and thus guides through surgery with the system supporting the entire OR team in real time. While the surgeon is focused on the current step, the scrub nurse and other team members can focus on the next steps and anticipate accordingly.

The system does not restrict the medical freedom (surgeons and their teams can always deviate from the pre-defined workflows designed to support them) and can accommodate multiple surgical approaches and preferences through its modular technology. Intraoperative events can also be documented during surgery.

Right after surgery, the system automatically generates a digital operative report that documents the workflow followed step-by-step. The report fields can be customized as required and pictures can be automatically imported and are linked to the right step in the surgical workflow. With a few clicks, the operative report can be reviewed, edited, printed, or sent to the hospital information system.

Real-life learning: support training and onboarding of new team members with step-by-step digital workflows

Structured surgical workflows can be accessed any time for training and educational purposes, aiming to accelerate the learning curve of resident and novice surgeons with steps, descriptions, imagery, and voice over available intraoperatively to support real-life learning. In addition, scrub nurses and residents and new team members can all study the surgeons' procedural approach in advance of an upcoming case.

Real-time insights: track, analyze, and interpret surgical performance

The surgeon and surgical teams have access to detailed case summaries and corresponding analytics that can provide insights on surgical performance. Surgical teams can also compare their performance to a benchmark for improvement, compare different surgical approaches and techniques to optimize their surgical performance and design targeted training plans.

SPI transforms the surgical experience by supporting care teams to operate in a synchronized and coordinated way, enabling surgeons and hospitals to deliver a consistent, high-quality care and efficiency in their OR.

Partnership

The AO Foundation and SPI have entered into a partnership with the aim to transform the surgical experience and promote excellence in patient care by combining AO's immense surgical expertise and proven standards with SPI's innovative technology to deliver best-practice workflows and support surgeons and surgical teams directly in their ORs.

In the past year, AO and SPI jointly defined and executed a pilot project with the objective to assess the applicability of AO standards with SPI's technology, and to identify variability in surgical performance among the participating centers. The AO standards, as defined in the AO Surgery Reference, of three crucial surgical procedures (malleolus, proximal femur [PFNA/TFNA], and distal radius) were transcribed and digitized into digital surgical workflows powered by SPI's technology. This technology along with AO workflows were implemented at four hospitals involving surgeons from the AO Technical Commission (AO TC) and their teams:

- Prof Paul Grützner, Berufsgenossenschaftliche Unfallklinik Ludwigshafen, Germany
- Prof Meir Liebergall, Hadassah Medical Center Jerusalem, Israel
- Prof Michael Raschke, Universitätsklinikum Münster, Germany
- Prof Florian Gebhard, Universitätsklinikum Ulm, Germany

All pilot sites made extensive use of SPI's digital platform with more than 200 live trauma procedures performed in just a few months. The results of the pilot project along with the user feedback from surgeons and nurses have been positive and encouraging, highlighting the value of AO workflows combined with SPI technology to support surgical teams real-time and confirming the potential of the AO and SPI transforming surgical experiences.

Building on this successful first year of collaboration, the AO and SPI are expanding their partnership and will jointly extend the offering of AO-approved workflows with the intention to make these workflows globally available, spanning all vital indications in trauma, spine, and craniomaxillofacial.

Involvement of the AO Innovation Translation Center

In a cooperation between the AO ITC's technology transfer and the AO TC, members of the latter are currently tasked on identifying key procedures where the availability of AO digital workflows will be most helpful, such as procedures with novel surgical techniques and approaches, where innovative and

new technologies, implant and instrument systems are used, and also high-volume procedures when a standardized approach is important.

One of our top priorities is to use the expertise available in our network to support the creation of an extensive collection of AO-approved workflows. The AO workflows will be designed so that they can be personalized to fit each clinic's unique setting and needs. Besides addressing educational requirements, the AO TC contributes once more to AO's mission by enabling the digitalization of the OR and promoting excellence in patient care and best outcomes in trauma and musculoskeletal disorders.



Figure Dedicated screen in the operating room (OR) guides and supports the entire OR team in real time through a surgery via the Surgical Process Institute (SPI) digital platform.

Portrait: Christina A Kabbash



Fig 1 Christina A Kabbash.

Christina A Kabbash is an orthopedic surgeon with specialization in foot and ankle surgery (Fig 1). Due to her expertise she is medical member of the Lower Extremity Global Expert Committee and the Foot and Ankle Expert Group of the AO Technical Commission.

Christina was born in Philadelphia, Pennsylvania, in 1968, and grew up in Old Saybrook, a small coastal town in Connecticut. After graduating from medical school at Columbia College of Physi-

cians and Surgeons in New York City, her initial plan was to join the Centers for Disease Control and Prevention (CDC), travel the world, and fight tropical diseases. She pursued a Master of Public Health and a medical degree simultaneously at Columbia University. To acquire research experience, she also worked in a laboratory investigating possible cures for bacterial infections and became so captivated by the research that she enrolled in the school's MD/PhD program. Wearing a "spacesuit" while handling the life-threatening tuberculin bacteria, she and her colleagues discovered a drug that killed all the drug-resistant strains of tuberculosis tested in the laboratory by a different mechanism than existing antibiotics. However, they could not get the industry enthusiastic about the compound. Still, she ended up with a PhD in cellular, molecular, and biophysical studies at Columbia University, and having her name on three patents.

Christina met her first husband in college, and they married in 1991 during the summer between her first and second year of medical school. They decided to have children, which meant she would not be traveling around the world, nor living in foreign countries for long periods, nor studying tropical diseases. Instead, during a third-year medical school rotation in orthopedics, she was fascinated with that specialty and switched tracks. She appreciated the variety of cases, the ability to fix a multitude of problems, improving patients' lives, and enjoyed all the equipment and tools available to accomplish this.

In 2007 she returned to Connecticut to join the Saint Francis Hospital and Medical Center staff at Greater Hartford Orthopedic Group. She still managed to travel the world, working for a period in Dubai while her daughter was studying there, and teaching foot and ankle orthopedic courses in destinations as far as Australia. As a member of the AO Trauma Foot and Ankle Education Task Force from 2011 to 2014 she was developing and producing teaching material for the AO Foot and Ankle Courses and served worldwide as international faculty for AO Foot and Ankle Master Courses. In 2018 she moved with her second husband to Naples in Florida and joined the Physicians Regional Medical Group. Here she found a better climate for her passion, which is swimming, biking, and running as an elite triathlete. She trains rigorously, averaging between 12 and 14 hours per week, and it would not surprise anyone knowing her that she has already run an early morning half marathon before she would start working in the clinic, teaching in an AO Course, or helping to develop new technologies in an AO Technical Commission Expert Group meeting. She qualified for the nationals in the Olympic distance category in 2016 and has completed several Ironman races (Fig 2). No wonder she is also experienced in treating sports athletes, as she is familiar with their demands. One of the benefits of treating athletes is that they tend to be fairly compliant because they are motivated to get back to their sports. In fact, in her experience this applies to most orthopedic patients because they know what it is like to be injured and they would like to get back to their preinjury functional status.

Christina is not only drawn to foot and ankle surgery because of its intricate nature but also because of the variety of cases. Even when doing eight surgeries in a row, none is the same. She is also grateful that she can sit while performing surgery (Fig 3).

During her residency, she spent a year as the only woman after her fellow female students graduated. It was then that she learned the value of having female coworkers to simply hang out with. Without that, she was missing out on valuable information shared informally. You need people to talk to, to bounce ideas off and to discuss issues with, she would say, and it is really nice having other women in a similar field who understand what the problems are. Currently, there are not too many women in her position.



Fig 2 Dr Kabbash is an elite athlete.



Fig 3 Dr Kabbash is a highly motivated surgeon.

Advanced Nailing System

The Intramedullary Nailing Expert Group (INEG) and DePuy Synthes (DPS) have been working on a comprehensive lower extremity nailing platform—the Advanced Nailing System. As the first part of this system, the TFN-Advanced Proximal Femoral Nailing System was launched for treatment of trochanteric fractures in 2014 (*Innovations magazine*; 2015). Four years later, the AO Technical Commission Trauma (AO TC Trauma) approved the FRN-Advanced Femoral Recon Nailing System comprising nails for fixation of femoral shaft fractures via the piriformis fossa as well as greater trochanter entry portals (*Innovations magazine*; 2018). We are happy to report that the portfolio of the Advanced Nailing System has been completed by the development of two further innovative nailing systems: TN-Advanced Tibial Nailing System and RFN-Advanced Retrograde Femoral Nailing System.

TN-Advanced Tibial Nailing System

Defining the clinical problem

In 2016, the medical members of the INEG thoroughly reviewed the clinical performance of the Expert Tibial Nail System (available since 2005) to identify the most important aspects that had to be addressed by a next generation tibial nailing system for improved patient care. Review findings were supported by discussions at the AO TC Trauma Experts' Symposia, verified by published literature, and confirmed by field studies as well as surgeon interviews conducted by DPS.

The following outcome-related problems were identified for tibial fracture treatment:

Delayed union, nonunion, and malunion

Intramedullary nailing (IMN) is the most popular and widely used method for treating tibial shaft fractures. From a biomechanical perspective, the nail is a central, load-sharing implant that provides high stability to support early postoperative patient mobilization. This device specific benefit, together with the advantage of the soft-tissue sparing instrumentation, guided surgeons to expand their nailing indications into the metaphyseal zones of the tibia. While plate fixation is decreasing, IMN is becoming increasingly popular for proximal and especially distal tibial fracture fixation.

Expanding the nailing indications toward metaphyseal tibial fractures results in the challenge to fix short bone fragments with adequate stability to promote bone healing and to avoid secondary loss of reduction. This challenge is pronounced in diminished bone quality, the occurrence of which is increasing because of the aging population. A multicenter study with the Expert Tibial Nail from DPS revealed a 12.2% rate of delayed union at 1 year [1]. A nonunion rate of 12% was reported for reamed IMN in a single-center study with 1003 patients [2]. A systematic review and metaanalysis of IMN versus minimally invasive plate osteosynthesis for distal tibial fractures resulted in a 14.8% malunion rate for nailing, which was significantly higher than the 8% malunion rate for plating [3]. All these numbers emphasize the importance to increase the fixation stability provided by IMN to avoid complications and to reduce the reoperation rate.

Patient pain and discomfort

In a recent retrospective observational study [4], 27% of 126 patients treated with a tibial nail described pain attributed to locking screws at follow-up. Interlocking screw prominence is a frequent reason for soft-tissue irritations that may require screw removal in a secondary intervention. Contributing factors for soft-tissue irritations are bad soft-tissue coverage (particularly around the distal tibia and in elderly patients), imprecise screw length measurement, and the size/design of the interlocking screw head and tip.

There are further procedure-related aspects that had to be addressed in the development of a new state-of-the-art tibial nailing system:

Anatomical nail fit

It is essential that the nail design is optimized to fit most of the anatomical variations of the tibial canal. Adequate nail fit is essential to facilitate implant placement and to avoid deformities or iatrogenic fractures due to nail insertion. So far, surgeons have used the cannulated Expert Tibial Nail which has been provided in two different nail design versions: (1) nail with 10.5° bend starting at 75 mm proximally with a radius of 376–1128 mm depending on the nail length; (2) nail with 10.5° bend starting at 65 mm proximally with a fixed radius of 100 mm and a 3° tip bend starting at 57 mm distally (called 'Expert Tibial Nail with Proximal Bend'). The latter has been used more frequently, especially for the treatment of proximal tibial fractures. During the development of a next generation tibial nail following questions had to be addressed: (1) Is there a more optimal nail design? (2) Is one nail design sufficient or is it required to offer two different nail designs with the inherent portfolio complexity?

Usability aspects

Implant systems should be easy and intuitive to use and to support consistent outcomes by reproducible instrumentation. Surgeon feedback is that some instrumentation steps of the Expert Tibial Nail are perceived as complex. Angular stable locking of the Expert Tibial Nail with the Angular Stable Locking System (ASLS, launched in 2010) is an example. This system requires dedicated ASLS screws, bioresorbable ASLS sleeves, and special instruments to achieve angular stable connections between the locking screws and the nail. The procedural complexity of ASLS contributed to the clinical demand for an easier angular stable locking solution.

Instrumentation for different surgical approaches

The infrapatellar approach in a flexed knee position is regarded as the standard approach for IMN of tibial fractures. However, approaches for semi-extended knee positioning are rapidly gaining popularity: intraarticular suprapatellar approach and extraarticular parapatellar approach. They can improve the surgeon's ability to obtain, maintain, and with image intensification evaluate fracture reduction, especially in proximal and distal tibial fractures [5]. Also, the semi-extended knee position requires less patient manipulation and eases image intensification during the surgical procedure.

Clinical solutions

TN-Advanced Tibial Nail

Computed tomographic-based bone models of various patient populations (Caucasian, Asian, male, female, small body size, large body size) were used to investigate the best tibial nail design in terms of anatomical fit by means of computer graphical methods [6, 7]. It was shown that the nail shape of the existing Expert Tibial Nail with Proximal Bend provided an excellent anatomical fit for smooth nail insertion

and final nail positioning. The fit was significantly better than the one provided by the other Expert Tibial Nail design version. Based on these study results, it was decided that the new TN-Advanced Tibial Nail (TN-A) should have the same nail shape and locking configurations as the Expert Tibial Nail with Proximal Bend (Fig 1). Furthermore, the anatomical studies revealed that a single nail design is sufficient to address a large variety of patient populations. Offering only one TN-A shape helps to reduce the nail inventory and to simplify the nailing system.

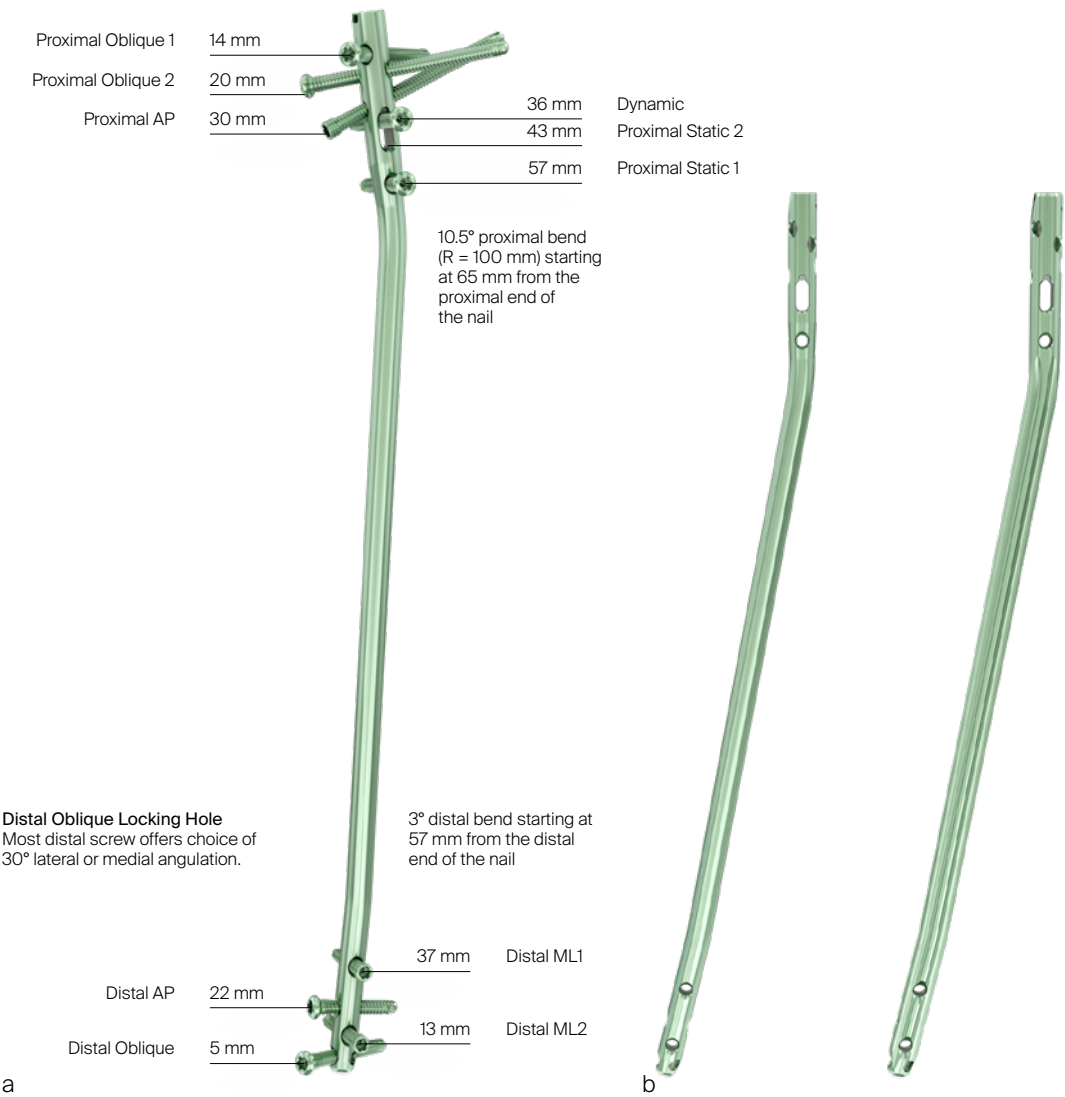


Fig 1a-b

- a Nail shape and locking configurations of the new TN-A.
- b The nail is provided in a design with round cross section for the nail shaft diameters of 8.2 mm, 9 mm, and 10 mm and in a fluted design for the nail shaft diameters of 11 mm, 12 mm, and 13 mm. The flutes of the larger diameter nails reduce the nail stiffness to facilitate nail insertion. The cannulated TN-A is supposed to be inserted over a 3.0 mm reaming rod (with a diameter of up to 3.8 mm at the widest rod geometry).

The TN-A is offered in the following nail diameters: 8.2 mm, 9 mm, 10 mm, 11 mm, 12 mm, and 13 mm. The proximal nail diameter is 11 mm for all nails with nail shaft diameters from 8.2 mm to 11 mm. For larger nail sizes the proximal nail diameter is the same as the nail shaft diameter. The following nail lengths are available: 255–465 mm in 15 mm length increments. The TN-A is made of a different material (TAV, Ti-6Al-4V) compared with the Expert Tibial Nail (TAN, Ti-6Al-7Nb). Both titanium alloys have similar mechanical properties.

The TN-A has five proximal and four distal multiplanar locking options with an innovative device feature to provide angular stability: there are preassembled polyether ether ketone (PEEK) inlays in the proximal and distal parts of the nail ([Fig 2](#)).



Fig 2a–b Built in polyether ether ketone inlays in the nail sections for proximal (**a**) and distal locking (**b**) warrant angular stability for improved construct stability in metaphyseal bone without impeding the flexibility of the nail.

Wherever locking screws are inserted in the locking holes of the TN-A (except in the proximal 7 mm nail slot for dynamic and static fixation), the inlays provide angular stability between the locking screws and the nail without the need for additional instruments and surgical steps. The PEEK inlays decrease nail toggle by up to 72% and reduce the risk of screw migration with secondary loss of reduction. For more information about the biomechanical stability of the TN-A, see the [dedicated article](#) in this magazine from ARI.

Various preclinical studies were performed to address potential concerns about PEEK debris due to the interaction between the screws and the inlays. Debris particle sizes, shapes, and volumes were analyzed. The amount of debris generated is like the one observed for the MultiLoc Proximal Humeral Nail, which has a preassembled polyethylene inlay. Since its introduction in 2011, no debris issues have been reported for the MultiLoc Proximal Humeral Nail.

The TN-A implants are intended for treatment of fractures in adults and adolescents (age, 12–21 years) in which the growth plates have fused. Specifically, the implants are indicated for:

- Open and closed proximal and distal tibial fractures
- Open and closed tibial shaft fractures
- Tibial malunions and nonunions

Locking screws and screwdriver options

Concerning screw sizes, 5 mm locking screws are used in all locking holes of the TN-A, except for the distal locking holes of the 8.2 mm nail, for which 4 mm locking screws are provided. The use of 5 mm screws in the 9 mm TN-A reduces the screw breakage risk compared with the 9 mm Expert Tibial Nail that relied on 4 mm screws.

Several improvements are introduced with the development of two new types of locking screws that are compatible across all nails of the Advanced Nailing System ([Fig 3](#)). The new headed Locking Screw ([Fig 4](#)) has an increased outer thread diameter portion below the screw head that improves the screw purchase in bone. This aspect is particularly important in poor bone quality and in the presence of thin cortical bone. In addition, modulation of the screw threads provides an improved tactile feedback indicating when the screw is fully seated to avoid inadvertent screw stripping.

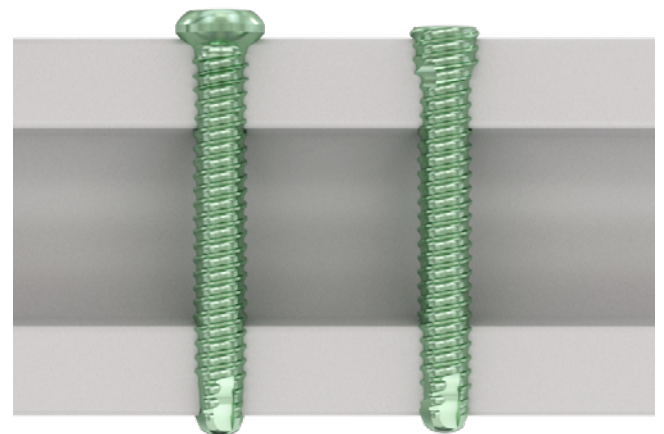


Fig 3 New headed Locking Screw (left) and new Low Profile Locking Screw.

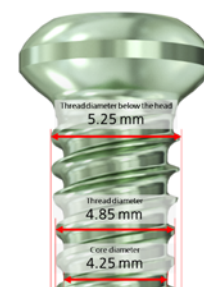


Fig 4 New headed Locking Screw with increased thread diameter below the screw head and smooth screw head design. Based on benchmark tests in foam simulating weak bone, the new screw provides 27% higher pull-out resistance and 92% higher stripping resistance compared with the previous DPS locking screw.

An additional screw type is provided with the Low Profile Locking Screw in a headless design (Fig 5). This novel screw was designed to reduce the risk of soft-tissue damage and irritations due to screw head prominence at areas of low-tissue coverage, eg, the distal tibia. Furthermore, screw purchase is markedly increased by the threaded conical design portion of the Low Profile Locking Screw, which is advantageous in osteoporotic bone.

Both locking screw types have a XL25 recess (Fig 6) and self-tapping rounded tips with two extra threads to ease screw insertion and to reduce soft-tissue irritations. All screws have a retaining feature to facilitate instrumentation (Fig 7 and Fig 8).

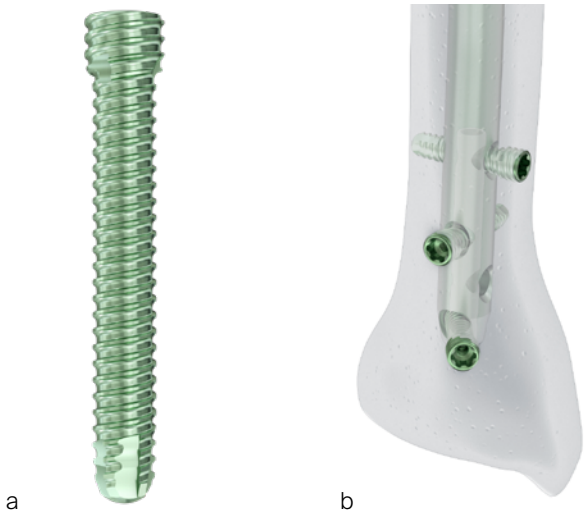


Fig 5a–b The new Low Profile Locking Screw (a) can be inserted almost flush to the bone to minimize soft-tissue irritations (b). Benchmark tests in foam simulating weak bone revealed that the large thread diameter in the proximal part of the screw increases the pull-out strength by 42% compared with the previous DPS locking screw.

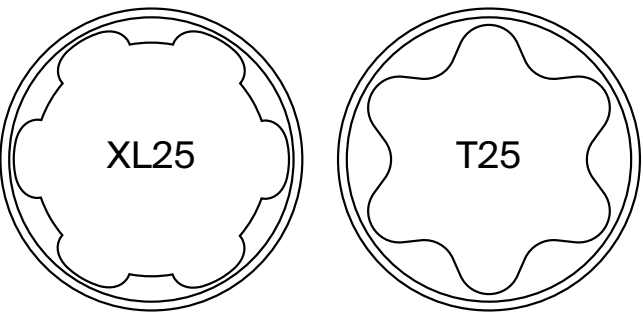


Fig 6 The new XL25 recess has the same star profile as the T25 recess of the previous DPS locking screws with similar torque transmission properties. However, the core diameter is larger to ease cleaning of the screw recess for removal purposes and preserve the strength of the cannulated screwdriver.

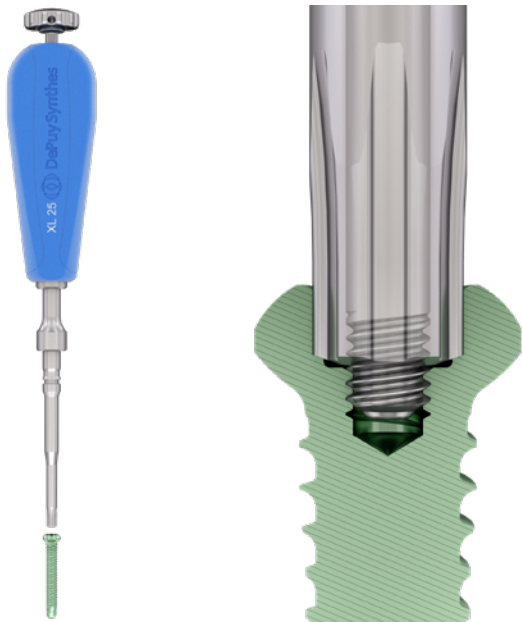


Fig 7 Retention feature of the new headed Locking Screw: the threaded recess allows to securely attach the screw to the screwdriver by use of a retention pin. According to mechanical testing data, the retention force is about 20 times higher compared with the retention force generated with the DPS Inter-Lock Screwdriver in the previous DPS locking screws. The new screw retention technology delivers an axial force of up to 2500 N (250 kg).

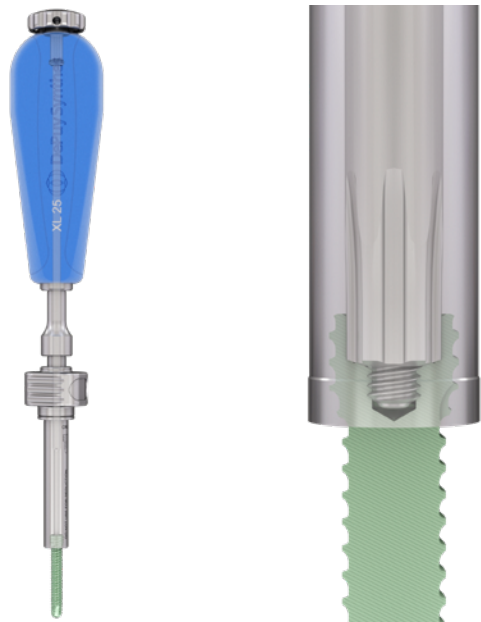
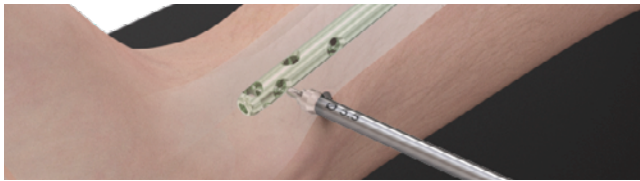


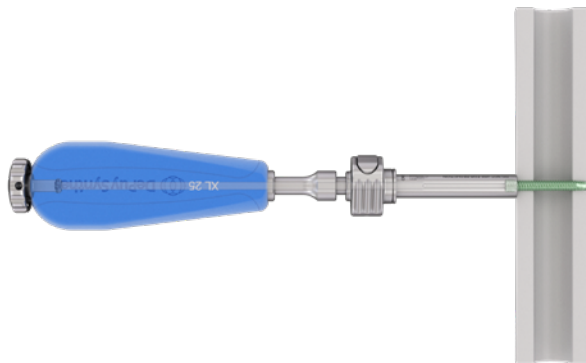
Fig 8 Retention feature of the new Low Profile Locking Screw. An optional sleeve is available indicating when the Low Profile Locking Screw is fully seated. The sleeve initially covers the head of the Low Profile Locking Screw to protect soft tissues from the screw head's cutting flutes.

The Low Profile Locking Screw is inserted in the following steps:

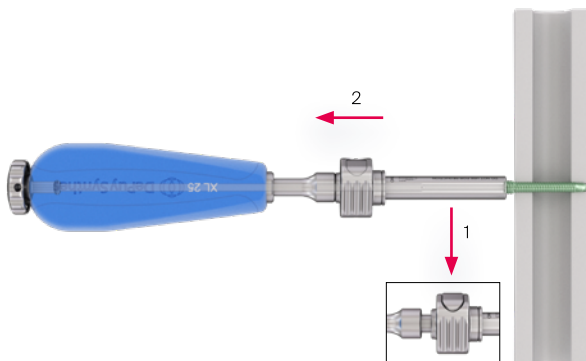
1. In hard bone it is recommended to enlarge the near cortex with a 5.5 mm reamer to make room for the screw head and to avoid excessive insertion torque.



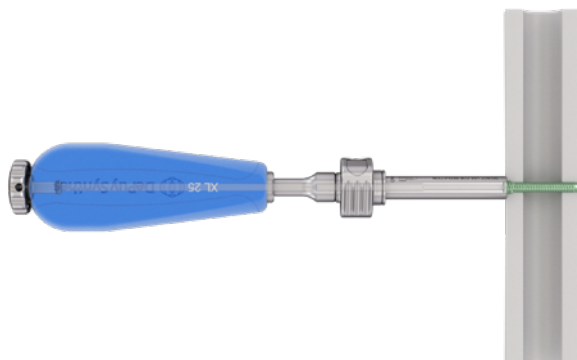
2. After mounting the Low Profile Locking Screw to the screwdriver and sleeve, the screw is advanced until the sleeve touches the cortex with tactile feel.



3. The sleeve is retracted by pushing the release button (1) and pulling it backward toward the screwdriver handle (2).



4. The screw is further advanced to sink the threaded screw head into the bony cortex. Once the sleeve touches the cortex a second time, the screw head is 0.5 mm proud of the cortex.



