

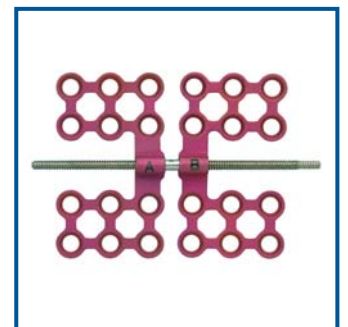
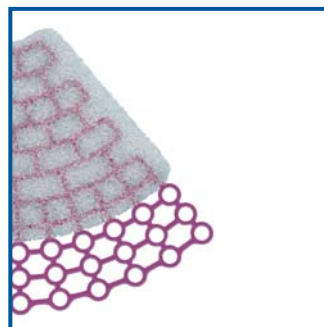


**AO Foundation**  
TK System

THE FIRST  
**50**  
YEARS

# News 2 | 08

## New CMF Products from AO Development



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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.



Dear reader,

It has been almost 3 years since the new structure of the TK System of the AO Foundation was established. Since then, craniomaxillofacial surgery is represented by its own specialty AOTK, and three dedicated Expert Groups have been working on product development projects for our specialty. Additionally, several Working Groups have been appointed to work on designated projects in this field. For instance, we now have a Sternal Surgery Working Group, which deals with development of plate and screw systems for thoracic surgery and we are glad to involve excellent representatives from this specialty in the work of the AO Foundation. Furthermore, there is the new Neuro Surgery Working Group opening the pathway to new developments for cranial and skull base, and neuro trauma surgery.

This is the second issue of the TK News focusing mainly on products for craniomaxillofacial surgery. Among the biggest achievements of CMF product development within the last two years has been the realization of the matrix system concept. The matrix concept allows one screw to be used in a range of plate strengths, thus providing consolidation of systems and ease of use for the surgeon.

The first two modules are now available: the matrix midface and the matrix neuro system, of which the latter has already been developed

with the aid of our colleagues from the Neuro Working Group. It offers a low plate–screw profile of 0.5 mm as well as self-drilling screws with a unique thread design for rapid screw starting and low insertion torque.

Following the same concept, the matrix midface system's main idea was to achieve simplification by standardizing on one screw diameter and four plate strengths that compare to other plating systems currently available.

The clinical feedback obtained from surgeons with experience in distraction osteogenesis, has led to the development of the new modular craniofacial distraction system for individual bone lengthening or transportation procedures, especially in the mandible.

Following numerous requests for stable yet flexible implants to use in CMF surgery, a whole line of polymer sheets has been developed. Designed for treatment of fractures of the orbital floor and walls as well as for cranioplasties or genioplasties, these implants come in different shapes, matching existing titanium implant designs or simple squares that allow for individual trimming.

Many of you may be familiar with Norian™ as it has been available for quite a while now. Since it has been officially approved for CMF surgical application last year you will find some detailed information about origins and possible applications of these products in this issue as well.

Risto Kontio is an oral surgeon from Helsinki, Finland. He has been appointed medical member of the AOTK (CMF) in 2007 because of his innovative spirit and interest in development. Learn more about Risto in the column Portrait.

It should be stated that the product descriptions on the following pages are for information only and are in no case to be used as a substitute for AO surgical techniques or teaching tools. More detailed information on these products can be obtained from AO or your local representative.

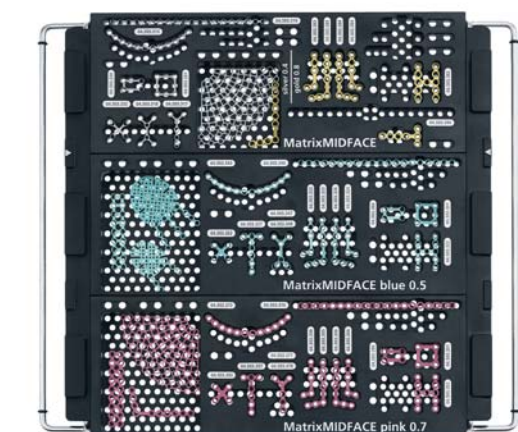
The TK System always encourages innovative surgeons from all over the world to share their ideas with us. Please do not hesitate to contact me if you have any questions or comments.

