HAZARDS AND LABELING

Due to varying countries’ legal and regulatory approval requirements please consult the appropriate local product labeling for approved intended use of the products described in this brochure. All devices in this brochure are AOTK approved. For logistical reasons, these devices may not be available in all countries worldwide at the date of publication.
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EDITORIAL

Dear reader,

Welcome to the 2017 edition of the AOTK System Innovations magazine. Following another year of collaboration with our industrial partner, which has witnessed the launch of 10 new products across Trauma, Spine, CMF, and Vet, the AOTK is excited to deliver another insightful magazine. As well as the usual showcase of AOTK innovations, this issue contains contributions from the AO Research Institute (ARI) and AO Clinical Investigation and Documentation (AOCID). We also have a special insight into the first episode of the collaboration between the AO Education Institute (AOEI) and Ethicon.

In our lead article, we introduce the Femoral Neck System (FNS). This innovation from the Lower Extremity Expert Group was designed to address clinical challenges faced in the current fixation of fractures in the neck of the femur. Further to the preclinical results published by ARI and reviewed in last year’s magazine, FNS continues to demonstrate its status as a less invasive competitor to the Dynamic Hip Screw.

Following years of development and hard work, the External Fixation Expert Group are happy to add the MAXFrame hardware hexapod ring fixator system to their robust portfolio. While hexapod systems are not a recent technology, the MAXFrame hardware introduces some new features that improve handling both by surgeons and patients.

Just as important as new product innovation is the maintenance of existing success stories. Both the Hand Expert Group and Joint Preservation and Osteotomy Expert Group have effectively worked towards expanding current portfolios in the distal radius and knee respectively. In this issue of TK Innovations, we look at the new sterile kits for distal radius fracture fixation as well as the next generation TomoFix Medial High Tibial plate complete with instrumentation intended to improve surgical accuracy and procedural efficiency.

AOTK Spine has approved the SYNFIX Evolution Secured Spacer System intended for stand-alone use in patients with degenerative disc disease (DDD). The SYNFIX implant technology has been in clinical use since 2004. The current design includes hyperlordotic cages and superior instrumentation technique intended to negate the need for additional fixation. Zero-P Natural is a zero profile anterior cage system using pre-contoured allograft in conjunction with an anterior plate and screw fixation to the cervical spine for anterior cervical decompression and fusion indications.
This year’s contribution from AOTK CMF provides an insight into the world of TruMatch Orthognathic, a technological platform that integrates virtual surgical planning and the production of intraoperative patient-specific tools and personalized implants. Not only is this system revolutionary, it reduces the need for splints and plate contouring and allows the surgeon to complete procedures while avoiding critical anatomical structures such as vessels and nerves.

The Small Animal Vet Expert Group provides a comprehensive insight into the 3.5/2.7 LCP Pancarpal Arthrodesis Plate designed specifically for carpal arthrodesis in skeletally mature dogs. The provision of two detailed case studies in this article portrays the complex nature of such salvage procedures and the subsequent benefit of such an intuitive implant.

The AOTK has experienced a record number of membership changes since January. We take the opportunity in this edition to celebrate change and reward specific TK members for their longstanding contributions to the Technical Commission and the wider Foundation.

With all of this and more, the 2017 edition of AOTK System Innovations promises to be an exciting and informative issue. We hope that you enjoy it.

We would like to reiterate that none of the articles in this magazine substitute for the AO’s surgical techniques and teaching tools. You can obtain more information about AOTK on the AO Foundation website. Please do not hesitate to contact AOTK at any time as we welcome your feedback and involvement.

Yours faithfully

Tim Pohlemann
AOTK (Trauma)

Daniel Buchbinder
AOTK (CMF)

Maarten Spruit
AOSpine TK
Femoral neck fractures represent 50% of all reported hip fracture cases. Although most common among patients aged 65 and older and often with comorbidities such as osteoporosis, such fractures also affect the young patient population as a result of high energy trauma.

While total hip arthroplasty (THA) and hemiarthroplasty (HA) remain the preferred treatment options for displaced femoral neck fractures in the older population, internal fixation with anatomical reduction (either closed or open) is considered state of the art for younger patients. Sliding hip screws offer a higher mechanical strength over cannulated screws for the fixation of such fractures but are usually accompanied by higher blood loss due to the invasive approach that is required for insertion. Both implants have also been reported to result in a likelihood of lateral thigh pain due to implant protrusion. Since 2011, the AOTK Lower Extremity Expert Group has been working on a solution to combat such problems. This has resulted in the development of the Femoral Neck System (FNS), a new implant designed for the minimally invasive fixation of femoral neck fractures of all types. In 2015, the AO Research Institute (ARI) published a preclinical biomechanical evaluation of the Femoral Neck System (FNS) in that year’s AOTK Innovations magazine (Fig1).

The system was directly compared to the fixation performance of the Dynamic Hip Screw (DHS) with an antirotation screw, DHS with blade, and three cannulated screws in the treatment of an unstable femoral neck fracture. While the DHS remains the gold standard for the fixation of unstable subcapital and transcervical femoral neck fractures, the outcome of the evaluation revealed that the less invasive FNS is undoubtedly a competitive product. The biomechanical performance of FNS was equal to both DHS implants and significantly better than three cannulated screws in terms of resistance to leg and neck shortening under cyclic loading.

Fig 1
ARI publish a summary of the FNS preclinical study in AOTK Innovations 2015.
This year, the AOTK approved the FNS technology (Fig 2) for market launch and while there are currently no case follow-ups to review, first experiences with the system seem positive.

The FNS was designed to meet the current clinical unmet needs associated with other treatment modalities for femoral neck fractures. The FNS implants form a fixed-angle gliding fixation device that allows for controlled collapse of the femoral neck, similar to existing dynamic hip screw systems. The lateral element is comprised of a small base plate with one or two locking hole options. Due to the small size of the base plate, a single plate barrel angle can cover the clear majority of caputcollum-diaphyseal (CCD) angles without major angulation and offset of the base plate on the lateral aspect of the femur. The barrel allows for gliding of the head elements, in this case the locked combination of bolt and antirotation screw (ARScrew), while simultaneously restricting rotation around the head-neck axis.

The Femoral Neck System is designed specifically for the fixation of femoral neck fractures. As a result of rotational and angular design features within the system, FNS aims to demonstrate a high resistance against varus collapse and femoral head rotation. In the ARI biomechanical study (Fig 3), FNS was proven to be twice as strong as multiple screws against femoral neck and leg shortening.

The bolt forms the central load carrier for the femoral head fragment. Its blunt tip reduces the risk of cut-out in the articular space. The bolt glides freely within the barrel of the base plate while rotational motion is restricted. This allows controlled collapse of the head fragment of up to 20 mm. Most of this collapse occurs within the barrel of the base plate reducing lateral protrusion to a minimum. The antirotation screw enhances the rotational stability of the head-neck fragment. It is locked with the bolt at a fixed angle and therefore glides assembled to the bolt in the barrel of the base plate. The antirotation screw also has a blunt tip that reduces the risk of cut-out in the articular space.

The unique rotational and angular stable design is achieved by two key elements of the system: the femoral neck bolt and antirotation screw (Fig 4). Unlike other systems that often demand the insertion of an antirotation screw separately, both implants in the FNS interconnect and work together to create a fixed angle construct with the benefits of a dynamic design. The bolt and ARScrew slide over a distance of 20 mm thereby enabling the controlled dynamic compression required for the fixation of femoral neck fractures.

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Parameters of interest for the implant systems (mean ± SEM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DHS–Screw</td>
<td>DHS–Blade</td>
</tr>
<tr>
<td>Axial stiffness [N/mm]</td>
<td>609.8 ± 44.2</td>
</tr>
<tr>
<td>Cycles until 15 mm leg shortening</td>
<td>20,542 ± 2,468</td>
</tr>
<tr>
<td>Cycles until 15 mm femoral neck shortening</td>
<td>20,846 ± 2,446</td>
</tr>
</tbody>
</table>

Fig 2
Intraoperative image of the FNS complete with insertion instrumentation.

Fig 3
Summary of results from the ARI biomechanical study comparing the axial strength of the DHS screw, DHS blade, and 3 cannulated screws with the FNS.

Fig 4a–b
The femoral neck bolt and antirotation screw before and after insertion.
The small base plate design of the FNS (Fig 5) results in an optimal implant footprint when compared with other sliding hip screw constructs. The ARScrew is inserted through the base plate and therefore avoids the need for additional soft-tissue dissection proximal to the plate. This facilitates a more minimally invasive surgical approach, which is an additional benefit of the FNS along with a reduced risk of lateral implant protrusion, lateral hip pain, and subsequent soft-tissue irritation.

Procedural efficiency for femoral neck fractures has been shown to differ significantly based on the method of treatment selected. The surgical technique required for sliding hip screws has been described as technically difficult and is often associated with increased intraoperative blood loss when compared with fixation by multiple screws. Subsequently, the instrumentation necessary for such demanding procedures should be intuitive with a minimization of surgical steps and maximization of procedural efficiency (Fig 6).

Fig 5a–b
The small implant footprint allows for a minimally invasive approach.

Fig 6a–b
The FNS is optimally designed to increase ease of use and enhance procedural efficiency though the creation of a simple instrument set designed to reduce intraoperative handling. Implant insertion is achieved using one primary instrument assembly (a) and one central guide wire (b).
Variable Angle Two-Column Plate

The Variable Angle (VA) Two-Column Plate (Fig 1) was the star of innovative thinking from the Hand Expert Group in 2016. Not only did it feature as the primary element of a new sterile system for the distal radius, it also benefitted from a slight makeover with the requirement to extend the plate’s indications. The essence of the plate, launched in 2009, proudly remains the same, and the LCP standards that are expected from AOTK approved technology are still there to be seen.

VA Two-Column Plate features

A quick recap of the plate’s features are as follows:

- Anatomical fit close to the palmar ridge with rounded plate edges, polished surface, and countersunk screws to reduce the risk of soft-tissue irritation
- Variable angle locking holes allow up to 15° off-axis screw angulation in all directions to address individual fracture patterns
- LCP combination holes allow both locking and nonlocking screw insertion

VA LCP Two-Column Plate-Extra Long

In December 2016, AOTK Trauma approved the VA LCP Two-Column Extra Long Plate (Fig 2) designed for the treatment of intra- and extra-articular fractures, osteotomies, and nonunions and malunions of the distal radius. The plate is available with 7, 10, and 13 holes in the shaft and is indicated for fixation with or without extension into the radial diaphysis. Use of trial implants can assist with determining the plate size appropriate for the patient.
Following the successful release of the VA Two-Column Plate in 2009, this anatomical palmar implant is now available as part of a new distal radius sterile kit (Fig 3) recently approved by the AOTK. The creation of a streamlined modular system represents the optimization of workflow efficiency in the operating room and drives repeatable consistent procedures by providing a complete core kit. The prepackaged implants and single-use instruments eliminate the need for sterilization and its subsequent operational cost. The disposable instruments are designed to a high standard, which enables the user to maintain the same surgical technique performed with conventional reusable instruments (Fig 4).

The system includes the following features:
- Self-contained depth gauge with single-hand actuation
- Ergonomically designed variable angle and coaxial drill guides
- An always new and sharp drill bit
- A new screwdriver every time ensures optimal screw retention, locking performance, and reliable torque transmission

Fig 3
Distal Radius Sterile System.

Fig 4
The system’s tool kit.

Distal Radius Sterile Kit

8 TRAUMA, UPPER EXTREMITY
Case 1: Multifragmentary distal radius fracture with extension into the diaphysis

A 26-year-old man suffered a multifragmentary fracture of his left distal radius with extension into the diaphysis (AO23 C3.3) (Fig 5). The VA LCP Extra Long Two-Column plate was used for fixation (Fig 6). After initial immobilization, the plate provided a good postoperative fixation of the fracture.

The fracture showed primary bone healing without callus formation. At the 3-month follow-up, the patient was full weight bearing with excellent clinical function (Fig 7). The radiological follow-up can be technically challenging due to the correct focus of the central ray.