In addition to manual screw insertion there is the option to use a power tool for partial screw insertion (Fig 9).



a



b



c

Fig 9a-c The quick coupling screwdriver (a) is used to partially insert the screw with a power tool (b). The manual handle must be used for final tightening of the screw (c).

If the screw heads are overgrown or the recess is damaged, additional instruments are available for screw removal (Fig 10).

Nailing instruments

The new nailing instruments were developed to streamline the instrumentation and to eliminate redundancy between nailing system (Fig 11). The TN-A utilizes intuitive instrumentation aimed to improve operating room efficiency. Several innovative solutions address key functionalities of the instrumentation (Fig 12).

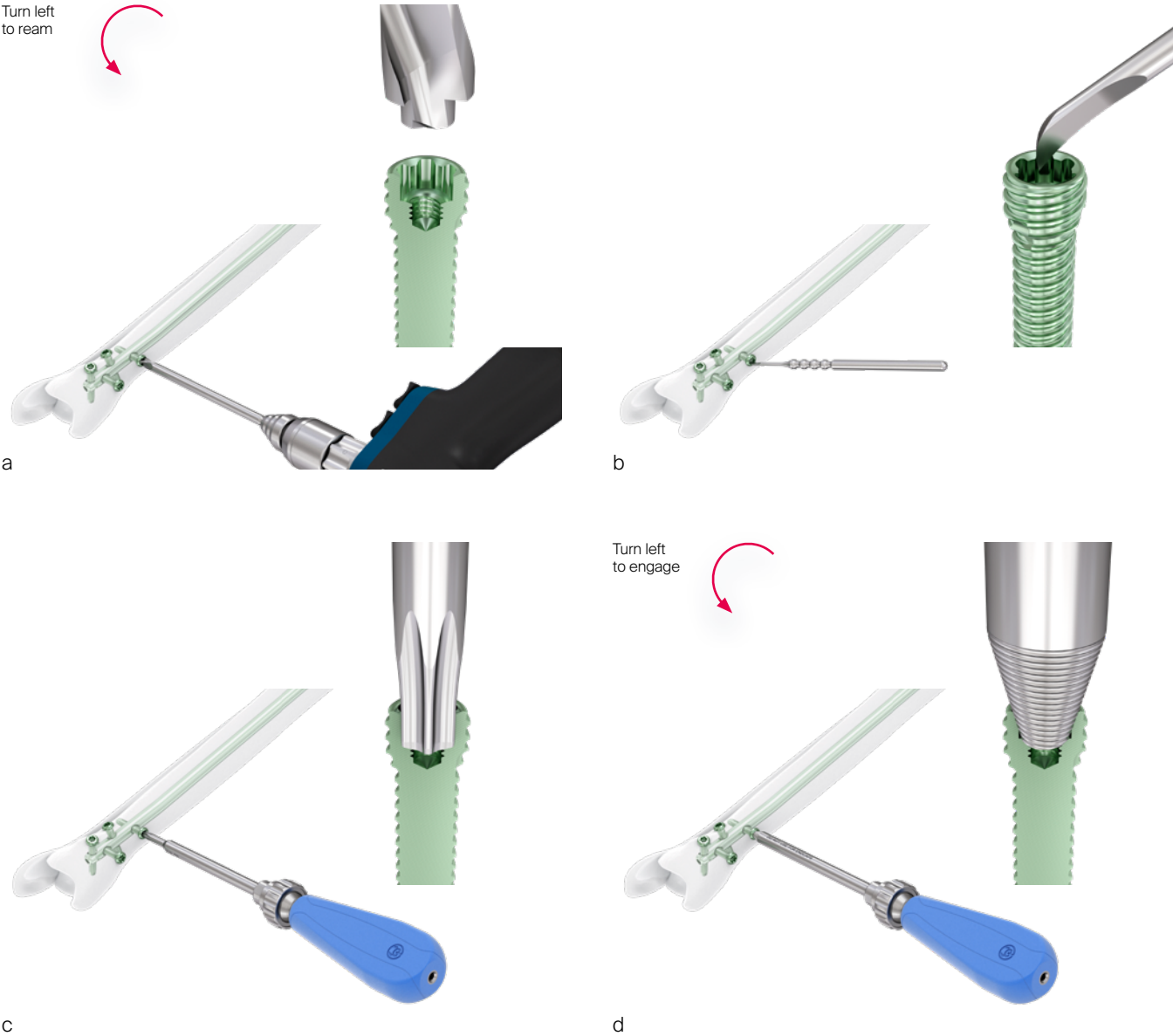


Fig 10a–d Clearing the recess and the screw head with the curette (a); sharp hook to clean out any remaining tissue (b); extractor shaft (c); and conical extraction screw to remove the screw (d).



Fig 11 There is a set of base instruments that is shared for the instrumentation of all nails of the Advanced Nailing System to reduce hospital storage requirements, system complexity, and staff learning efforts.

QUICK CONNECT LATCH

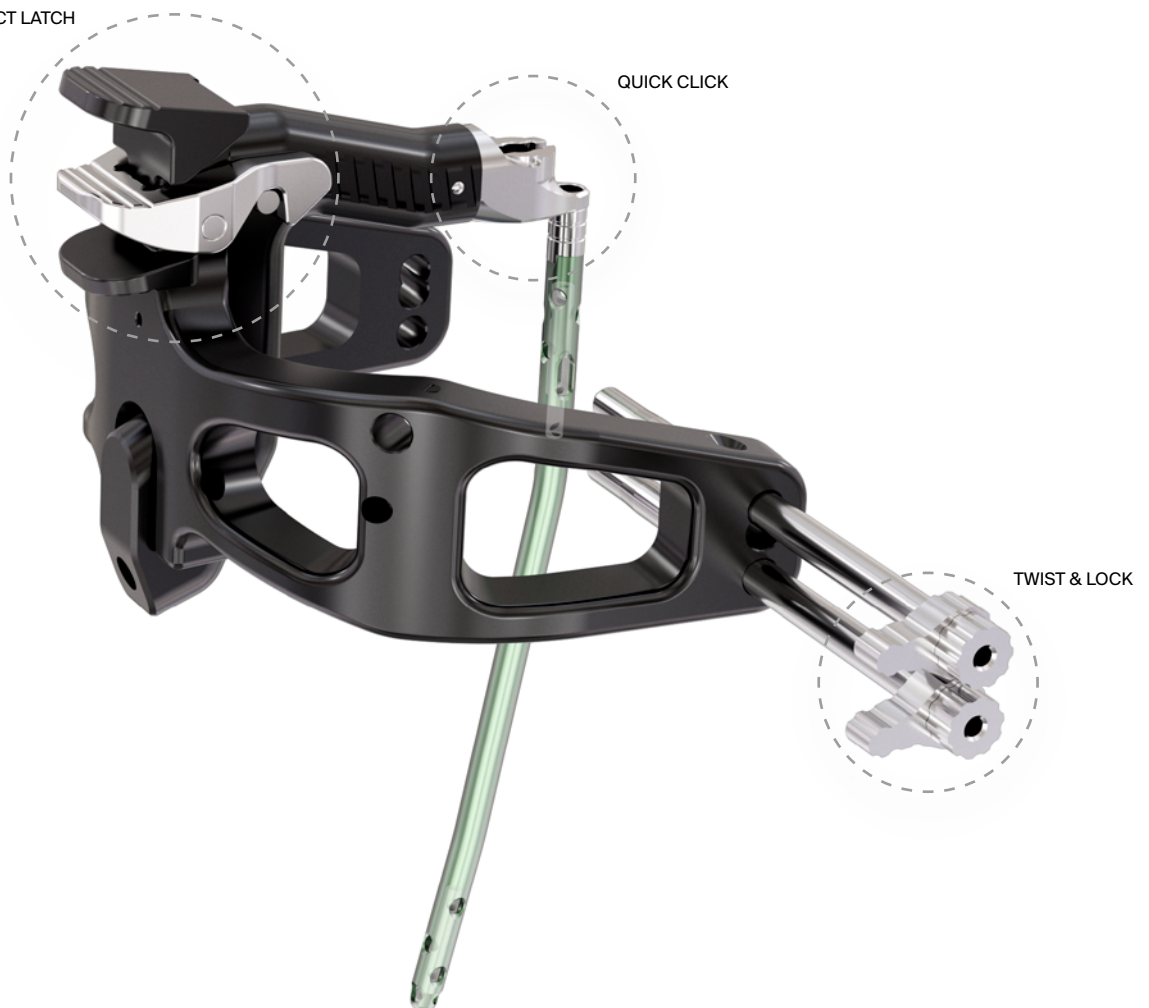


Fig 12 Design features to optimize instrumentation. QUICK CLICK: attachment of the insertion handle to the nail ([Fig 13](#)); QUICK CONNECT LATCH: connection of the insertion handle to the aiming arm ([Fig 14](#)); TWIST & LOCK: protection sleeves are secured in the aiming arm with one quarter twist which allows single-handed instrumentation.



Fig 13a-b QUICK CLICK.

- a** The nail is connected to the insertion handle by aligning the markings on the nail with the two slots on the barrel of the insertion handle and by pushing both parts together until they snap into place.
- b** The connection is designed to hold the nail in place until the connecting screw is tightened.

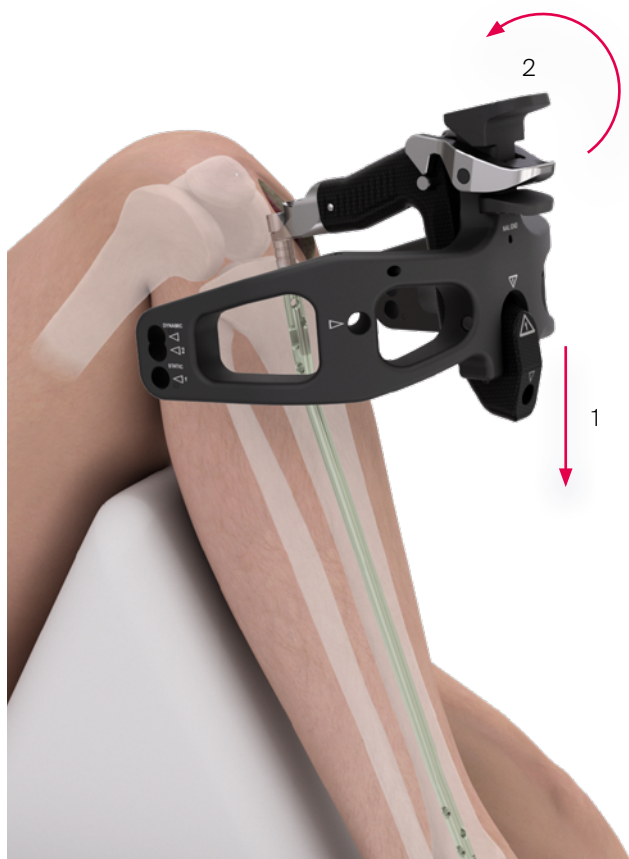
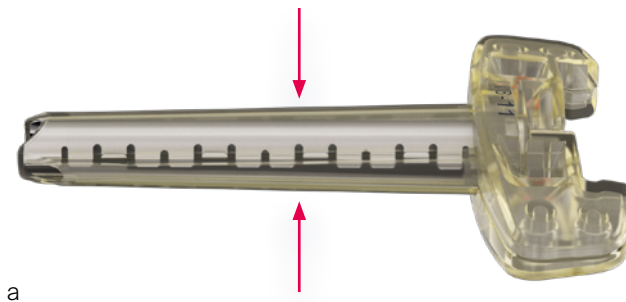


Fig 14 QUICK CONNECT LATCH: The aiming arm is attached to the insertion handle (illustration for intrapatellar approach) by sliding it into the hook at the distal part of the insertion handle (1) and then rotating the latch toward the insertion handle (2) for both parts to connect.

An important aspect for the development of the TN-A instrumentation was to provide instruments for the intrapatellar, intraarticular suprapatellar, and extraarticular parapatellar approaches.

Dedicated suprapatellar insertion instruments have been available for the Expert Tibial Nail since 2012 ([Innovations magazine; 2012](#)). These instruments comprise a soft outer protection sleeve to protect the patellofemoral cartilage and soft tissues as well as an inner metal protection sleeve through which the required cutting and reaming instruments and the nail can be inserted in a safe manner. However, the disadvantage of this instrumentation concept is that the pressure on the patellofemoral joint due to the presence of the sleeves is constantly kept at the same level and for the whole time until the nail is inserted. The new suprapatellar TN-A instrumentation features a compressible and disposable suprapatellar sleeve that is designed to reduce the pressure on the patellofemoral joint whenever possible ([Fig 15](#)). The sleeve expands as required by the size of the instruments as these are inserted through it. The compressible sleeve is provided in two sizes: small sleeve for nails with diameters of 8.2-11 mm and for reamer heads up to 12.5 mm; large sleeve for nails with diameters of 8.2-13 mm and for reamer heads up to 14.5 mm.

A multihole wire guide can be inserted through the protection sleeve to determine the correct entry point and entry path for the guide wire. This instrument can also be used before the insertion of the protection sleeve, thereby increasing the maneuverability of the wire guide in tight knees ([Fig 16](#)). Adjustments to the entry point location can be made by turning the multihole wire guide ([Fig 17](#)).

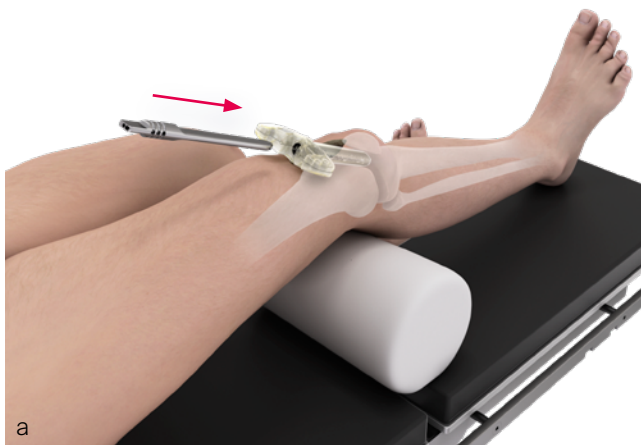


a



b

Fig 15a-b The amount of patellofemoral joint pressure depends on the sleeve size. Since the sleeve only expands when needed due to instrument presence, the pressure level on the cartilage and its duration are much lower compared with that induced by a rigid sleeve.



a

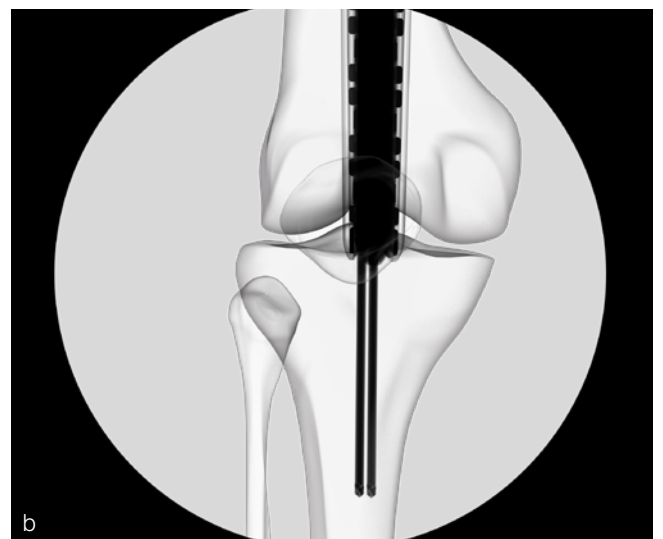


b

Fig 16a-b Insertion of the wire guide through the protection sleeve (a) and wire guide placement without protection sleeve (b).



a



b

Fig 17a-b The guide wire position can be adjusted by rotating the instrument around the first central guide wire. Thus, a second guide wire can be placed at 4 mm distance from the first guide wire to correct the position.

Once the protection sleeve is in its correct position it can be anchored to the femur via the protection sleeve handle using 3.2 mm K-wires. There are alternative protection sleeves available to allow anchoring to the tibial plateau (Fig 18).

The opening drill bit (rigid as well as flexible opening drill bits are available) and the reamers are pushed over the guide wire through the compressible suprapatellar sleeve. Drilling and reaming are supposed not to be started before the cutting instruments are placed down to the bone.

The surgical technique guides for instrumentation of the TN-A with the various supported approaches were optimized based on anatomy lab experiences (Fig 19).

The TN-A may be removed by a suprapatellar or by a traditional infrapatellar approach. End cap removal and connection of the removal instrument to the nail is more difficult when using the suprapatellar approach for nail removal.

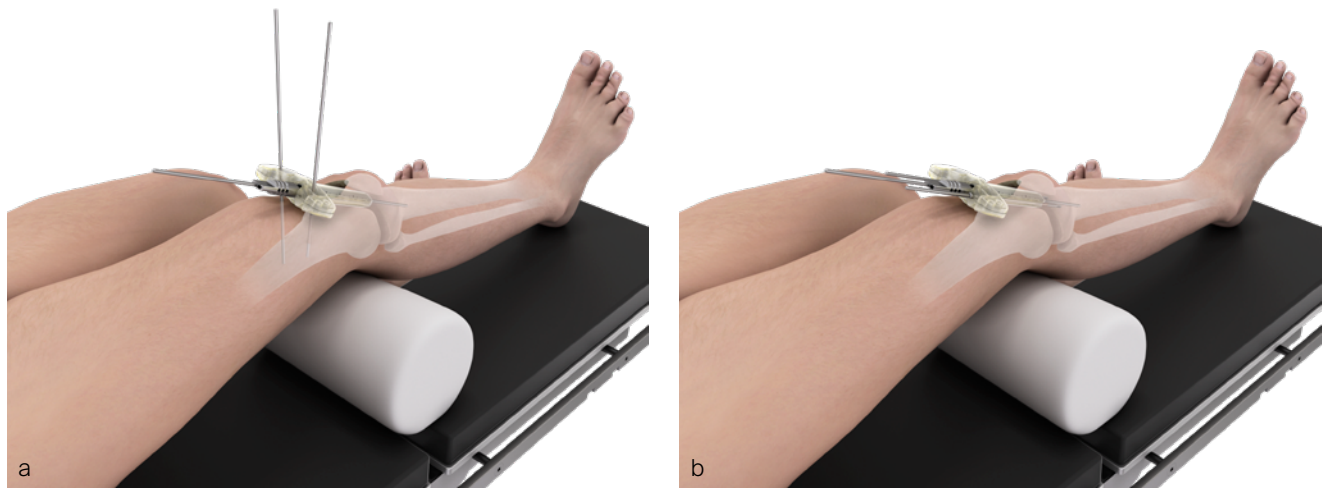


Fig 18a–b Anchoring of the protection sleeve to the femur (a) and to the tibia (b) as an alternative fixation method. K-wire fixation to the femur allows higher sleeve stability.



Fig 19 Review of the new suprapatellar nailing instrumentation in an anatomy lab by Christopher Finkemeier, INEG Chair.

Summary

The new TN-A has been developed to address current clinical challenges associated with an ageing population and an increased use of tibial nails for the treatment of proximal and distal metadiaphyseal tibial fractures. It is specifically designed to improve stability while further reducing implant prominence and to advance system usability to save time in the operating room.

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Retrograde Femoral Nailing System

Defining the clinical problem

Distal femoral fractures typically occur in young patients because of high-energy trauma and in elderly patients because of simple falls. After the age of 60 years, a rapid increase in the incidence of distal femoral fractures has been reported in both genders, with a large female predominance [1]. Depending on the degree of comminution, patient factors, revisional history, and the possible involvement of prostheses, treatment of distal femoral fractures can be challenging. Surgical management aims to provide adequate stability for fracture healing, to maintain reduction, and to allow early postoperative patient mobilization. The latter aspect is significant because of the growing number of elderly patients with limited ability to comply with partial weight bearing protocols. Hence, there is a demand for fracture fixation solutions that can resist high loads across the fracture site. Retrograde IMN as well as locked plating are commonly used techniques to treat distal femoral fractures. Similar nonunion and revision rates have been reported for both surgical procedures for native [2] and periprosthetic fractures [3]. From a biomechanical perspective, IMN offers a higher load-bearing capacity compared with lateral locked plating because the fixation device is closer to the weight bearing axis of the femur. However, with retrograde nailing of native and periprosthetic distal femoral fractures, the following disadvantages compared with locked plating are: (1) limited implant anchorage possibilities in far distal fractures, (2) challenging implant placement in the presence of prosthesis components or other implants. Insufficient implant anchorage may result in malunions, delayed unions, or nonunions requiring revision surgery with corresponding burden on the healthcare system. The Periprosthetic Fracture Task Force and the INEG (Fig 20) considered all these aspects in the development of a state-of-the-art retrograde nailing system—the new RFN-Advanced Retrograde Femoral Nailing System.



Fig 20 Anatomy labs were performed throughout the 6-year development time of the RFN-A. Christopher Finkemeier (far left, chair of the INEG) and Martin Hessmann (second from left, INEG member), observing how surgeons use the new nails and instruments for the first time. Intuitive use and ease of instrumentation are among the key factors for the success of a new implant system.

Clinical solutions

RFN-Advanced Retrograde Femoral Nail

The first aspect in the development of the RFN-Advanced (RFN-A) Retrograde Femoral Nail was the analysis of the best nail shape based on an anatomical study with many femoral CT scans. The study revealed that two nail shapes with different distal bends are required to adequately address native and periprosthetic fractures. The RFN-A is therefore provided with a 5° bend and a 10° bend (Fig 21a). The nail with the 10°

bend is advantageous for fixation of periprosthetic fractures where the entry point is forced to be more posterior due to the presence of a total knee arthroplasty. Thus, the risk of an extension deformity because of a posterior nail entry portal can be reduced (Fig 21b). The surgeon can choose between the two nail shapes based on the fracture configuration and implant placement factors. There could be periprosthetic fracture cases where the 5° bend nail might be better than the 10° bend nail. Similarly, the 10° bend nail might be preferred over the 5° bend nail to address native fractures.

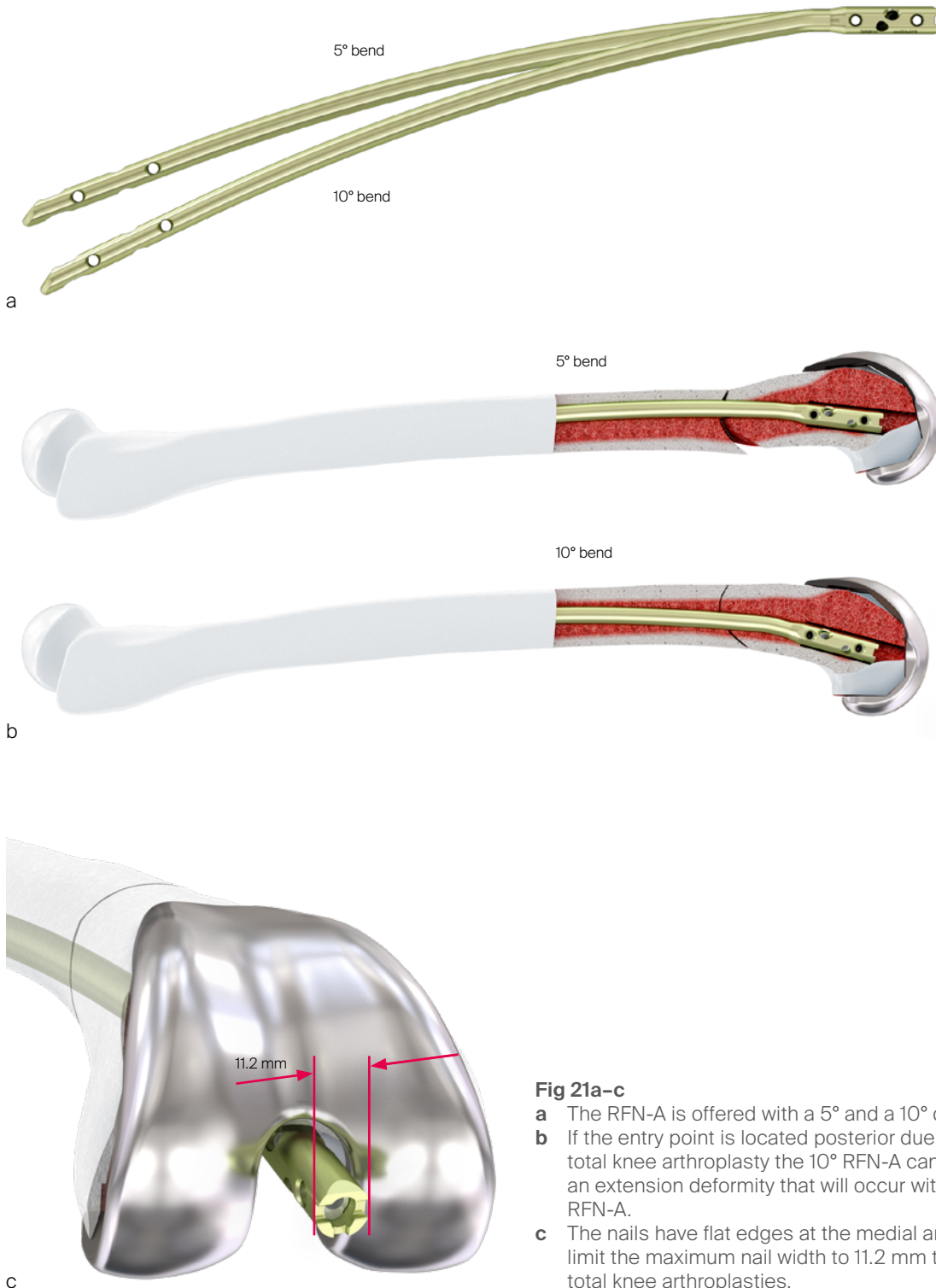


Fig 21a-c

- a** The RFN-A is offered with a 5° and a 10° distal bend.
- b** If the entry point is located posterior due to the presence of a total knee arthroplasty the 10° RFN-A can be chosen to avoid an extension deformity that will occur with the use of the 5° RFN-A.
- c** The nails have flat edges at the medial and lateral sides to limit the maximum nail width to 11.2 mm to fit through most total knee arthroplasties.

All nails have a 1.0 m radius of curvature to address the anterior bend of the femur. This nail bend is the same as for the TFN-Advanced Proximal Femoral Nail and the FRN-Advanced Femoral Recon Nail. The RFN-A is made of the same material as the TN-A (Ti-6Al-4V). The universal nail design for the left and right femur helps to reduce the nail portfolio.

The RFN-A is offered in the following diameters and lengths:

- Nail diameters: Ø 9 mm, Ø 10 mm, Ø 11 mm, Ø 12 mm, and Ø 14 mm (only 5° bend nail).
- Nail lengths: 160–280 mm in 40 mm increments and 300–480 mm in 20 mm increments.

The nail cross section is round for the nail diameters Ø 9 mm and Ø 10 mm and fluted for the larger diameter nails.

Nail locking options and locking screws

All nails have four multiplanar distal locking options (Fig 22). For proximal locking, the long nails (300–480 mm nail length) have two lateral to medial (LM) and two anterior to posterior (AP) locking options. The short nails (160–280 mm nail length) allow locking with 2 LM screws.

The RFN-A has a preassembled polymer inlay at the distal nail part to achieve angular stable locking between the locking screws and the nail. Angular stable locking reduces interfragmentary motion and screw toggle. According to development test data, the angular movement of a locking screw in the nail without sleeve was more than twice as high

as that of an angular stable locking screw in the nail with sleeve.

The nail is locked with Ø 5 mm titanium locking screws. The same new screw types are used as for the TN-A: Locking Screw (headed design) and Low Profile Locking Screw (headless design). The Low Profile Locking Screw can be helpful to avoid soft-tissue irritations at the lateral femoral epicondyle.

In poor bone quality even angular stable locking screws may cut through the bone resulting in loss of nail fixation. To improve distal implant anchorage and increase resistance against cut through, the surgeon can choose one of the following two enhanced fixation options.

Enhanced fixation option 1: titanium nuts and washers for locking screws

The RFN-Advanced Retrograde Femoral Nailing System comprises optional titanium condylar nuts and washers.

Nut and washer designs

The conical design of the nut (largest outer diameter: 14 mm) increases the interlocking surface in the bone of the femoral condyles (Fig 23). The nuts can be assembled to sit underneath the locking screw head and at the screw tip. The surgeon can either use nuts on both sides of the femoral condyles or only on one side. The nut has a friction feature to avoid unintentional loosening from the locking screw. A countersink can be used to ease insertion of the nut in hard bone.



Fig 22 Proximal and distal locking configurations of the RFN-A.

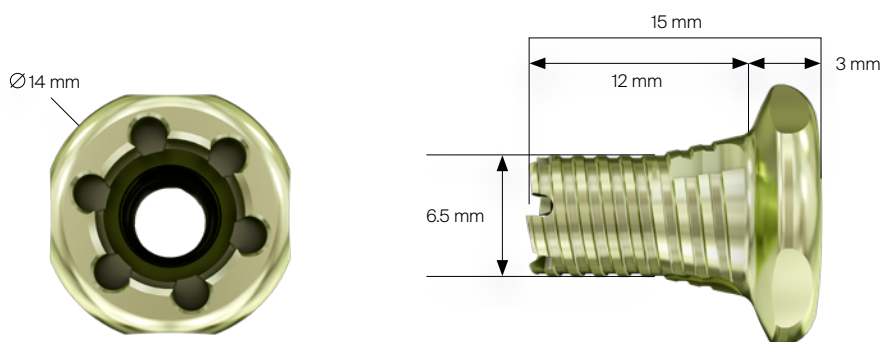


Fig 23 Dimensions of the titanium nut with conical design.

Titanium washers with 1.1 mm thickness are available for the nut to increase the outer diameter of the locking construct to 17 mm, which reduces the risk of the nut sinking into the bone. There are also titanium washers of 1.2 mm thickness for the standard locking screws available to increase the outer diameter without use of the nut to 14 mm. Locking screws, nuts, and washers should be assembled such that there is the same outer diameter of the locking configuration at the lateral and medial femoral epicondyles which warrants similar resistance against sinking into the bone (Fig 24).

The use of nuts and washers may be limited in patients where the nail is inserted deeply into the femoral canal or in small stature patient because of insufficient nut insertion depth resulting in premature contact of the nut with the nail (Fig 25). Furthermore, using nuts and washers in combination with the most proximal of the distal locking screws can result in

unwanted hardware prominence which could lead to soft-tissue irritations.