Yours faithfully,

Edward Ellis III

Scott P Bartlett, Lim K Cheung, Daniel Buchbinder, Edward Ellis III, Warren Schubert

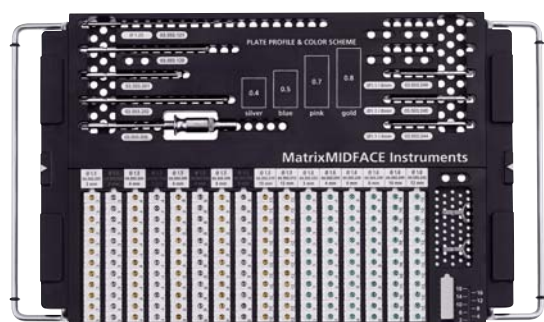
## NEW CRANIOMAXILLOFACIAL PRODUCTS



### Matrix Midface System

The matrix midface system is part of a whole new plating platform for internal fixation of the craniomaxillofacial skeleton. Addressing neuro, craniofacial, mandibular, and orthognatic surgery, the matrix systems are simple yet comprehensive sets providing implants and instruments for all plate and screw osteosynthesis procedures of the CMF area in accordance with the AO principles.

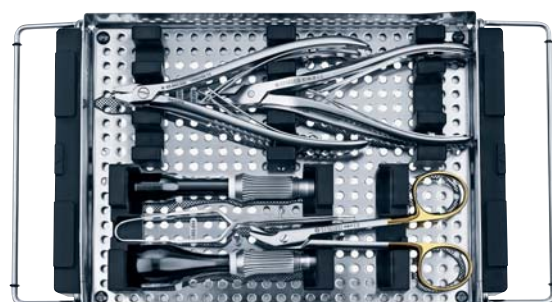
The new matrix midface plate and screw system is intended for use in selective trauma of the midface and craniofacial skeleton, craniofacial surgery, reconstructive procedures, and selective orthognatic surgery of the maxilla and chin. One of the main intentions was to make the system flexible and easy to use.



The system offers a full range plate selection for NOE, ZMC, LeFort I, and a variety of other craniofacial indications. The plates are made of commercially pure titanium, and available in four thicknesses: 0.4 mm (silver), 0.5 mm (blue), 0.7 mm (pink), and 0.8 mm (gold); the color coding designates the plate strength.

### Only one screw diameter and one screwdriver blade

To make the system more user-friendly and simple it is designed in a way that all the screws are compatible with all the plates within the entire set. Furthermore, only one screwdriver blade is necessary as this works for all screws within the system. The screws are available in 3–18 mm lengths with a color coding to indicate self-drilling (silver), self-tapping (bronze), and emergency (blue) designs. In comparison to the existing set, the major advantages are a screw recess for improved retention and reduced cam-out as well as faster insertion due to the 0.6 mm thread pitch design. All the screws in the set are made of titanium alloy (Ti-6Al-7Nb).



Other improvements are the reduced plate–screw profile and the self-retaining screws/blades allowing for easier screw–blade reengagement and reduced screw cam-out. The edges on the plates are rounded to avoid soft-tissue damage. An overall reduced screw–plate profile has been achieved.

The standardized instrumentation makes the matrix midface system more efficient and helps reduce inventory for hospitals without compromising clinical solutions.



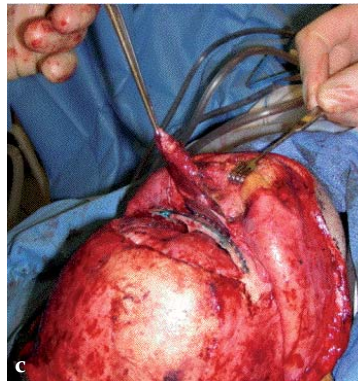
The matrix midface system has been tested at a large number of sites before achieving TK approval. When compared to existing sets, the new system was reported to be much easier to use, and the consolidation of the matrix system was found to be an important step forward. Additionally, the improved screw-plate profile (when compared to the existing 1.5 mm system) and screw insertion and retention were found to be significantly superior to current systems.