Cases provided by Max Daniel Kauther and Marcel Dudda, Essen, Germany
Case 2: Open radius shaft fracture
A 59-year-old farmer suffered a crush injury with an open forearm fracture (AO22 C2, Gustilo and Anderson IIIb) (Fig 8). Initial stabilization was carried out by external fixator (Fig 9). After four rounds of debridement and capillary ingrowth of a splitting skin graft at day 17, the VA LCP Extra Long Two-Column plate was used for fixation of the radius. A 2.7 mm LCP Condylar Plate was used for fixation of the ulna. The plates provided good stability for a functional after-treatment.

At the 3-month follow-up, the patient was full weight bearing with healing fractures (Fig 10).
Development of an AO Fracture Classification for fractures at the chest wall

The AO Fracture Classification System is arguably the most well-known, the most well used, and the most validated classification system in the trauma and orthopedic world. First published in 1987, the AO Classification system has enabled many young surgeons to identify fracture types, determine fracture severity, and select the most beneficial treatment scenarios. For the previous thirty years, the AO Classification System has successfully represented 189 bones in the human skeleton. Until today, the remaining 25 bones have been a mystery.

What happened to the rest of the skeleton?
In today’s clinical culture, thoracic surgery involving bone fixation is gaining popularity. Within a trauma environment, there appears to be a move towards chest wall intervention as opposed to traditional nonoperative management. Not only is this good news for the thoracic trauma patient in terms of rehabilitation, but presents additional justification for the great work undertaken by the AOTK Thoracic Expert Group.

In December 2016, medical members of the Thoracic Expert Group began to pursue their goal to create a fracture classification for this largely untreated area. The aspiration of such a thorax—ribs and sternum—classification was to eradicate the mystery and provide much needed guidance to fixation at the chest wall (Fig 1).

Fig 1
The chest wall: facts.

1. A system of 25 bones connect to the vertebral spine involving 12 levels
2. The only system to demonstrate elastic movements
3. A protection for the vital organs containing bone and cartilage
4. Contains 24 costovertebral joints, 14 sternovertebral joints, 20 osteocartilage conjunctions, and 6 confluences of the cartilage

Fig 2
Excerpt from the AO/OTA Thorax classification showing the classification of the sternum.
We thank the AO Fracture Classification team and especially the AOTK Thoracic Expert Group for helping to solve the mystery and complete the skeleton (Figs 2–3).

Acknowledgement
The Thoracic segment classification has been developed with the collaboration of the AO Foundation TK Thoracic Surgery Expert Group. The members are:
- Mario Gasparri, Madison, USA
- Arthur T Martella, Phoenixville, USA
- Edward A Black, Al Ain, United Arab Emirates
- Stefan Schulz-Drost, Berlin, Germany
- Fredric M Pieracci, Denver, USA

Fig 3
Excerpt from the AO/OTA Thorax classification showing the classification of the rib.
Joint-preserving therapies and specifically realignment osteotomy have been steadily gaining importance over the past decade. The combination of malalignment and unicompartmental osteoarthritis, most often encountered on the medial side, is a common problem that arises in all age groups. The high tibial osteotomy (HTO) is an established procedure for the treatment of knee osteoarthritis and can be performed through either an additive open wedge approach or a subtractive closed wedge procedure.

In 2001, the Knee Expert Group (KNEG) and AOTK in collaboration with Synthes, approved the world’s first open wedge high tibia valgusized osteotomy system with plate fixator. It was named TomoFix and has remained a global market leader in the field of joint preservation and knee osteotomy for fourteen years.

Earlier this year, AOTK approved a next generation of TomoFix in the form of a new Medial High Tibial Plate indicated for:
- Unicompartmental medial or lateral gonarthrosis (knee degeneration) with malalignment of the proximal tibia
- Idiopathic or posttraumatic varus or valgus deformity of the proximal tibia

The TomoFix knee osteotomy system is based on the trusted locking compression plate (LCP) technology, enabling angular stable connections between the screws and the plate. This angular stability allows the stable fixation of an osteotomy intended for early and safe mobilization in accordance with AO principles.

The new generation of joint preserving technology – TomoFix Anatomical

The TomoFix Anatomical Medial High Tibial Plate is contoured to provide an anatomical fit. When compared with the TomoFix Standard and small plates, the new design is intended to reduce both implant prominence and postoperative implant irritation. Fig 1 shows x-rays from the one patient. The right sided surgery took place in 2009 and the left in 2017.
Features

Features include:

- The 5° slant of the plate helps achieve parallel fixation of the proximal plate to the plateau slope of smaller statured tibia (Fig 2)
- The new plate shape facilitates plate placement towards the medial side, providing support on the medialposterior edge of the tibial plateau. This also functions to help prevent neurovascular damage caused by possible screw protrusion (Fig 3)
- The TomoFix MHT plate is designed to accommodate both small and large oblique osteotomies (Fig 4)

Not only does the new TomoFix Knee Osteotomy System contain a new MHT plate with more anatomical features, it also includes new osteotomy instrumentation intended to improve both surgical accuracy and procedural efficiency. The new instrumentation is compatible with the existing Standard and small TomoFix Medial High Tibia plates. Fig 5 shows a patient with posttraumatic deformity after a proximal tibial fracture (at the 6-week follow-up after open wedge HTO in descending technique and fixation with the TomoFix MHT anatomical plate).

High tibial osteotomy is a technically demanding procedure. Complications commonly include postoperative malalignment, imprecise correction, and damage to the tibial dorsal neurovascular structures. Correcting malalignment to the desired angle with precision is a key element of the surgery. The new TomoFix Osteotomy Instrumentation is intended to assist surgeons to define the osteotomy line and maintain steady sawing during the osteotomy cut. Additionally:

- The aiming arm and K-wire guide support the insertion of K-wires to help maintain tibial slope and aim at the hinge points (Fig 6)
- The saw guide allows surgeons to perform biplanar osteotomy under x-ray guidance (Fig 7)
- The radiolucent retractor is intended to protect the posterior neurovascular structures while sawing (Fig 8)
Case: Knee pain following epiphysiodesis

A patient presented with a congenital varus malalignment and complained of medial knee pain following epiphysiodesis at the proximal tibia. The MRI showed no cartilage lesion. A varus deformity of -8° in conjunction with medial knee pain was the indication for surgery. Fig 9 presents the deformity analysis of the left knee. Because of the deformity in the distal femur and proximal tibia, a double level osteotomy was planned and digitally simulated (Fig 9b).

Surgery was initiated with an arthroscopy. No cartilage lesion was observed and removal of the lateral staples followed. The osteotomy started at the femur as a lateral closed wedge biplanar DFO. The new radiolucent hook from the TomoFix Anatomical system was tested during this aspect of the procedure. The hook is ideal in the adoption of a minimally invasive approach for use in patients with normal soft tissue (Fig 10).

Following completion of the DFO and fixation with the TomoFix MDF Anatomical (Fig 11) the new aiming arm and K-wire guide system was used for the open wedge HTO.

Fig 9a–b
Congenital varus malalignment. Digital deformity analysis with mediCAD, Hectect (Landshut, Germany). The left image shows a combined deformity comprising a mechanical tibiofemoral angle (mTFA) of -8°, a mechanical lateral distal femur angle (mLDFA) of 91°, and a mechanical medial tibia angle (MPTA) of 83° (a). The right image shows the simulation of a double level osteotomy (b). Aim was a mTFA of 1° (valgus), a mLDFA of 87°, and a MPTA of 87°. The distal femur osteotomy was planned as a closed wedge distal femoral osteotomy (DFO) and the tibia osteotomy was planned as an open wedge HTO.

Fig 10
New radiolucent hook from the open wedge HTO system used for the DFO.

Fig 11a–d
a–b Lateral view of the distal femur after biplanar distal femur osteotomy and fixation with the TomoFix MDF Anatomical.

c The AP view.

d Control of alignment after the DFO using the alignment rod of the TomoFix set. Partial correction.
After performing a minimally invasive approach at the medial proximal tibia, the first step of the new K-wire guiding system is definition of the hinge point with a K-wire from the lateral aspect (Fig 12). The guiding arm for the osteotomy was then inserted with the radiolucent hook in situ (Fig 13). The guiding arm should be adjusted under intensifier control and finally fixed with a K-wire. At this stage two K-wires for the osteotomy can be inserted and the guiding arm can be removed. The saw guide is then mounted and guides the sawblade safely (Fig 14 and 15).

Fig 12
To ensure precision, it is important to define the hinge point according to preoperative planning.

Fig 13
After mounting the guiding arm for the first K-wire, the lateral tibial slope should be in AP position. The guiding device can be rotated in AP until the holes are round in the intensifier. Next steps include fixation from anterior to posterior using a K-wire, followed by insertion of two K-wires from medial for the osteotomy.

Fig 14
The saw guide is mounted and fixed.

Fig 15
The saw guide with the sawblade for the transverse cut.
The saw guide enables three different angulation options for the ascending cut (Fig 16). Following completion of the osteotomy, the opening is performed in the traditional way using chisel and spreader. Fixation is performed with the new TomoFix MHT Anatomical plate (Fig 17 and 18).

Fig 16
The saw guide with the saw for the ascending cut.

Fig 17
The TomoFix Anatomical plate is inserted.

Fig 18a–e
Alignment is checked with the alignment rod.
Clinical result of the minimally invasive double level osteotomy and alignment.
Monobloc Flexible Reamers: Innovation from the AOTK Intramedullary Nailing Group

The AOTK is proud to announce the recent approval of the Monobloc Flexible Reamer System (Fig 1). Originally designed in response to a clinical need for reaming in the humeral shaft, this monobloc system has been engineered to facilitate reaming procedures prior to nail insertion and provides an extension to the existing Flexible Reamer Systems. The flexible shafts and deeply fluted reamer heads (Fig 2) function to reduce intramedullary pressure and increase the flow of bone debris and marrow during reaming.

Currently available in 0.5 mm increments and in 10 reamer diameters between 6.0 mm and 10.5 mm, there are potential plans to expand the range to include larger diameters. Each flexible shaft has a front-cutting head and is constructed from a single piece of laser-cut stainless steel (Fig 3). As with all other reamer systems, the monobloc flexible reamers are compatible with the 2.5 mm ball tipped reaming rod.

The reamers have been an ongoing project within the Intramedullary Nailing Expert Group (INEG) for a number of years. The system has been thoroughly tested during prototype anatomical specimen labs with AOTK’s primary industrial partner (Fig 4).

Fig 1
Monobloc Flexible Reamer System.

Fig 2
The system features flexible shafts and deeply fluted reamer heads.

Fig 3
Shafts are made of laser-cut stainless steel.

Fig 4a–c
X-ray images of the reamers being tested in a humerus during an INEG prototype lab. Humeral reaming from distal approaches (a–b). Image of the ball tipped reaming rod and reamer in situ at the proximal humerus (c).
Innovations from the External Fixation Expert Group: Introduction to MAXFrame technology

One of the unique features of the MAXFrame deformity correction system (Fig 1) is that it required software development and a new approach to planning and teaching. The MAXFrame is the first and only technology in the AO/DPS portfolio of products in which the hardware provided is directly used as an “input” for the software planning, calculating the treatment plan. Furthermore, MAXFrame technology provides the first planning software capable of transforming x-ray images based on identified hardware components into a real-time 3-D reconstruction. The MAXFrame system can also be used as a temporary reduction tool in case of acute correction and plate or nail fixation. In this case, the reduction can be checked using a C-arm or, for exact planning and positioning, the MAXFrame 3-D software is used with perspective frame matching.

The MAXFrame specific components of the hexapod frame are the rings and footplates, and the struts. The rings and footplates are mounted onto bone fragments using wires and half-pins similar to the DO Ring Fixator system. The components are available in several sizes and can be used in multiple configurations in order to provide the stability and range of motion required for the correction. Surgeon preference drives the use of the MAXFrame hardware to ensure optimal correction and patient comfort throughout the treatment.

Six struts connected to two rings in a specified order build a hexapod frame. Through changing the length of the struts, the rings move in a calculated relationship to each other. As this calculation between the rings is basically dependent on an 8th degree trigonometrical system of equations, the MAXFrame 3-D software is required to provide controlled change of strut length and movement, in accordance with a treatment plan with defined limiting factors for patient safety. The standard method (manual measuring and data input) workflow in the MAXFrame 3-D software provides all of the parameterization required to calculate the treatment plan for any 3-D correction based on well-established knowledge. In addition to the standard method commonly used in hexapod systems, the MAXFrame 3-D software provides the perspective frame matching (PFM) method and the acute intentional deformation (AID) method. The PFM workflow is briefly described later in this article. The AID workflow is a straightforward method usually adopted when the strut values required to enable a simple transition from the deformed to corrected state is known and calculated.
Surgeons “language” used to define parameters/values
The MAXFrame 3-D software does not use a special technical language. Deformation parameters are not defined according to your chosen reference ring as with other hexapod systems, but rather in the same way clinical deformity is determined. Input values are defined in sentences rather than in abstract numbers in order to avoid misunderstanding or misinterpretation of the definition of the value.