There are two different instrumentation techniques to place the nut and washer:

- Nut-Over-Screw Technique: In this technique the locking screw is inserted first before the nut is placed over the screw tip at the opposite side. Tightening of the nut at the far cortex must be performed while applying counter-torque at the locking screw with the screwdriver at the near cortex.
- Nut-Over-Drill Bit Technique: In this technique the drill bit is kept in position after drilling. Subsequently, the nut is inserted over the drill bit tip until it is fully seated in the bone. After removal of the drill bit the locking screw is inserted through the nut. Tightening of the locking screw must be performed while applying counter-torque at the nut in the far cortex with the nut driver.

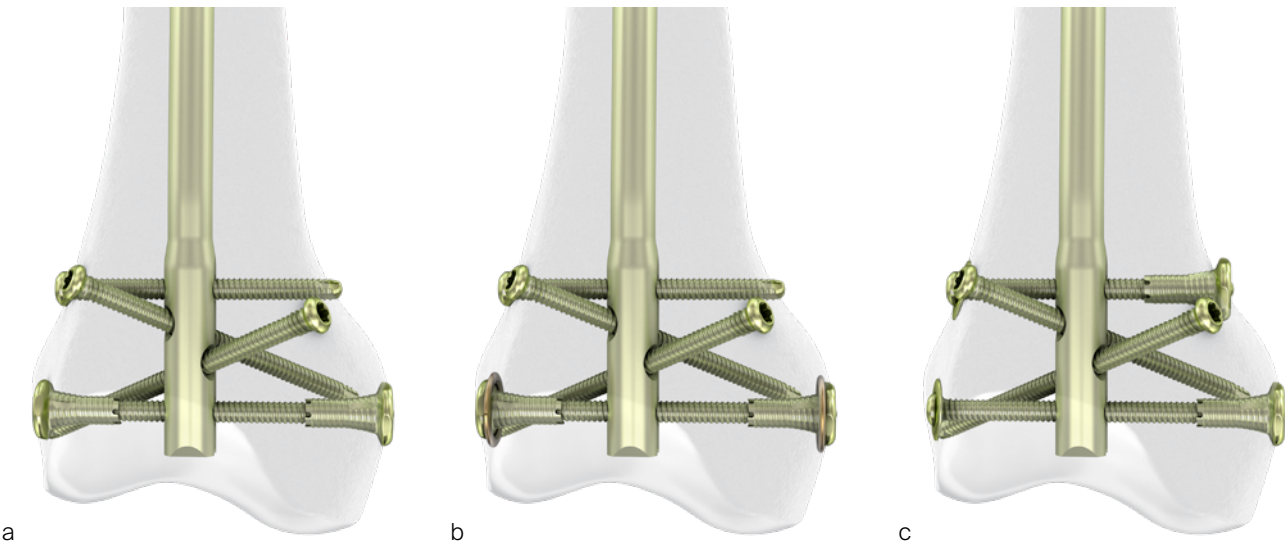


Fig 24a-c Possible nut and washer configurations.
a Nuts on both sides of the most distal locking screw.
b Washers and nuts on both sides of the most distal locking screw.
c Washers underneath the locking screw heads and nuts at the screw tips of the most distal and most proximal locking screws.

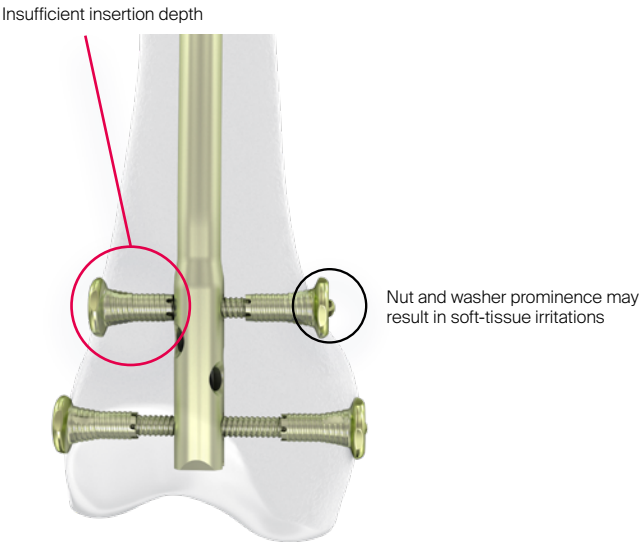


Fig 25 There should be a minimum distance of 20 mm between the outer cortex and the nail to ensure enough insertion depth for the 15 mm long nut. This criterion should be fulfilled if a bicortical distance of 48 mm or larger is measured and if the nail is in a central position.

Enhanced fixation option 2: Locking Attachment Washer

The Locking Attachment Washer (LAW) can be regarded as the most important innovation of the RFN-A System. This novel fixation option is expected to significantly improve retrograde nailing of native and periprosthetic distal femoral fractures by optimizing distal implant anchorage (Fig 26). The LAW concept allows to connect an anatomically shaped 6-hole plate (the locking attachment washer) at the lateral femoral epicondyle to the retrograde nail in an angular stable manner. This is accomplished by placing two 5 mm variable angle (VA) interlocking screws through the LAW and the two LM nail holes. In addition, four 3.5 mm VA screws can be inserted in

the remaining LAW holes thereby enhancing nail anchorage in the distal femur.

Surgeons already use nail and plate combinations in clinical practice to improve distal femoral fracture fixation (see “Improving the treatment of complex distal femoral fractures” article in the *Innovations magazine*, 2019). However, current implants used for this so-called double fixation technique are not specifically designed for the purpose of connecting a plate and a nail. In this regard the LAW concept pioneers fracture fixation. It offers the advantages of nailing and plating in one fixation construct.

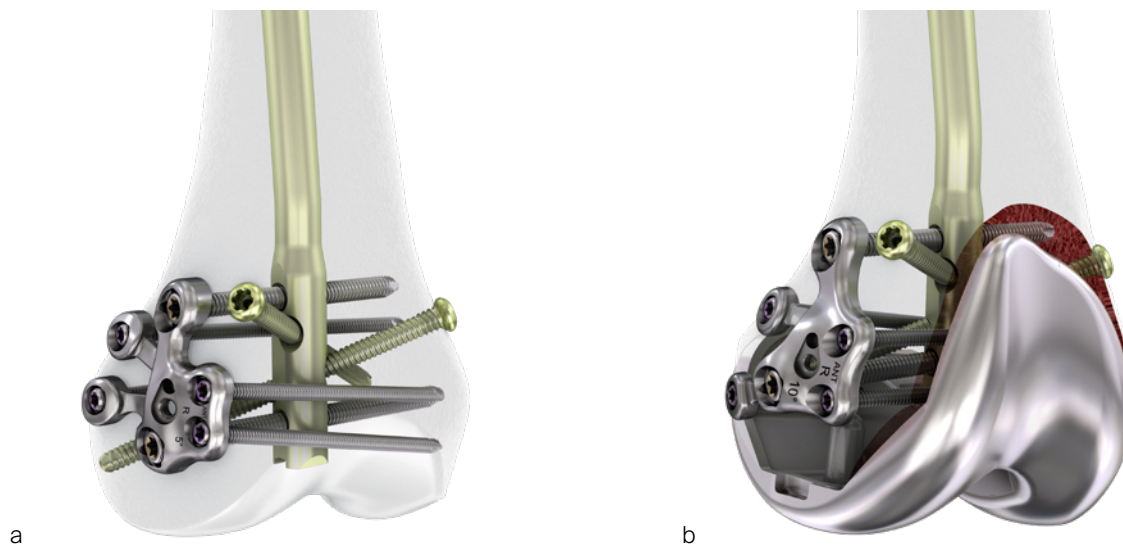


Fig 26a–b Locking Attachment Washer connected to the RFN-A to address native (**a**) and periprosthetic fractures (**b**).

LAW design

The LAW is made of stainless steel. It is pre-contoured and offered in 5° and 10° design versions to closely match the anatomy of the lateral femoral epicondyle when paired with the retrograde nail of the corresponding bend (Fig 27). In certain patients, it might be preferred to pair the 5° LAW with the 10° bend nail to achieve better LAW fit. For the same reason, the 10° LAW might be used in combination with the 5° bend nail. The 10° LAW has a larger out-of-plane offset between the two 5.0 mm VA screw holes compared with the 5° LAW. This could be beneficial for the transition from the lateral

femoral epicondyle if the proximal LM screw is located more superior due to patient anatomy, nail insertion depth, or the presence of a total knee arthroplasty femoral component (Fig 26b). OPTILINK 5.0 mm VA Locking Screws are used to connect the stainless steel LAW to the titanium alloy nail. These stainless steel screws have undergone carburizing, a low temperature heat treatment in an environment enriched with carbon atoms to allow safe pairing with titanium implants. For more information about the OPTILINK technology refer to the article about the VA-LCP Condylar Plate 4.5/5.0 in titanium alloy in the [Innovations magazine 2016](#).

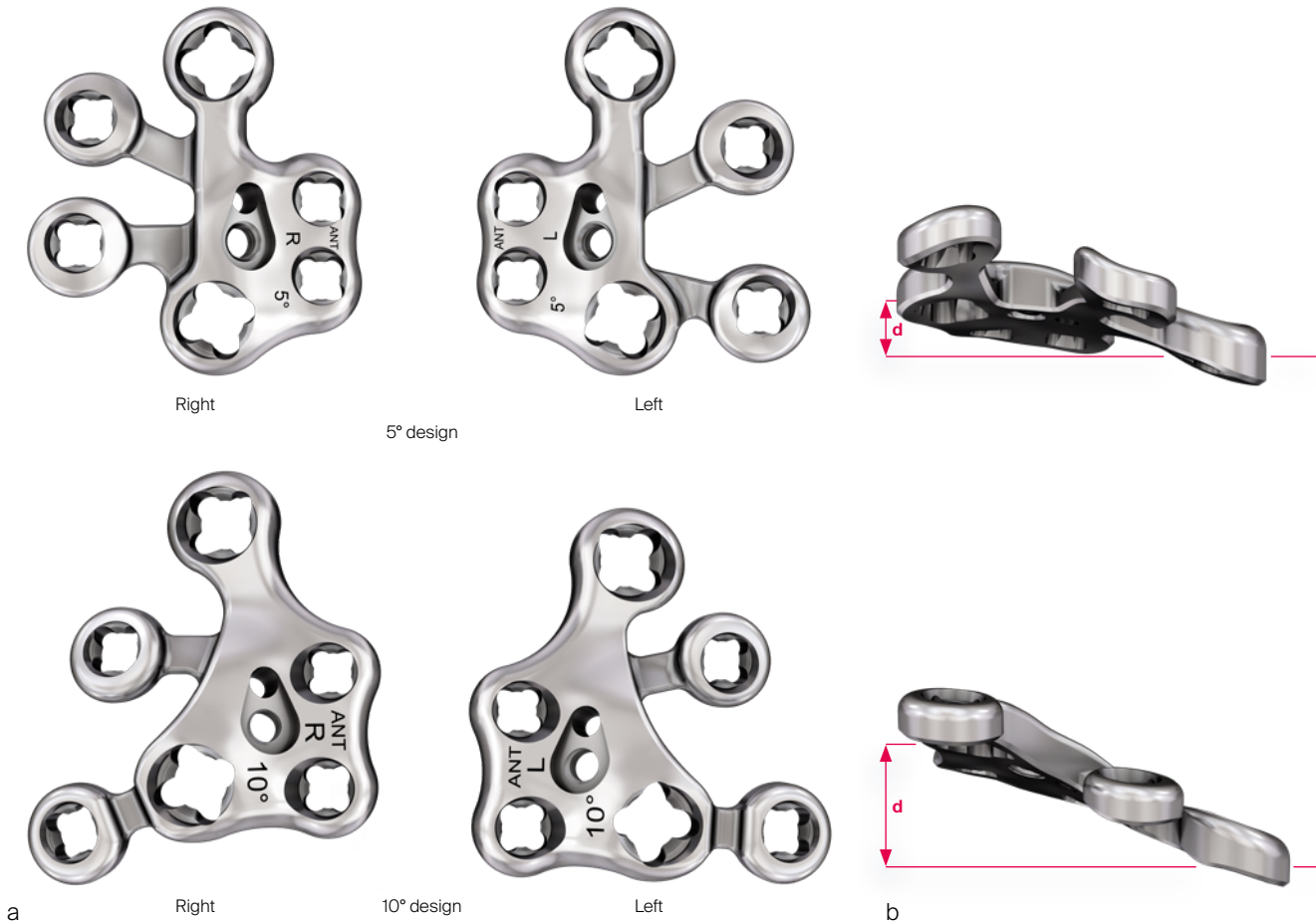
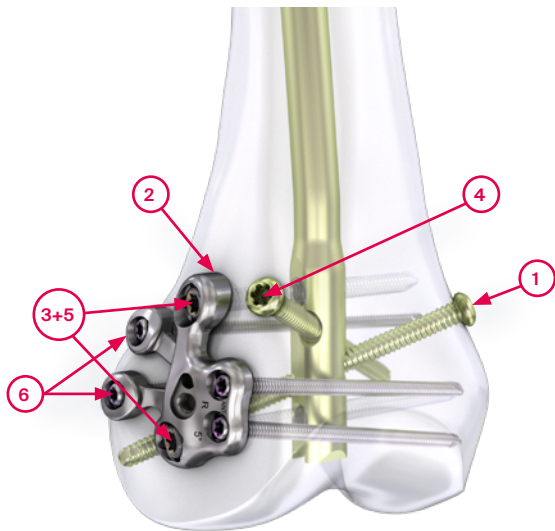


Fig 27a-b

- a** Locking Attachment Washers are provided in 5° and 10° designs for the left and right femur. The LAW contains etch details to provide information on the LAW type, left- or right-side use as well as orientation. The positions of the posterior 3.5 mm VA locking screw holes are different between the left and right locking attachment washers because this accounts for the descending oblique screw trajectories when the universal RFN-A is used in the left or right femur.
- b** The out-of-plane offset d between the two 5 mm VA screw holes is larger for the 10° LAW compared with the 5° LAW.

Surgical technique for LAW placement

After nail insertion and attachment of the aiming arm to the nail insertion handle, the LAW is applied in following surgical steps:



Step 1: Secure the nail position with a screw or drill bit in the medial oblique locking hole.

Step 2: Place the LAW (with available handle). Once the LAW is properly oriented, hold it in position on the bone using the protection sleeves through the aiming arm.

Step 3: Partially insert the two 5.0 mm VA locking screws stopping approximately 1 cm short before full insertion.

Step 4: Insert the lateral oblique screw (optional).

Step 5: Adjust the LAW fit and hold it in place. Fully insert and lock the two 5.0 mm VA locking screws with 6 Nm.

Step 6: Contour the two posterior LAW holes with their tab features to the bone by using the bending drivers in situ. Insert the four 3.5 mm VA locking screws and lock them with 2.5 Nm.

The LAW increases the fixation density of the nail in the distal femur, which is especially useful to stabilize short distal bone segments.

Based on a compression test in a standardized distal femoral foam model the RFN-A with a fully instrumented LAW provided a 42% higher load to failure and a 30.5% higher axial stiffness than the RFN-A without LAW. In both constructs two distal nail interlocking screws were used to analyze the sole benefit of the LAW.

The improved nail anchorage distally contributes indirectly to the stability at the fracture site although the LAW does not bridge the fracture.

Potential next development

It is reasonable to assume that the combination of a nail and a long plate that crosses the fracture site will provide even higher fracture stability (see the article on “Improving the treatment of complex distal femoral fractures” in the *Innovations magazine*; 2019). Although such an implant combination is interesting from a biomechanical perspective, it must be emphasized that too high fracture stability may also result in delayed unions or nonunions. It is important to adequately balance the stability provided by the implants which bridge the fracture. In this regard the following aspects must be clarified:

- Plate size: is a small or large fragment plate required?
- Implant linkage configuration: is it required to connect the plate to the nail? If yes, at which locations—distal and/or proximal?
- Type of implant connection: is an angular stable connection between nail and plate required?

A better understanding of these functional device requirements is mandatory to adequately balance the clinical value of a potential implant solution against its technical feasibility and ease of use.

RFN-A Instruments

The instrumentation of the RFN-A is supported by the same set of basic instruments that is also used for the other nails of the Advanced Nailing System. Like the TN-A, there is a QUICK CONNECT LATCH mechanism to ease the assembly of the aiming arm to the insertion handle (Fig 28). The TWIST & LOCK technology allows to secure the protection sleeves in the aiming arm with one quarter twist.



Fig 28 The aiming arm is attached to the insertion handle by sliding it into the hook end of the insertion handle (1) and then rotating the aiming arm toward the insertion handle (2) such that the latch connects to the insertion handle.

The surgical technique of implanting the RFN-A was optimized based on anatomy lab experiences and finally confirmed in validation labs by evaluating every surgical step of the procedure (Fig 29).



Fig 29 Karl Stoffel (Chair of the former AO TC Periprosthetic Fracture Task Force and medical member of the AO TC Lower Extremity Global Expert Committee) during a validation lab assessing each step of the surgical technique guide according to a checklist.

Indications

The RFN-A System is intended to stabilize fractures of the distal femur and the femoral shaft, including:

- Supracondylar fractures, including those with intra-articular extension
- Combination of ipsilateral condylar and diaphyseal fractures
- Ipsilateral femoral/tibial fractures
- Femoral fractures in patients with multiple trauma
- Periprosthetic fractures
- Fractures in the morbidly obese
- Fractures in osteoporotic bone
- Impending pathological fractures
- Malunions and nonunions

Summary

The RFN-A offers new implant features for distal nail fixation to improve treatment of native and periprosthetic fractures. The enhanced fixation options will be beneficial to expand the retrograde nailing indications toward far distal fractures, to improve implant anchorage in poor bone quality, and to support early patient mobilization.

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RIA 2 System

In the [2019 Innovations magazine](#) we reported about the upcoming next generation reamer-irrigator-aspirator system—RIA 2—which had been developed by the RIA Task Force. RIA 2 offers several new device features to improve reaming and bone harvesting procedures. The possibility to use smaller reamer head sizes (down to 10 mm diameter) can be named as one of the most important advantages compared with the previous RIA system to allow improved access to smaller sized bones, such as the tibia or humerus. Additionally, with the new system it is easier to exchange the reamer head.

In April 2020, RIA 2 received device approval as ‘On Request’ by the AO Technical Commission (AO TC) to start a limited release in the United States and in EMEA countries.

Limited release feedback and user experience survey

So far about 800 clinical cases have been performed and overall surgeon feedback has been positive. The RIA Task Force set up a survey to systematically collect device handling information in ten participating centers. The survey includes a rating assessment to evaluate the surgeon’s experience with the RIA 2 system compared with the first-generation device.

Furthermore, the survey allows documentation of any handling issues potentially encountered during RIA 2 procedures. Based on the survey results it is expected that RIA 2 will receive AO TC Trauma approval as ‘Recommended’ by end of 2020.

Clinical cases

Case 1: RIA 2 use for bone grafting at the tibia (by Brent Norris, Tulsa, Oklahoma, US)

A 59-year-old man working for the city of Tulsa suffered an open distal tibia plafond fracture on the left leg when he fell into a sewer hole with raw sewage ([Fig 1](#)). The wound was grossly contaminated, and he was taken immediately to the operating room (OR) for incision and drainage and application of a spanning external fixator. Bone loss was noted anterior and medial (about 2.5 or 3 cm) but only about 20–25% of the bone circumference.

After repeated incision and drainage, 2 days later the fracture was repaired with an anterior lateral tibial plafond plate ([Fig 2](#)). Vancomycin and tobramycin impregnated antibiotic beads were placed in the bone defect.



Fig 1a–b Injury x-rays (AP and ML).



Fig 2a–b Postoperative x-rays (AP and ML).

The patient was discharged on hospital day 6 to a rehabilitation facility with his left lower extremity in a splint and touch down weight bear allowance. He returned 2 weeks later with drainage from the medial traumatic wound. In addition, he had a gastrointestinal bleed from use of nonsteroidal antiinflammatory drugs. Once the gastrointestinal bleed was stabilized, he was taken the next day to the OR for another incision and drainage. Further, more significant, devitalized bone was resected, and an antibiotic cement spacer was placed (Fig 3). Deep culture samples were taken despite knowing the antibiotic resorbable beads had been placed in the wound at the time of initial closure. The plate was left in place, but a planned exchange plate/nailing was to be performed pending final culture results.

Cultures eventually yielded *Klebsiella pneumoniae* and *Enterobacter cloacae*. The patient was administered intravenous

antibiotics for 6 weeks and was discharged home with therapy and nursing. He returned to the clinic with wound breakdown and an exposed cement spacer at 10 weeks after injury. Further bone debridement, spacer exchange, repeated culture samples, and plastic surgery were undertaken to help with wound coverage with a rotational flap. The microbiological culture was still positive for *Klebsiella pneumoniae*.

Two months later, the patient had a staged cement spacer removal and hardware removal followed by a new spacer placement (Fig 4). When microbiological cultures were negative for 5 days he was taken to the OR for definitive fixation and bone grafting. A RIA 2 bone graft from the ipsilateral femur was taken, and a new anterior lateral plate was placed with an adjunct IM nail (and angle stable screws) as the distal plafond was now one articular block (Fig 5).

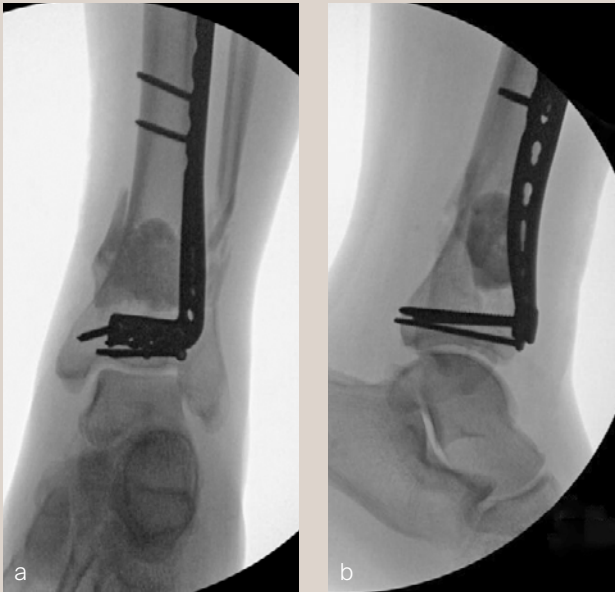


Fig 3a-b X-rays at 4 weeks postoperative (AP and ML).



Fig 4a-b AP and ML x-rays before RIA 2 bone graft and repeated fixation.

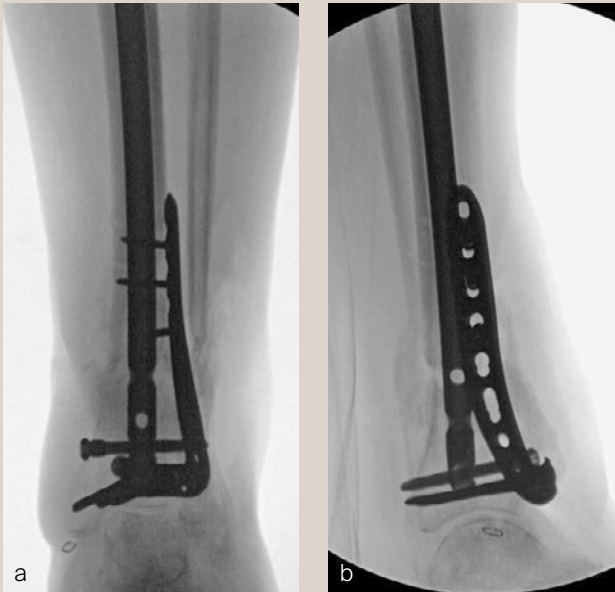


Fig 5a-b AP and ML x-rays after RIA 2 bone graft and repeated fixation.

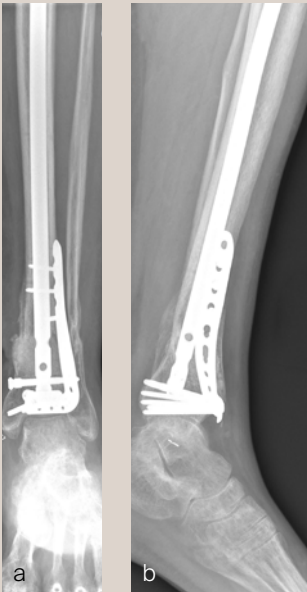


Fig 6a-b AP and ML x-rays with healed tibia at 5 months after the RIA 2 bone graft procedure.

The patient has been followed up monthly for more than 5 months and has shown continued consolidation of the bone defect (Fig 6). Furthermore, he is weight bearing as tolerated without significant pain. The leg lengths are equal and the range of motion at the ankle is 10°/25° dorsiflexion/plantarflexion. He has mild pain over the ankle joint but no pain at the fracture site.

Case 2: RIA 2 use at the humerus (by Mark Lee, Sacramento, California, US)

The patient was an 83-year-old right-hand dominant man who sustained a closed right humeral shaft fracture approximately

10 months before presentation. He was not initially offered surgical care and was treated with functional bracing. He had moderate pain but mainly complains of instability and lack of strength in his right arm. He was offered surgical nonunion repair with autogenous iliac crest bone grafting but declined iliac crest harvest. X-rays showed oblique nonunion with resorption and confirmed diagnosis of pseudarthrosis (Fig 7).

After debridement and resection of the pseudarthrosis, we accessed the distal segment of the humeral canal and used a small caliber RIA 2 reamer head to harvest intramedullary bone graft (Fig 8) for final plate fixation (Fig 9).



Fig 7a-b AP and lateral x-rays of the pseudarthrosis.

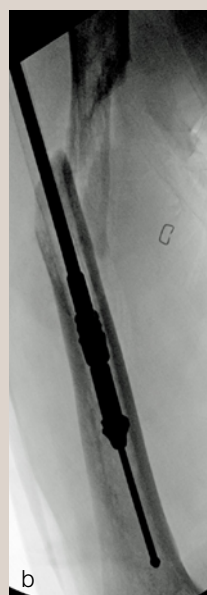
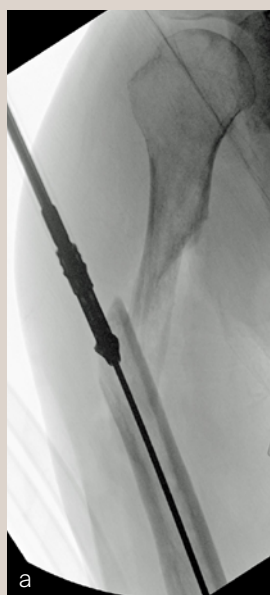


Fig 8a-d Intraoperative x-rays of RIA 2 bone harvesting for plate fixation.

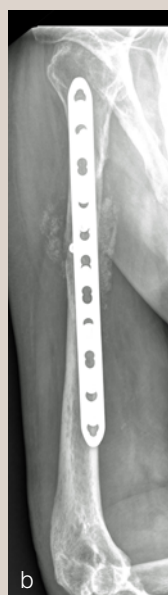
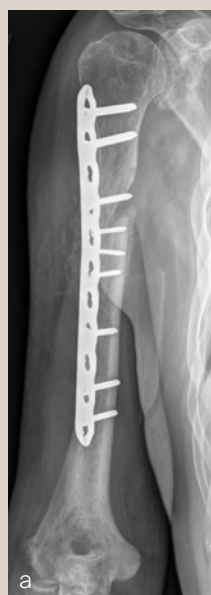


Fig 9a-b Postoperative AP and lateral x-rays of the stabilized nonunion. The lateral image reveals graft around the nonunion site.

DePuy Synthes Hammertoe Continuous Compression Implant

Hammertoe deformities are one of the most frequent deformities treated by foot and ankle surgeons. In terms of occurrence, pes planus foot posture has been associated with increased odds of developing such deformities [1]. Hammertoes are of concern in patients with diabetes, as the risk is increased for developing foot ulcers [2]. In rigid and structured hammertoe deformities not suited for nonoperative management, arthrodesis of the proximal interphalangeal (PIP) joint represents the standard treatment [3]. Temporary K-wire fixation is the most frequently used low-cost fixation method for PIP joint fusion. However, reported complications associated with K-wires have prompted the development of new implants over the past decade. Most of these are intramedullary implants, such as cannulated screws, absorbable pins, or more sophisticated shape memory devices for continuous compression at the fusion site. To address weaknesses of intramedullary fixation concepts (eg, limited rotational stability), the Foot and Ankle Expert Group approved the first extramedullary continuous

compression implant (CCI) to treat hammertoe deformities—the DePuy Synthes (DPS) Hammertoe Continuous Compression Implant (DPS Hammertoe CCI).

The DPS Hammertoe CCI has a staple-like design with four legs and a low-profile connecting bridge (Fig 1). It is made of biocompatible Nitinol, a metal alloy of nickel and titanium that is known for its superelastic properties and shape memory behavior. For more detailed information about the use of Nitinol implants and their function in orthopedic procedures see the corresponding article in the [2018 Innovations magazine](#).

The DPS Hammertoe CCI System is delivered to the operating room in a disposable, sterile kit containing the following components: Insertion Stick with pre-loaded implant (Fig 2), one Drilling Template, one Drill Pin, one K-wire, and three Locator Pins.