Succeeding the matrix neuro system (see page 18), the matrix midface system will later be followed by systems for mandible and orthognatic surgery.



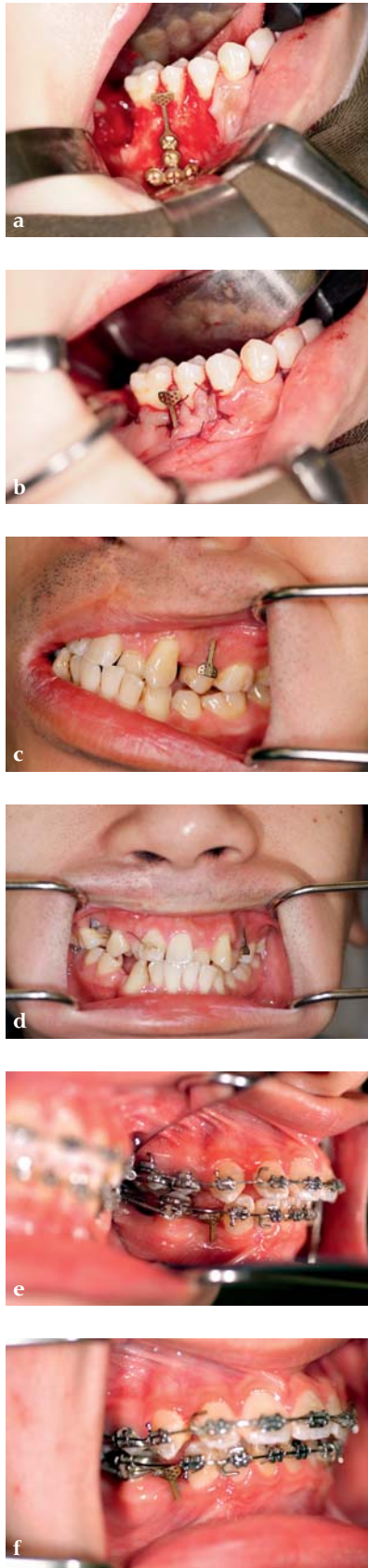
**Fig 1a–b**

Treatment of zygomatic fracture with matrix midface plates.



**Fig 2a–d**

Highly comminuted panfacial fracture.



### Orthodontic Bone Anchor

The technique of using a fixed anchorage point for precise orthodontic alignment of posterior teeth has become standard procedure in orthodontics for more than a decade. Initiated mainly in Asian countries, it is now gaining more popularity in other parts of the world. For the development of the system, feedback was obtained from more than 100 oral and maxillofacial surgeons and orthodontists working in the US, Japan, Canada, Europe and Hong Kong.

The newly designed orthodontic bone anchor (OBA) system is intended to be implanted into the jaw bone via an intraoral approach and used as a stable fixation point for the orthodontic procedures. This system eliminates the need for headgear or similar extra-oral anchorage and is able to offer more control than traditional techniques. The system is composed of a variety of screw anchors, plate anchors, and respective instruments for implementation.

The anchor devices of the OBA system provide fixed anchorage for improved orthodontic control of tooth movement and enable immediate loading of anchorage force for the teeth to be moved. They can be used in combination with a variety of orthodontic arch wires, elastics and springs.

The screw anchors are available with thread lengths of 6, 8, 10 mm, and they are all self-drilling and self-tapping. A 1.5 mm nonthreaded gingival collar beneath the screw head was added to prevent soft-tissue compression and burying of the screw heads. All anchor screws have through-holes that accommodate orthodontic wire with a cross section of  $0.5588 \times 0.7112$  mm. The thread diameter of the screws is only 1.55 mm, which allows for placement into the alveolar bone between the tooth roots.