3-D animation – a comparison to reality
One of the highlights of the MAXFrame 3-D software is the 3-D animation of the frame and bone segments in all scenarios during the treatment plan. This animation is a very helpful tool used to check the parametrization and view the structure from any angle. If the 3-D animation looks different to what is viewed when looking at the frame, input values should be checked for errors and amended (Fig 2).

Perspective Frame Matching (PFM) – a new planning tool based on 3-D reconstruction
A 3-D reconstruction of a clinical situation is commonly used in navigation. One of the prerequisites for 3-D reconstruction based on two x-rays is the matching of characteristic landmarks or markers of a known body. The perfectly known body in a MAXFrame is the frame construct itself. As we are already aware, the geometry of a MAXFrame is perfectly defined through specific placement of rings and struts. The perspective frame matching method workflow uses this defined frame geometry to produce a perfect 3-D reconstruction of the clinical situation in the individual case. The struts as seen in the x-ray images are matched by their joints and/or axis and the 3-D reconstruction is calculated based on this matching on both images. The images do not need to be rectangular or perfectly shot along the axis. The only prerequisite is that all struts, preferably with the joints, are visible in both x-ray images (Fig 3).

The primary advantage of this method is that artefacts of X-ray imaging are no longer a problem for getting true and exact values. An x-ray is, by definition, only a projection of the real structure like the shadow of a pencil on a piece of paper. As the size of the “shadow” is dependent on the distance between the object and the source of the light, all structures are magnified on an x-ray and exact values cannot really be measured. In addition, if the structure is in an oblique as opposed to parallel plane when compared to the x-ray, the size of the object is shortened in the direction rectangular to the axis that is common to both planes. The challenges presented by x-ray can be solved with a 3-D reconstruction, enabling the definition of points and axis in space. After the PFM is complete with acceptable precision, the points of reference, the bone axis, and any structure of interest can easily be identified by “marking” them in both x-ray images. All the distances and angles between the structures of interest are directly calculated based on these markings and no value needs to be “measured” in the traditional way.
Case: Tibial malunion

A 54-year-old man suffered bilateral tibial fractures 20 years earlier, both treated in a cast. He now experiences pain in the medial right knee. Images taken showed that both legs had substantial malunion, but the right knee caused pain because it was out of mechanical axis (Fig 4). The patient was successfully treated with the MAXFrame system (Figs 5 to 8).

Fig 4a–b
Preoperative images showing malunion and deformity.

Fig 5a–b
The AP and medial postoperative images show the MAXFrame in position.

Fig 6a–b
Postoperative AP and medial images used for perspective frame matching.

Fig 7a–c
Images after MAXFrame correction according to initial treatment plan. As a residual deformity, a translation is visible in the lateral view (b).

Fig 8
Final correction after replanning the lateral translation with the standard method.
**Zero-P Natural Anterior Cervical Plate**

The Zero-P Natural plate is a zero profile anterior cervical plate that provides anterior plate and screw fixation of the cervical spine. The plate is anchored by four locking bone screws, which forms a rigid bone wedge for stability. The plate delivers strength and stability comparable to a traditional cervical plate as demonstrated in mechanical and biomechanical testing [1].

The Zero-P Natural plate was designed for use with the Corticocancellous (CC) Natural allograft spacer processed by the Musculoskeletal Transplant Foundation (MTF) (Fig 1). It features retention arms that are designed to securely attach to the allograft spacer and its height is slightly undersized to the corresponding CC Natural allograft spacer offering potential to avoid stress shielding.

**True Zero-Profile design – Designed to minimize contact with local anatomical structures.**

The plate is contained within the excised disc space and does not protrude past the anterior wall of the vertebral body, limiting the risk of damage to vessels and adjacent soft tissue. In addition, preparation of the anterior surface of the vertebral body is not necessary because the plate does not lie against this surface (Fig 2). It is also designed to prevent contact with adjacent levels. Cervical plates placed near adjacent level discs may contribute to bone formation near or around the adjacent level [2].

**Ease of use**

The Zero-P Natural plate firmly attaches to the allograft spacer. This enables simultaneous insertion for a more streamlined surgical technique. Each plate is supplied sterile-packaged and mounted to an assembly tool that allows the plate to be coupled to the allograft spacer (Fig 3).
Fig 4a–e
One-step locking head screws (a–c), and plates that accept different sized footprints and profiles (d–e).

Features
Features include:
- One-step locking head screws (Fig 4a–c) that form a bone wedge with a $40^\circ \pm 5^\circ$ cranial/caudal angle and $2.5^\circ$ medial/lateral angle
- Self-tapping screws improve thread purchase
- Self-centering trilobular thread-cutting flutes
- Lengths 12, 14, 16 mm
- The zero-profile titanium alloy plate provides a secure rigid locking screw interface
- The plate accepts different footprints and profiles of the CC Natural allograft spacer (Fig 4d–e)

The CC Natural allograft spacer (Fig 5)
- Eases surgical technique by eliminating the need to shape the allograft spacer or to harvest bone from the patient
- Corticocancellous construction offers fusion potential with structural support
- Pyramidal teeth on superior and inferior surfaces create resistance to expulsive forces
- Demineralized surfaces are intended to expose proteins inherent to bone growth and necessary for fusion of the allograft with the adjacent vertebral bodies [3]
- Size and shape options to suit patient anatomy and surgeon’s ACDF technique preferences:
  - Standard and large footprint
  - Lordotic ($7^\circ$ angle) and parallel sagittal profiles
  - Heights 6–12 mm, 1 mm increments

References
1. Synthes report: The ZERO-P NATURAL Plate and an MTF CC Natural allograft spacer compared to a one level VECTRA-ONE Cervical Plate with an MTF CC Natural allograft spacer in a cyclic cadaveric range of motion study: ASTM F1717. Test number 0000220895.
Case 1: Progressive shoulder and arm weakness with neck pain
A 56-year-old man, partly left-hand dominant partly right-hand dominant depending on the activity, presented with progressive left shoulder and arm weakness with pain radiating from his neck down to his left shoulder and an EMG documenting a left C5 radiculopathy (Fig 6). The patient claimed a normal state of health until 5 weeks previous. This then began to backtrack to the neck and to develop weakness in his left arm to the biceps and deltoid. On examination, the patient had 4/5 deltoid and biceps strength on the left and decreased sensation along his lateral shoulder.

The patient showed normal lordosis in his extension x-rays. He has approximately 2 mm of anterolisthesis of C4 on C5 in his extension on his flexion x-ray. This increases to approximately 5–6 mm and persists in his normal upright film with again some component of spondylolisthesis at that level. The patient’s earlier MRI shows severe left-sided C4-C5 foraminal stenosis and multilevel disc degeneration with very mild central narrowing at C3-C4, C6-C7, and C7-T1. He also has a small right paracentral disc herniation at C6-C7. The new MRI of the C4-C5 showed mild uncovering of the disc posteriorly due to grade 1 anterolisthesis. There is also mild left facet arthropathy with left uncovertebral joint osteophytes resulting in moderate left neural foraminal narrowing. The right neural foramen is adequately patent.

Follow-up (4 months)
At the patient follow-up at 4 months postoperative, he described complete resolution of left upper extremity pain (Fig 7). He was also happy with his left upper extremity strength and was extremely pleased with his progress. He continued to have no left upper extremity pain. He also believed that he had made significant progress in terms of his left upper extremity range-of-motion and strength.
Case 2: Neck pain with cervicogenic headaches

The patient works at a grocery store as a produce stocker and has a history of C5 through C7 ACDF done in 2005 (Fig 8). Her symptoms were relieved at that time, but she had quite severe neck pain and bilateral radicular symptoms. She had chronic C6 radiculopathy since recovery from that procedure, however, was able to return to work. Unfortunately, over the last 3–4 months, she has had a recurrence of symptoms, with constant neck pain and occasional cervicogenic headaches. She will occasionally get bilateral pain, a pins and needles-type sensation through a number of distributions, including C5 through her shoulders, less occasionally through a C7 or C6 distribution. Movement of her neck was becoming increasingly painful, particularly with flexion and lateral flexion to the right and left. She has tried a number of conservative modalities including narcotic pain medications, rest, heat, ice, physical therapy-type exercises, activity avoidance, and oral steroids. She states that she has had a steroid injection. These were not helpful for her. Eventually, she got an MRI and was found to have adjacent level disease.

On manual muscle testing, the patient had 5/5 strength bilaterally with shoulder abduction, elbow extension and flexion, wrist extension and flexion, finger abduction and grip strength. The patient has appropriate range of motion through her cervical spine with flexion and extension, and lateral flexion and rotation. She gets grimacing pain with extreme ends of flexion as well as bilateral rotation and lateral flexion. She has no tenderness to palpation of the spinous process or paraspinous musculature of her cervical spine. She has decreased sensation in bilateral C5 distributions.

Follow-up (6 months)

The patient is now about 6 months status post a C4-C5 discectomy and interbody fusion with removal of preexisting C5 screws (Fig 9). She was recovering well and has not been taking any narcotic pain medication. She takes acetaminophen.
**Case 3: A 46-year-old woman with neck pain and upper extremity paresthesia**

A 46-year-old woman presented with one-year history of neck pain, upper extremity paresthesia, weakness, and subjective numbness (Fig 10). Her right upper extremity was worse than her left, with loss of function and debilitating pain. She described cramping in her upper extremities without etiology and without alleviating factors. She had not been responsive to antiinflammatory medications nor other nonoperative treatment including physical therapy. She had trouble with many of her activities of daily living due to breaks that must be taken due to her pain, as well as the inability to do certain things like open jars due to weakness.

Musculoskeletally she had no obvious deformity in any of her extremities. Her bilateral upper extremities had strength testing of 5/5 in shoulder abduction, elbow flexion/extension, wrist extension/flexion, and finger abduction/extension. Bilateral lower extremities showed 5/5 strength with hip flexion bilaterally, as well as bilateral 5/5 strength knee extension, dorsiflexion, plantar flexion of the ankle, and firing EHL. She had sensation that is intact in all dermatomes. She had no pathological reflexes and no clonus. There was normal tandem gait.

Review of the patient’s outside imaging showed congenital stenosis of the cervical spine, as well as multilevel disk disease and concomitant acquired stenosis in the foramen of C4-C5, C5-C6, and C6-C7 where it was at its most significant level.

**Follow-up (4 months)**

At the 4-month follow-up, the patient’s symptoms were largely resolved and she has been able to return to work (Fig 11). She was very satisfied with her outcome, made significant progress in terms of his left upper extremity range-of-motion and strength.
Stand-alone anterior interbody fusion with the Synfix Evolution

The Synfix Evolution secured spacer system is a stand-alone anterior interbody fusion (ALIF) implant that is intended for use in patients with degenerative disc disease (DDD). It employs the Synfix implant technology, which has been used clinically in the Synfix LR implant since 2004. This technology is a zero-profile construct that includes four diverging locking screws. This design negates, in most circumstances, the need for additional fixation.

Implant overview

The Synfix Evolution implant has been designed to preserve the biomechanical stability of the Synfix LR implant by delivering the following:

- An integrated titanium plate with four diverging locking screws that form a fixed angle construct, creating a wedge of bone designed as an anchor to potentially prevent fixation failure
- A nonrigid connection between locking plate and PEEK spacer allowing for load sharing
- PEEK spacer with elastic modulus similar to cortical bone
- Self-tapping cortical threads

Fig 1a–b
Synfix Evolution implant. Frontal view showing the zero-profile integrated titanium plate, fine and blunt tip self-tapping screws, and a graft retention ridge to enhance graft retention (a). The four lordotic angulations of 6°, 10°, 14°, and 18° support sagittal alignment restoration (b).