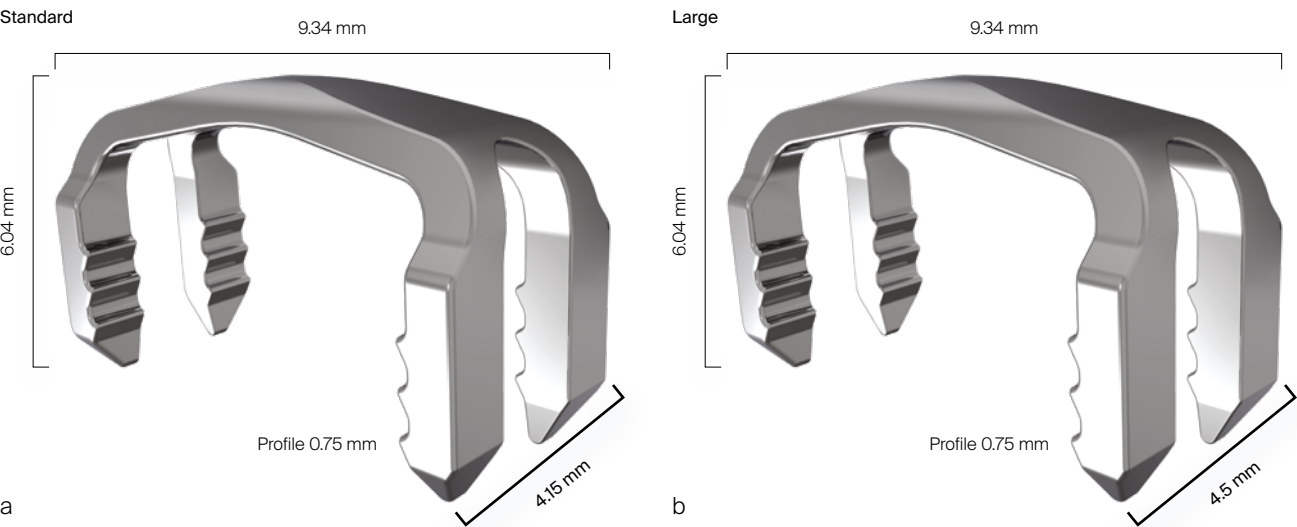


Fig 1a-b The DPS Hammertoe CCI is available in two sizes, which differ in implant width to address varying patient anatomy of the foot.

- a** The standard size implant accommodates a 1.25 mm K-wire.
- b** The large DPS Hammertoe CCI can be used in conjunction with a 1.6 mm K-wire.



Fig 2 Insertion Stick assembly including the activated implant in a constrained state, with the legs held open.

The appropriate implant kit is chosen based on the diameter of the K-wire required for the toe. The straightforward surgical technique comprises six main steps to place the DPS Hammertoe CCI (Fig 3).

Once the DPS Hammertoe CCI is inserted into the bone and released from the Insertion Stick, the implant attempts to regain its original shape with converging legs thereby providing active continuous compression at the fusion site (Fig 4 and Fig 5). The implants do not require any external heating

since they are already activated when preloaded on the insertion stick. The DPS Hammertoe CCI is not supposed to be reused after it has been discharged from the Insertion Stick because any processing, reprocessing, or mechanical manipulation may reduce the effectiveness of the implant. If for any reason the implant must be removed from the bone during the operation, then it must be replaced by a new one. Regarding patient aftertreatment, immobilization of the fusion site using routine methods (casting, splints, and so on) must be maintained until bone healing has occurred.

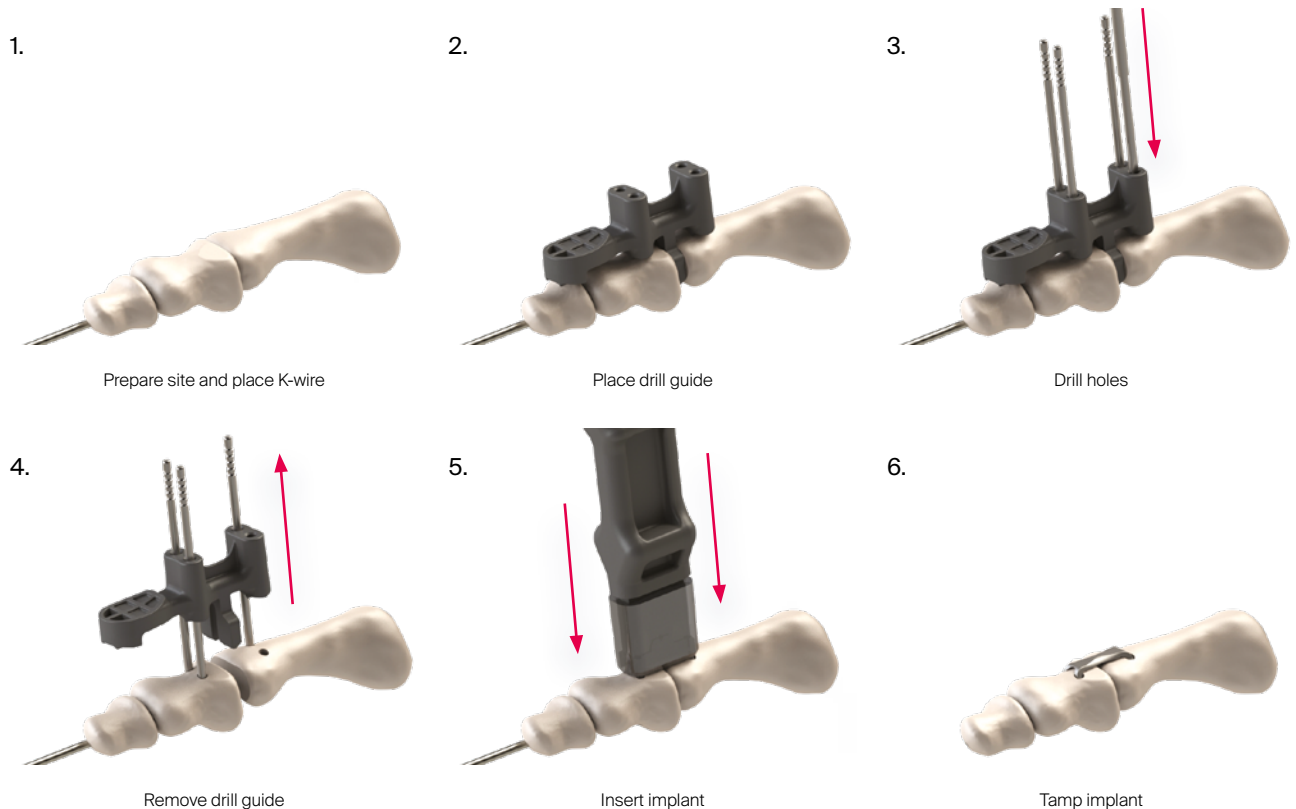


Fig 3 Placement of the DPS Hammertoe CCI: (1) Preparation of the fusion site and placement of the K-wire after proper phalange alignment. (2) Placement of the Drilling Template dorsally over the PIP joint so that the spacer of the Drilling Template slides into the PIP joint and attaches securely onto the K-wire. Before any drilling is started the joint must be in the desired position. (3) The Drill Pin with positive stop is used to drill the holes for the legs of the DPS Hammertoe CCI. Locator Pins are inserted into the first three drill holes after each drilling procedure to stabilize the Drilling Template and to keep the bone alignment. (4) Removal of the Drilling Template leaving the Locator Pins in place to mark the positions of the drill holes and reduction of the PIP joint until the bones are flush. Proper rotational alignment can be established by verifying that the Locator Pins are parallel to each other. (5) Insertion of the DPS Hammertoe CCI with the Insertion Stick after removal of the Locator Pins. The implant is automatically released as the legs of the implant are inserted into the holes and the implant is fully seated. (6) The implant can be tamped further into the bone if needed.



Fig 4 The Nitinol material of the DPS Hammertoe CCI allows continuous compression at the fusion site which supports distraction resistance. The extramedullary implant position is advantageous for bone stock preservation, rotational stability, and ease of implant removal. The low-profile design of the DPS Hammertoe CCI is intended to minimize soft-tissue irritations.



Fig 5 X-ray of the implanted DPS Hammertoe CCI.

Since the DPS Hammertoe CCI is an extramedullary implant, it offers higher rotational stability than intramedullary implants (Fig 6). Its design with the four legs orthogonal to the bone axis and the active compression feature are beneficial for the distraction resistance (Fig 7).

Due to the extramedullary position of the DPS Hammertoe CCI, bone stock is preserved, and the intramedullary pathway of callus formation is not affected. Furthermore, implant removal is simplified compared with intramedullary devices.

The DPS Hammertoe CCI System is indicated for small bone reconstruction and fusion of the phalanges in toes. Contraindications include: comminuted bone surface that can militate

against implant placement; pathological conditions of bone such as osteopenia that would impair the ability to securely fix the implant; foreign body sensitivity to metals including nickel. Where material sensitivity is suspected, appropriate tests should be made before implantation. So far, the DPS Hammertoe CCI System is only available in the United States. However, it is under consideration for introduction to other countries.

In summary, the DPS Hammertoe CCI with its extramedullary application and continuous compression properties offers the potential to reduce the complication rate of PIP arthrodesis. The implant is more expensive than K-wires and in-depth cost-benefit studies are required to justify the use of the DPS Hammertoe CCI as standard treatment.

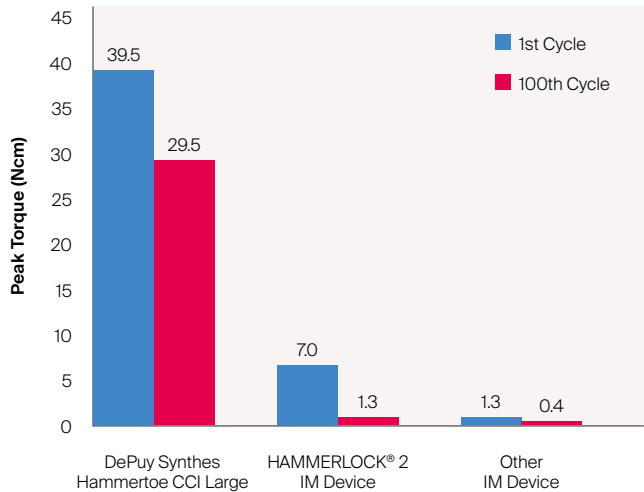


Fig 6 Cyclic benchmark testing was performed in a foam model to investigate the torsional load required for 15° rotational displacement. The DPS Hammertoe CCI provided a significantly higher rotational stability compared with the HAMMERLOCK® 2 Nitinol Implant (DPS) and another IM device initially and after 100 load cycles.

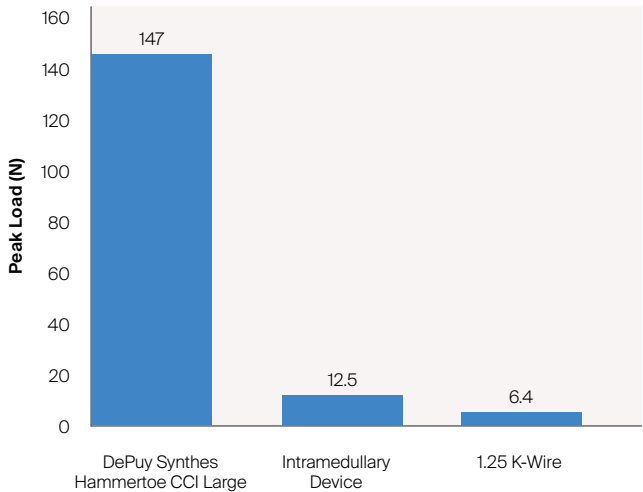


Fig 7 Benchmark distraction tests were performed in a foam model. The DPS Hammertoe CCI had a significantly higher failure load compared with the HAMMERLOCK® 2 Nitinol Implant as well as a 1.25 mm K-wire.

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New Templates for Universal Small Fragment System

In 2019, the Universal Small Fragment (USF) System was launched and consists of a core set and eight streamlined modular anatomic implant trays to support small fragment procedures with non-locking, locking, and variable angle locking plate technologies (*Innovations magazine*; 2019).

The USF System was designed to improve ease of instrument use and to reduce operating room complexity as well as reduce hospital costs associated with maintaining equipment. Templates for plating have gained importance because of the increasing request of sterile packaging of plates in many regions of the world. To enable proper implant selection, we are pleased to report that new templates complement all anatomic plate types of the USF System.

To provide an economical and effective solution, the new templates are manufactured using 3D printing technology and utilizing non-implantable stainless steel. The templates mimic the shape of the respective anatomic plates (**Fig 1**) and allow reprocessing for repeated use. They are radiopaque, and K-wire holes indicate the location of plate holes (**Fig 2**). To minimize system complexity, templates are provided for the shortest and most common length of an implant. Determination of other plate sizes can be deduced from straight measurements. The templates are labeled “DO NOT BEND”, as they will no longer mimic the partnered implant and repeated bending can result in template breakage.

The following plate families are supported by the templates:

Upper extremity:

- Proximal humerus: LCP® Proximal Humerus (PHILOS) and LCP® Periarticular Proximal Humerus
- Clavicle: LCP® Superior Anterior and Superior Clavicle (with extension and standard), VA LCP® Anterior Clavicle
- Elbow: VA LCP® Medial Distal Humerus, VA LCP® Lateral Distal Humerus, VA LCP® Posterolateral Distal Humerus, VA LCP® Proximal Olecranon, VA LCP® Olecranon, LCP® Extra-articular Distal Humerus, LCP® Hook

Lower extremity:

- Proximal Tibia: VA LCP® Proximal Tibia (small and large bend), LCP® Proximal Tibia (standard and low bend), LCP® Posteromedial Proximal Tibia, LCP® Medial Proximal Tibia
- Distal Tibia: VA LCP® Medial Distal Tibia, VA LCP® Anterolateral Distal Tibia, LCP® Anterolateral Distal Tibia, VA LCP® Posterolateral Distal Tibia, VA LCP® Posterolateral Distal Tibia T-Plate, LCP® Low Bend Medial Distal Tibia
- Distal Fibula: VA LCP® Lateral Distal Fibula, LCP® Lateral Distal Fibula, LCP® Hook

The new templates will be made available worldwide in a sequential manner beginning early 2021. Japan, Germany, the United Kingdom, and the Nordic countries are among those markets where the templates will be released first.



Fig 1 Anatomic template for the 11-hole LCP® Anterolateral Distal Tibia plate.

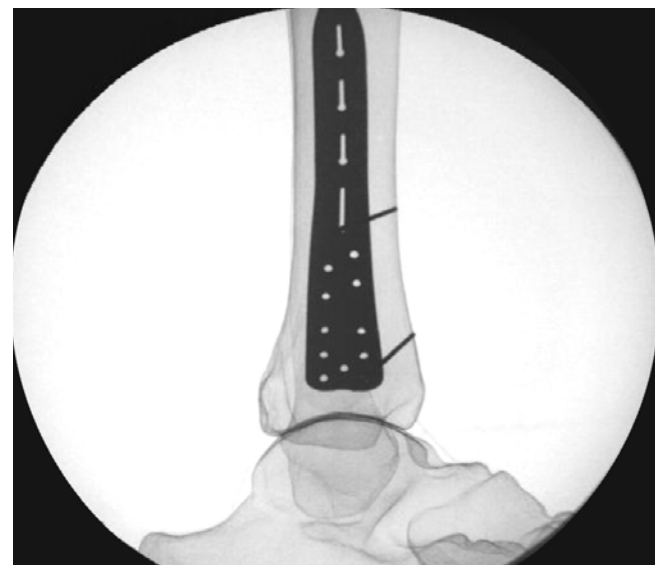


Fig 2 Radiopaque appearance of the template for the VA LCP® Medial Distal Tibia plate on a human anatomical specimen.

Simplicity derived from complexity: the development of the new variable angle clavicle fixation system based on digital modeling of anatomy and pathoanatomy

The changing concepts of clavicle fracture management

Nonoperative management has been the common standard of care for shaft and distal fractures of the clavicle. When it occurs, nonunion after nonoperative treatment has been considered to be benign. Little attention has been paid to neural and vascular symptoms of retroclavicular space compression or distortion presenting as thoracic outlet syndrome after malunion, yet these symptoms may be more common than previously diagnosed. This is the subject of a current application for a research project within the AO Research Institute Davos (ARI). Understanding the functional disability consequent on fixed scapular displacement after malunion of the clavicle (nearly always in ventral rotation with anterior, inferior, and medial displacement of the lateral fragment) has been hindered by the difficulty of characterizing the position and motion of the scapula in clinical and laboratory practice. This is compounded by taking x-rays of the injured clavicle in only the frontal plane and excluding the scapula with no comparator views of the opposite clavicle and scapula. The fracture displacement is commonly described as displacement of the medial fragment since this is apparently displaced superiorly in relation to the lateral fragment. This is not the case, as it is the lateral fragment (therefore also the scapula) that displaces away from the medial fragment. Since the center of rotation of the shoulder joint is determined by the position of the scapula, a clavicle fracture will always have a consequence for shoulder joint motion. The amount of consequential shoulder and shoulder girdle dysfunction is variable and can be accommodated by the wide range of motion of the shoulder joint, so that it becomes difficult both to evaluate and to measure or categorize accurately when using current scoring systems to justify and to compare between treatments. Patients with nonoperative management of displaced clavicle fractures take longer to return to work, have more pain, and achieve poorer functional outcomes than those who undergo operative fixation of similar fractures. Scapular postural disturbance and altered patterns of scapular motion result from the common inferior, anterior, medial, and rotational displacement of the lateral fragment. Recent randomized-controlled trials of operative versus nonoperative management of displaced clavicle shaft fractures have convincingly shown that functional outcomes and the interval to return to work are favored by operative fixation. The incidence of malunion and nonunion are both reduced by internal fixation. However, excessive subcutaneous prominence of current plate systems, and dissatisfaction with the intraoperative 'fit' of the plate systems in common use mitigated against a generally accepted operative approach. Recent detailed cost analyses of clavicle fracture fixation suggested that it may be possible during the early phase of follow-up to predict which fractures will not eventually heal and/or have a good functional outcome. Those fractures were considered for delayed operative intervention achieving good rates of union. This strategy was pragmatic and cost-efficient since fewer fractures were fixed than might have otherwise been the case had all displaced fractures been fixed in the first place. The overall reoperation rate including removal of prominent plates was reduced. It is hoped with

the advent of quick, low risk computed tomographic scanning with 3D reconstructions which include the scapulae that the evaluation, prediction, and risk stratification of functional outcomes will be facilitated.

Although the rates of infection, nonunion and malunion among surgically treated clavicular fractures are low (< 4.2%), the rate of surgical device removal or revision was reported to be high (83%) in a retrospective database analysis in the United States [1]. The associated costs for the healthcare system are significant and improved surgical options to reduce the rate of unplanned reoperations are necessary.

Motivation for changing clavicle fracture internal fixation system

The poor fit of current clavicle internal fixation systems originates in the combination of implant design and anatomical variability of the clavicle.

1. Implants are mainly designed for fractures of the middle third of the clavicle and have a shape that matches the clavicle anatomy in this region. Robinson [2] showed that clavicles are better described as having subdivisions into fifths, ie, five segments starting from the lateral end. Most diaphyseal fractures occur between the second and third fifths, for which a middle third plate is inappropriate. Compromising between plate fit and plate position with respect to the fracture could lead to imbalanced fixation, and failure of fixation. Describing a fracture as the 'middle third' according to a frontal x-ray leads to incomplete diagnosis and inaccurate treatment.
2. The complex topographical anatomy of the clavicle challenges the definition of an internal fixation system which accommodates all variants of surface shape, dimension, and form.
3. The surgical goal to avoid further fracture-related soft-tissue damage to prevent additional periosteal injury and consequent risk of failure of periosteal perfusion leading to delayed union.

An ARI research project [3] investigated the implant-preferred pathway (IPP) on the clavicle through 3D computational modeling of its shape. The IPP represents a continuous linear region of interest where the least possible soft-tissue disruption is necessary for plate fixation. Vectors created perpendicular to the tangent of the IPP define the 'twist' of the bone. This feature has not been designed into existing implants accurately for most fracture locations. The twist was a constant 35° independent of length and bowing of the clavicle. Furthermore, the radii of the antecurve and retrocurve segments had different consequences for clavicle morphology. The radius of curvature of the IPP in the retrocurve segment (the most lateral two fifths) was invariant between clavicles of different length and gender. Principle component (PC) analysis showed that clavicular length is the primary determinant of clavicular shape:

the radius of curvature of the medial antecurve segment, the medial three fifths of the bone, was directly related to length. Further PC analyses determined that the clavicle shape obeyed 'rules' that were simple if a single IPP was considered.

A group of internal fixators might be designed based on these underlying 'rules' of the IPP concept. The length of an internal fixator which determined the arc of curvature medially could be predicted from the patient's other clavicle or from his/her height and span, since these were also correlated to the clavicle length.

Market opinions

Hardware prominence and related pain, and reoperation for hardware removal are common concerns with clavicle osteosyntheses, so the focus was on better fitting, lower profile implants for various clavicle fractures, including lateral fractures with associated acromioclavicular joint dislocations in which a hook plate is indicated. Although minimally invasive percutaneous bridging osteosynthesis is acceptable for many anatomical regions, including the clavicle, a full spanning internal fixator is questionable for most surgeons. The absolute need for clavicular hook plate removal because of acromial lysis and subacromial bursal disease is a major barrier to its general use. Better design characteristics for a clavicular hook plate were required because of the high-complication rate noted in the literature and through personal experience.

Evolution of the design features of the next generation internal fixator for clavicle fractures

Since a plate has a footprint and the IPP is a line, the IPP cannot fully describe the shape of a novel plate for the clavicle. The lateral fifth is a relatively flat bone segment for the attachment of muscles on its superior surface and the suspensory ligaments on its inferior surface. This lateral fifth morphs into a cylindrical bone at the transition region between the second and third fifths of the clavicle with constant twist (see above). The novel plate shape had to respect this surface topography, which is considered complex. The recognition of 'rules' underlying the IPP triggered the question of the existence of similar 'rules' for the shape of a plate.

At the same time, variable angle (VA) technology was introduced into many systems for internal fixation, and screw design evolved to accommodate the qualitative and biomechanical differences between cortical and metaphyseal bone. These available technological advancements allowed for a broader reconsideration of the next generation internal fixator, in terms of screw sizes and screw hole pattern. The standard 3.5 mm screw fixation systems were too stiff for the caliber of some clavicles, and an investigation was initiated into the validity of a 2.7 mm screw-based system for the clavicle. Recognizing that the introduction of a 2.7 mm rather than a 3.5 mm screw system will raise questions about the strength of the fixation, considerations of required screw density and clustering, as determined by fracture patterns, were also initiated. A better understanding of specific patterns and locations of the clavicle fractures and their frequency was identified as a requirement to determine the optimal range of plate lengths, allowing for a 'balanced' fixation with a 2.7 mm system.

To answer all these questions a 'back-to-basics' approach was required: opinion was sought, and expertise valued but not relied on. The topics identified for basic and applied scientific evaluation included the specific regional anatomy of the intact bone and its variants, epidemiological studies of actual fracture patterns and frequency, biomechanical behavior of various options for the internal fixation systems, and likely

behavior of fracture after fixation with respect to the risk of complications. To enable these themes to produce useful material for the design process, computational modeling, virtual design development, predicate and evolved plate biomechanical testing, fracture and fixation simulations were all undertaken, with dry and wet laboratory testing of several iterations of the prototype fixators. Market research and usability testing in laboratory programs were initiated and valued with expert opinions from the Upper Extremity Expert Group (UEEG) and surgeons not affiliated with the UEEG. This package of evidence generation and continuous 'sense-checking' was unique to the process of development of a novel internal fixation system.

An analysis of computed tomographic scans of intact clavicles from a broad patient population investigated the underlying 'rules' of the clavicle shape by correlating the relevant anatomical parameters with individual patients' metadata, such as height or ethnicity [4]. Although many studies analyzed clavicles parameters, such as length or curvature, the relationship between the morphometric parameters and patients' demographics was partially described in the literature. The results showed that there is a strong correlation between the patients' height and clavicle length, as well as between the clavicle length and specific shape parameters, such as curvature radii. This means that the shape of the clavicle is ruled by its length and ultimately by the stature of the patient. Smaller patients have shorter and more curved clavicles, whereas taller patients have longer and less curved clavicles. The novel internal fixator system was developed based on this predictable relationship between length and shape.

Different elements of the research were addressed by different groupings of the members of the UEEG with colleagues in the ARI, members' university establishments, and DePuy Synthes (DPS) development and design engineers and marketing departments. The results were discussed, assessed, and analyzed within the UEEG in partnership with our colleagues from DPS in a collaborative effort. The consistent collaboration of the core group was instrumental in the continuing progress of the project through phases of organizational changes.

Evolution of the design features of the next generation internal fixator for the distal clavicle fractures, distal clavicular fracture-dislocation, or equivalent acromioclavicular separations

Distal clavicular fractures are characterized by splitting of fragile bone in a horizontal plane as well as vertically, with fragments which are often closely associated through the soft tissues around the fracture zone. Fixation of these fractures requires complex and variable orientation of fixation in the weaker distal bone and optimal balanced fixation in the stronger diaphyseal bone while respecting the trapezius, deltoid, and pectoral muscle attachments and permitting repair and reconstruction of coracoclavicular ligaments where required. Low-profile fixators are tolerated better, screw head prominence should be avoided, and fixation in the shaft should not compromise fixation in the distal clavicle, and vice versa. A prototype fixator used in a user-evaluation laboratory is shown in (Fig 1).

It has long been recognized in clinical practice that use of the clavicular hook plate for a range of distal clavicular injuries was complicated by inadequate understanding of the topographical anatomy of the deep surface of the acromion. This mismatch leads to small regions or points with high-compressive loading by the tip of the hook on the deep surface of the acromion, in bone which under normal conditions is subject

largely to tension, and therefore has thin cortices. This localized loading of the hook resulted in frequent acromial pain, acromial osteolysis, and occasional acromial fracture. Subacromial bursitis and superior surface rotator cuff damage was also recorded.

These complications mandated a redesign of the hook plate system in conjunction with the novel internal fixation system considered for the clavicle shaft fractures.

Little was known about the acromial surface morphology and how this related to the position and other design attributes of the hook plates (depth, length, orientation in all planes, tip design etc).

A separate research project based on 3D imaging of the acromion and distal clavicle was initiated (Martin Zenker et al, unpublished data). This aimed to describe the variation in morphology of the deep surface of the acromion with respect to the distal end of the clavicle, and to relate this to the optimal size and shape for the entire hook, not just the tip as a neutralization device for the realignment of the distal clavicle with respect to the acromion. The study concluded that there exists a high inter-patient variability of the deep acromion morphology. However, it was possible to identify a sweet spot, where this variability is minimized. Hook plates should aim at this spot to best reduce the risk of pin-point contact, sub-acromial undercut and impingement. With these insights, hook plates with optimized hook inclination, torsional angle, depth, and length were developed within the novel internal fixator system.

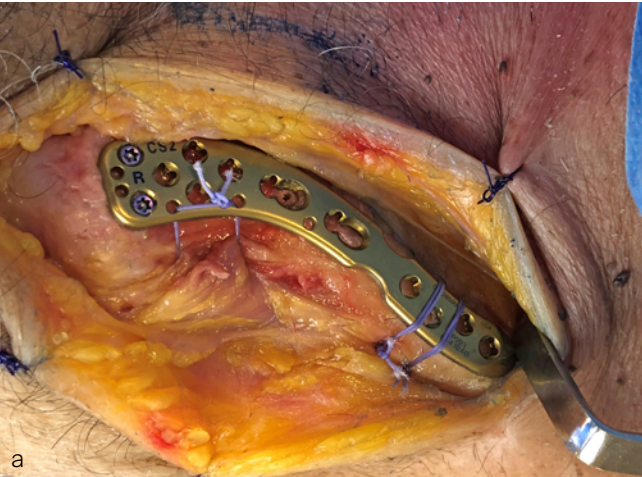


Fig 1a–c Distal clavicular fixation during prototype evaluation of the novel VA Clavicle System. Lateral is to the left in all figures. Conformation of the plate to the superior topography of the distal clavicle is designed to facilitate positioning of the distal margin of the plate parallel to the acromioclavicular joint (a) and respects the almost universal 12° downward tilt of the distal clavicle in the lateral fifth of the bone (b), while also allowing the plate to follow the beginning of the twist region at the junction of the second and third fifths of the bone (c).

Discussion

The continuous collaboration between UEEG members and DPS project team members focusing on clinical unsolved needs, advanced morphological investigations, prototype usability and reassessment of fixation technologies was the key for succeeding in developing a new internal fixator system for the clavicle. This new system was developed on the foundation of an extensive analysis of clavicular and shoulder computed tomographic scans, where plate shapes were designed and optimized based on the underlying rules and correlations of the clavicle anatomy. The optimized plate shape with the implementation of a low profile, smaller screw diameter, and VA technology in the system allow the surgeon to achieve a balanced fixation of a wide variety of clavicle fractures while ensuring optimal fit and reduced plate prominence.

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Acknowledgment

Simon Lambert contributed to this article on behalf of the former AO Technical Commission UEEG, and Arabella Fontana and Martin Zenker belong to the DPS project team.

The former AO Technical Commission UEEG, now part of the Upper Extremity Global Expert Committee, comprised Stefaan Nijs, Martin Jaeger, Chunyan Jiang, Harry Hoyer, and Simon Lambert. The DPS project team comprised (at different periods in the development pathway) André Galm, Arabella Fontana, Martin Zenker, Daniel Andermatt, Paul Franer, Regan Barber, Martin Bammerlin, Manish Gupta, and Thomas Doerdelmann.

Symphony for complex C-spine revision surgery— a case report

Launched in November 2019, the Symphony Occipito-Cervico-Thoracic System is an enhanced set of instruments and implants for posterior fixation of the upper (cervico-thoracic) spine (Fig 1). The system was described in detail in the 2019 issue of the *Innovations* magazine. The use of Symphony in a complex cervical case is described below.

Patient medical history

The woman was a 67-year-old internal medicine specialist who had six spine surgeries over the last 22 years. Beside her cervical spine problems, she was fit, healthy and slim. She first underwent cervical spine surgery in 1998 with a Frykholm procedure at C6/C7. Four years later she had another Frykholm procedure at C3/C4, followed shortly by an anterior cage stand-alone fusion procedure at C3/4. In 2015 she underwent a cage stand-alone anterior decompression and fusion at C5/C6 and C6/C7. Another 2 years later she had total disc prosthesis at C4/C5, and finally 16 months ago a posterior stabilization from C2 to C4.

Complaints

When the patient was seen for the first time in February 2020, she complained of significant load-dependent neck pain (Visual Analog Scale [VAS] score: 6 points) and an “awful” crepitation. She also reported bilateral arm pain (VAS score: 5 points) radiating to the ulnar side. She scored 30 points on the Neck Pain Disability Index. With neck flexion she experienced pain relief but also some tingling in her legs. The patient had tried to reduce the pain by conservative means including physiotherapy, massage, acupuncture, and multimodal pain treatment including continuous morphine therapy, but she did not improve substantially.

Clinical evaluation

Clinically, the patient had local pressure pain in the motion segments C4/5, C5/6, and especially C7/Th1 accompanied by a C8 radiculopathy on both sides. The slim neck and the muscle atrophy allowed an easy palpation of the posterior implants that was painful on the right side. Neurological and neurophysiological evaluation confirmed C8 root compression and residual myelopathic changes with prolonged Medianus-SEPs and MEPs. The ear, nose, and throat evaluation were within the reference range.