In cases where a strong fixation is required or more favorable orthodontic vectors are needed, plate anchors are included in the set as well. They can be adapted to the patient's bony anatomy and positioned further away from the tooth roots. The anchor plates can be fixed with self-drilling screws (1.55 mm). It is recommended to use at least three screws per plate for optimal fixation. If any screw gets loose upon insertion in the bone, emergency screws (1.85 mm) are available in the set for use. The plate anchor neck is malleable to allow for later adjustments if necessary.

All implants are manufactured from commercially pure (CP) titanium and titanium alloy (Ti-6Al-7Nb). The set contains a screwdriver handle with hex coupling, the new matrix midface screwdriver blade, bending pliers, and plate cutters.

Not intended for use in:

- Less than 5 mm bone thickness or insufficient bone quality
- Deciduous or mixed dentition
- Active or chronic infection
- Abnormal habits of mastication or bruxism

Fig 1a-f

Case images courtesy of Lim K Cheung, Hong Kong, HK



### Threaded Reduction Tools

As a result of requests from our surgeons for a tool to aid the reduction of bone fragments in craniomaxillofacial procedures, new threaded reduction tools have been developed. These instruments allow for easy percutaneous manipulation and reduction of bone fragments in fractures of the zygomaticomaxillary complex (ZMC).

The threaded reduction tool is available in three configurations which are included in the set:

- One 2.4mm version of the threaded reduction tool, sterile-packed for single use only. The 2.4mm thread is self-drilling, thus eliminating the need to predrill. If predrilling is required, the use of the additionally available 1.8mm drill guide is recommended. The device has a ball stop to hold back the soft tissue during manipulation of the bone fragments. This tool is 78 mm in length.
- Two 3.5 mm self-tapping reduction tools, which can be reused. They are provided in two sizes: One with a length of 78 mm and a shorter 43 mm version. For these devices the set also contains a 2.4 mm drill bit in corresponding color code, and a respective drill guide to protect the soft tissue while predrilling.

All threaded reduction tools are equipped with a hex drive coupling. This allows mounting onto the new T-handle with hex coupling, developed as the main control device for the reduction tools. A key requirement in the development process was the achievement of uncomplicated attachment and detachment of the reduction tools. Thus, the surgeon now has the option for removal of the T-handle following reduction, for better visualization of the fracture during surgery. Furthermore, the reduction tools can be inserted with a standard screwdriver handle if preferred.

The T-handle is designed to provide the surgeon with sufficient leverage to reduce even complex bone fractures. To ensure easy cleaning after use, small drainage holes have been added.



Fig 1a-c

Use of the reduction tool with a standard screwdriver (a) or the new T-handle (b-c).



### SynPOR

The new porous polyethylene implants (SynPOR) are ideally suited to meet the growing demand for flexible yet strong implants for the use in craniofacial reconstruction, cosmetic surgery, and in the repair of craniofacial trauma.

Manufactured from an inert, nonabsorbable polymer and formulated to contain a network of open and interconnecting pores approximately 100–250 µm in size. These interconnected pores allow fibrovascular tissue ingrowth and relative host incorporation. The result is fast integration and stabilization, which can be advantageous over the host encapsulation of implants as it can be seen when using implants with a smooth surface.

The material used for these implants is an ultra-high molecular-weight polyethylene (UHMWPE), which meets the requirements of ASTM standards and has passed ISO standard tests for biocompatibility. It provides strength and stability where required but remains flexible. The implants can easily be trimmed and contoured and can be fixated with screws, tacks, wire or suture depending on the surgeon's method of choice. Final shape modifications can be made in situ.

Among possible clinical applications are orbital, cranial or facial augmentation, and reconstruction cases such as fractures of the orbital floor and wall, cranioplasty, or genioplasty.

SynPOR implants are not intended for use in the presence of:

- Active or latent infection
- Inadequate coverage of healthy, vascularized tissue
- Full load-bearing applications
- Systemic disorders that cause poor wound healing or may lead to soft-tissue deterioration over the implant

SynPOR implants are available in 50×50mm sized squares in four different thicknesses: 0.45 mm, 0.8 mm, 1.5 mm, and 3.0 mm.