Fig 2a–d
Synfix Evolution implant posterior view (a). The implant uses a PEEK spacer to facilitate radiographic assessment of fusion, and comes in a wide range of implant heights. The bullet nose allows for ease of insertion (b). The deeper footprint option provides 3 mm of additional depth in the AP direction to accommodate varied anatomies (c–d).
Comprehensive implant portfolio

The Synfix’s implant portfolio includes:
- 126 implants to support an optimal fit and fill of disc space and restoration of sagittal alignment (Fig 3)
- 6 footprints
- 6 heights
- 4 angles

Instrumentation overview

The instruments were conceived and designed to simplify and minimize the number of instrumentation steps, while maintaining a high level of safety and precision (Fig 4).

Fig 3a–g
Synfix Evolution implant portfolio.

Fig 4
Synfix Evolution instruments: includes aiming device with detachable holder, screwdriver, soft tissue retractor, squid inserter.
Case provided by Paul Heini, Bern, Switzerland

Case: 47-year-old patient with chronic back pain
A 47-year-old woman was suffering chronic low back pain for several years, with severe pain attacks and with uncontrolled movements becoming increasingly disabling due to DD and erosive osteochondrosis at L4/L5. Condition after sciatica due to a disc herniation L4/L5, having nonoperative treatment. The MRI findings progressive compared to April 2014 are shown (Fig 5 and 6).

Anterior lumbar interbody fusion surgery was undertaken in July 2016 using the Synfix Evolution with InductOs (6 mg) (Fig 7). Intraoperative: routine operation, no complications. Postoperative: uneventful postoperative course.

6-month follow-up
By the planned 6-month follow-up, the patient was pain free and fully active. Evaluation with CT scans was undertaken, consolidation was starting (Fig 8).
Anterior Cervical Interbody Spacer (ACIS): Focused Registry study

Degenerative cervical spine conditions can lead to chronic neck and arm pain. Surgical treatment may require anterior decompression and fusion, which is usually established with a cage implant. A recent systematic review described the evolution of cervical cage materials [1]. It noted that the evolution of cage materials had accompanied the changes in design and found that three materials had primarily been used in the manufacture of cage implants:

- Carbon fiber reinforced polymers (CF-P)
- Titanium (Ti)
- Polyetheretherketone (PEEK).

The study found that when initially trialed, CF-P cages achieved high rates of fusion and good to excellent clinical outcomes, however, they have largely been superseded by PEEK due to its superior elastic modulus. Titanium and its alloys were one of the first materials to be utilized for cages in the 1980s. Used by the orthopedic world since the 1940s, Ti is a robust biomaterial with excellent corrosion resistance and a low density that can undergo surface modification to improve osseointegration and cell adhesion. PEEK cages were introduced in the 1990s as an alternative to Ti cages and provide the advantages of radiolucency and an elastic modulus close to bone, thereby avoiding the stress shielding associated with Ti [1].

Today, controversy exists regarding the use of Ti versus PEEK cages [1]. Although PEEK has theoretical advantages, this has not clearly transferred into the clinical setting due to the difficulty in determining and controlling for other surgical factors, including the roles of endplate preparation, area of contact, and overdistraction. However, the majority of studies have reported improved fusion rates, lower subsidence rates, and radiolucency with PEEK versus Ti cages, with one long-term study reporting limited differences in the early postoperative period, but better maintenance of intervertebral height, cervical lordosis, and clinical outcomes by PEEK cages by the 7-year follow-up [2].

Thus, it seems that PEEK cages are the most promising recent development in the field. The Anterior Cervical Interbody Spacer (ACIS), which was the subject of this study, is made from PEEK and has only recently been made commercially available. It can be used as a standalone implant or with additional anterior plate fixation. The choice to add a plate or not, as well as the choice of the filling material (bone or bone substitute), was left to the surgeon’s discretion.
An AO focused registry was conducted in accordance with the ethical principles set forth in the Declaration of Helsinki (DoH) including amendments as well as the International Conference of Harmonization Good Clinical Practice (ICH GCP) guidelines, the European Standard EN ISO14155/2003–2011, and the laws and regulations of the individual countries in which the research was conducted.

**Title of the clinical study**
AO Spine TK ACIS registry-A Focused Registry on Anterior Cervical Interbody Spacer procedures in patients with cervical spine degeneration (Clinical trial registry number NCT02016794).

**Purpose of the clinical study**
The purpose of the study was to document the clinical experience of a new PEEK cage (ACIS) used for anterior cervical decompression and fusion (ACDF) by prospectively collecting (a) clinical data on pain, function, activities of daily living (ADL), adverse events, and length of hospital stay, (b) radiological outcomes, eg, fusion status, and (c) implant handling data.

**Study population, design, and dates**
Patients with a degenerative cervical condition that required anterior decompression and fusion on single or multiple levels. Prospective observational case series. Clinical study initiation date: first patient March 26, 2015. Clinical study completion date: the last follow-up was carried out January 12, 2016.

**Results of the clinical study**
This focused registry of the Anterior Cervical Interbody Spacer (ACIS) included nine patients. For less than half of the included patients, information was collected immediately postoperatively. Based on the small number of patients, the generalizability of the study results is overall limited. This particularly applies to the information collected immediately postoperatively, which will not be considered for result interpretation.

The primary outcome measure of this study was the Neck Disability Index (NDI) after implantation of ACIS. A distinct improvement of the mean NDI from 18.4 (SD= 8.7) preoperatively to 8.0 (SD = 6.2) 6 months after surgery was seen as time after surgery progressed. Secondary outcomes were pain for neck and arms using a Numeric Rating Scale (NRS) ranging from 0 for “no pain” to 10 for “worst imaginable pain”, implant handling details, length of hospital stay, adverse events, and radiological outcomes.

Both neck and arm pain NRSs improved steadily with time after surgery from a preoperative mean of 5.4 (SD = 2.3) to a mean of 2.8 (SD = 2.4) at 6 months for neck pain and from a preoperative mean of 4.7 (SD = 3.6) to a mean of 0.9 (SD = 1.1) at 6 months for arm pain.
A wide range of implant handling aspects was documented, including endplate preparation with endplate rasp, trialing with trial implants, packing bone into the implant, implant insertion with insertion device, implant insertion with implant holder, implant insertion with ACF holder, and overall ease of use. Each of these aspects were either rated as “easy” or “very easy” by the investigators. None of the handling aspects was rated as “moderate”, “difficult” or “very difficult”. All investigators would use ACIS again for this application.

The mean length of hospital stay was 3 days (SD=0.9). No adverse events were reported within the 6 months timeframe of the study, however, in one patient, cage subsidence was recorded as an adverse event 235 days after surgery. The patient was reported to have recovered without any persistent damage.

Upon radiological evaluation, fusion was determined in 56% of patients (5/9). The x-rays of two patients were not assessable and two patients were evaluated as having pseudarthrosis. The reason for pseudarthrosis was subsidence in one patient and radiolucency around the cage in the other patient.

Conclusions
Even though the limited number of patients does not permit us to draw final conclusions on the clinical performance of the implant, the fact that no adverse events were reported in the 6 months timeframe of the study and that no reoperations had to be performed in the study population is highly encouraging. The improvement in pain and function as well as the positive feedback with regard to implant handling further adds to the positive impression.

Study device description
The ACIS implant is designed to meet the specific demands of anterior cervical interbody fusion procedures, as described in various publications [3–8].

In order to enable visualization of the implant position, the implant possesses three radiographic marker pins as shown on the image above (Fig 1) and the x-ray below it (Fig 2).
The implant features a large central canal and is available in three different sagittal shapes (convex, parallel, and lordotic) and comes in 3 footprint sizes (small, ie, 11.5 mm × 12.5 mm, standard, ie, 13 mm × 14 mm, and large, ie, 15 mm × 16 mm) and 8 heights ranging from 5 mm to 12 mm in 1 mm increments to accommodate various patient anatomies.

Pyramidal teeth provide resistance to implant migration, whereas the large central canal accommodates autogenous bone graft or other bone graft substitute to allow fusion to occur through the implant (Fig 3).

**Intended use of the study device**

The ACIS system is intended to replace cervical intervertebral discs and to fuse adjacent vertebral bodies at vertebral levels C2–C7 following anterior cervical discectomy for reduction and stabilization of the cervical spine. The use of autologous bone or bone graft substitute is recommended.

**Indications:**

Cervical pathologies for which segmental arthrodesis is indicated:
- Degenerative disc diseases and instabilities
- Ruptured and herniated discs
- Pseudarthrosis or failed spondylodesis

For multisegmental fusions with the ACIS system supplemental fixation is recommended.

**Contraindications:**
- Osteoporosis
- Severe instabilities
- Vertebral body fractures
- Spinal tumors
- Infections

**References**

Treatment planning for orthognathic surgery is complex and has traditionally been dependent on the surgeon’s personal clinical experience, 2-D x-rays, and manual plaster model surgery. Such approaches lack detail about the 3-D configuration of relevant anatomical structures, meaning that planned movements cannot be accurately transformed into occlusal splints. Over the last decade, there has been considerable growth in the use of computer-assisted planning and surgery for the treatment of orthognathic deformities. However, computerized and customized wafers have not allowed surgeons to achieve desired accuracy of outcomes in maxillary repositioning. The recent development of TruMatch Orthognathics, a system of patient-specific 3-D printed osteotomy and drilling guides and personalized plates for orthognathic surgery, allows waferless maxillary positioning with a high level of accuracy.

The TruMatch Orthognathics platform addresses the challenge of vertical maxillary positioning in cases of complex facial asymmetry, and supports accurate transfer of the surgical plan to the operating room. Additionally, the system reduces the need for splints and plate bending, and allows the surgeon to avoid critical anatomical features including vessels and nerves.

The TruMatch Orthognathics platform integrates virtual surgical planning, and the production of intraoperative patient-specific tools and personalized implants. As well as enhancing accuracy, the system improves efficiency by optimizing preoperative planning and reducing the number of procedural steps. Patient benefits include reduced operative time and pleasing aesthetic results.
Titanium 3-D printed plates

The titanium 3-D printed plates are individually designed to meet the requirements of patients and surgeons, and exist in various designs (Le Fort I, bilateral sagittal split osteotomy (BSSO), and genioplasty plates, Figs 2–4). The plates are intended to be used in conjunction with the titanium 3-D printed guides. The screw locations and vectors are defined according to surgical access, bone volume, and the avoidance of key anatomical obstacles (nerves, tooth roots). Markers facilitate correct plate placement, and the plates are available with either 0.8 mm or 1.0 mm profile. The plates are compatible with MatrixOrthognathic and MatrixMid-face screws and drill bits.

Fig 2a–c
Le Fort I titanium 3-D printed plates. A range of designs and patterns is available, including in-line or clover leaf hole patterns, and 2+2 or 3+3 hole designs.

Fig 3a–c
BSSO titanium 3-D printed plates.

Fig 4a–b
Genioplasty 3-D printed titanium plates.
Titanium 3-D printed surgical guides

The surgical guides (Figs 5–8) are designed to assist with osteotomies and to accurately transfer the virtual surgical plan to the patient. The guides incorporate cutting slots to guide the planned osteotomies (according to the surgeon’s preference). Pilot hole locations and drilling vectors are defined according to surgical access, bone volume, and the avoidance of key anatomical features. The guides include temporary fixation holes and are color-coded to the matching plates for ease of surgical use. Anatomical markers facilitate correct placement of the guides.
Orthognathic splints/wafers

TruMatch Orthognathics splints are patient-specific devices used to transfer the virtual surgical plan to the operating room, indicating the steps of the surgery based on the occlusal information. Intermediate and final occlusion splints are available (Fig 9), with a range of impression depths and buccal contour widths. Use of the TruMatch Orthognathics titanium 3-D printed plates and guides reduces or completely obviates the requirement for splints.

Fig 9a–b
TruMatch Orthognathics splints, available for both intermediate (a) and final (b) stages of occlusion.
Case workflow

The surgeon uses Proplan CMF software to upload the patient’s (CB) CT data and to select the relevant options for planning, guides, splints, models, and implants (Fig 10). The Proplan CMF software generates 2-D and 3-D visualizations of the preoperative patient anatomy, which can be combined as appropriate with facial pictures and scans of the dentition. The technology allows virtual simulation and optimization of the skeletal osteotomies and reconstruction, and offers multiple cephalometric analysis options. Soft tissue simulation and photomapping in 2-D or 3-D is also possible.