Radiographic evaluation

Her preoperative radiographic evaluation comprised two standard plane radiographs, functional radiographs, computed tomographic and magnetic resonance imaging scans (Fig 2) demonstrated:

- A fusion of the motion segments C2/3/4 and C6/7
- A moderate implant loosening of the posterior C2 screw on the right side
- An afunctional disc prosthesis at the level C4/C5 with significant heterotopic ossifications (grade III) accompanied by a facet joint osteoarthritis in this motion segment
- A nonunion at the level C5/C6 with residual mobility in this motion segment
- A highly mobile degenerative spondylolisthesis at the level C7/Th1 with bilateral neuroforaminal stenosis

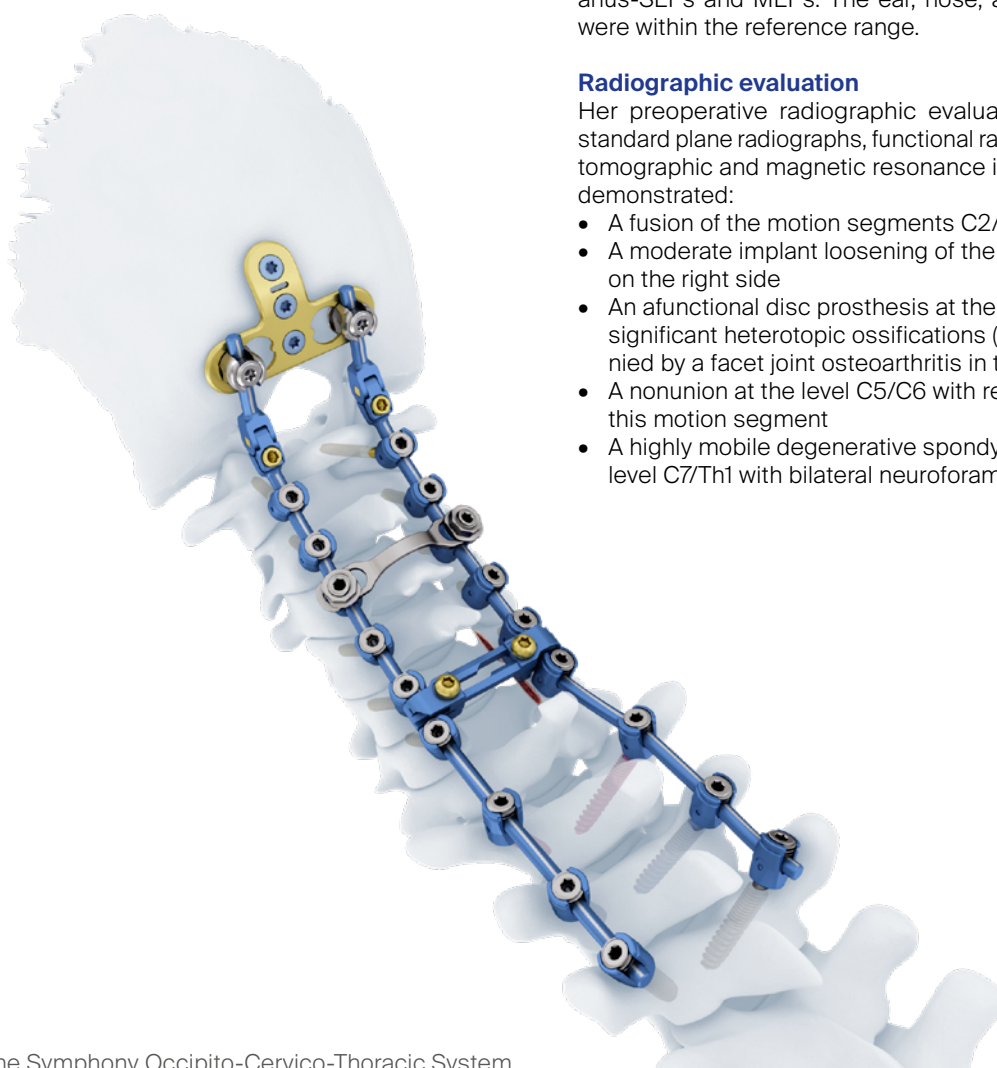


Fig 1 The Symphony Occipito-Cervico-Thoracic System.

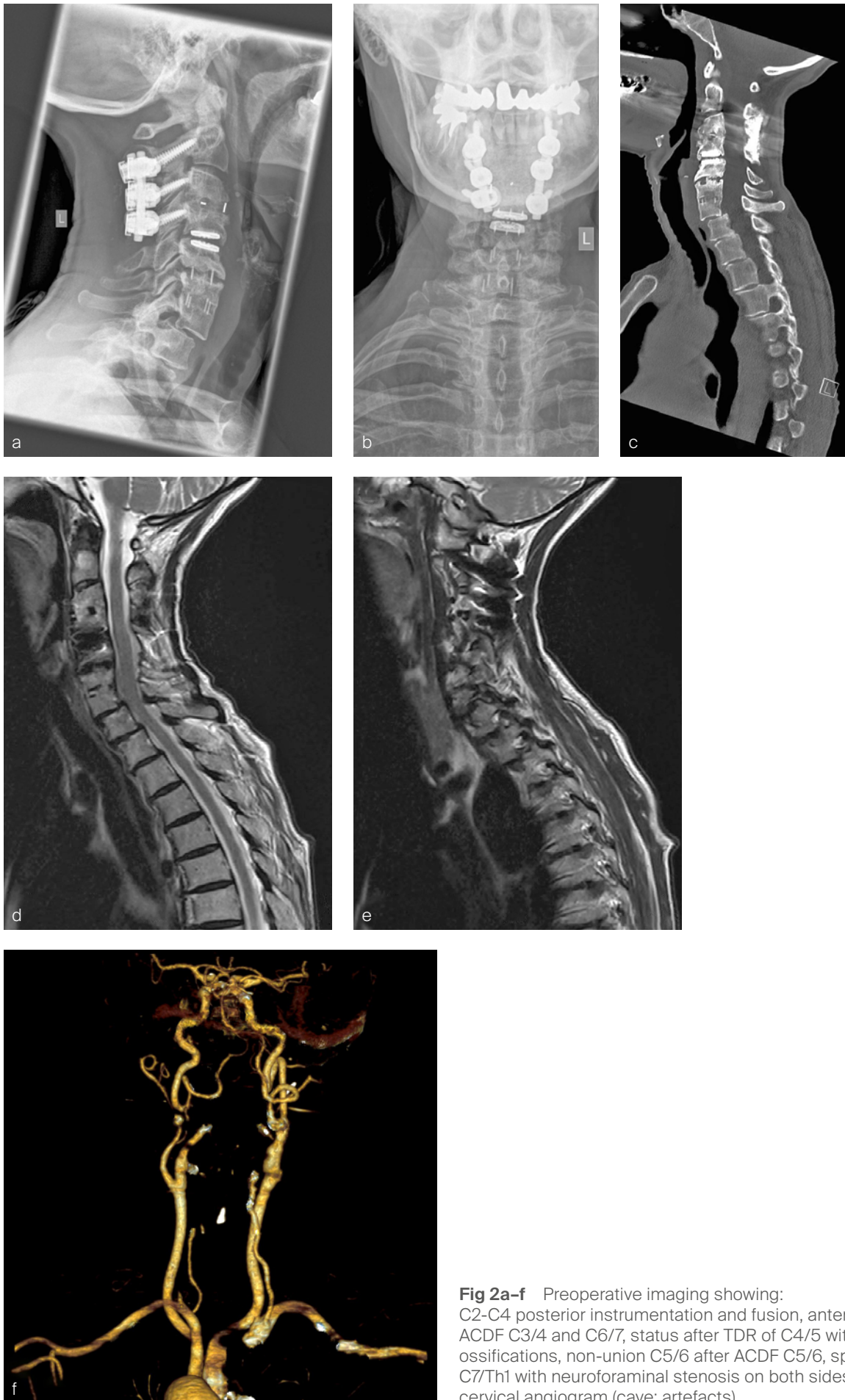


Fig 2a-f Preoperative imaging showing: C2-C4 posterior instrumentation and fusion, anterior fusion after ACDF C3/4 and C6/7, status after TDR of C4/5 with heterotopic ossifications, non-union C5/6 after ACDF C5/6, spondylolisthesis C7/Th1 with neuroforaminal stenosis on both sides and a normal cervical angiogram (cave: artefacts).

Surgery

Based on the findings detailed above and the patient's excruciating pain, an anteroposterior revision surgery was performed in June 2020.

First, a C7/Th1 anterior cervical decompression and fusion was performed via a left-sided approach. After decompression of the spinal canal and bilateral neuroforaminal decompression of the C8 nerve route, stabilization was achieved with a stand-alone Syncage-C (DPS) that already significantly reduced the spondylolisthesis.

Second, a posterior revision surgery was performed including implant removal of the posterior instrumentation between C2 and C4 followed by a laminectomy of C7 with bilateral foraminotomy of the C8 nerve routes. Re-instrumentation with isthmic screws at the level C2, lateral mass screws at the level C4, C5, and C6, as well as bilateral pedicle screws at the level T2 and T3 were performed using the new Symphony system (DPS). The Symphony system offered the opportunity to place 4.0 mm screws in the previous loosened screw location at the level C2. The 3.5 mm screws were placed in C4, C5, and C6, and 5.5 and 5.0 mm screws at T2 and T3, respectively. The 4.0 mm rod allowed a good direct connection between the cervical spine isthmic and lateral mass screws and the thoracic pedicle screws, providing adequate stability and allowing excellent reduction. An intraoperative image is shown in Fig 3. Postoperative radiographic evaluations are displayed in Fig 4.

Postoperative course

The patient improved significantly postoperatively regarding her C8 radiculopathy, which disappeared the day after surgery. Her neck pain also improved significantly and on the day of discharge from the hospital (day 5 after surgery) she only needed analgesic medication (administration of 600 mg ibuprofen three times daily).

At 6-week postoperative follow-up, the patient was taking 600 mg ibuprofen once daily for a "good night's sleep" and she was satisfied with the postoperative course (VAS neck pain score: 2; arm pain score: 0). Hence, her rehabilitation program was started.

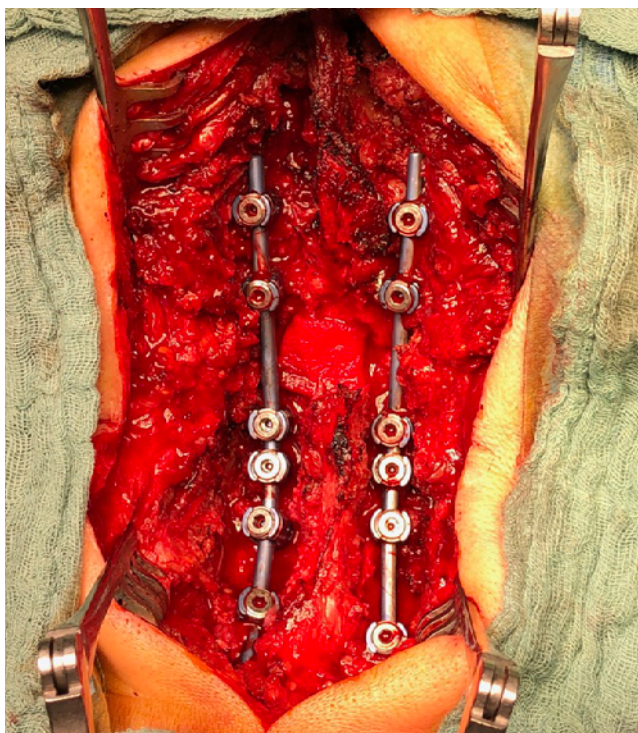


Fig 3 Intraoperative image indicating the Symphony instrumentation in situ.



Fig 4a–e Postoperative imaging showing anterior cervical decompression and fusion C7/Th1 (Syncage C) and posterior stabilization with Symphony of C2, C4, C5, C6, Th1, and Th2 using 3.5 (C4/5/6) 4.0 (C2), 5.0 (Th2) and 5.5 (Th1) mm screws and 4.0 rods.

Task Force work and approaches to evaluate new technologies in craniomaxillofacial surgery

The AO Technical Commission Craniomaxillofacial (AO TC CMF) has gone through a remarkable change in structure and strategy. The former Expert Groups have been dissolved to focus on specific task and projects in new task forces for more flexibility and less overlap among the groups working in the area on new solutions. In 2020 the AO TC CMF established two task forces and initiated two initiatives to evaluate further technologies to set the base for future projects.

1. Patient Specific Solutions Task Force

The CMF area has been the front-runner in digitalizing planning in fracture and deformity treatment and the first area where the use of patient specific implants and guides has become not only an option but also in some indications the state-of-the art treatment. As with all new technologies the first years involve a lot of enthusiasm and learning by doing, it has become obvious that certain principles and rules in patient care still need to be followed. Therefore, the AO TC CMF initiated the collection of clinical data in specific areas where patient specific implants are mostly used. In AO TC CMF Workshops and the first CMF Symposium the AO TC CMF together with key opinion leaders in the field elaborated on specific workflows with common standards for the clinical image-based planning of the treatment, the design of the implants and guides and the planning of the surgical procedure with the patient specific instrumentation. The newly established Patient Specific Solutions Task Force is now in charge to further develop and harmonize the workflows with providing basic principles for the imaging and clinical analysis for specific indications, establishing rules for the planning and design of the patient specific implants for those indications and the adapted surgical procedures where applicable. The goal is to provide information and guidance to help surgeons to safely start using this technology and acquire experience without the difficulty of making avoidable mistakes.

2. CMF Distraction Task Force

The CMF Distraction Task Force was established to support the introduction of the new CMF Distractor into the market and collect clinical data to provide clinical evidence for this new tool as well as for distraction procedures in the CMF area in general. Further development in digital planning and the use of patient specific footplates for the distractors is the next step in development. The evaluation of enhanced technologies for distraction control and the collection of feedback about the distraction forces and the established bone formation for the further development of new solutions are long-term goals of this task force.

3. Initiatives to evaluate new technologies

The AO TC CMF invited a small company to present its solution for TMJ Replacement based on patient specific implants to evaluate this technology. As the introduction of new devices in TMJ Replacement is strongly regulated by the US Food and Drug Administration and its Medical Device Reporting surveillance tool, the development of new solutions has to overcome major hurdles, which makes the development from scratch a difficult and risky journey. Consequently, the AO TC CMF decided to evaluate further solutions and compatible partners experienced in TMJ Replacement for a collaboration in this field.

A second interesting new technology is the use of patient specific graft cages for bridging critical gaps in bony structures because of bone loss after ablative surgery or trauma. The AO TC CMF supports a sheep study to prove the concept of using patient specific graft cages in the mandible to regain bony structures, which will be able to close the gap and support the fixation of dental implants to recover full function.

3.5 LCP Distal Femoral Osteotomy Plates

Background

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. Traditional surgical correction of canine patellar luxation includes procedures such as sulcoplasty and tibial tuberosity transposition. These techniques are often insufficient in more severe cases resulting in recurrence of patellar luxation. Complex limb deformities involving both the femur and tibia (eg, distal femoral varus, femoral torsion, and a compensatory tibial valgus and/or torsion) typically explain these surgical failures. Distal femoral osteotomy/osteotomy (DFO) was developed to address distal femoral varus (with or without torsion) and has led to markedly improved clinical outcomes. Current implants for canine DFO are not anatomically specific to follow both the femoral procurvatum and condylar morphology, nor do they guide screw trajectory to avoid the femoral intercondylar notch and the femoral trochlea, especially with locking implants. As such, veterinary surgeons may encounter challenges with plate contouring and screw placement.

Plate design

The recently approved 3.5 LCP DFO plate is indicated for treatment of distal femoral angular deformities and distal femoral fractures. The plate curvature was designed to accommodate procurvatum (anatomical curvature in the sagittal plane) and optimize screw trajectories into the widest portion of the femoral condyle while simultaneously avoiding the regions of the intercondylar notch and femoral trochlea in medium and large breed dogs. The plates are available in 7- or 8-hole lengths to account for variable femoral sizes encountered in medium and large canine patients. Additionally, the plates are specific for left and right limbs (Fig 1). They are compatible with both 3.5 mm locking and cortex screws (Fig 2). The trajectories of the three distal locking screws were designed to avoid the intercondylar notch, maximize screw purchase in the caudal portion of the femoral condyle, while also avoiding cranial screw placement so as to preserve bone for concurrent sulcoplasty (Fig 3). The tapered, curved design minimizes interference of the distal plate with both the patella and periarticular soft tissue.

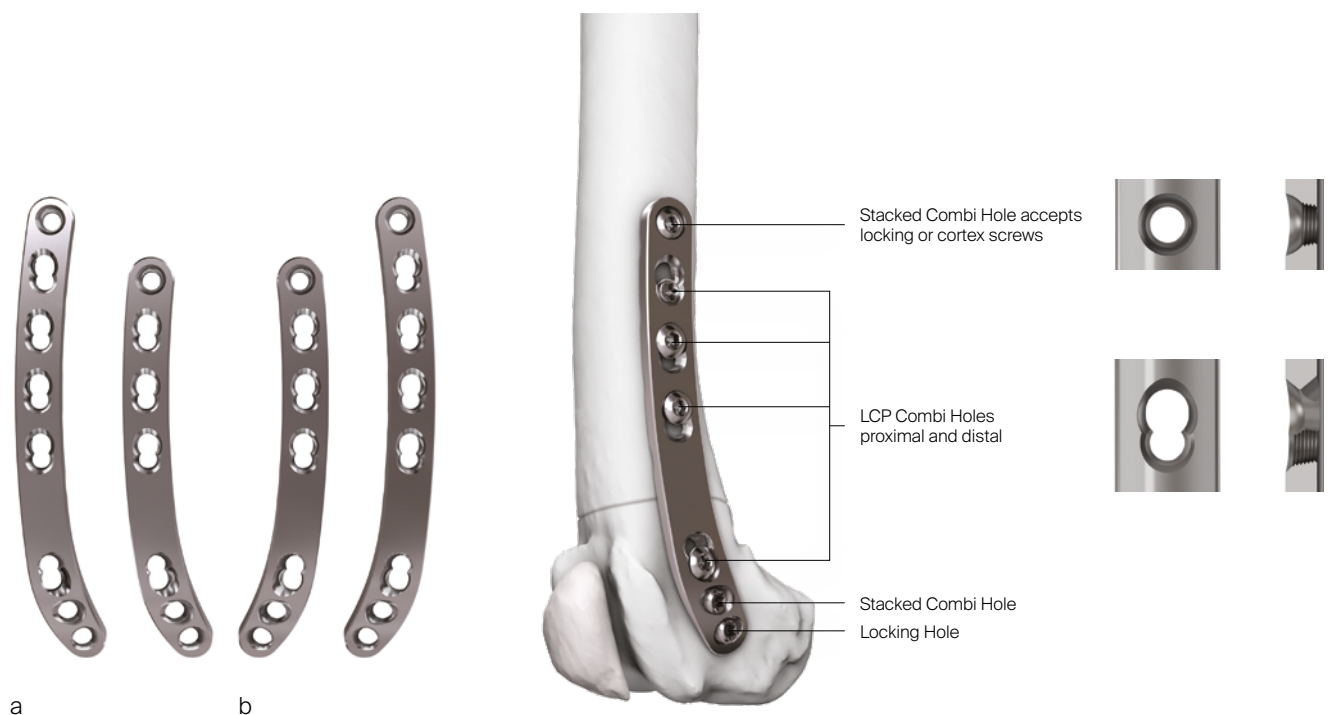


Fig 1a-b Left (a) and right (b) 7-hole and 8-hole 3.5 LCP Distal Femoral Osteotomy Plates.

Fig 2 Distribution of LCP and stacked combi holes in the 3.5 LCP Distal Femoral Osteotomy Plate.



Fig 3a-c Screw trajectories on the distal end of the 3.5 LCP Distal Femoral Osteotomy Plate.

The 3.5 LCP DFO plate has been designed based on the following three key features:

1. **Anatomical fit:** the plate contour matches the 3D shape of the distal femur. The plate follows the shape of the femur in the frontal plane (craniocaudal view) with an in-plane bend that flares over the distal femoral condyle. The plate also follows femoral curvature in the sagittal plane (lateral view) to match the anatomical procurvatum of medium and large breed dogs. Plate design includes a tapered distal geometry for low-profile fit. These design features decrease the likelihood of impingement with the patella, parapatellar fibrocartilage, or joint capsule.
2. **Multiple screw placement options:** the plate contains LCP combi holes, stacked combi holes, and allows compression across the osteotomy for primary bone healing.
3. **Precise locking screw trajectories:** screw trajectories are designed to avoid intraarticular structures while maximizing transcondylar bone purchase. This feature allows the surgeon to perform a sulcoplasty as needed without screw interference. Screw trajectory also avoids penetration of the intercondylar notch and damage to the cruciate ligaments.

Using the 3.5 LCP DFO plate in distal femoral corrective osteotomies or distal femoral fractures facilitates plate application while simultaneously preserving the subchondral bone of the trochlea. These features allow concurrent sulcoplasty, reduces the need for perfect plate contouring, and may improve construct stability.

Clinical cases

The following two cases (kindly provided by Michael Kowaleski, North Grafton, Mass, USA, and Erik Asimus, Toulouse, France) illustrate common canine femoral deformities associated with moderate to severe medial patella luxation and demonstrate application of the 3.5 LCP DFO Plate.

Case 1: Distal femoral osteotomy in a 4-year-old female spayed mixed breed dog with medial patellar luxation

A 4-year- and 6-month-old spayed female mixed breed dog weighing 25.1 kg was presented for chronic progressive left

pelvic limb lameness. Orthopedic examination and preoperative x-rays revealed a grade 3/4 medial patellar luxation without concurrent cranial cruciate ligament rupture. A preoperative computed tomography (CT) was performed to screen for femoral varus and/or femoral torsion. Femoral varus was documented (anatomical Lateral Distal Femoral Angle [aLDFA] 104°, normal 92–96°). The femoral torsion angle was 26° and was like the unaffected contralateral limb and within the normal range. The planned correction was a 12° lateral closing wedge osteotomy, with concurrent sulcoplasty and tibial tuberosity transposition (Fig 4).

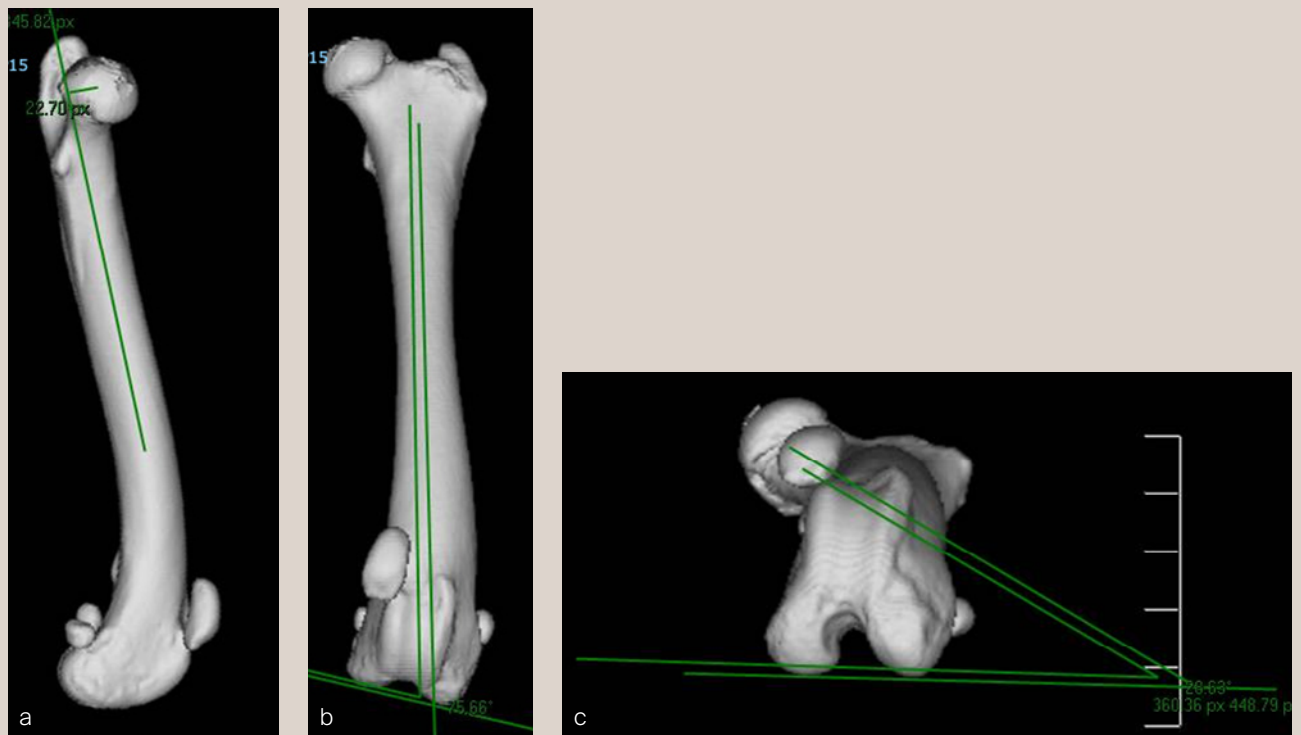


Fig 4a–c Preoperative computed tomographic 3D reconstruction of the left femur.

- a** Mediolateral view illustrates anatomical anteversion of the femoral head and neck and procurvatum of the femur.
- b** Craniocaudal view confirms distal femoral varus (anatomical Lateral Distal Femoral Angle, 104°).
- c** Femoral long axis view shows anteversion angle (26°).

A routine lateral approach to the distal femur and stifle joint was performed. Results of the cruciate ligaments examination were normal. The lateral joint capsule was dissected to expose the distal femoral condyle. An alignment jig was placed in a craniocaudal direction to ensure that deformity correction was limited to the frontal plane. A 12° lateral closing wedge osteotomy was performed and the femoral condyle was reduced and temporarily stabilized with divergent K-wires. A 7-hole left 3.5 LCP DFO plate was placed on the lateral femur and secured

with a combination of 3.5 mm cortex and locking screws. The compression function of the plate was used to compress the ends of the two bone segments. Temporary K-wires were removed and a wedge sulcoplasty was performed to deepen the trochlear groove for improved patella articulation. A tibial tuberosity transposition was performed and stabilized with two pins and tension band wire. Routine closure was performed. Total surgical time was 1 hour and 45 minutes (Fig 5 and Fig 6).

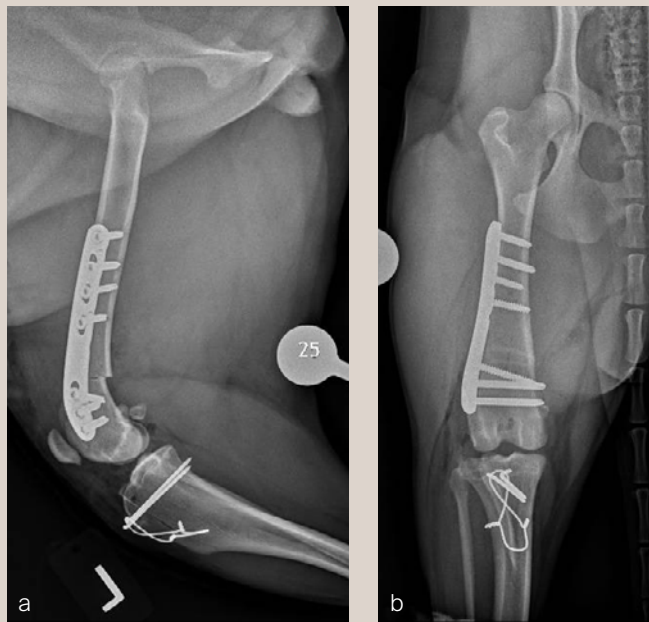


Fig 5a-b Postoperative x-rays demonstrating position of a left, 7-hole, 3.5 LCP DFO plate and associated tibial tuberosity transposition.

- a** Mediolateral view. Note that plate contour matches the normal distal femoral procurvatum and screws are positioned caudally away from the trochlea. This allows for an unimpeded sulcoplasty while maximizing screw purchase caudally. The compression applied with the plate has resulted in excellent apposition. The patella is visible within the trochlear groove.
- b** Craniocaudal view. The plate contour matches the anatomical contour of the distal femoral condyle. The anatomical Lateral Distal Femoral Angle is reduced to 92°.

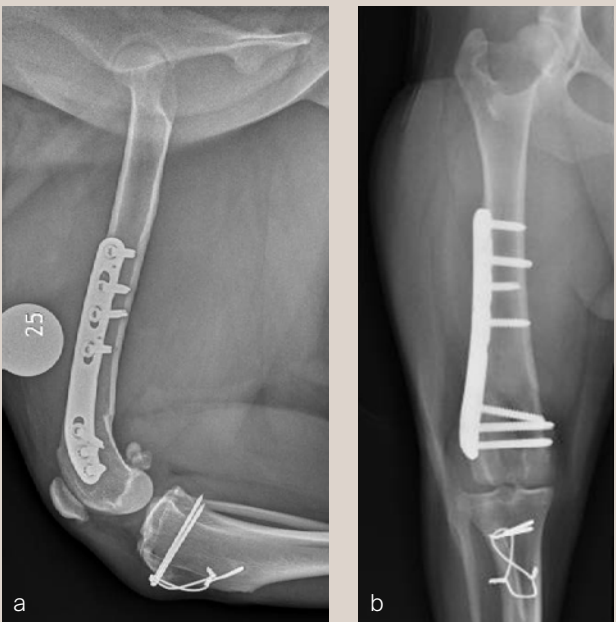


Fig 6a-b Follow up after 8 weeks. Clinical signs have resolved, limb use is excellent, and stifle joint range of motion is normal without evidence of pain.

- a** Mediolateral x-ray. The osteotomy has healed. Plate and screw position remain unchanged. The tibial tuberosity transposition is healing, and implants remain unchanged. The patella remains reduced within the trochlear groove.
- b** Craniocaudal view. The osteotomy has healed and is no longer visible. Implants are stable and the patella is tracking normally.