They are provided sterile and pyrogen-free for single patient use. Common cutting and trimming instruments such as scissors, mesh cutters, or scalpels (no electrosurgical devices) can be used for shaping. Loose particles can be removed by rinsing with sterile saline solution. Where contouring is desired, the sheets can be immersed in heated sterile saline (70° C/160° F or higher) for a short while, after which the implant is removed and contoured until the desired form is achieved. The implant will return to the original stiffness but maintain its new contour after cooling.





### Anatomical shapes and incorporated titanium

For the treatment of orbital floor fractures SynPOR implants are also available in anatomical shapes: The “guitar pick” shaped version comes in 24 × 24 mm, 30 × 30 mm, and 35 × 35 mm sizes, each one either 0.8 mm or 1.5 mm in thickness. The fan plates measure 35 mm in radius and are either 0.8 mm or 1.5 mm thick.

To combine the strength of titanium mesh and the material advantages of porous polyethylene, the new SynPOR titanium reinforced sheets consist of commercially pure titanium mesh encapsulated in two layers of UHMWPE. Thus the concern of soft-tissue entrapment may be reduced when placing a titanium mesh implant trimmed to a smaller size.

Unlike the other original SynPOR implants, the implants reinforced with titanium allow the surgeon to use an implant which is much thinner in order to span a large orbital floor defect. In addition, the incorporation of titanium allows for intraoperative and postoperative visualization of implant placement, using standard radiographic imaging.



### Craniofacial Plate Line Extension

To compliment the range of existing craniofacial plates a series of new plates has been developed in order to fulfill clinical requests for intermediate sizes:

Straight sagittal split plates 2.0 with 4 holes, available in 22 mm, 29 mm, and 36 mm lengths.

Curved sagittal split plates 2.0 with 6 holes, available in 6 mm and 10 mm lengths; both versions are also available as plates with low profile.

90° L-plates 1.5, available in 17 mm, 19 mm, 23 mm lengths.

All plates are made of CP titanium and are indicated for use in selective trauma of the midface and craniofacial skeleton such as craniofacial surgery, reconstructive procedures, and in selective orthognatic surgery of the maxilla and chin.

Scott P Bartlett, Lim K Cheung, Carl-Peter Cornelius, Daniel Buchbinder

## NEW MANDIBLE PRODUCTS

### Mandible External Fixator II

After the release of the first mandible external fixator in July 2004 the feedback from clinicians, often requesting more technical ease and versatility, led to the development of the mandible external fixator II.

Although the mandible external fixator II system comes with many new features, it addresses the same clinical indications as the original system:

- Severe open mandibular fractures
- Highly comminuted closed fractures
- Nonunions and delayed unions (especially associated with infection)
- Tumor resections
- Facial deformity correction
- Gunshot wounds
- Panfacial fractures
- Burn maintenance
- Bone grafting defects

A strong impetus from surgeons was the request for an increased number of snap-on clamps in the kit. Thus, instead of the original eight, the new system contains a larger number of clamps.

The set contains self-drilling anatomic Schanz screws with two thread lengths for each anatomical region (symphysis, body, ramus) and a shoulder stop to prevent overinsertion. The shaft length of the screws is adapted to the local skin thickness and respects the regional geometry of the mandible (symphysis, body, ramus). The Schanz screw shaft allows for use with rapid driver systems.

The 4.0mm titanium connecting rods are available in four sizes (full mandible, full mandible with ramus, three-quarter mandible, and one-half mandible). Anatomically prebent to the mandibular shape the metal rods cover a wide anatomic variety but can be contoured to match individual patient needs with the included rod bender.