Following data upload, an interactive virtual surgical planning session is undertaken with a clinical engineer (Fig 10). The surgeon then approves the virtual surgical plan and the designs for the patient-specific tools and personalized implants. The guides, models, and implants are then manufactured and delivered to the surgeon, who transfers the virtual plan to the patient in the operating room. The design workflow for plates and guides is shown in Fig 11.
Fig 11a–f
Design workflow.

- a: Preoperative
- b: Planned
- c: Final screw position
- d: Plate design
- e: Preoperative with holes and osteotomies
- f: Guide design
Case provided by Frank Wilde, Alexander Schramm, Germany

**Case: 22-year-old male patient with Class III malocclusion**

**Patient profile and preoperative situation**

A 22-year-old man was referred from a local orthodontist for evaluation of a combined orthodontic surgical approach for correction of a Class III malocclusion. The challenges included a frontal and lateral open bite in combination with a maxillary transversal deficiency (Fig 12). The patient showed a midfacial hypoplasia, which resulted in concave facial profile and positive lip step. The large tongue showed lateral teeth impressions and the patient had an immature swallowing pattern.

The patient had difficulty eating and especially biting. Prior to the start of orthodontic treatment, the third molars were removed. After an intensive case discussion with the orthodontist, the first idea of a rapid palatal extension prior to the bimaxillary surgery was discarded and a two-piece Le Fort I osteotomy with maxillary advancement and posterior widening in combination with a mandibular setback was planned. The patient returned to the orthodontist to be set up for surgery.

**Fig 12a–c**

Preoperative lateral (a) and frontal views (b), and x-ray (c) showing Class III malocclusion, and frontal and lateral open bite.
**Treatment plan**
Following the additional orthodontic leveling and aligning, the surgical plan included the following procedures:

- Two-piece Le Fort I osteotomy with maxillary advancement
- Posterior maxillary widening to compensate the transversal deficiency
- Posterior maxillary impaction to close the open bite and normalize the occlusal plane
- A bilateral sagittal split osteotomy with mandibular setback and autorotation

**Virtual surgical planning**
Preoperative multislice computer tomography (MSCT) was obtained and uploaded in Proplan CMF Connect. During a web-based meeting with a clinical engineer, the surgical procedures were planned (Fig 13).

The skull was oriented in the natural head position in accordance to the Frankfurt horizontal plane and the bi-pupillary line, and a two-piece Le Fort I osteotomy with maxillary advancement and posterior impaction was planned. The plan included a posterior maxillary widening to compensate the transversal deficiency in relation to the mandible. A bilateral split osteotomy with mandibular setback and autorotation was simulated to achieve the final occlusion (Fig 13c–d). As the final step, the midline, the position of the incisors, the maxillary canting, and the chin position were checked in relation to the facial midline, the lips, and the natural head position. Fine tuning of the position was performed by moving the mono-block out of maxilla and mandible in final occlusion. A soft tissue simulation in the planned position of the bones was also performed (Fig 14).
Implant and guide design

After the final position of the maxilla was virtually determined along with the necessary osteotomies, the placement, clustering, and angulation of the screws was determined taking into consideration bone availability, teeth roots, and surgical access. The plates were designed based on these constraints (Fig 15).

Next, the osteotomized bone segments (with the associated planned screw position and osteotomies) were virtually moved back to the preoperative position (Fig 16a–b). The guides were then designed with the drilling and cutting features as virtually planned (Fig 16c–d).

The plate and the guide were then produced from Pure Titanium Grade 2 using a laser melting process (Fig 17).

Fig 15a–d
Plate design (c–d) based on the planned position of the bone and screws (a–b).

Fig 16a–d
Guide design (c–d) based on the planned position of the osteotomies (a–b) and final screws.

Fig 17a–b
Plate (a) and guide (b) set ready for surgery.
**Intraoperative surgical details**

Under general anesthesia via nasal endotracheal intubation, a maxillary vestibular approach was used to gain access for the two-piece Le Fort I osteotomy. Upon maxillary exposure, the surgical guide was placed and fixed with two MatrixMidface 1.5 mm screws on the maxilla (Fig 18a). The position of the guide was determined by the precise fit of the guide, which allows a unique position. The screw holes were predrilled (black arrow) and Le Fort I osteotomy (white arrow) was performed in accordance to the surgical guide (Fig 18b). After removal of the guide, the two-piece Le Fort I osteotomy was completed and the down fracture in combination with the midline split was performed (Fig 18c).

Maxillary positioning in all three dimensions (sagittal, transversal, and vertical) was achieved by fixing the patient specific plate in accordance with the predrilled screw holes at the maxilla first and at the midface second (Fig 19a). Additional transversal stability of the two-piece Le Fort I osteotomy was achieved by using a transversal wire enforced palatal plate, which was manufactured prior to surgery by the dental technician.

The new maxillary position in sagittal, transversal, and vertical dimension is encoded in the shape of the patient specific plate. No additional splint (wafer) or intraoperative measurements were necessary for positioning of the maxilla. After closing the maxilla, a classical BSSO with semi rigid SplitFix fixation was performed (Fig 19b) and the final occlusion (Fig 19c) was adjusted using a splint (wafer) in final occlusion.

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**Fig 18a–c**
Intraoperative guide positioning (a), maxillary osteotomy in accordance with the guide (b), and complete midline osteotomy (c).

**Fig 19a–c**
Intraoperative view of the plate attached in accordance with the primary predrilled screw holes (a), the BSSO fixed using a SplitFix plate (b), and the final outcome (c).
Results and discussion

The patient did well postoperatively. A stable Class I occlusion could be achieved and the open bite could be closed safely (Fig 20). He had full sensation along the V2 and V3 distribution of the trigeminal nerve six weeks postoperatively. More recent postoperative images shown (Fig 21).

There are two main benefits of this waferless maxillary positioning. The first benefit is the high precision of maxillary positioning according to the virtual plan without the loss of vertical control of the maxilla. The authors could achieve an accuracy between plan and result of median below 0.5 mm in all 3 axes x, y, and z (in a series of 12 cases). The second benefit is the significant reduction of surgery time of up to one hour due to the straightforward procedure, without the need of an intermediate splint/wafer, which eliminates the intraoperative plate bending and any measuring for the adjustment of the vertical dimension.

Fig 20a–d
Postoperative images (a–c) and x-ray (d) showing Class I occlusion and no open bite.

Fig 21a–c
Postoperative appearance after removal of orthodontic brackets and wire, frontal view smiling (a), lateral view (b), and frontal view of dentition (c).
LCP Pancarpal Arthrodesis Plate 2.7/3.5

Background

Pancarpal arthrodesis is a surgical technique used as a salvage procedure for the treatment of carpal disorders including hyperextension injuries, severe fractures or luxations, degenerative joint disease, and congenital malformations. Despite its biomechanical disadvantage, the most common procedure relies on a dorsally applied bone plate for anatomical considerations. Complications include wound dehiscence, infection, failure of the central (radiocarpal) or distal screws, and fractures of the third metacarpal bone.

Plate design

The recently launched Pancarpal Arthrodesis (PCA) Plate (Fig 1) was designed specifically for carpal arthrodesis in skeletally mature dogs of 20–40 kg and should be contoured to achieve an appropriate carpal extension angle; an angle of 15–20° is recommended.

The following features are implemented in its design to mitigate the previously mentioned complications (Fig 2):

- 2.7 mm/3.5 mm hybrid construction to occupy a smaller percentage of bone diameter in the third metacarpal bone
- Locking technology providing better stability and to preserve the bony vascular supply
- Combi-holes that accept either cortex or locking screws, and allow compression between radiocarpal, intercarpal, and carpometacarpal joints
- Optimized plate length with tapered thickness proximally and distally to accommodate soft-tissue closure and a reduced stiffness at the ends of the plate
- A center hole that accepts either a 2.7 mm or 3.5 mm screw and provides up to 25° of proximal angulation
Case 1: Hyperextension injury in a Labrador Retriever dog

A 5-year-old neutered male Labrador Retriever weighing 24.6 kg presented with a right forelimb lameness of 4-month duration. The lameness occurred acutely and the dog was initially nonweight-bearing. The cause of the injury was not observed. Physical examination revealed a weight-bearing lameness of the right forelimb. The region of the right carpus was swollen compared to the left due to periarticular soft-tissue proliferation. A mild increase of synovial fluid and joint capsule distension was palpated. The right carpus was painful on extension and could be hyperextended to 30 degrees. The normal left carpus would extend to 10 degrees, which is the normal range of motion. Mild muscle atrophy of the right forelimb was observed. The neurological exam was normal. Radiographic examination revealed mild hyperextension, periarticular soft-tissue proliferation, and mild osteoarthritis (Fig 3). It was difficult to determine the joint level of instability of the right carpus based on the radiographic views. A diagnosis of hyperextension injury of the right carpus was made. The surgical plan included arthroscopic examination of the right carpus to assess the antebrachiocarpal joint to determine if it was affected, which would necessitate a pancarpal vs partial carpal arthrodesis.

The patient was anesthetized and placed in ventral recumbency. Arthroscopic evaluation of the right antebrachiocarpal joint revealed synovitis and partial tearing of the palmar radiocarpal and ulnocarpal ligaments (Fig 4). A decision was made to perform a pancarpal arthrodesis due to arthroscopic evidence of damage at this level of the joint. A dorsal approach was made to the right carpus. The articular cartilage was debrided at all levels of the carpus. An autogenous cancellous bone graft was harvested from the right proximal humerus and was applied at the arthrodesis site.

A Pancarpal Arthrodesis Plate 2.7/3.5 was applied to the dorsal aspect of the carpus using a combination of locking and cortical screws. A 2.7 mm cortical screw was used to attach the plate to the radiocarpal bone. Five 2.7 mm locking screws were used to attach the plate to the 3rd metacarpal bone. Five 3.5 mm locking screws and one 3.5 mm cortical screw were used to attach the plate to the dorsal surface of the radius. The cortical screw was placed in an eccentric position to provide compression across the radiocarpal joint. The incision was closed in routine fashion.

Fig 3a–c
Preoperative x-rays revealed mild periarticular soft tissue and mild osteoarthritis. Mild hyperextension of the right carpus is seen on stress view (c).

Fig 4a–d
Inflammation of the antebrachiocarpal joint was evident arthroscopically, consistent with joint injury at this level (a). Appearance of a normal palmar ulnocarpal ligament (b) and palmar radiocarpal ligament (c) in a dog having a carpometacarpal hyperextension injury, but a normal radiocarpal joint. Appearance of a partial tear of the palmar ulnocarpal ligament and radiocarpal ligaments in this Labrador Retriever dog with hyperextension injury involving the radiocarpal joint (d).
A pancarpal arthrodesis was performed using the Pancarpal Arthrodesis Plate and an autogenous cancellous bone graft. This plate allowed use of 2.7 mm screws in the smaller bones (metacarpus and radiocarpal bone) and 3.5 mm screws in the radius. A combination of locking and cortical screws were used to provide compression and achieve excellent stability and limb alignment.

Postoperative x-rays revealed proper joint orientation and compression of the multiple antebrachiocarpal joint levels (Fig 5). Implant placement was considered excellent.

A custom fiberglass palmar splint was applied from the paw to just distal to the elbow after surgery. The splint was used for 4 weeks followed by a soft padded bandage for 4 weeks. Bandage changes were performed weekly. Activity was restricted to leash walks only for 12 weeks postoperatively. Radiographic examination 8 weeks after surgery revealed early healing of the pancarpal arthrodesis and stable implants. No complications were noted (Fig 6).

The patient was returned to normal activity 4 months after surgery. Radiographic examinations at 6 and 6.5 months after surgery revealed stable implants and fusion of the carpus (Fig 7 and 8). Functional outcome was excellent 1 year postoperatively. The patient had returned to full weight-bearing without lameness and the carpus was pain-free and stable.

Radiographic examination 8 weeks after surgery showed early bone healing and stable implants.

Following implant removal (at 6.5 months) there was excellent limb alignment and fusion of the carpus.
Case provided by Amy Kapatkin, Davis, USA

**Case 2: Traumatic hyperextension injury in a Labrador Retriever**

A 7-year-old, 32.5 kg, Labrador Retriever became acutely lame on the left thoracic limb while catching a ball. It was evaluated three weeks later and had carpal swelling, pain, and instability of the left carpus. Flexed lateral, cranio-caudal, and extended mediolateral view images of the left carpus revealed a dorsal chip fracture at the carpometacarpal joint and hyperextension of the left carpus (Fig 9).