Case 2: Distal femoral osteotomy in a 1-year- and 6-month-old spayed female Appenzell Cattle Dog

A 1-year- and 6-month-old spayed female Appenzell Cattle Dog weighing 29 kg presented for a second opinion after two previous surgical procedures (Fig 7 and Fig 8) to address a traumatically

induced medial patellar luxation. Orthopedic examination and preoperative x-rays revealed a grade 3/4 medial patellar luxation (Fig 8). Femoral varus was documented (aLDFA 104°; reference range, 92–96°) by CT scan (Fig 9). The planned correction was a 10° lateral closing wedge osteotomy, with concurrent sulcoplasty.



Fig 7a–b Initial surgery performed at 1 year and 6 months of age. The patellar luxation was treated with a lateral imbrication. No primary orthopedic procedures were performed. X-rays were obtained 6 weeks postoperatively, and document persistence of the medial patellar luxation.



Fig 8a–b Revision surgery performed to address persistent patellar luxation. A tibial tuberosity transposition was performed to realign the insertion of the patellar tendon without addressing femoral deformity. X-rays were obtained 2 months postoperatively. The patellar luxation persists despite transposition of the tibial tuberosity.

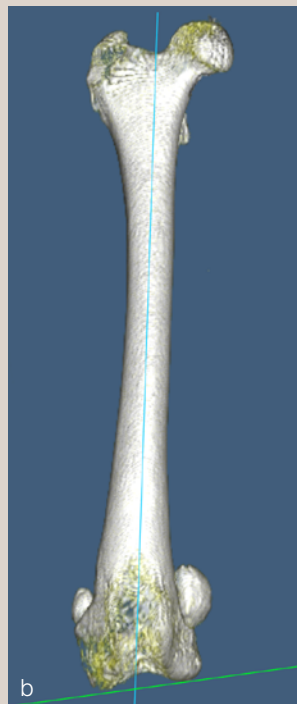


Fig 9a–b Preoperative computed tomographic 3D reconstruction of the right femur confirming distal femoral varus (anatomical Lateral Distal Femoral Angle was 104°). Planned correction was to perform a 10° lateral closing wedge osteotomy.

A routine lateral approach to the distal femur and stifle joint was performed. Standard DFO technique was used to create a 10° lateral closing wedge osteotomy. A 7-hole 3.5 LCP DFO plate was placed on the lateral femur and secured with a combination of 3.5 mm cortex and locking screws. The compression function

of the plate was used to compress the ends of the two bone segments together. A wedge sulcoplasty was performed to deepen the trochlear groove for improved patella articulation. After routine closure, total surgical time was 1 hour and 30 minutes (Fig 10 and Fig 11).

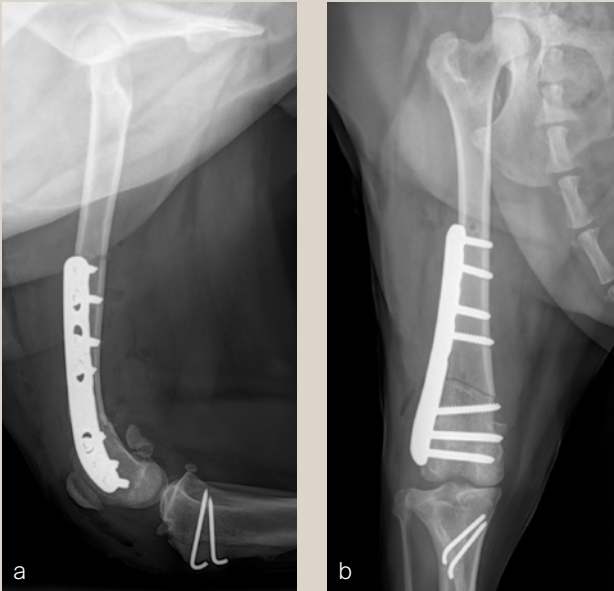


Fig 10a–b Postoperative x-rays demonstrating position of a 7-hole, 3.5 LCP DFO plate.

- a** Mediolateral view. Plate contour matches the distal femoral procurvatum. The compression applied to the plate results in excellent apposition. The patella is visible within the trochlear groove.
- b** Craniocaudal view. The plate contour matches the anatomical contour of the distal femur. The anatomical Lateral Distal Femoral Angle has been reduced to 94°.

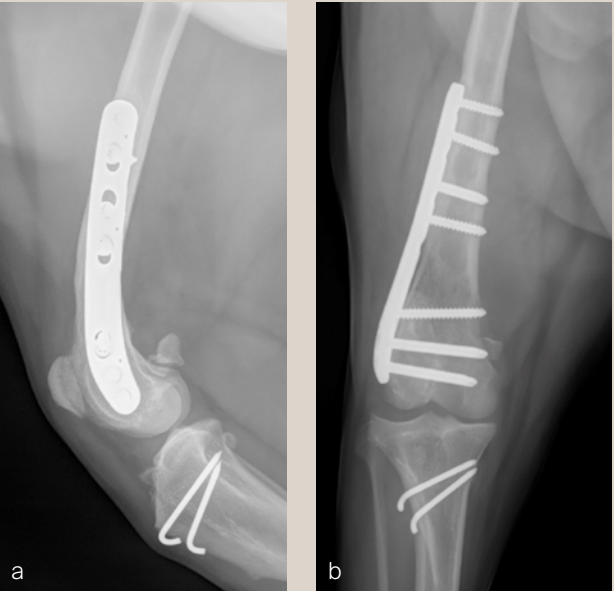


Fig 11a–b Follow up after 1 year. Clinical signs have resolved, limb use is normal and range of motion of the knee is also normal.

- a** Mediolateral x-ray. The osteotomy has healed. Plate and screw position remain unchanged. The tibial tuberosity transposition is healing, and implants remain unchanged. The patella remains reduced within the trochlear groove.
- b** Craniocaudal view. The osteotomy has healed and is no longer visible. Implants are stable and the patella is tracking normally.

Fracture-related infection: new consensus on diagnosis and treatment

Fracture-related infection (FRI) is one of the most complex problems in modern orthopedic trauma surgery. Even after exemplary surgical care, patients can still suffer from infection at the site of the operation, and this has significant impact on their recovery. In recent years, the problem of implant-related bone infection has gained greater attention, but the primary focus has been periprosthetic joint infection rather than FRI.

Since its inaugural meeting in August 2016, the Technical Commission's Anti-Infection Global Expert Committee (AIGEC; [link to AO Technical Commission](#)) has focused its efforts on pioneering work to improve the prevention, diagnosis, and treatment of infection. Chaired by Prof Michiel Verhofstad (Rotterdam, NL), the AIGEC is composed of global key opinion leaders in the field of infection, including orthopedic and trauma surgeons, microbiologists, infectious disease specialists, and basic scientists.

AIGEC members saw a clear opportunity to address FRI by leveraging the reputation and global reach of the AO Foundation to bring together key opinion leaders to reach a consensus on current clinical issues. Together with the AO Research Institute and the AO Trauma Clinical Priority Program on bone infection, two international consensus meetings were convened.

At a first consensus meeting in December 2016 ([Fig 2](#)), a group of invited experts, including representatives from the European Bone and Joint Infection Society (EBJIS) and prominent orthopedic trauma centers with a major interest in FRI, achieved consensus on the fundamental features of FRI, and established a definition for FRI that was published in 2017 ([link to Injury](#)). This international consensus definition offers the opportunity to standardize clinical reports in daily practice and improve the reporting of clinical studies in FRI.

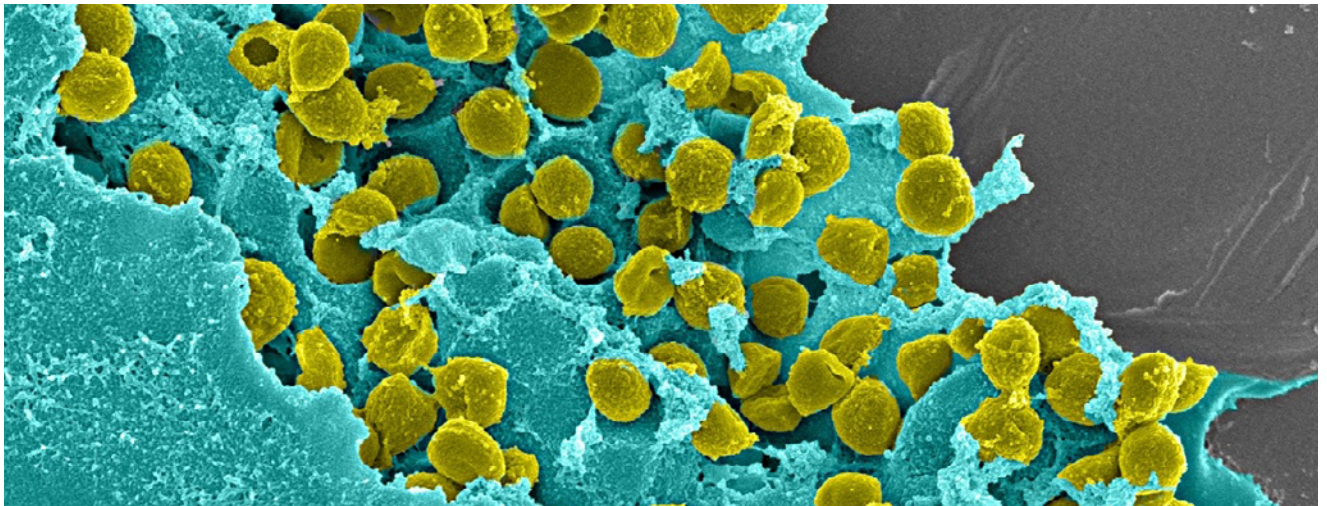


Fig 1 A *Staphylococcus aureus* biofilm; commonly present in fracture-related infection.



Fig 2 Willem-Jan Metsemakers (University Hospitals Leuven, Belgium) addresses members of the international expert group discussing the development of a definition of fracture-related infection.

A broad consensus on diagnosis and treatment principles for FRI was achieved at a second meeting held in Zurich, Switzerland, in February 2018 (**Fig 3**). Supporting the meeting were 35 experts and key opinion leaders in the field of FRI including surgeons, infectious disease specialists, clinical researchers, and research scientists. Representative organizations included the EBJIS, the Orthopedic Trauma Association (OTA), and the PRO-IMPLANT Foundation. Importantly, the new definition of FRI was updated here and endorsed by the different organizations (AO, OTA, EBJIS, and the PRO IMPLANT Foundation). In 2018 this consensus definition was also endorsed by the delegates of the International Consensus meeting held in Philadelphia, US ([Musculoskeletal Infection in Orthopaedic Trauma](#)).

Four papers containing recommendations for the diagnosis and treatment of FRI were published in early 2020.

- [Diagnosing Fracture-Related Infection](#)
- [Evidence-Based Recommendations for Local Antimicrobial Strategies](#)
- [Recommendations for Systemic Antimicrobial Therapy](#)
- [General treatment principles for fracture-related infection](#)

Trauma surgeons worldwide need access to a single, reputable site to access these FRI recommendations, and work is underway within the AO Foundation to build an online platform to achieve this aim. At the same time, dissemination of the FRI recommendations is also proceeding via several other channels:

- Symposium session at major orthotrauma congress (ie, opening symposium at the annual OTA meeting, Denver, Colorado, US, 2019)
- Meet the Experts session in Davos, December 2019
- Inclusion of the new guidelines in future AO Basic and Advanced Principles Courses

The global availability and adoption of the new guiding principles for FRI should enable improvements in clinical studies on infection incidence, reduce the cost of treatment, lead to more effective treatment strategies, and promote better patient outcome.

The consensus work of the AIGEC is firmly based on both interdisciplinary and cross-organizational collaboration. Bringing different specialists from diverse fields together creates powerful synergies and new opportunities to solve the long-standing problem of FRI. "Within this consensus group we are one team leading together, those more experienced were always supportive, and that's what makes this project so great—support from the AO and the entire scientific community," says Michiel Verhofstad, AIGEC Chair.

Building on the achievements of the last 4 years, the AIGEC is now focusing on new international initiatives in collaboration with other organizations, including further consensus work on the prevention of FRI, and the validation of the diagnostic criteria for FRI. The AO is honored to play a leading role in international efforts to combat FRI and to support the AIGEC in driving forward this vital work and improving patient care.



Fig 3 Members of the international consensus group from Argentina, Belgium, France, Germany, the Netherlands, South Africa, Switzerland, the UK, and the US assembled in Zurich to discuss the diagnosis and treatment of fracture-related infection.



Fig 4 AIGEC members, Willem-Jan Metssemakers (University Hospitals Leuven, Belgium) and Bill Obrebsky (Vanderbilt University Medical Center, Nashville, Tenn, US,) present the recently published fracture-related infection consensus recommendations in a *Meet the Expert* session to a live audience in Davos and an online audience of more than 500 trauma surgeons.

Update from the Smart Digital Solutions Task Force

Under the guidance of the Chair, Benedikt Braun from Germany, the Smart Digital Solutions Task Force (SDSTF) pursues the vision of enhancing the patient journey in trauma with digital technologies. One of its first goals was to assess available technologies, their current and potential applications in orthopedic trauma surgery, and to provide an overview for the modern trauma surgeon. The group has recently published its first whitepaper “Finding NEEMO” [1] that provides an overview of how current digital solutions can match the needs of orthopedic trauma surgery. The article includes a suggestion of basic rules intended to guide the development and use of new digital solutions as they are introduced—the NEEMO framework principles.

At the ORS Annual Meeting 2020, the group conducted a workshop on ‘Digital Patient Outcomes Using Sensors as Wearable Monitors: Opportunities, Methods and Applications.’ The attendance made clear that the interest on this topic is generally high. As expected, the discussions revealed that even though various groups are performing clinical studies

using wearables to measure outcome parameters, the clinically most relevant and meaningful outcome parameters, and the most efficient ways to measure them have yet to be defined.

Besides collaboration in emerging digital projects with AO’s trusted partner DePuy Synthes, the SDSTF is currently working on a systematic assessment for the use of wearable technology to measure activity in orthopedic trauma patients. The ambitious goal is to eventually make recommendations on best evidence-based practices of using wearable devices to measure activity, and to advise on clinically relevant outcome parameters.

The members of the SDSTF are Bernd Grimm (Luxembourg), Meir Marmor (United States), Peter Richter (Germany), and Sureshan Sivananthan (Malaysia). Andrew Hanflik (United States) is a regular guest at the task force meetings. Within the AO Technical Commission, the SDSTF reports to the Computer Assisted and Image Guided Surgery Global Expert Committee (CIGEC).

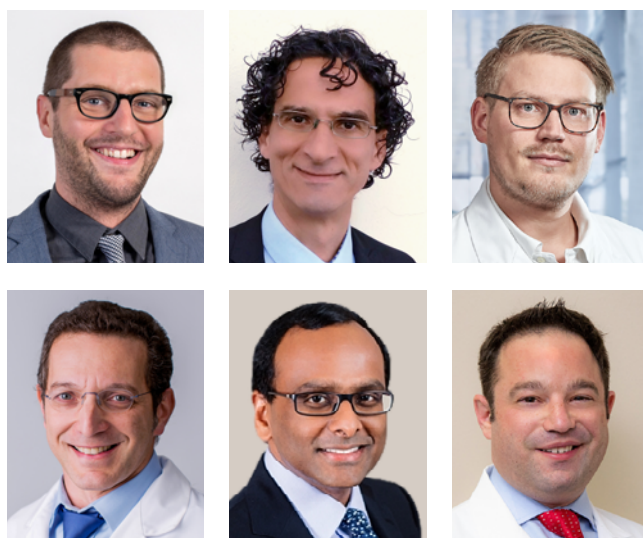


Fig 1 Top left to right: Benedikt Braun, Bernd Grimm, and Peter Richter; bottom left to right: Meir Marmor, Sureshan Sivananthan, and Andrew Hanflik.



Fig 2 The article written by members of the SDSTF for the official journal of the European Federation of National Associations of Orthopaedics and Traumatology (EFORT Open Review).

Reference

1. **Braun BJ, Grimm B, Hanflik AM, et al.** Finding NEEMO: towards organizing smart digital solutions in orthopaedic trauma surgery. *EFORT Open Rev.* 2020 Jul;7:408–420.

AO Technical Commission Meet the Experts sessions 2019

As in previous years, the AO Technical Commission (AO TC) organized a series of Meet the Experts sessions during the AO Davos courses in December 2019. Seven sessions were held by the AO TC to inform the course participants about new implants, instruments, and surgical techniques to address clinical problems. All events were streamed live to allow attendance from the worldwide audience. Online viewing of the recorded sessions is possible through this [link to AO Technical Commission Meet the Experts](#). In this article a comprehensive overview of the events is presented.

1. RIA 2: The next generation Reamer Irrigator Aspirator

RIA 2 is the next generation Reamer Irrigator Aspirator system that allows efficient clearing of the intramedullary cavity of debris and harvesting of autograft (see the RIA 2 article in [Innovations magazine; 2019](#)). Furthermore, it offers fewer complications during reaming compared with iliac crest bone graft harvesting, efficient management of infection, reduced procedure time, and improved patient outcomes. Trauma surgeons Brent Norris and Martijn Poeze presented the new and improved features of RIA 2 including an overview of the device technology, indications for use, and case examples ([Fig 1](#)). The lively and interactive session included a hands-on demonstration of device assembly and femoral reaming. The surgeons shared their considerable expertise and experience with this technology to offer tips and tricks for effective use of the RIA 2 system. These tips encompassed reaming entry points, measurement of the intramedullary canal, optimal reaming technique for bone harvesting, and the avoidance of potential technical challenges.

2. Fracture-related infection: new consensus on diagnosis and treatment

Fracture-related infection (FRI) remains a challenging complication that creates a heavy burden for orthopedic trauma patients, their families and treating physicians, and for health-care systems. Standardization of the diagnosis and treatment of FRI has been lacking, which has made it difficult for researchers to perform and compare studies in this field. In this Meet

the Experts session, key opinion leaders in FRI, Willem Metsemakers and Bill Obrebsky, presented the recently published consensus recommendations for the diagnosis and treatment of FRI ([Fig 2](#)). Developed by an international group of recognized experts in FRI, the evidence-based recommendations encompass confirmatory and indicative features for the diagnosis of FRI; general treatment principles including risk stratification, patient optimization and a multidisciplinary team approach; surgical management and antimicrobial treatment.

The primary aim of the international consensus group is to improve the outcome for patients with FRI by disseminating these proposals to the global community of healthcare providers and promoting the standardization of treatment principles and outcome measures. In the longer term, this standardization will also improve the comparability of future studies and trials. Further information is provided in the article in this [Innovations magazine](#) on “[Fracture-related infection: new consensus on diagnosis and treatment](#).”

3. Minimal invasive rib stabilization

Chest wall trauma with multiple rib fractures and flail chest are injuries with mortality rates as high as 20% and major complication rates of up to 40%. The number of surgical procedures for rib fracture stabilization has increased as dedicated implants and instruments became available. The development of improved tools has led surgeons to perform rib fracture fixation through smaller incisions. Innovative surgical techniques make this type of surgery available to an increasing number of patients. Stefan Schulz-Drost and Mario Gasparri, two leading experts in thoracic surgery, provided an insight into minimally invasive rib stabilization using the MatrixRIB Fixation System (for rib and sternum fractures) and the recently developed self-drilling screws. Schulz-Drost provided a comprehensive overview about the different surgical procedures available for the median, lateral, and posterior chest wall regions. A hands-on demonstration led the participants through a minimal invasive procedure for sternal fracture fixation.



Fig 1 Left to right: Brent Norris and Martijn Poeze presented the new RIA 2 System.



Fig 2 Left to right: Willem Metsemakers and Bill Obrebsky guided the audience through the consensus recommendations for the diagnosis and treatment of fracture-related infections.



Fig 3 Left to right: Stefan Schulz-Drost and Mario Gasparri explained innovative treatment solutions for rib fracture stabilization.

4. Elastic nailing for children's fractures: how to avoid complications

Elastic stable intramedullary nailing (ESIN) has become the method of choice for internal fixation of long bones in children and teenagers aged 4–14 years. However, ESIN treatment can also lead to complications like loss of reduction following push-out of the nails at the entry site, especially in unstable femoral shaft fractures. Nail migration with subsequent soft-tissue and skin irritation has been reported to be as high as 5–12%. In this Meet the Experts session, Unni Narayanan and Theddy Slongo, from the AO TC Pediatric Expert Group, presented in a hands-on session the best practices with ESIN to avoid complications in pediatric fracture treatment (Fig 4). Slongo explained the basic biomechanical principles of ESIN to provide stability: symmetrical bracing and 3-point contact. The two presenters shared femoral, tibial and forearm fracture cases with recommendations for preoperative planning as well as for correct insertion and positioning of ESIN.



Fig 4 Left to right: Theddy Slongo and Unni Narayanan shared their experiences with elastic nailing of pediatric fractures.

5. Patient specific procedures in craniomaxillofacial—state of the art

Patient specific implants (PSIs) and cutting guides are widely used in orthognathic procedures, in orbital and midface trauma, and post-ablative reconstruction of the craniomaxillofacial skeleton. The PSIs are available as 3D printed titanium, milled titanium or reinforced PEEK devices depending on application and surgeon preference.

Daniel Buchbinder and Damir Matic, key opinion leaders and members of the AO TC CMF, presented this innovative technique along with comprehensive workflows developed in the AO TC CMF (Fig 5).

The combination of 3D printed implants and 3D printed cutting guides has revolutionized planning and execution of these procedures resulting in improved efficiency in the operating room and more predictable outcomes. The workflow includes 3D imaging, image analysis and segmentation, virtual osteotomy planning, virtual positioning of the bone segments to the desired alignment and occlusion, planning of PSIs in the planned position to fix the fragments with predictive screw hole location, planning of the cutting and predictive screw hole drill guides, production of the PSIs and guides and finally the execution of the fully guided procedure in the operating room. Several peer-reviewed publications have reported minimal deviations between the planned procedure and the surgical result if the surgical plan is strictly followed.

Cutting guides are also produced for the donor site in reconstructive cases following ablative surgery to aid in the harvest and contouring of the bone flap following the virtual reconstructive plan. In addition, the guide also incorporates predictive holes for the fixation of the bone flap to the patient specific milled or 3D printed reconstruction plate. Finally, virtual planning can also be used to determine the ideal location for the placement of endosseous titanium fixtures that will be used to anchor a dental prosthesis; thus, ensuring good functional outcomes for these patients.



Fig 5 Left to right: Daniel Buchbinder and Damir Matic highlighting the benefits of patient specific procedures in craniomaxillofacial surgery.

6. Planning and performing maxillo-mandibular distraction osteogenesis

Complex congenital and acquired deformities in the mandible, the midface, or cranium might require gradual correction with distraction osteogenesis. The treatment must be performed in such a way that not only new bone can be formed and finally shaped for better fit but also the surrounding soft tissue can grow during the distraction procedure. The CMF distractors are used for patients from birth to almost every age depending on the clinical situation. Callus distraction and final shaping along a guiding fixation allows the correction of complex deformities and filling of voluminous voids in bone structures. Virtual planning of the distraction vector for callus formation or bone transport as well as the fixation of the distractor and the final reconstruction are currently state of the art. Digital planning and simulation may even replace complex calculations, and the production of 3D bone models allow for the visualization and construct planning/testing. Alberto Rocha Pereira presented exemplary cases and emphasized the wide variety of applications of CMF distraction in the mandible and midface area to solve different clinical problems to improve patients' outcomes (Fig 6).



Fig 6 Alberto Rocha Pereira gave an overview on the distraction osteogenesis in craniomaxillofacial surgery.

7. Application of the LCP Distal Femur Plate in comminuted fractures of the proximal phalanx in horses

Comminuted fractures of the proximal phalanx are common injuries in horses and even though the prognosis for survival is guarded and complications are common, the currently recommended treatment is to immobilize the distal limb in a transfixation cast. Christoph Lischer, Fabrice Rossignol, and Jeffrey Watkins from the AO TC Large Animal Expert Group presented the biological bridge plating using the human LCP Distal Femur Plate that can provide a better alternative with fewer complications and better long-term outcomes (Fig 7). The plate is pre-contoured, low profile, and features combi holes along the shaft and threaded locking holes in the plate head. The left and right version of the human 9- and 11-hole plate has recently been approved for veterinary application, specifically for comminuted P1 fractures in horses. During the highly informative session, the three experts outlined the underlying principle, provided detailed information about surgical steps, and exemplified those in a practical demonstration on a bone model. Rossignol, the driving force behind this newly developed technique, underlined the necessary postoperative management including casting, adequate trimming, and shoeing to improve patients' outcomes. More information and clinical cases can be found in the 2019 *Innovation* magazine ([link to LCP Distal Femur Plate for Veterinary Applications](#)).



Fig 7 From left to right: Jeffrey Watkins, Fabrice Rossignol, and Christoph Lischer showed how to use the human LCP Distal Femur Plate for treatment of comminuted fractures of the proximal phalanx in horses.

The importance of AO Technical Commission Experts Symposia

The Experts Symposia of the AO Technical Commission (AO TC) are well-established events to foster exchange among surgeons and representatives of our industrial partners with the overall goal to improve patient treatment. To achieve this objective, it is essential to review the clinical performance of implants, instruments, and the surgical techniques. Open and straightforward discussions are fundamental for identifying potential device improvements and refinements of surgical procedures. Consequently, the symposium format is fundamental in fulfilling the AO TC quality assurance mandate for newly developed devices when they become available for surgeons. The symposia have proven to be invaluable for defining the remaining unmet clinical need that is not yet addressed by existing solutions. This type of information is imperative to justify the initiation of new development projects, which makes the Experts Symposia highly appealing to our industrial partners. The information exchange at the symposia is strictly confidential.

The experiences over the past few years have reinforced the benefits of inviting experienced surgeons of all age groups to the symposia. While the more senior surgeons are familiar with the development history of implants and instruments as they became available, younger surgeons may be more apt to think out of the box. Innovation is further nourished by interdisciplinary exchange, which is an approach to analyze clinical problems from different perspectives.

Since the initiation of the AO TC Experts Symposia in 2006 about 920 surgeons have participated in these interactive events; consequently, this AO TC network is rapidly expanding. The network knowledge is extremely helpful to obtain consolidated feedback on aspects that are relevant for the success of future developments. We gratefully acknowledge all the symposia participants who provided their feedback in surveys that were sent by the AO TC. By sharing your opinion, you play an active role in the development of future solutions.

Newly developed implants and instruments may not be available or affordable in all countries. Thus, it is important to consider region-specific aspects in the symposia discussions. This is addressed by conducting the AO TC Experts Symposia in various parts of the world: Europe, Asia Pacific, United States, and Latin America.

The following is a brief overview of the 2019 symposia.

Sixth US AOTK Experts Symposium

Every 2 years there is a trauma-related AO TC Experts Symposium in the United States. In 2019, it was hosted by

Mark Lee from the University of California, Davis in Sacramento, who is currently a medical member of the Intramedullary Nailing Expert Group. The symposium was on September 13–14, 2019, in San Francisco, which was attended by 45 participants (Fig 1).

The symposium program consisted of five sessions. The session “My novel solution to a difficult problem/unusual new technique or implants I am trying/implants that need improvement” was an excellent opportunity for participants to present their innovative solutions for difficult clinical problems. Such an open forum fosters out-of-the box thinking across anatomical regions that could trigger new implant and instrument developments. The other four sessions were focused on specific clinical problems. The session on femoral neck fractures was an opportunity to analyze in clinical case discussions the performance of the Femoral Neck System from DePuy Synthes that was launched in 2017 (*Innovations magazine*, 2017).

The prize for the most interesting case presentation of the symposium was awarded to Brett Crist (University of Missouri, Columbia, US).



Fig 1 David Forsh (Mount Sinai Hospital, New York, US) presenting a case on syndesmosis reduction and fixation during one of the symposium sessions.

14th European AOTK Experts Symposium

The annual European AO TC Experts Symposium was on October 11-12, 2019, at the Charité hospital, Berlin, Germany. The symposium was chaired by Ulrich Stöckle (Charité Universitätsmedizin Berlin) and Michael Raschke (Chair AO Technical Commission Trauma), which was attended by 30 surgeons from 16 European countries (Fig 2).

The program of the trauma-related symposium was divided into four sessions. Three of them addressed the following topics: humeral shaft fractures, complex tibia plateau fractures, and peri-implant infections. The latter topic was chosen to emphasize the global need for better diagnostic methods and treatment algorithms for fracture-related infections. The special session on infection was an opportunity to present the most recent achievements of the Anti-Infection Global Expert

Committee (see also the article on “Fracture-related infection: new consensus on diagnosis and treatment” in this *Innovations magazine*) and to discuss strategies for further improvement with the audience. The fourth session of the symposium program was dedicated to the most recent AO TC innovations and how these influence clinical practice.

Frank Beeres (Kantonsspital Luzern, Switzerland) was honored for the most interesting case presentation of the symposium that was related to the treatment of a complex proximal tibia plateau fracture.

In the past, the European AO TC Experts Symposia were mainly in Germany and Austria. However, in the future we plan to organize the symposia in various European countries to extend their reach and to better address the European role of this event format.



Fig 2 Participants of the 14th European AOTK Experts Symposium held at Charité hospital, Berlin, Germany.

First AOTK CMF Experts Symposium

The first AOTK CMF Experts Symposium was on November 13–14, 2019, in Tampa, Florida, US. Daniel Buchbinder (Chair AO TC Executive Board) chaired the symposium that was attended by 14 surgeons and 9 representatives from the industry. The three symposium sessions focused on patient-specific implants and cutting guides as well as the workflows to use these. The participants exchanged their case experiences to discuss and to identify opportunities for improvement. Recent advances in digital planning and innovative approaches to design and to manufacture patient-specific surgical guides and implants allow that complex surgical procedures can be performed in a highly reproducible manner independent of the surgical experience. Although the costs that are currently associated with the use of patient-specific implants and cutting guides are high, there is a clear trend toward their increased use because of the high predictability and accuracy that can be achieved and the potential to reduce operating room time.

Rüdiger Zimmerer (Medizinische Hochschule Hannover, Germany) won the award for the most interesting case presentation (Fig 3).

Fourth AO TC Trauma Experts Symposium (Latin America)

The Fourth AO TC Trauma Experts Symposium (Latin America) was on March 6–7, 2020, in Rio de Janeiro, Brazil. It was chaired by Paulo Barbosa (Centro Ortopédico Ipiranga) who

was a longstanding member of the AO TC Intramedullary Nailing Expert Group. Twenty-seven Latin American surgeons from 12 countries attended and contributed to the lively discussions (Fig 4). The symposium program covered the following topics: infection, calcaneus fractures, ankle fractures, proximal femoral fractures in osteoporotic bone, and nonunion in general.