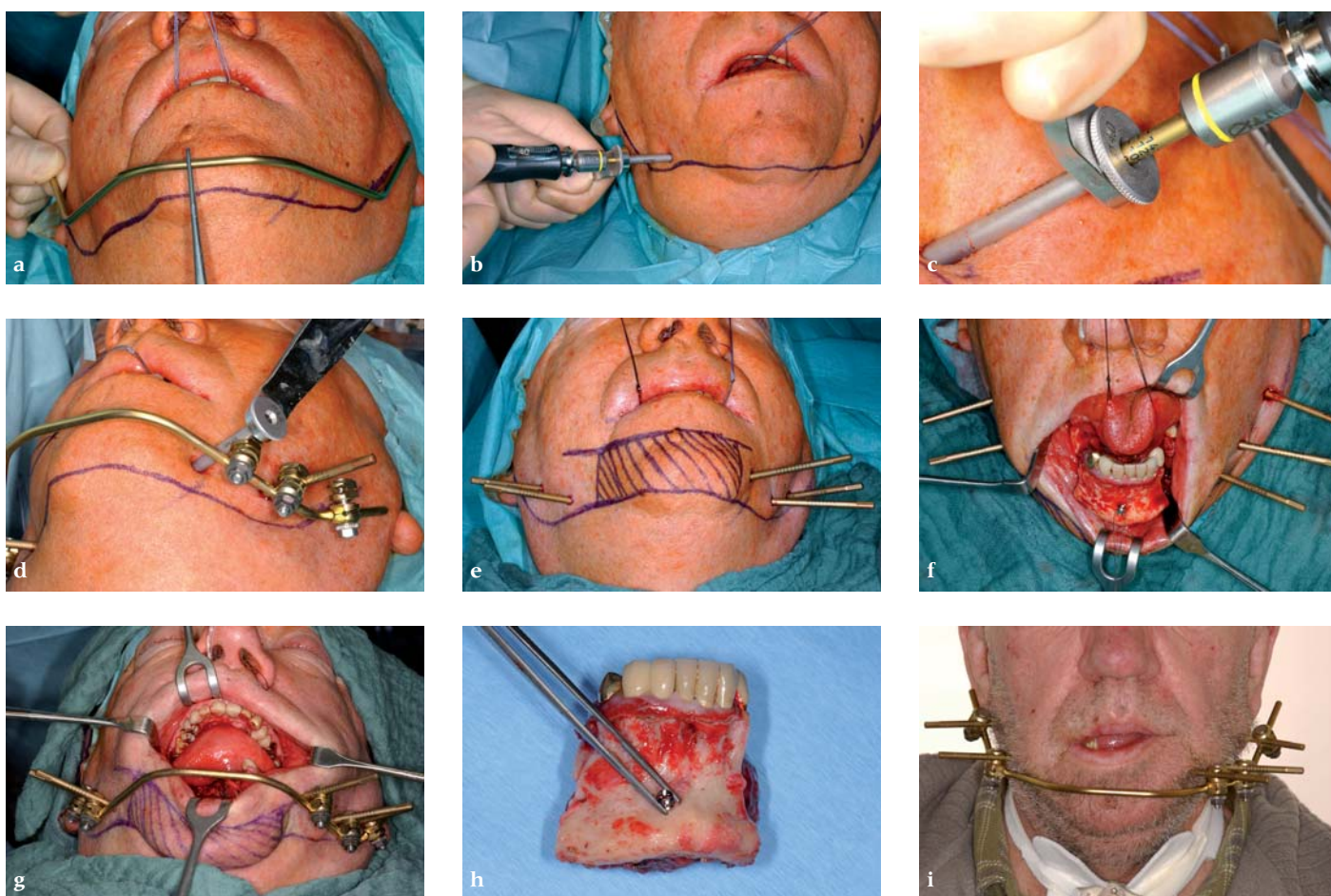
To ensure optimal stability of the framework construction the connecting rods should be positioned approximately one fingerbreadth away from the patient's skin surface, evenly around the mandibular circumference, in order to keep the cantilevers along the Schanz screws short. At least two Schanz screws should be placed on large segments: One in close proximity (10mm) to the fracture or resection line and another one preferably another 10mm away from that.