Treatment with a splint for several weeks resulted in no improvement. A pan-carpal arthrodesis was performed with the Pancarpal Arthrodesis Plate 2.7/3.5 and a combination of standard cortical and locking screw fixation. An autogenous cancellous bone graft was collected from the left proximal humerus and placed at all joint levels.

Immediate postoperative images confirmed anatomic alignment and adequate carpal extension (Fig 10). At the 11-week postoperative follow-up examination, functional recovery was very good with images revealing stable implants and healing of the arthrodesis (Fig 11). The dog was then allowed to return to normal activity.
The AOTK Meet the Experts sessions held during the Davos Courses remain one of the most important activities organized by the TK System each year. Please join us live in 2017 during lunch times in the Café Chamonix for more exciting product innovation demonstrations from the Experts. For more information regarding the 2017 program, please review the schedule on the back page of this magazine.

Missed it? Don’t worry! Catch up at the AO Approved Solutions page on the AO Foundation website.

**Treating Chest Wall Deformity using Sternal Plates: Ed Black and Stefan Schultz-Drost**

In May 2015, the MatrixRIB long straight plates (24 and 30 hole) were launched as part of the Chest Wall Deformity Reconstruction system. Following the additional launch of the sternal plates in 2016, members of the Thoracic Expert Group were happy to promote the complete system (Fig 1), which provides users with a comprehensive and varied portfolio for chest reconstruction. The session covered elective procedures including the management of chest wall deformity as well as the treatment of sternal fractures in the trauma patient.

**Reduction Techniques in Proximal Femoral Fractures: Paulo Barbosa, Michael Blauth, and Hiroaki Minehara**

The achievement and maintenance of optimal reduction is a key element in any successful operative procedure. In this engaging Meet the Experts session, three medical members from the AOTK Intramedullary Nailing Expert Group provided an overview of the most important aspects of fracture reduction in the proximal femur (Fig 2).

The session started with a comprehensive insight into the various types of malalignment that can result from malreduction. The importance of optimal reduction in the achievement of correct implant placement was highlighted. Through a focus on over-reduction and a subsequent explanation of the importance of avoiding a loss of correction intraoperatively, the presenters portrayed a helpful list of tips and tricks through reference to their own case scenarios. Throughout the session the members were also able to demonstrate some key elements of the TFNA instrumentation specifically designed to facilitate optimal reduction.
3-D Deformity Corrections with External Fixation: Theodor Slongo and Spence Reid

3-D deformities can be treated with the Distraction Osteogenesis Ring Fixator, which enables lengthening and axial correction in one plane. The application of this system on a tibia was demonstrated at this Meet The Experts session by Theddy Slongo and Spence Reid (Fig 3). The MAXFrame 3-D software was also presented to demonstrate future options in 3-D deformity correction. This specific session demonstrated how the MAXFrame software technology could be used. The software assists with a patient’s treatment plan by calculating the daily strut length change required to correct the relational position between 2 bone fragments from the deformed to the corrected alignment. This system allows any 3-D correction in all 6 degrees of freedom while maintaining independence from the mounting of the rings.

Small Bones, Small Plates—Clinical Application of Mini LCP: Michael Kowaleski and Erik Asimus

Small breed dogs and cats have intrinsically small bones with a variety of shapes and sizes. In order to address the spectrum of musculoskeletal disorders in these patients, an array of implant solutions is necessary. The 1.5 mm LCP System was initially approved as recommended in 2013. As a result of the fact that many surgeons still seem to struggle with fractures in small breed patients, the Veterinary Expert Group appealed for standard approval of the system in 2016 encouraging opportunities for education. Besides reviewing several clinical cases, this highly informative Meet the Experts session covered the specific design features and benefits of the mini LCP systems as well as the application of a 1.5 mm LCP plate in a distal radius fracture on a canine bone model (Fig 4).

Important Considerations Regarding the Safe and Efficient Use of Powered Pedicle Screw Insertion: Jean Ouellet

Montreal based spine surgeon Jean Ouellet presented recent advances in pedicle screw insertion and demonstrated the newest development in dedicated power tools. The main benefits of power drill usage for pedicle screw insertion were highlighted. These include enhanced ergonomics, increased speed and efficiency, and a safer, more accurate approach with regard to navigation and decreased radiation exposure. Jean provided a number of illustrative cases as well as a practical demonstration of the Expedium 5.5 Power Instrument Set (Fig 5).
Hyperlordotic Cages with Integrated Screw Fixation: Paul Heini and Maarten Spruit

Paul Heini and Maarten Spruit demonstrated how innovation can enhance management of sagittal profile preservation through lumbar lordosis correction in the treatment of degenerative disc disease (DDD) by providing a comprehensive overview of the Synfix Evolution (Fig 6).

The session included a demonstration of the Synfix design improvements that enabled the creation of the Synfix Evolution. Improvements to the implants include a more anatomical shape and dual lead cortical screw thread for faster insertion while instrumentation alterations have resulted in a detachable 4-hole aiming device, which allows for insertion of all screws without an additional rotation step. A variety of clinical cases demonstrated successful lordotic correction results.

Zero-P From the Beginning to Natural: Richard Bransford

Seattle based spine surgeon Richard Bransford provided an overview of the Zero-P development history (Fig 7). Following the success of Synfix LR, Zero-P has since become the gold standard for stand-alone Anterior Cervical Disc Fusion (ACDF). The session included an explanation of the Zero-P philosophy to provide an alternative to existing anterior fixation, and a demonstration of the primary implant features and related benefits. Clinical cases were presented and discussed with the audience. For more information on Zero-P, see the Zero-P article in the Spine section of this year’s TK Innovations.

Powertools in Neurosurgery: Christian Matula and Stephen Lewis

Neurosurgeons Christian Matula and Stephen Lewis delivered a highly engaging webcast describing recent innovations in surgical powertool technology, specifically the new design features of the Anspach High Speed Electric Drill and its various attachments (craniotomes, burrs, and diamond tips), which now offer enhanced performance and precision (Fig 8). The presenters outlined the use of powertools in various neurosurgical scenarios, and discussed considerations for complex cranial access. The session included a demonstration of surgical techniques for effective use of the high-speed drill in skull base drilling. Clinical cases were presented including acoustic neuroma, meningioma, and cranial nerve decompression. The session was broadcast live to AO members around the world and the presenters also addressed a number of interesting questions from the internet audience.
New Frontiers in Orthognathic Surgery with 3-D-Printed Titanium Plates: Scott Bartlett and Alexander Schramm

Craniomaxillofacial surgeons Scott Bartlett and Alexander Schramm delivered a session describing recent advances in orthognathic surgery, highlighting the recent development of 3D-printed titanium plates (Fig 9). Topics discussed included the evolution of the techniques used in orthognathic surgery, and the steps involved in virtual surgical planning using ProPlan CMF software.

The surgeons explained how the TruMatch Orthognathic platform was developed in response to unmet clinical needs, and how the system allowed accurate surgical planning without the use of splints. They outlined the steps involved in the design workflow for cutting guides, drilling guides, and plates. The session featured an explanation of the surgical steps used in orthognathic surgery using 3D-printed plates and an outline of the various surgical scenarios when they might be used, and included Le Fort I, BSSO, and genioplasty. Data was presented demonstrating the enhanced surgical accuracy and time savings that can be achieved using the new technology, with clinical cases further illustrating discussion. The session was concluded with a lively question and answer session during which the surgeons addressed questions from the audience. Participants also had the opportunity to handle the titanium plates and guides.

Solutions for the Arthritic Knee: Mauricio Kfuri, Takeshi Sawaguchi, Michel Müller, and Bartolomé Allende

AO Recon delivered their very first Meet the Expert Session on Solutions for the Arthritic Knee (Fig 10). Chaired by Mauricio Kfuri, the session focused on providing practical advice and recommendations on the management and treatment of knee arthritis. Each of the experts presented a variety of treatment outcomes through a demonstration of best and worst-case scenarios. The nature of such case discussion provided participants with an insight of how to deal with complex procedures.
Simplified navigation system to control rotational osteotomies

Corrective osteotomies are frequent procedures in trauma and orthopedic surgery aimed at the restoration of healthy anatomical relations. Particularly after intramedullary nailing, the incidence of rotational malalignment is high. For malrotations at the femur greater than 15° a correction is recommended as a result of the risk of knee instabilities and pain. However, an important concern with corrective osteotomies is that the correction is often inaccurately executed and a deformity remains. Computer-aided approaches might be helpful to avoid this problem but current solutions lack wider acceptance due to considerable disadvantages regarding complexity, costs, and effectiveness.

A recently introduced implant positioning and tracking approach called X-in-One shows strong potential to overcome these issues. A dedicated X-in-One module for controlling corrective osteotomies was subsequently developed, for use with a conventional C-arm, and consisting of not much more than two metallic flags with holes and an image processing unit. Holes serve as markers for tracking the performed correction. The flags are attached to the routinely used Schanz pins (Fig 1). An image processing algorithm detects both flags in a conventional x-ray image and computes their spatial relation based on the projections of their holes (Fig 2). The achieved correction in terms of the three spatial angles of rotation are computed and displayed intraoperatively.

A prototype system was realized in collaboration with the Joint Preservation and Osteotomy Expert Group (JPEG). Feasibility of the device was proven in ex vivo experiments and bench tests. The accuracy in axial rotation was $0.65° ± 0.55°$ (mean ± SD), which is believed to fulfill clinical requirements. A clinical feasibility trial is currently running at the BG Unfallklinik Tübingen, Germany, as a first step towards transferring the technology into clinics.
Analyzing the skeletal anatomy is important in musculoskeletal research and implant development, as well as for orthopedic surgery and trauma care. Bony anatomy largely differs between individuals. Variations occur dependent on anatomical site and gender, and are influenced by medical conditions such as decreased bone mineral density. A specific and challenging task is the analysis of the complex bone anatomy of the pelvic ring that entails the innominate bones and the sacrum. Several anatomical features such as pelvic shape, size, and pattern of the pelvic bone mass distribution require detailed evaluation for pelvic surgery procedures such as trans-osseous implant positioning or optimal anchorage of acetabular cups.

The aim of this project was to analyze the anatomy of the pelvic bone for new fixation concepts in pelvic and acetabular fractures. A total of 150 intact pelvic computed tomography (CT) scans of adult Asians and Europeans were acquired and techniques for three-dimensional (3-D) statistical modelling were used. A unique 3-D statistical pelvic computer model was generated and analyzed using specific software tools (Fig 1). This model permitted specific pelvic and acetabular features to be assessed. In particular, the model was applied to evaluate the following pelvic criteria:

- Variations in shape and size
- Mean models (eg, female vs male mean model)
- Specified angle and length measurements (eg, pelvic incidence was used for further description of the spatial relation between sacrum and innominate bones)
- Patterns of the pelvic bone mass and its distribution
- Osseous corridors (eg, trans-sacral and sacro-ilial corridors, acetabular corridors) for safe trans-osseous implant positioning
- Comparison: Asian vs European pelvic CT data

In addition, distinct anatomical features critical for different pelvic surgery procedures were identified, for example, for safe implant positioning through trans-sacral corridors. The present computer model can be used to develop new fixation concepts as well as enhance current anatomical knowledge with regards to pelvic and acetabular surgery.

Further data analysis and processing can be performed on request. This might include the evaluation of specific anatomical regions or comprise the computation of gender specific pelvic mean models. The results of this project may be archived within a database, used in a teaching environment, or subjected to additional analysis, modelling, or simulations (finite element analysis, artificial intelligence) in order to design or optimize osteosynthesis constructs, evaluate bone strengths, predict fracture risk, or enhance anatomical understanding.

The CT-based 3-D statistical model of the pelvic ring used for anatomical evaluation of new fixation concepts in pelvic and acetabular fractures. Assessment of shape and size variation (yellow) with comparison to mean model (grey) (a–b). Positional changes of the three ring-building bones and evaluation of the trans-sacral corridors at S1 and S2 levels (c–d). Evaluation of pelvic parameters eg, 3-D pelvic incidence (e). Evaluation of the bone mass distribution via a virtual bore probe (supra-acetabular region, CT values of line curve given in Hounsfield Unit) (f).
NEWS FROM AOCID

A general update on registry activities and clinical studies
With a team of around 30 specialists (medical doctors, project managers, statisticians, medical writers, data managers, clinical research associates), AO Clinical Investigation and Documentation (AOCID) supports AOTK in its clinical studies as well as providing services such as statistical support, literature searches, and medical writing and editing.