In the session on proximal femoral fractures, the discussion was how augmentation in nail fixation can improve clinical results. Paulo Barbosa shared his tips and tricks to facilitate reduction (see also the [Meet the Experts Session 'Advances in Femoral Nailing'](#)).

The winner of the contest for the most interesting case presentation was Emilio Fantin (IMC Instituto Modelo de Cardiología de Córdoba, Argentina) who shared a femoral nonunion case after intramedullary nailing, which he managed by increasing the stability at the nonunion site with an intracortical percutaneous compressive screw.

Numerous AO events, like the AO TC Experts Symposia in 2020, are impacted by the COVID-19 pandemic. Subsequently, we are implementing online solutions for the CMF, European and Asia Pacific AO TC Experts Symposia. The 2021 symposia will take place at locations that were selected to host the face-to-face symposia in 2020. Do refer to our symposium website at [AO Technical Commission Experts Symposia](#) for the latest information.



Fig 3 Daniel Buchbinder presenting the award for the most interesting case presentation to Rüdiger Zimmerer.



Fig 4 Matheus Lemos Azi (Manoel Victorino Hospital, Salvador, Bahia, Brazil) answering questions on infection from participants during his case presentation.

Markus Windolf receives Certificate of Merit from AO Technical Commission

Markus Windolf, the Focus Area Leader of Concept Development at the AO Research Institute Davos (ARI), received the Certificate of Merit from the AO Technical Commission (AO TC) (Fig 1). The award ceremony took place at the AO TC Chairs Meeting in December 2019 after Windolf presented the latest development progress on the [AO Fracture Monitor](#) and the [Biphasic Plate](#). Michael Raschke (Chair of the AO TC Trauma) honored Windolf in the presence of all Chairs of the AO TC and representatives of DePuy Synthes. He explained that the Certificate of Merit is awarded to Windolf's outstanding contributions in the development of innovative orthopedic concepts and novel treatment solutions for advancement in patient care.

In particular, Windolf received the prestigious AO TC prize for the development of a simplified navigation system based on shape recognition (X-in-One concept) [1], which can be universally applied to improve various orthopedic procedures and for a concept to automatically determine the required screw length during drilling (Fig 2) [2], which eliminates the need to measure screw length with a manual depth gauge. Both concepts were received with great interest by the Expert Groups of the AO TC. These concepts are now in translation to clinical applications, which is a clearly visible sign that the Concept Development Focus Area under the thoughtful leadership of Windolf plays an essential role in the efforts of the AO Foundation to foster innovation.

When asked what the Certificate of Merit means to him, Windolf replied "It is an honor to receive this award in recognition of all the efforts which have been required to advance these concepts to stages which allow final product realization. The highest reward for every inventor is to see ideas become

reality. Medical device development is a bumpy road. There are so many influential factors which must be considered to turn a concept into a solution." He noted that his daily work is never predictable and added, "Without the support of my whole Concept Development team it would not have been possible to be so successful. We have achieved this intermediate milestone together. The Certificate of Merit is some extra motivation for all of us and shows that we are heading in the right direction."

Since he started working for ARI in 2004, Windolf has filed 13 patent families that underlines his innovative drive to solve clinical problems. The Concept Development team tries to seek better solutions in various areas of interest, like simplified implant positioning, systematic implant optimization, and assessment of bone healing by means of smart implants. However, Windolf knows "You have to focus on the most important topics. It doesn't make sense to try to solve everything at once. Bundling resources and staying focused will be our key to success."

Another development focus currently propelled by Windolf and his team is the Biphasic Plate, an implant concept to install a beneficial mechanical environment for bone healing at the fracture site. For more information, see the dedicated article in this magazine.

The new AO Innovation Translation Center is providing an environment that will support inventors like Windolf to convert concepts into reality. We wish Windolf and his team continued success in the development of new solutions that make a positive difference in surgeons' and patients' lives.



Fig 1 Markus Windolf receiving the Certificate of Merit from Michael Raschke, MD (left, Chair of the AO TC Trauma), and Claas Albers (right, Director of the AO Innovation Translation Center).

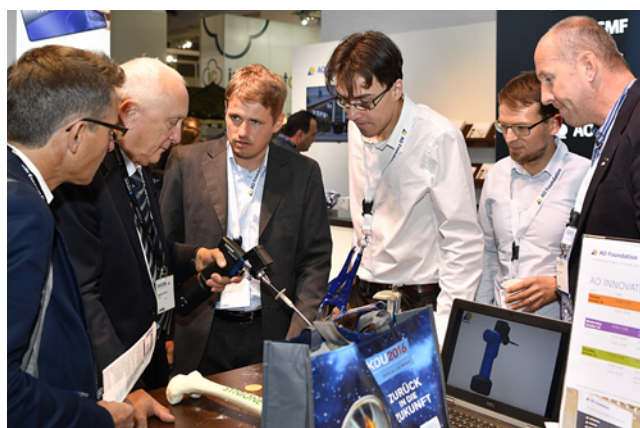


Fig 2 Markus Windolf explaining the AutoGauge concept, a smart drilling device, at the AO Innovations Desk that was held at the German Congress for Orthopedics and Traumatology on October 2016, Berlin, Germany.

References

1. [Innovation magazine](#), 2017. X-in-One concept. Accessed June 23, 2020.
2. [Innovation magazine](#). AutoGauge. (Available at: [link to Solutions](#)). Accessed June 23, 2020.

AO Technical Commission Innovation Prize for Reamer Irrigator Aspirator Task Force

The winner of the AO Technical Commission Innovation Prize 2020 is the Reamer Irrigator Aspirator (RIA) Task Force, in recognition of the group's exceptional work in the development of RIA 2, the next generation Reamer Irrigator Aspirator system (see *Innovations Magazine* 2019 RIA 2 article at: [Innovations magazine](#), and the RIA 2 article in this current magazine). This prestigious prize is awarded by the AO Technical Commission to individuals or groups for outstanding innovative contributions to a development project.

The RIA Task Force is an international group comprising nine expert surgeons in trauma, orthopedics, and long bone reconstruction (**Figure**). The RIATF members are: Hans-Christoph Pape (Chair; University Hospital Zurich, Switzerland); Brent Norris (Tulsa Orthopedic Specialists, Oklahoma, US); Brett Crist (University of Missouri Health System, US); Christof Müller (City Clinic Karlsruhe, Germany); David Hak (Hughston Clinic Trauma Division, Florida, US); Gerhard Schmidmaier (University Hospital Heidelberg, Germany); Ingo Marzi (University Clinic Frankfurt, Germany); Martijn Poeze (Maastricht University Medical Center, Netherlands); and Peter Giannoudis (Leeds General Infirmary University Hospital, UK).

Since its inaugural meeting in December 2013, the RIA Task Force has worked tirelessly to test RIA 2 prototypes in the anatomy laboratory setting and to guide technical improvements from a global clinical standpoint. The RIA Task Force members are at the forefront of evidence creation relating to indications for RIA usage, complications associated with RIA usage, and biomechanical considerations during reaming. Additionally, the RIA Task Force seeks to educate orthopedic surgeons throughout the world in conjunction with AO Trauma to facilitate successful use of the new system.

A video demonstrating the use of RIA 2 by Brent Norris and Martijn Poeze at the 2019 Meet the Experts session in Davos, Switzerland, can be viewed here ([AO Technical Commission Meet the Experts](#)). The Technical Commission congratulates the RIA Task Force on its achievements in further advancing the care of trauma and orthopedic patients and looks forward to additional successful collaboration in the future.



Figure Members of the RIA Task Force undertook RIA 2 prototype testing in Solothurn, Switzerland, in May 2016.

AO Global Data: poised to revolutionize medical data collection and drive innovation

Delivering value to patients and society is at the heart of acclaimed London orthopedic surgeon Simon Lambert's mission. With more than 35 years of clinical experience, 100-plus peer-reviewed publications, 20 book chapters—including a revision of *Gray's Anatomy* chapters on the shoulder girdle and shoulder joint—to his credit and a keen interest in innovation, Lambert explains why he is a champion and early adopter of AO Global Data, the new AO initiative offering surgeons participation in and access to the world's largest and most comprehensive orthopedic outcomes database.

How did you come to the AO and to the AO Technical Commission Upper Extremity Expert Group (UEEG), which you chair?

My AO career began in education when, as a student, I took my first AO basic course in 1982. Later I introduced AO operating room personnel (ORP) courses into my training program hospital, and subsequently advanced to become a faculty member and chair for AO courses in the United Kingdom, Davos, Switzerland, and internationally. I served under Prof Norbert Suedkamp from 1998 to 2013 and succeeded him as chair of the AO Technical Commission UEEG. I got to know great colleagues at the AO Research Institute (ARI) and AO Clinical Investigation and Documentation, now part of the AO Innovation Translation Center, and undertook research relevant to the UEEGs' goals of innovation and development in the field of upper extremity trauma. During this research, and through other experience in outcomes research, I came to appreciate the value of developing questions using high-quality data. Given this background, I am very much a champion of the opportunities afforded by AO Global Data.

Regarding patient-reported outcomes (PROs), what are some of the challenges/needs surgeons currently face in their daily clinical practices?

Most important is justification of what we do in terms of the value to an individual and society. There are lots of things we like to do, but we don't know what value they bring to an individual or to the community. In terms of orthopedics, what we believe we do is resolve people's painful impairments which lead to disability and therefore represent a cost to them and to society. Our challenge is to justify our interventions in terms of cost effectiveness for the patient and then financial cost effectiveness, and the only way to do that is to measure outcomes.

Historically, in outcomes, the surgeon has liked to measure, for example, how much angle something bends more than it did before an intervention, or how much distance someone can walk, or how much pain the patient experiences. What that didn't do was drill down into what actually the patient recognized as value. All those objective, observer-based parameters assume that they are what the patients find important in their lives, and they are not always valuable. Some people are prepared to put up with a certain level of discomfort if they can achieve a certain level of social independence; other people are very much disabled by pain and find themselves unable to become socially independent. So, there are huge, interpersonal variations, and PROs try to expose that: Per patient, is there a value in that intervention? And from that, we can gain some insight into how useful the intervention is.



How can AO Global Data help resolve these challenges/ meet these needs and serve surgeons in their daily clinical practice?

As a tool to collect vast amounts of data across a number of different communities, AO Global Data can allow us to see common dominators, understand the demographics and what matters to patients, and how to better meet their needs. There is a clear recognition within the AO and by its industrial partners that fixation techniques and technologies are only part of the answer. Factors, such as rehabilitation, reintegration into society, functional independence are quite difficult to elucidate. By adding patient-reported outcomes, such as the Patient-Reported Outcome Measurement System (PROMIS) scores, we start to get not just the functional outcome, but psychological and personal impacts as well.

AO Global Data makes it easy for clinicians to collect patient-reported data: The only thing the surgeon does is fill in the metadata; the rest is generated by the patients themselves. AO Global Data also allows us to get information remotely, instead of bringing the patient back to the clinic.

How can AO Global Data support the AO Technical Commission to gather clinical evidence for innovation?

When we develop something, either a derivative of an existing device or revolutionary, we currently understand it in small,

prospective cohorts which cannot be randomized very easily, so we don't have a clear feeling of the effect size of an intervention. AO Global Data allows us to engage more centers with clinical questions, to introduce innovation into a bigger sphere, and to put that data to work. Musculoskeletal health is arguably the biggest cost to society across the world, in trauma, metabolic

bone disease, and degenerative disease, and in terms of the economically important population. Many regions of the world, China and India for

instance, have huge populations at risk of the health and economic effects of osteoporosis, but we don't know clearly how we can help to improve the health of those populations. AO Global Data will help illuminate such areas of need.

As a solution for gathering PROs, how is AO Global Data unique or better than existing solutions?

AO Global Data's uniqueness lies in the first two letters of its name: AO. The AO has a credibility that is independent of commercial, university, or governmental interests. It reaches more than 225,000 surgeons globally per year, so its footprint in terms of education, research, and innovation is far and away the biggest of any organization. And it has this vision of making life better for patients. AO Global Data can drive innovation because we can respond to what it tells us. The information is relevant to the real-time management of the patient, not just to future documentation and research. For more information [see AO Global Data](#)

Biphasic Plate

AO Innovation Translation Center—Technology Transfer

Fast, robust healing of long-bone fractures through confident weight bearing is the goal of the Biphasic Plating concept, a new solution devised by the AO Research Institute Davos (ARI) in Switzerland and Queensland University of Technology (QUT) in Brisbane, Australia. Due to the development incubator funding from the AO Innovation Translation Center (AO ITC), the development phase of the distal femur version started in 2018 and today the plate is in zero-series production in preparation for clinical trials in early 2021 in Switzerland.

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 focuses 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:

- 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 support in vivo feasibility of the Biphasic Plating concept, which were published in the August 2020 issue of the *Injury* journal [1].

The project team engaged 41medical AG, a manufacturer located in Bettlach, Switzerland, to produce Biphasic Plate Distal Femur prototypes and zero series. With laboratory and bench testing completed, next steps include applying for CE mark and a multicenter clinical study that will be conducted by AO ITC Clinical Evidence.

Pending the certification process, the Biphasic Plate Distal Femur could be available for European surgeons within the next two years. Application for US Food and Drug Administration approval is expected to follow.

Reference

1. **Hofmann-Fliri L, Epari DR, Schwyn R, et al.** Biphasic Plating—*in vivo* study of a novel fixation concept to enhance mechanobiological fracture healing. *Injury*. 2020 Aug;51(8):1751-1758.

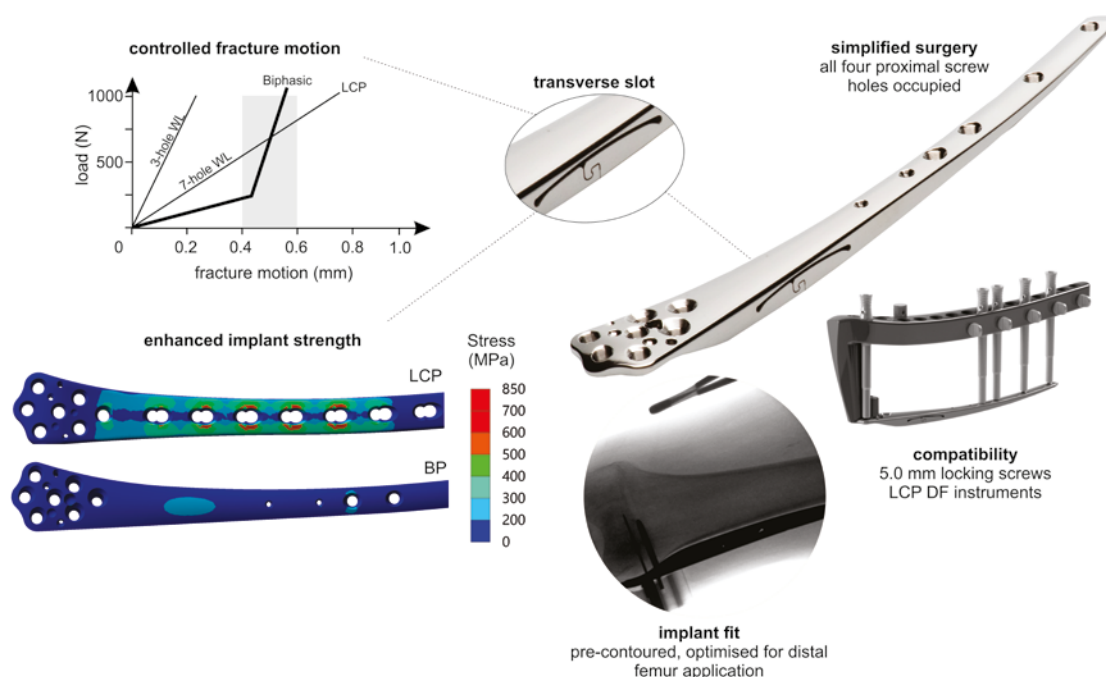


Figure Biphasic Plate DF (Distal Femur) features a transverse slot in a region of increased thickness that simultaneously provides controlled fracture motion and enhanced implant strength, as indicated by substantially lower stresses in the implant. Standard locking plates produce variable fracture motion 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 DePuy Synthes locking screws and insertion instruments. The implant is pre-contoured for optimal fit with the region of increased thickness accommodated in the supracondylar region of the distal femur.

Development and validation of a robotic system for sacroiliac luxation/fracture reduction and fixation

AO Innovation Translation Center—Technology Transfer

Background

In recent years, various surgical disciplines have developed minimally invasive procedures that aim at decreasing patient morbidity and complication rates, enhance patient recovery, and improve operating room (OR) personnel safety. An essential component that has facilitated this change is the improvement of intraoperative imaging (IOI) and navigation. Certain surgical specialties (eg, cardiothoracic and vascular surgery) have led the way in this evolving field by incorporating innovative imaging devices in the OR. This approach is the foundation of an integrated OR, where imaging devices are digitally linked to patient and operating table and can be connected to a navigation system. While numerous systems have been developed to optimize implant placement, the design of an integrated OR, capable of assuring a seamless workflow, remains challenging. These challenges stem from multiple factors, including the following:

1. Interaction among IOI, navigation, and robotic systems

The individual systems are typically manufactured by different companies and seamless integration of the devices is, therefore, challenging.

2. Current limitations of optical navigation systems

Most standard navigation systems use infrared cameras and optical sensors for simultaneous registration of the patient bones as well as IOI equipment and surgical instruments. Infrared-based optical navigation systems are susceptible to inadvertent displacements of the patient and/or equipment and OR personnel movements. Disruption of the infrared beam among patients, imaging equipment, and surgical instruments may require reiteration of the lengthy registration process.

3. Suboptimal fracture reduction and fixation

Since slight movement of the registration unit can result in malposition and/or malalignment of bone fragments and surgical instruments and implants, the risk of potentially severe complications remains a serious limitation of current optical navigation systems. Although the use of multiple cameras and sensors can help improve tracking accuracy, it also adds complexity to the system that can become cumbersome and unsuitable for an effective intraoperative workflow.

4. Aiming errors during fracture fixation

While navigation enables confirmation of initial instrument orientation, successful implant placement ultimately relies on the surgeon's ability to maintain this optimal alignment while drilling. This is particularly critical in spine surgery, including sacroiliac luxations or fractures (SIL/F), where the targeted

bones are small (eg, vertebral pedicles or sacral body) and surrounded by essential neurovascular tissues. Aiming errors due to manual control of instruments are well-recognized sources of inaccuracy during drilling of pilot and lag holes for screw fixation of SIL/F and represent an additional and critical limitation of current minimally invasive osteosynthesis (MIO) repairs of these lesions.

5. Radiation exposure

Another shortcoming of current MIO technique is the exposure of the OR personnel to ionizing radiation during image acquisition throughout surgery.

To overcome the limitations of current MIO of SIL/F in dogs, Prof Loïc Dejardin, Wade O. Brinker Endowed Chair of Veterinary Surgery, Head of Small Animal Orthopedics at the Michigan State University (MSU) College of Veterinary Medicine, US, devised a novel sacroiliac instrumentation system (SILIS) for the MIO treatment of SIL/F in dogs and cats. The SILIS uses DPS reduction handles and a new minimally invasive lucent aiming device (MILAD) coupled to table-bound 6-axis friction arms to manually reduce and then accurately fix the SIL/F (Fig 1). Dejardin and his team demonstrated that SILIS-MILAD-assisted MIO of SIL/F was significantly more accurate and reliable than open reduction and internal fixation (ORIF) (Fig 2). Furthermore, because the 6-axis arms provide stable reduction and drill guide alignment, IOI imaging is performed while the OR team is away from the C-arm; thus, reducing exposure to radiation. Despite demonstrated advantages of SILIS-assisted MIO of SIL/F (accuracy, reliability, and safety), the scope of this technology remains limited and could be significantly improved through the development of a comprehensive, integrated navigation and robotic system that will consistently optimize SIL/F treatment from reduction to fixation (Fig 3). Additionally, improving implant placement must remain user-friendly for the surgeon or rapidly risk falling into disuse.

Project development

With a grant from the AO Innovation Translation Center's Strategy Fund, Dejardin and a team of engineers and robotics specialists led by Prof Ranjan Mukherjee from MSU College of Engineering are blazing a path to the future with a project to develop a novel, comprehensive integrated navigation and robotics system for SIL/F reduction and fixation. Other members of the team include Catherine Wilhm, Dean of Lansing Community College, Michigan, US, and Peter Richter, MD, from Ulm University, Germany. The team is collaborating on a comprehensive navigation system with lightweight 6-axis robotic arms to assist in fracture reduction and fixation (Fig 4). This approach can overcome the limitations of currently available navigation systems as well as manual reduction and fixation of orthopedic injuries under image intensification guidance.

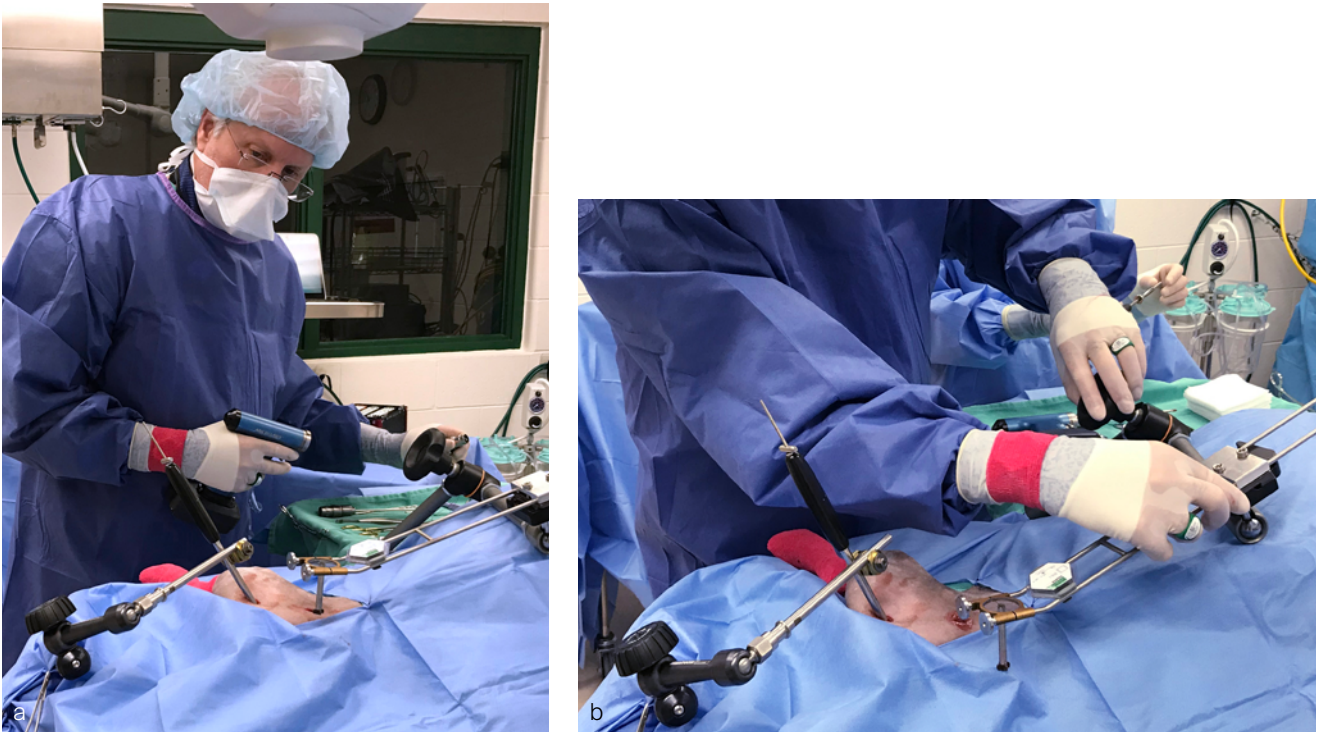


Fig 1a-b Intraoperative photographs showing the use of the SILIS-MILAD in a dog. Table-bound 6-axis arms and a radiolucent aiming guide are used to reduce and to fix SIL/F via minimally invasive techniques.

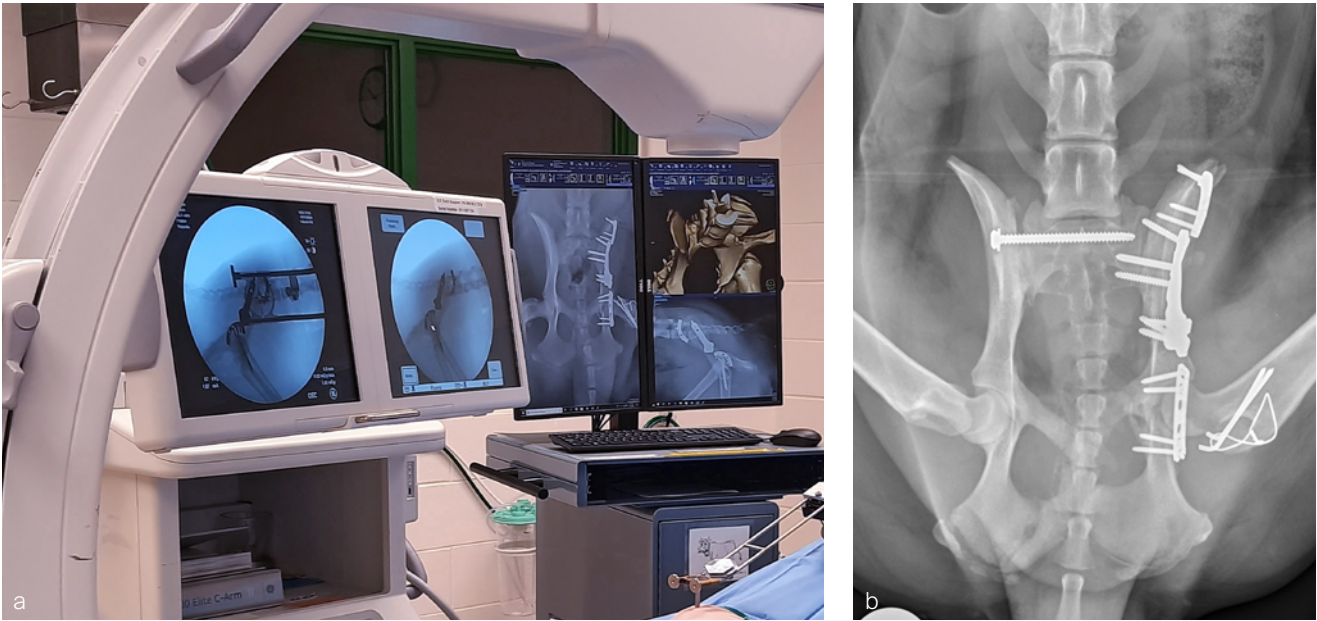


Fig 2a-b

- a** Intraoperative imaging is used to verify reduction of the SIL/F as well as accurate location and orientation of the iliosacral lag screw. A complex contralateral ilium and acetabular fracture had been repaired using open reduction and internal fixation the day before MIO of the SIL/F.
- b** Postoperative ventrodorsal x-ray at 12 weeks.



Fig 3 Building on the SILIS-MILAD platform, the purpose of the current proof-of-concept project funded by the AO Innovation Translation Center's Strategy Fund is to develop an integrated navigation and robotic system for the treatment of SIL/F.



Fig 4 Electromagnetic and optical sensors will be used to register bone fragment and eventually guide lightweight robotic arms during reduction and fixation of SIL/F. From left to right: Ranjan Mukherjee (Co-PI, PhD, robotic engineer), Loic Dejardin (PI, DVM, MS, DACVS), and Mahmoud Abdullatif (Co-I, PhD, robotic engineer).

"With our 3 years' project, which started in November 2019, the AO will be part of the development of an innovative, unique, reliable and effective operative system designed to improve minimally invasive reduction of spinal and pelvis fractures, prevent implant malposition in complex anatomical regions during fixation, and improve operating personnel safety during surgery," said Dejardin. "This system will reduce complication rates and improve clinical outcomes of spine and pelvis surgeries."

While the project's early proof-of-concept work will focus on spinal and pelvis trauma, Dejardin said that following validation, its application could extend to long-bone fractures and eventually total joint replacement procedures. He believes the technology will prove invaluable for all all AO clinical areas.

"Robots are more precise and reliable than humans and can perform repetitive tasks without fatigue. Although robotic surgical systems are available, we do not have the confidence to say that existing technologies can be used to reduce a fracture or register bone fragments. Robots, equipped with the right set of sensors, could do that work—and it would be revolutionary," said Mukherjee, who has worked on developing surgical robotic systems. Industrial robots today perform a wide range of tasks like picking up windshields, registering them to the chassis of cars, and accurately and reliably placing them in the correct position. He added: "If we could do that in surgery with the same degree of accuracy and reliability, we could improve patient outcomes while improving cost effectiveness."

Biomechanical benefit of combined nail and plate fixation for treatment of osteoporotic comminuted distal femoral fractures

Osteosynthesis of native or periprosthetic comminuted distal femoral fractures using either a lateral locking plate or a retrograde intramedullary nail alone is considered to allow for early protected weight bearing only, especially in case of osteoporosis. Combining the two techniques may offer a stronger well-balanced fixation construct providing sufficient stability under full weight bearing. The rationale behind this implementation assumes a more balanced load sharing between bone and implants. Moreover, distal interlinking of the nail and plate could potentially result in even smoother transition of forces and moments and superior stability under immediate full weight bearing.

The project goals were to evaluate (1) the potential benefit of combined lateral plating and retrograde intramedullary nailing, and (2) the added primary stability via distal interlinking of the two implants with a single screw, in comminuted distal femoral fractures by means of finite element analysis, considering the nail fixation as baseline.

A finite element model was generated from the computed tomographic (CT) scan of a left intact osteoporotic distal femur from a 64-year-old woman donor weighing 57 kg. A transverse osteotomy with a 40 mm gap was cut 45 mm proximally to the distal end of the femur to mimic an AO/OTA 33-A33 fracture. A fixation with an 11 mm non-reamed retrograde intramedullary femoral nail (Expert R/AFN Retrograde/Antegrade Femoral Nail) and a proximally truncated lateral variable-angle (VA) condylar locking plate (VA-LCP Condylar Plate 4.5/5.0) was simulated using computer-aided design (CAD) models of both implants (**Fig 1**).

The nail was bicortically locked in the distal fragment occupying its two most distal screw holes, and proximally with two anteroposterior screws. The plate was applied by occupying its three most distal VA locking holes for monocortical fixation of the distal fragment and inserting three bicortical VA locking screws in the shaft adjacent to the osteotomy. The two implants were positioned so that they could be interlinked with one common distal lateromedial (LM) screw.

Three different fixation configurations were simulated using (1) intramedullary nail only, (2) intramedullary nail and lateral plate without interlinking (the distal LM screw was only connected to the nail, but not to the plate), and (3) intramedullary nail and lateral plate, interlinked with the distal LM screw.

All materials were simulated as linear elastic. The Young's moduli of the bone elements were scaled according to the underlying local volumetric bone mineral density measured from the CT scan. All screws were modeled without threads bonded at the bone-screw and nail/plate-screw interfaces. Contact with friction was set between the nail and bone.



Fig 1a-b Anterior and medial views of the finite element model of comminuted distal femoral fracture, fixed with a retrograde intramedullary femoral nail and a proximally truncated lateral condylar locking plate.

The distal femoral joint surface was loaded with 570 N, split over the lateral and medial condyles at a ratio of 20–80% to simulate a physiologically relevant full weight bearing situation with worst case scenario. The forces were directed toward the femoral head center with both condyle surfaces loaded according to a Gaussian distribution (Fig 2). The displacement of the femoral head was fully constrained, whereas the central point between the condyles was constrained in the transverse plane but free to move longitudinally. Primary stability of all three fixation configurations was evaluated by calculating the magnitude of the interfragmentary movement at the medial aspect of the fracture gap.

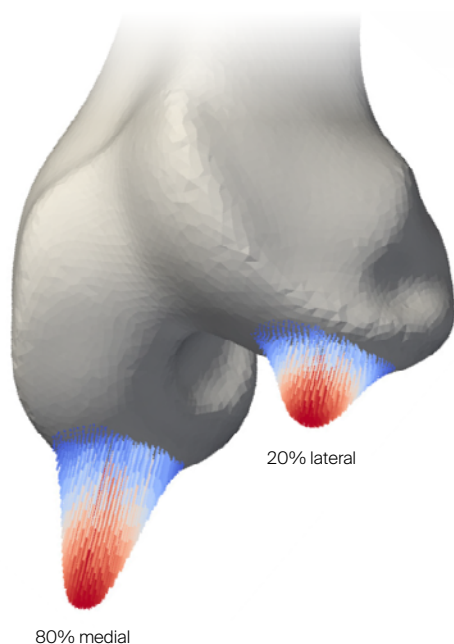


Fig 2 Visualization of simulated loading on the distal femoral joint surface, split at a ratio of 20–80% between the lateral and medial condyles and distributed according to a Gaussian distribution.

Combining retrograde intramedullary nail and lateral plate fixation without interlinking could increase primary stability by 39%, whereas interlinking the two implants with a single distal LM screw provides 57% increase in stability compared with nailing alone (Table).

Fixation configuration	IFM, mm	Normalized primary stability, %
Nail	0.42	100 (baseline)
Nail and plate—not interlinked (LM screw in nail)	0.30	139
Nail and plate—interlinked with one LM screw	0.27	157

Table Interfragmentary movement (IFM) from the finite element modeling of the three fixation configurations evaluated at the medial aspect of the fracture gap under full weight bearing; the corresponding primary stability was normalized to the nail only configuration.

From a clinical perspective, combined nail and plate fixation could be biomechanically beneficial for treatment of native or periprosthetic osteoporotic comminuted distal femoral fractures with desired immediate full weight bearing. Further in vivo corroboration is needed to utilize this implant combination in the clinical practice.

Peri-implant fractures in short versus long cephalomedullary nails following pertrochanteric fracture consolidation

Pertrochanteric femoral fracture fixation with the use of cephalomedullary nails (CMNs) has become increasingly popular in the recent past. Known complications after fracture consolidation include peri-implant fractures following the use of both short and long nails, with fracture lines around the tip of the nail or through the interlocking screw holes, resulting in secondary midshaft or supracondylar femoral fractures, respectively. Limited research exists to help the surgeon deciding on the use of short versus long nails, though both have their benefits.

This project aimed to investigate one of the newest generations of short and long CMNs in a human anatomical model, in terms of construct stability and generation of secondary fracture pattern following pertrochanteric fracture consolidation.

Sixteen paired human anatomical femora from eight donors (five women and three men) aged 83.4 ± 7.7 years (range, 74–95 years) were assigned to two groups of eight specimens each for nailing with short or long CMNs. The newest generation CMNs of the series Trochanteric Fixation Nail Advanced (TFNA) of 10 mm diameter and 130° neck-shaft angle were used with reaming of the intramedullary canal to a diameter of 11 mm before insertion of the long nail. Based on a multi-ethnic computational analysis, this generation features an improved nail shape with 1.0 m radius of curvature designed to better fit the patient's anatomical bow and enhance implantation. The length of the short nails was 170 mm, whereas the length of the long ones was chosen distally to the metaphyseal flare. Helical blades were used as head elements, ensuring an appropriate tip-to-apex distance of less than 20 mm. The short nails received one distal interlocking screw in the static position, and the long nails also received one distal interlocking screw in the most proximal static hole. The implantation was performed without a fracture to simulate a peri-implant fracture in a united femur.

Each specimen was first biomechanically preloaded at 1 Hz over 2000 cycles in superimposed synchronous axial compression to 1800 N and internal rotation to 11.5 Nm (Fig 1). Next, internal rotation to failure was applied over an arc of 90° within 1 second under 700 N axial load. Torsional stiffness as well as torque, angle, and energy to failure were evaluated. Digital image correlation analysis was performed by means of stereographic optical measurements using a contactless full-field deformation technology to calculate the strain at the fracture site. Fracture patterns were analyzed.

Outcomes in the groups with short and long TFNA were 9.7 ± 2.4 Nm/ $^\circ$ and 10.2 ± 2.9 Nm/ $^\circ$ for torsional stiffness, 119.8 ± 37.2 Nm and 128 ± 46.7 Nm for torque at failure, $13.5 \pm 3.5^\circ$ and $13.4 \pm 2.6^\circ$ for angle at failure, and 887.5 ± 416.9 Nm $^\circ$ and 928.3 ± 461.0 Nm $^\circ$ for energy to failure, respectively, with no significant differences between them ($P \geq .17$).

Minimum major strain at the fracture site measured immediately before initiation of the fracture line was $0.327 \pm 0.114\%$ for short and $0.262 \pm 0.081\%$ for long nails, with no significant difference between them ($P = .32$).



Fig 1 Setup with a specimen mounted for biomechanical testing. The axis of the femur is aligned to the machine axis and the bone surface is sprayed with fine black-white speckle pattern for digital image correlation analysis.

The group with short nails had a fracture through the head element in three specimens, all of which appeared to have a spiral fracture line in continuity with the distal interlocking screw hole (Fig 2). Two additional specimens in this group had a fracture through only the distal interlocking screw hole. Moreover, three femora with short nails had a fracture through only the shaft, not involving the distal interlocking screw hole or head element. Two of the fractures were multifragmentary, both of which were only through the shaft.

In the group with long nails six specimens were fractured through the distal interlocking screw hole (Fig 2). Two femora were fractured at only the head element, with an additional specimen being fractured through the head element and distal interlocking screw hole. However, the latter did not have a fracture in continuity with the head element and distal interlocking screw hole in contrast to the group with short nails. Five multifragmentary fractures were observed, ie, four through the distal interlocking screw hole and one through only the head element.

From a biomechanical perspective, the risk of secondary peri-implant fracture after intramedullary fixation of pertrochanteric fractures is similar when using short or long TFNA. Moreover, for both nail versions the fracture pattern does not unexceptionally involve the distal locking screw hole.

This investigation supports more recent clinical and biomechanical research on the peri-implant fracture risk in short and long CMNs. It seems reasonable that if a patient has a canal amenable to a well-fitting short nail, the quicker operation and less blood loss can make it the better procedure, especially for the sicker patient. Moreover, a revision of a secondary fracture around a long nail might be more demanding because of fracture lines being potentially closer to the knee joint.



Fig 2a-b Fracture patterns in two specimens implanted with Trochanteric Fixation Nail Advanced (TFNA): (a) short TFNA; (b) long TFNA. The femur with short nail demonstrates a fracture through the head element with a spiral fracture line in continuity with the distal interlocking screw hole. The femur with long nail is fractured through the distal interlocking screw hole with a multifragmentary pattern.

Integrated angular stable locking in the novel Tibial Nail Advanced (TN-A) in combination with low-profile retaining locking screws improves fixation stability in a distal tibial fracture model

Unstable distal tibial fractures are challenging injuries requiring surgical treatment. Intramedullary nails are one of the implant options; however, insufficient fixation of the distal fragment may lead to postoperative loss of reduction, delayed healing, malunion, or nonunion. Recently, a novel design for angular stable locking has been developed that maintains the basic principle of intramedullary nailing, ie, relative stability, but introduces improvements expected to reduce nail toggling, screw migration and secondary loss of reduction, without the requirement for additional intraoperative procedures.

Core TN-A design features are polyether ether ketone (PEEK) inlays integrated in the proximal and distal canal portions of the nail for angular stable screw locking, and low-profile retaining locking screws with enhanced purchase in the near cortex (Fig 1 and Fig 2) (see the TN-A article in this *Innovations* magazine).

This project aimed to compare the biomechanical competence of the novel angular stable TN-A concept versus the conventional nonangular stable Expert Tibial Nail (ETN) fixation in a human anatomical model of an unstable distal tibial fracture under dynamic loading.

Ten pairs of fresh-frozen human anatomical tibiae with a simulated AO/OTA 42-A3.1 fracture were assigned to two groups for reamed intramedullary nailing using either a nonangular stable ETN with three distal screws or the novel TN-A with two distal angular stable low-profile retaining locking screws (Fig 2). Testing conditions included quasi-static and progressively increasing combined cyclic axial and torsional loading in internal rotation until failure of the bone-implant construct, with monitoring by means of motion tracking (Fig 3).

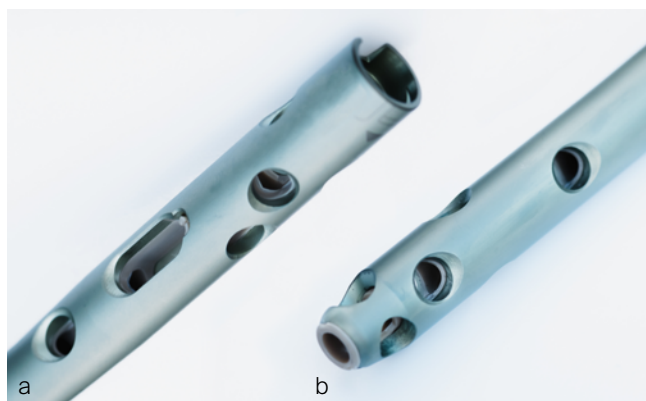


Fig 1a–b Photographs of the proximal (a) and distal (b) Tibial Nail Advanced (TN-A) portions with integrated polyether ether ketone (PEEK) inlays for angular stable screw locking.

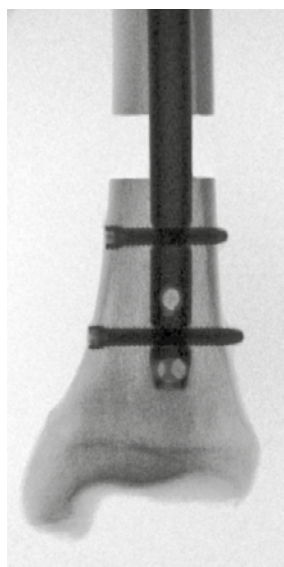


Fig 2 AP x-ray of the distal tibia of a specimen with an AO/OTA 42-A3.1 fracture model and a Tibial Nail Advanced (TN-A), locked with two angular stable low-profile retaining screws.

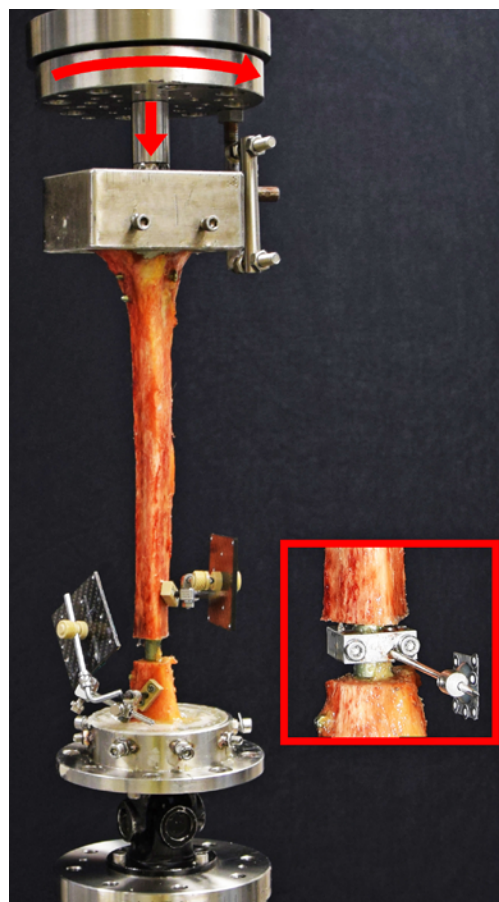


Fig 3 Setup with a specimen mounted for biomechanical testing. Retro-reflective markers are attached to the proximal and distal tibial fragments for motion tracking. Embedded picture presents additional markers mounted to the nail for monitoring of the initial distal fragment toggling at the beginning of testing.

Initial axial construct stiffness did not differ significantly between the two nail systems ($P = .29$). In contrast, initial torsional construct stiffness was significantly higher for TN-A compared with ETN ($P = .04$). Initial nail toggling of the distal tibial fragment in varus and flexion was lower for TN-A compared with ETN, being significant in flexion ($P = .91$ and $P = .03$). After 5000 cycles, interfragmentary varus, flexion, internal rotation, axial displacement and shear displacement movements at the fracture site were at least 54% lower on average for TN-A compared with ETN, with flexion and shear displacement being significant ($P = .14$, $P = .04$, $P = .25$, $P = .11$ and $P = .04$; Fig 4). Cycles to failure until interfragmentary 5° varus

and 5° flexion were at least 16% higher on average for TN-A compared with ETN and were significantly different ($P = .04$).

From a biomechanical perspective, the novel angular stable TN-A concept incorporating two improvements, namely (1) PEEK inlays and (2) low-profile retaining locking screws:

- Provides increased relative construct stability and maintains it over time while reducing the number of required locking screws without impeding the flexibility of the nail itself
- Reduces the tilting of the distal fragment in any direction by up to 72%
- Resists better toward loss of reduction

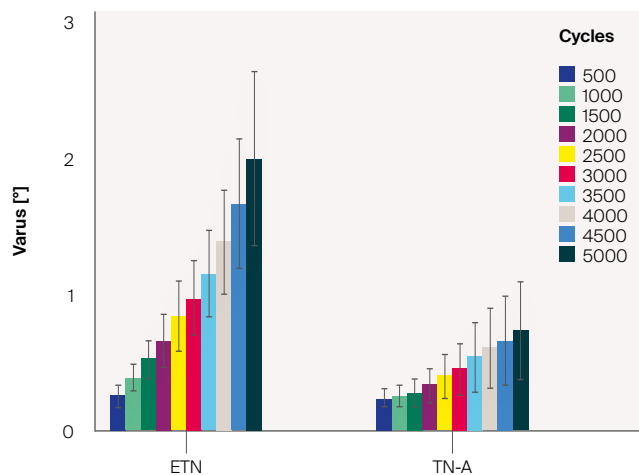


Fig 4 Varus interfragmentary movements of the specimens implanted with Expert Tibial Nail (ETN) and Tibial Nail Advanced (TN-A) between 500 and 5000 test cycles, demonstrating less varus for TN-A compared with ETN, with progressively increasing difference over cycles.

First tarsometatarsal joint fusion in foot—a biomechanical human anatomical specimen analysis with use of continuous compression implants

Advanced deformities of the first tarsometatarsal (TMT-1) joint—being accompanied by a considerable increase in the first intermetatarsal angle—are often associated with relative hypermobility and instability of the joint. Arthrodesis is an established technique for management of such deformities and arthrosis of different origins.

Currently, the standard TMT-1 arthrodesis technique is fixation with two crossed screws, having the disadvantage of necessitating 6–8 weeks immobilization in a short-leg cast and related to implant failure rates of up to 4.5% and nonunion in up to 15%. Use of locked plates as an alternative fixation technique could conceivably allow for earlier weight bearing and improve bony union; however, controversial findings are reported.

On the other hand, the ability of low-profile superelastic shape-memory Nitinol staples to act as continuous compression implants (CCIs; Fig 1) by applying and maintaining a uniform active compression at the fusion site offers an attractive alternative to conventional screw and plate arthrodesis. Moreover, in contrast to screw fixation that occupies valuable area across the joint interface, CCIs could allow full joint coaptation by maximizing the footprint for fusion.

In 2018, AO TC Trauma provided product approval as 'Recommended' for the following DePuy Synthes (DPS) BME CCI series for usage in the foot: SPEED™, SPEEDSHIFT™, SPEEDARC™, SPEEDTITAN™, SPEEDTRIAD™, and ELITE®. However, biomechanical and clinical research evaluating the use of CCIs for TMT-1 fusion is scant.

The aim of this project was to investigate under dynamic loading the potential biomechanical benefit of fusion with CCIs in two different configurations in comparison with screws and locked plating in a TMT-1 human anatomical model.

Thirty-two paired human anatomical lower legs were randomized to four groups:

- (1) Crossed-screw fusion with two DPS 4.0 mm fully threaded stainless steel lag screws inserted in standard fashion, ie, first screw from the first metatarsal to medial cuneiform and second screw from medial cuneiform to the plantar base of the first metatarsal (Fig 2a).
- (2) Plate-and-screw fusion with a DPS 4.0 mm standard mid-foot fully threaded stainless steel cortex screw, inserted cortically in lag fashion, and a DPS 6-hole TMT-1 stainless steel VA Fusion Plate 2.4/2.7 (Fig 2b).
- (3) CCI fusion with 2 two-leg staples DPS SE-1818TI BME SPEEDTITAN™ and DPS SE-2520TI BME SPEEDTITAN™ placed orthogonally to each other (Fig 2c).
- (4) CCI fusion with 1 two-leg staple DPS EL-1818S2 BME ELITE® and 1 four-leg staple DPS EL-2520S4 BME ELITE® placed orthogonally to each other (Fig 2d).

All fusion procedures were performed on intact feet with preparation of the joint articulations and under image intensification control according to the implant manufacturer's guidelines.

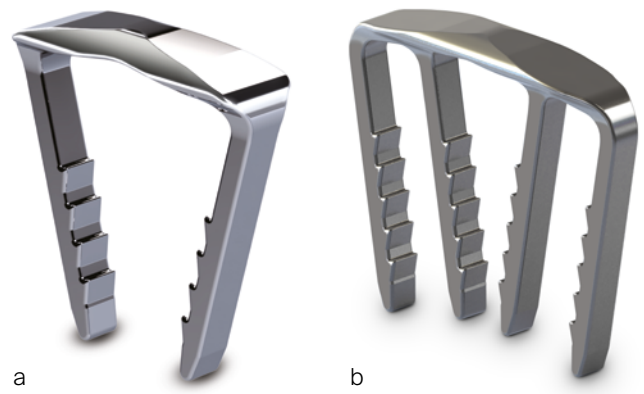


Fig 1a–b Two-leg (a) and four-leg (b) continuous compression implants from the series BME ELITE®.

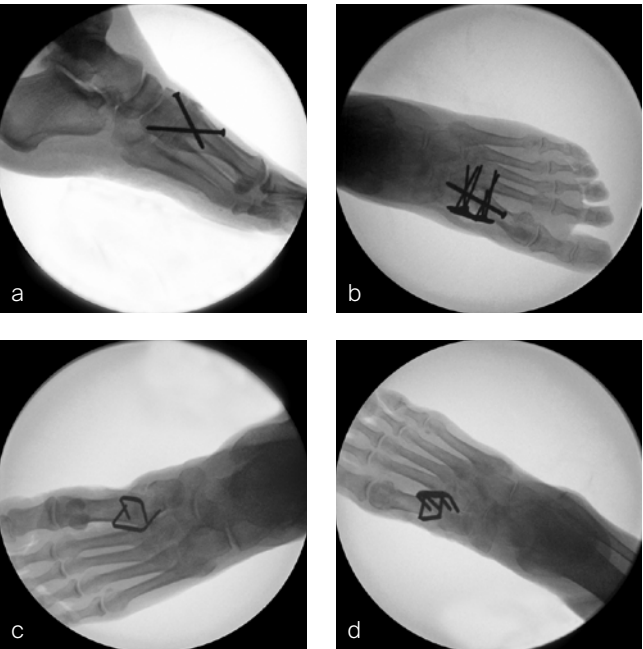
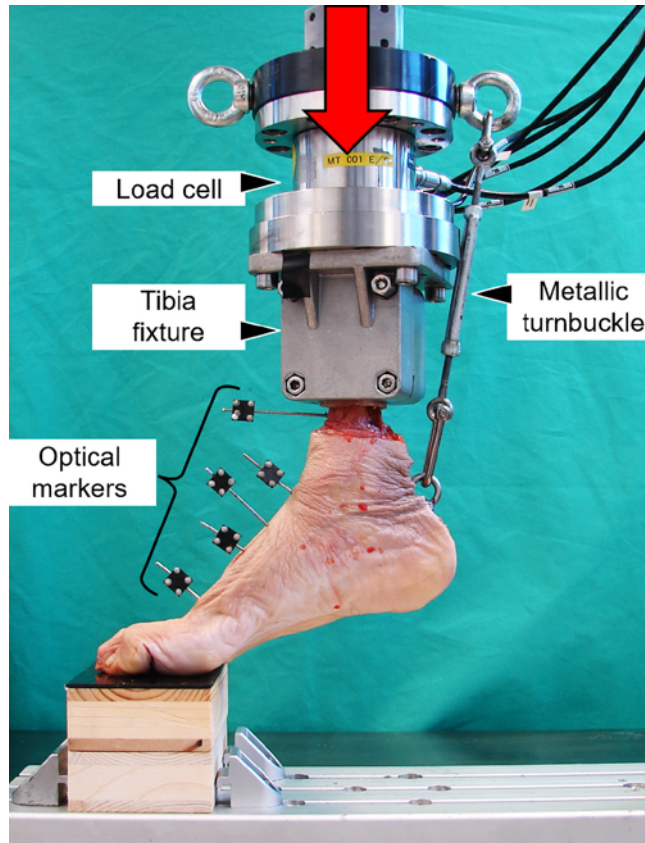


Fig 2a–d Radiographs visualizing fusion of the first tarsometatarsal (TMT-1) joint with use of crossed-screws (a); plate-and-screw technique (b); two CCIs from the series DPS BME SPEEDTITAN™ (c); and two CCIs from the series DPS BME ELITE® (d).

Each specimen was biomechanically tested using a setup simulating forefoot weight bearing on the toes and the metatarsals (Fig 3). The testing was performed at 35–37°C under initial quasi-static axial ramped loading, followed by progressively increasing cyclic axial loading, and accompanied by triggered medio-lateral x-rays and optical motion tracking, the latter capturing movements in the joints forming the medial column of the foot.



The lower legs were randomized to the four groups, with bone mineral density (measured at the distal tibia) being not significantly different between them ($P = .92$).

Initial stiffness of the specimens did not differ significantly among the four fusion techniques ($P = .87$).

Combined adduction and dorsiflexion movement of the TMT-1 joint in unloaded foot condition increased significantly between 500 and 2500 cycles ($P < .01$); however, no significant differences were observed among all pairs of groups ($P \geq .13$). In contrast, the amplitude of this movement between unloaded and loaded foot conditions within each cycle was significantly bigger for the two CCI fusion techniques compared with both crossed-screws and plate-and-screw techniques ($P \leq .04$). No significant differences were detected between the two CCI fusion techniques, as well as between the crossed-screws and plate-and-screw techniques ($P \geq .49$).

Displacements at the superior and inferior aspects of the TMT-1 joint in unloaded foot condition together with their amplitudes between unloaded and loaded foot conditions within each cycle increased significantly between 500 and 2500 cycles ($P \leq .04$) but did not differ significantly among all pairs of groups ($P \geq .22$).

From a biomechanical perspective based on human anatomical specimen setting, the low-profile superelastic shape-memory Nitinol staples used as CCIs for more elastic stabilization under active compression might demonstrate comparable performance to established crossed-screws and plate-and-screw techniques for fusion of the TMT-1 joint, which could allow full joint coaptation by maximizing the footprint for fusion.

Fig 3 Setup with a specimen mounted for biomechanical testing and equipped with optical markers for motion tracking, attached to the distal tibia, talus, navicular, medial cuneiform, and first metatarsal.

Intrathoracic versus extrathoracic rib fracture plating

A considerable amount of data has emerged in the recent past demonstrating the benefits of surgical rib stabilization for treatment of multiple rib fractures, particularly incorporating a flail component. The AO TC Trauma approved in 2009 the MatrixRIB Fixation System to improve treatment outcomes. Self-drilling screws were added to the portfolio in 2019, complementing the existing self-tapping screws. Despite medical and scientific evidence indicating that successful implantation decreases complications, mortality, and length of hospitalization for surgical rib stabilization, the number of treated patients who could potentially benefit from this treatment is still small.

One of the barriers is related to challenges associated with the surgical procedure itself. Large incisions can increase the risk of infection and severe postoperative complications, raising concerns whether the treatment is more detrimental to the patient than the original trauma. Minimizing incision's size reduces infection risk; however, a large incision is often needed to treat multilevel fractures or address challenging locations, for example, within the subscapular region. Implants placed on the intrathoracic curve of the rib through small incisions from the contralateral side will reduce the risk of infection. However, construct stability following intrathoracic rather than extrathoracic plating has not yet been investigated. Therefore, the aims of this project were (1) to investigate the biomechanical performance of intrathoracic versus extrathoracic plate fixation in a human anatomical rib fracture model and (2) to compare the effect of rib plating with two versus three screws per fracture fragment. It was hypothesized that the fixation stability following intrathoracic plating—with the plate placed on the tension rib side—is superior; therefore, three bicortical screws may not be required per fracture fragment.

Twenty pairs of fresh-frozen human level-five ribs from elderly female donors (age 82.4 ± 7.8 years; age range, 65–97 years) were assigned to four different groups of ten specimens each, splitting each pair for intrathoracic and extrathoracic plating with either two or three screws per fracture fragment. The specimens were fractured in a three-point-bending test and fixed with an 8-hole titanium MatrixRIB universal plate with four or six self-tapping screws. First, all constructs were cyclically tested over 400,000 cycles applying a combined torsional and tensile-bending loading to replicate the physiological situation during breathing (Fig 1). Stiffness was evaluated every 100,000 cycles and overall construct subsidence was monitored. Second, a destructive quasi-static axial bending test was performed to assess the ultimate compression failure force. Test data was used to validate a finite element model predicting the failure location of plated ribs under axial compression bending (Fig 2).

Stiffness of the intrathoracic plated specimens increased significantly compared with their intact state. In contrast, stiffness of the extrathoracic plated ribs decreased significantly versus intrathoracic. Plate positioning and the number of screws did not demonstrate significant differences in construct subsidence or change in stiffness during cyclic and ultimate quasi-static testing.

Intrathoracic plating of the rib allows for a minimally invasive approach; and, thus, can reduce risk of infection. Moreover, intrathoracic plate fixation demonstrates significantly higher stiffness versus extrathoracic plating, supporting its advantages as a fixation method. The number of screws does not seem to influence significantly construct stability regardless of the plate position, suggesting that two screws per fracture fragment can be sufficient to achieve stable fixation. In the clinical context, using fewer screws mean not only lower surgery costs but also shorter surgery time; therefore, reduction of the infection's risk.

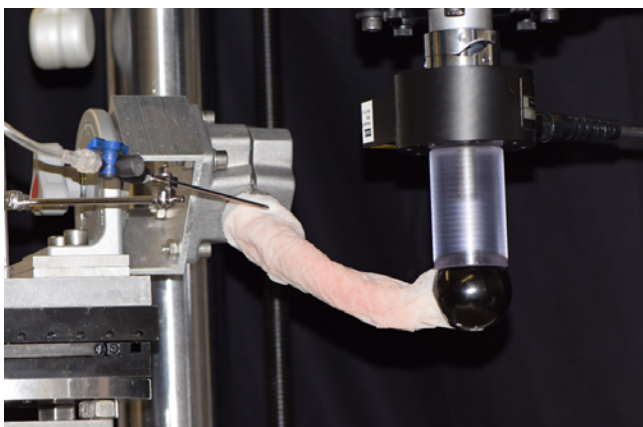


Fig 1 Setup with a specimen mounted for cyclic biomechanical testing under combined torsional and bending loading, replicating the physiological situation during breathing.

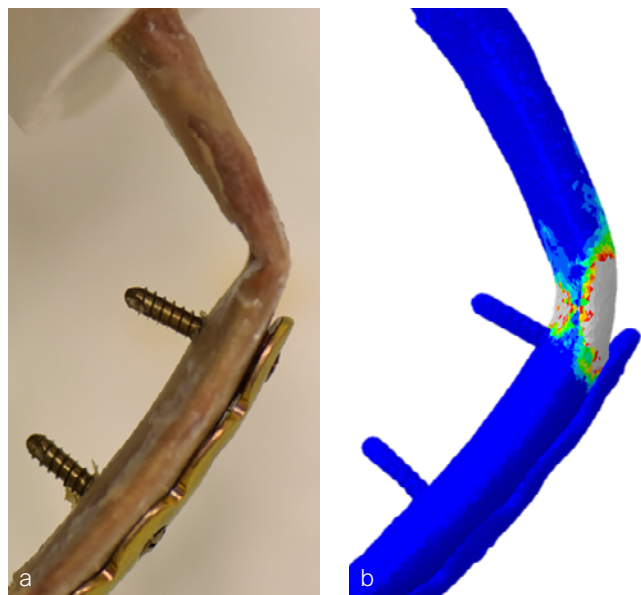


Fig 2a–b Experimental failure mode of a plated rib (a) and the predicted failure region by means of finite element analysis (grey, b).

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Issue:

December 2020
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