New and simplified process for collaboration
It is now even easier to translate ideas into clinical studies. To turn study ideas into “one-pager” study proposals to be approved by the technical commission (TK), expert groups can contact AOCID for support. Together with clinical experts, AOCID refines study ideas, performs feasibility checks, and prepares budget estimates. This codevelopment process ensures the efficient and timely development of new studies.

Activity highlight: Ongoing and upcoming registries
The health care landscape is rapidly changing. Authorities and payers demand more and more safety and effectiveness proofs of medical devices. Manufacturers are increasingly expected to provide real-world data such as costs, treatment modalities, and patient outcomes.

Patient data registries are an ideal instrument for collecting real-world data in a standard of care setting. Due to their observational, noninterventional nature, registries provide data with high external validity, ie, the findings are likely to be valid in real-life settings. The implementation of registries potentially provides the possibility to a) collect a broad range of standard of care data on defined diseases or injuries and b) enroll a large number of patients in multiple centers. Registries are used to complement and supplement interventional trials and are of increasing importance in the decision making process for health care.

Together with AOTK, AOCID has identified the need to set up different kinds of registries and has launched several registry projects. The setup of these registries varies according to their purpose. Smaller registries may be used for collecting first clinical evidence. This is then used by the TK experts for the technical commission’s approval of new implants. Larger registries allow the collection of a wide range of real-world clinical data, which may include cost effectiveness assessments. Data from large registries can be mined to answer multiple clinical or health economic questions. Two such registries launched in recent months exemplify the collaboration between AOTK and AOCID, and are described as follows.
Periprosthetic Femur Fracture registry (PPFx)
The PPFx registry is an initiative of the TK Periprosthetic Fracture Taskforce. It is a collaborative effort funded jointly by TK Trauma, AOTrauma, and DPS. Funding is guaranteed for the first six years, when at least 600 patients will be enrolled in up to 12 centers and followed up for one year after periprosthetic fracture treatment. At the moment, enrollment is limited to osteosynthesis patients treated with and without arthroplasty revision for periprosthetic fractures around the hip or knee (Fig 1). Ultimately, it is the vision of all involved parties to develop long-term funding to open the registry for more sites and other treatment modality of periprosthetic fractures. Potentially, this could be an open-ended project.

Pediatric Femur Fracture registry (PedFemFx)
The PedFemFx registry is currently under development but will allow participating investigators in Germany and North America to collect clinical and cost data on children and adolescents (ie, patients with open growth plates) with femoral shaft fractures (Fig 2). All treatment modalities are within the scope, and the registry will provide much needed clinical and health economic evidence.

Study highlight: Clinical studies on sensor insoles
Supported by the AOTK during the early development phase, OpenGo (Moticon GmbH, München) (Fig 3) is a new generation sensor insole designed to measure real weight bearing. Completely wireless and non-invasive, the insole contains 13 capacitive pressure sensing pads, a 3-D accelerometer sensor, and an embedded microsystem. These components allow the sensor insole to collect long-term weight bearing, gait, and motion data without affecting patients’ daily life. Currently, AOTK is funding several clinical studies using the insole, three of which are fully conducted or supported by AOCID and are scheduled to start enrolling patients this year.
Open wedge high tibial osteotomy
After an open wedge high tibial osteotomy (HTO) procedure, the surgeon’s advice to patients is usually partial weight bearing for 2 weeks followed by full weight bearing. However, knowledge on the capability of partial weight bearing after the surgical procedure is scarce so far. This study aims to document real-life weight bearing in patients after HTO surgery using the OpenGo insole. Such data will allow healthcare professionals to gain better understanding in patient compliance to the postoperative weight bearing protocol and lead to improvement and individualization of the postoperative treatment protocol.

Trochanter Fixation Nail Advanced
The optimal postoperative weight bearing protocol after an intramedullary nail fixation of femoral trochanteric fractures is still a matter of debate. Patients suffering such fractures are usually older and presumably unable to perform partial weight bearing due to multiple reasons. Some experts, however, are of the opinion that fixation with the TFNA allows unrestricted immediate weight bearing as tolerated (WBT) regardless of the fracture type and bone quality. In this study, early WBT will be monitored using the OpenGo insole in patients treated with TFNA for fracture reduction. The results will provide clinical evidence whether immediate full weight bearing after TFNA reduction is a recommendable protocol.

AO Fracture Monitor
A novel device (AO Fracture Monitor) for continuous and noninvasive monitoring of the healing progress accompanying external fixation has been developed by the AO Research Institute (ARI). This device proved to be a promising tool for monitoring fracture healing on a small scale (10 tibia shaft fracture patients) study. Additionally, ARI has now refined the device (AO Fracture Monitor V3) and improved the design to enhance data processing and optimize energy management. In the planned follow-up study, the relevance and reliability of the data derived from the AO Fracture Monitor V3 will be examined and compared with the data collected from the concomitantly applied OpenGo sensor insole. The results of this study should provide insight into the relationship between healing process and weight bearing capability.
NEWS FROM AO FOUNDATION

The AO Development Incubator: A tool to support innovation

Background
Since the formation of the AO Foundation, innovation in the treatment of musculoskeletal disorders has been paramount. The AO Foundation has recently created a variety of new innovation initiatives to complement those that already exist in an attempt to foster the innovation potential of the AO community. While the AO Strategy Fund and AO Invest have been referred to in previous AO publications, the AO Development Incubator (AODI) is the latest initiative to be launched in this field, with its primary goal of helping bridge the gap that can exist between an inventor and a potential valorization (capital funding) partner (Fig 1).

During 2017, AODI had already began to support some initial projects. The second call for inventor concepts was closed in November 2017 and there is great confidence about accepting further exciting projects to the fund. A new call will be launched in the first half of 2018.

AODI supports inventors in specific ways to achieve a Proof of Concept
Depending on the resources already available to the inventor, AODI is able to offer expert advice, both financial and for human resources, as well as project management support. Outlined below are the areas in which AODI is able to assist with innovation:
- Provide advice in the patent application process
- Define and help in planning a Proof of Concept aimed at attracting the interest of a potential partner
- Provide knowledge, manpower, and financing needed to achieve the Proof of Concept
- Provide access to the AO network
- Find appropriate partners for the valorization of the concept

Prior to any project initiation, a contract defining all related developmental rights must be signed between the inventor and the AODI.
Calls for applications twice per year
Each year, AODI launches two calls for applications. All potential inventors are expected to present a solution that can be patented in the current development stage. If a patent has already been obtained, it must be no more than 5 years old. The solution should address an important clinical problem and the inventor should be prepared to invest time into the project and willing to be closely involved in any further development of his or her idea. Projects are expected to last between 1 and 5 years.

The applications are evaluated by the AODI Board, which is comprised of both surgeons and members with vast experience of business and product development (Fig 2). Evaluation criteria includes:

- Ratings of the clinical need
- Technical feasibility
- Market considerations
- IP evaluations
- Regulatory aspects

A shortlist of projects is selected for presentation to the Board. Support is provided by the AODI to the inventor to prepare a presentation about the invention according to the “Lean canvas” principles (concise and effective business case methodology). Any ideas that are not selected for funding receive feedback and advice for future direction.

A variety of applications from all over the world were received in response to the first call for ideas in March this year. The proposals that were eventually selected cover the clinical areas of trauma, hand surgery, and rehabilitation, with the aim of simplifying procedures and enhancing patient recovery. We are confident that the selected concepts will materialize into usable products and help to further strengthen the innovation landscape of the AO Foundation.

Fig 2
The members of the AODI Board cover a cross section of medical practice, business, and industry. The Board members are (left to right) Han Jo Kim, Michael Schütz, Keita Ito, Todd Dollinger, and Robert Frigg.
Ethicon Collaboration—the soft-tissue initiative

In June 2015 at the annual AO Trustees Meeting held in Chiang Mai, the AO Foundation and DePuy Synthes signed a Cooperation Agreement to secure future collaboration until 2020. The Cooperation Agreement not only represents the continuation of a historical relationship but also provides for the opportunity for future collaboration with other industrial partners. One such collaboration established in 2016 and implemented this year has stemmed from a relationship that now extends beyond DePuy Synthes and into the wider network of Johnson and Johnson. With a shared interest in surgeon education, the AO Foundation and Ethicon are striving forward to build a relationship that will benefit the future of patient healthcare.

Ethicon is part of the Johnson and Johnson family of companies specializing in wound closure, endoscopic instrumentation, and energy devices for dissection. In 2015, a rationale for a new AO initiative was identified during an initial meeting between the AO surgeon leadership and Ethicon. Following an assessment of the incidence of surgical site infection and its impact on hospital readmission rates, and the subsequent impact on healthcare costs, the decision to incorporate soft-tissue management and wound closure into current AO curricula was made.

This year has witnessed the successful organization of several symposia focusing on soft-tissue management (Fig 1 and Fig 2). Each symposium took place alongside either a global course or congress such as OneAO in Palm Springs, USA and the Annual Meeting of the German Surgical Society DGCH in Munich, Germany. As a result of the interest from audience members at each event, the symposia content was adapted accordingly and subsequently chaired by a specialist in the specific field. Post-evaluation reports showed a high interest in the topic of soft-tissue management. More than 90% of participants indicated they would recommend this kind of event to their colleagues, while a clear majority (more than 65%) would be likely to attend another educational event on soft-tissue management. The content was rated as very useful (achieving an average of 4 out of 5 on a 5-point scale).

The next step involves focusing on patient problems, the target audience, and their competencies in order to develop a series of educational courses on soft-tissue management aimed at orthopedic surgeons globally. Those involved look forward to this continuing and exciting collaboration.
The 2018 revision of the **AO/OTA Fracture and Dislocation Classification Compendium** provides the user with a streamlined, concise, and clinically relevant tool for classifying the majority of fractures. This revision intends to extend the relevance of the compendium to nontrauma orthopedic subspecialties by integrating existing standard classifications.

Significant updates to the **AO/OTA Fracture and Dislocation Classification Compendium** include:

- Separate codes for the radius/ulna and the tibia/fibula
- The integration of additional validated classification systems, including a preliminary fracture classification for the thorax
- Universal modifiers—descriptive terms for fracture morphology, displacement, associated injury, or location that are generalizable to any fracture
- Additional detailed descriptions to better define certain fracture patterns
- Revision of certain codes to better align fractures within their groups

Further information about the 2018 revision will be available soon through AO’s various communication channels.
**New edition of the AO Principles of Fracture Management book to be released in December**

The key AO publication *AO Principles of Fracture Management* has served many generations of surgeons around the world as the source of knowledge and essential reference in the field of orthopedic trauma surgery. And while the fundamental principles of fracture surgery have not changed in 60 years, biological and clinical knowledge, as well as technological advancements, have extended new possibilities in surgical treatment and offered surgeons the opportunity to explore new ways of applying the AO principles.

AOTrauma is excited to announce the *AO Principles of Fracture Management—Third Edition*, which has been expanded to include new knowledge and explore state-of-the-art technology. It also addresses pressing challenges that face orthopedic surgeons today, such as the exponential rise in fragility fractures resulting from demographic changes and an aging population.

The key features of the latest edition include:

- Contributions from more than 60 highly renowned surgeons, scientists, and medical professionals
- Close to 3,000 high-quality illustrations, images, and video presentations
- New chapters on periprosthetic fractures, knee dislocations, fragility fractures and orthogeriatric care, and additional information on operating room setup and planning
- Immediate access to AO’s continually evolving range of online educational offerings via QR codes for mobile devices including animations, webcasts, webinars, lectures, AO Surgery Reference, AOSTART, and more

AOTrauma is pleased to bring you this new expanded, comprehensive, and updated edition of the *AO Principles of Fracture Management*, which will be officially launched in December during the Davos Courses 2017. Visit the AO Publishing booth to view this and the complete range of AO published surgical texts and reference books or for more information visit www.Thieme.com.
New osteoporotic fracture care book to improve understanding of the older patient

With an increase in the longevity of the global population, care of the functional, cognitive, and physical health of older adults has become increasingly important.

In 2018, AOTruma will publish the *Manual of Osteoporotic Fracture Care—Medical and Surgical Management*, which will be the first book of its kind to offer a well-rounded and comprehensive resource on fragility fractures and orthogeriatric care. This new AO publication is designed to help new and experienced surgeons, geriatricians, physicians, and care personnel to develop interprofessional and interdisciplinary systems to treat older patients more effectively.

The book will cover the principles of osteoporotic care, how to improve current systems of care, and provides an entire case-based section to outline decision-making and special considerations in surgical care. Watch out for the *Manual of Osteoporotic Fracture Care* in the new year.
Experts’ Symposium held in Chiang Mai

On Sunday May 14 2017, in conjunction with the AOTrauma Asia Pacific Courses, AOTK was proud to host the 11th Asia Pacific Experts’ Symposium in Chiang Mai, Thailand (Fig 1). This one-day symposium, chaired by Theerachai Apivatthakakul from Chiang Mai University Hospital, attracted close to 60 participants and was split into two sessions. The first session focused on lower extremity and the pelvis while the other session involved the upper limb. Complete with an outstanding international faculty, the symposium successfully delivered a variety of topics along with case reviews provided by participants. During the lower extremity session, participants attended presentations on femoral nailing and the benefit of augmentation as well as an open forum focusing on pelvic fracture fixation. In the upper extremity portion of the symposium, faculty shared their insights into the challenges presented by complex elbow fractures and clavicle fixation.

One of the prerequisites for attending such a symposium is participants’ submission of a challenging clinical case in any of the symposium’s clinical areas. As with every AOTK symposium event, many exciting cases were received. Unfortunately, not all cases can be presented but we would like to acknowledge this year’s selection, with particular congratulations going to Surasak Jitprapaikulsarn from Thailand (Fig 2) and Sam-Guk Park from South Korea (Fig 3) for their outstanding case presentations on complex elbow fractures, and proximal humeral fixation strategies respectively. Both speakers received an AOTrauma book prize for their efforts.
AOTK Executive Board welcomes new Chairman

During the AO Foundation Trustees Meeting in Miami in July 2017, the role of AOTK Executive Board (TKEB) Chairman was accepted by Daniel Buchbinder, the current Chair of the AOTK CMF group. He follows in the footsteps of outgoing TKEB Chairman Tim Pohlemann, whose term as Chair has ended after an eight-year reign.

Following announcement of his successful nomination, Daniel said that he was excited to have been given this opportunity to move TK innovation forward. “The TKEB has been well managed by Tim Pohlemann for many years, and I feel very confident about taking this new role in the knowledge that the group and its surrounding infrastructure has been highly successful and effective in its set up.”

On leaving his post, Tim Pohlemann stated that he felt he was always simply the spokesperson for the TKEB and proudly referred to the group’s effective work as a combined effort between the specialties. “The TKEB hasn’t always been formed in the way that it is today, and I am proud of the achievements that have taken place during my tenure,” he said.

Following his acceptance of the role in 2009, it soon became clear to Tim that unification between all specialties was required. “In order to work together as a group of surgeons that valued each other’s perspectives, the AOTK needed to embrace all disciplines equally so that patient care could benefit from cross-specialty input.” Tim promotes the introduction of the Product Fayre (product showcase) at the TK Chairman’s meeting every December as an example of such shared experience. “We are a group of doctors from the fields of Trauma, Spine, CMF and Veterinary working together for a future of better patient care.”

“Working with the AOTK is always enjoyable even in the most challenging of climates,” said Tim. “The recent years have witnessed many changes including a restructure of our industrial partner and a slightly amended contract that enables the TK Expert Groups to collaborate with alternative companies outside of DePuy Synthes and Johnson & Johnson. Both of these events have created opportunities for exciting new developments, which Dan can now begin to explore.”

Tim sights previous strategy meetings as being influential in determining the future of Orthopedic and Trauma product development within the AOTK. Referring to one such meeting in 2014, Tim noted the foresight that TK Chairmen had to predict the trends and clinical needs that we now see in healthcare environments across the globe.

Having been a member of the TK Executive Board for four years, Daniel is no stranger to the group and has lived through the very moments that Tim recounts as his most memorable occasions as Chair. Contemplating the months ahead as new Chairman, Daniel showed his appreciation for Tim’s continued input. “While Tim has many other commitments within

Fig 1
Former Chair Tim Pohleman congratulates Daniel Buchbinder following his appointment as the new AOTK Executive Board Chairman.
the AO Foundation, including his position as Chairman of the AOTK Trauma group and a long-standing affiliation with AO Germany. I am encouraged by his decision to remain a valued member of the TKEB for the next 12 months. I see the year ahead as a transition year in which I can really benefit from Tim’s mentoring.”

Dan acknowledges that there is a need to do business differently now but views this as an opportunity to embrace. “It’s certainly an interesting time to be on the ground.”

The AOTK System would like to take this opportunity to thank Tim Pohlemann for his dedication and commitment to the AOTK Executive Board and wish Daniel Buchbinder a successful start in his new Chairmanship role.

**AOTK team welcomes new colleague**

In March this year, the AOTK team welcomed new colleague Sarah Carbis (Fig 1). After graduating from the University of Applied Science in Chur with a BSc in Information Science, Sarah worked for the media center at the College of Education Graubunden (PHGR). She first joined the AO Foundation in September 2016 as a part-time Project Assistant in the Process Management Program, and this year became a full-time Project Assistant within the AOTK. She is responsible for the logistical organization of the CMF portfolio and Trauma Expert Groups, and is greatly appreciative of the opportunity to be able to further her insight into the medical world. Welcome aboard Sarah.

**AOTK Restructure**

At the time this magazine was approaching completion, Spine Project Manager Andrea Chierici (Fig 2) announced his resignation from the AOTK. Andrea joined the Technical Commission in 2012 and has since managed a variety of exciting spine projects and witnessed the launch of products such as Zero-P ChronOS and Syncage Evolution. We would like to take this opportunity to thank Andrea for his contributions and wish him all the best in his new adventures.

Lois Wallach, AOTK CMF Project Manager has agreed to step into Andrea’s shoes and will begin to manage the Spine portfolio with immediate effect. Christoph Noetzli will subsequently take full responsibility for AOTK CMF adding to his existing management of the Foot and Ankle Expert Group and Asia Pacific Group. We wish both Lois and Christoph a good start in their new roles.
AOTK Innovation Award

The prestigious AOTK Innovation Award is awarded in recognition of continued improvement to patient care. In 2016, it was awarded to a team of AOTK CMF members for their development of ProPlan CMF, a workflow tool that enables surgeons to utilize software and interactive services to assist in procedure planning. The final surgical procedure is completed using specifically designed guides and anatomical models. Current planning services are available for mandible and midface reconstruction, distraction, craniosynostosis, and orthognathic surgery.

Not all members were available to attend the awards ceremony when it was held at the end of last year, however, Daniel Buchbinder, Carl-Peter Cornelius, and Scott Bartlett (left to right, Fig 1) were on hand to accept the award for the whole group. Other members recognized in the award included Damir Matic, Nils Gellrich, Rainer Schmelzeisen, and Alf Nastri.

Two deserving winners receive AOTK Recognition Award

The AOTK was proud to combine the 2016 and 2017 Recognition Award this year and present it to two deserving recipients. During the 2016 Davos Courses, the award was presented to Dankward Höntzsch, who joined the AOTK in 1985. In July of this year during the Trustees Meeting in Miami, David Helfet was pleasantly surprised when the prestigious award was also presented to him in honor of his 18-year commitment to the AOTK.

Having featured in last year's Innovation Magazine as a key member of the AOTK, Dankward Höntzsch (Fig 1) accepted the AO Recognition Award following 31 years with the organization. Dankward promotes the release of the Universal Tibial and Femoral Nails, EXFIX clamps, and ASLS as the innovative highlights of his commitment to the Technical Commission.

David Helfet (Fig 2), Professor of Orthopedic Surgery at the Presbyterian Hospital in New York, joined the AOTK in 1999. Through his valued membership in the AOTK Trauma Group for the previous 8 years, David has been a central figure in the approval of new products through to market launch, and truly appreciates the opportunity that this has presented to him in being able to work with all members of the AO family.
Jean Ouellet is a spine surgeon by profession yet considers himself more an academic due to his passion for innovation, teaching, and research. His area of expertise is complex pediatric and adult spinal deformity surgery. Born in 1968, Jean graduated from the University of Ottawa Medical School and moved to Montreal to complete his orthopedic training with Professor Max Aebi. Through the mentorship of Professor Aebi, he was introduced very early to the AO family and has remained dedicated to the core principles of the AO Foundation: education, innovation, research, and friendship.

After completing orthopedic training, he spent two years abroad, firstly for a year at the Texas Scottish Rite Hospital in Dallas completing a Pediatric Orthopedic and Scoliosis Fellowship. He then spent a year in Europe with John Webb and Michael Grevitt doing a Spine Fellowship in Nottingham. He then returned to the McGill spinal unit joining Max Aebi, Dante Marchesi, and Vincent Arlet. From 2005, he transformed the unit, creating an endowed 3 million dollar Chair that has been supporting a multidisciplinary team of basic and clinical researchers focussed on translation and fundamental research. Two large programs have since emerged that have received more than 2 million in external international and national funding including from AO. One program focusses on studying the intervertebral disc and novel regenerative medicine, which can be tested in an in-hospital bioreactor developed by the spine unit. The other research axis focusses on optimisation of perioperative pain management using quantitative sensory testing.

Serving as the McGill Spine Fellowship Director for the last 13 years, Jean has trained well over 30 spine fellows from across the globe. Jean joined AOTK in 2006 as expert group member and became Chairman of the Deformity Expert Group in 2010, developing new implants and novel education tools, and building strong partnerships with team members. From the beginning, Jean has enjoyed his involvement with AOTK and his enthusiastic attitude and pragmatic approach were drivers to new concepts and clinical solutions.

Examples of his excellent contribution include his initiative for a new surgical technique he conceived, and his contribution to the development of a new spinal implant for the treatment of early onset scoliosis (EOS). The Modern Trolley project, is a revolutionary self growth guiding system for early onset scoliosis based on the Luqué spinal construct. Development started with proof of concepts and prototypes in 2007 and, based on promising outcomes from animal studies in 2014, a prospective non-
Jean is a great educator and has been part of the AO Faculty since 2001 when he lectured at the Davos Courses as a newly graduated Spine Fellow from Queen Medical Centre in Nottingham. Since then, he has chaired several AONA Deformity Expert Courses and has been an invited guest lecturer across the globe. He is currently Medical Director of the new Shriners Pediatric Simulation Center in Montreal, leading changes in surgeon training with the use of medical simulation.

Jean soon realized that there was a need for additional hands-on training support, so he developed the Spine Deformity Tool Box. This interesting portable tool-kit uses both single-use and reusable cartridges with various insertion angles meant to test and improve the tactile skills of the surgeon and improve their ability to insert pedicle screws correctly when using a free hand technique. During Davos Courses 2016, testing sessions were offered to surgeons of different seniority, in order to assess and validate the Spine Box. Jean has also contributed by chairing sessions of the AOTK Meet the Experts, one of the key AOTK events organized during AO Davos Courses each year.

In 2016 Jean and colleagues from McGill University prepared a new spine project called Measuring Insole for Pediatric Patients Undergoing Spinal Fusion Surgery, using insole technology developed by Moticon GmbH. The primary objective is the perioperative assessment of pain perception in relation to physical functioning impairment, with the hypothesis that greater pain intensity is correlated with a decrease in physical functioning observed and measured with the OpenGo system. Sixty patients between the ages of 10 and 18 with a diagnosis of adolescent idiopathic scoliosis (AIS) and scheduled for spinal fusion surgery at the Shriners Hospital for Children in Canada will be invited to participate in the study. The Moticon project once more illustrates Jean’s ability to find useful research applications and turn new technology into meaningful innovation.

Jean is a dear friend. He spends his free time travelling, sailing, and playing raquet sports, but above all with his wife Krista and his three children Philippe, Sophia, and Nicholas. Lately, he has started renovating an old farmhouse and learning new things such as dancing tango. We hope he will continue to dance the halls of AO for many more years to come.
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