To allow the surgeon to build a longer modular frame, a new 120 mm carbon fiber connecting rod has been included in the set. Extended carbon fiber rods with lengths of 140, 160, 180, and 200 mm are available on request, but will not fit inside the tray of the graphic case.

Instruments specifically designed for this system are the ratcheting screwdriver handle, the rapid driver and the Schanz screw adapter for tightening of the Schanz screws.

The new mandible external fixator II can be adjusted throughout the whole operating procedure and is MR safe.



**Fig 1a-i**

**Stabilization of the mandible during primary resection of a floor-of-the-mouth carcinoma with infiltration of the symphyseal bone. The sequence shows the application starting in the angles, stepwise assembly, temporary removal of the connecting bar for en bloc tumor resection and remounting.**

Case images courtesy of Carl-Peter Cornelius, München, DE



Fig 1

### Craniofacial Distraction System

Since its introduction to craniomaxillofacial surgery in the early 1990s, distraction osteogenesis (DO) has become an increasingly popular technique in the correction of congenital and posttraumatic deformities of the mandible by gradually initiating and controlling new bone growth and expansion of the surrounding soft tissues. Most common amongst the numerous congenital craniofacial anomalies which result in an undersized or retrusive mandible are Treacher Collins syndrome, Pierre Robins Sequence (PRS), Nagers syndrome and hemifacial microsomia. Associated with, and directly related to the bony hypoplasia are serious airway, nutrition and sleeping disorders, which can often be life threatening.

Distraction osteogenesis has become the subject of AO events such as the Advanced Course in Hong Kong in November 2007 or the first Distraction Experts' Symposium in Naples, Italy, in September 2007, where craniomaxillofacial surgeons from eight different countries discussed their experience using different distraction systems with a focus on the potential improvement of existing systems.

The clinical feedback obtained over the past years from surgeons with experience in DO has led to the development of the new CMF distraction system (Fig 1).

A modular family of internal distraction osteogenesis devices that are used to gradually lengthen the mandibular body and ramus. Each device, when assembled, is comprised of a distractor body, two footplates, and a machine screw to secure the assembly. The system also includes optional activation arms, which can be attached to the activation end of the device to move the point of activation to an area accessible by the activation instrument. Additionally this arm can be removed during the phase of consolidation (Fig 2).

The new CMF distraction system includes two configurations of distractor bodies: The AB (center translating) distractor and the BC (end translating) distractor. Both distractor bodies have an internal threaded lead screw, which engages the threaded footplates.

The AB distractor (Fig 3) is designed for placement on both sides of the osteotomy, ie, at the anterior side or midbody of the mandible. In contrast the BC distractor is designed to be used when most of the distractor body can be placed on one side of the osteotomy, ie, at the posterior body or ramus for advancement of the mandibular body, while leaving the temporomandibular segment motionless.

The AB distractor works with two footplates marked as "A" and "B". Both footplates are initially threaded to the center of the lead screw. When the device is activated, the two footplates move away from each other in opposite directions along the lead screw.



Fig 2a



Fig 2b



Fig 2c



Fig 3

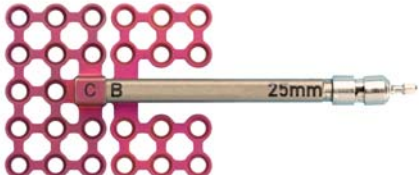


Fig 4



Fig 5

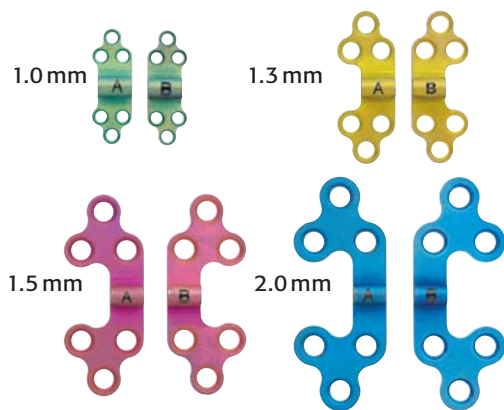


Fig 6a Cloverleaf footplates

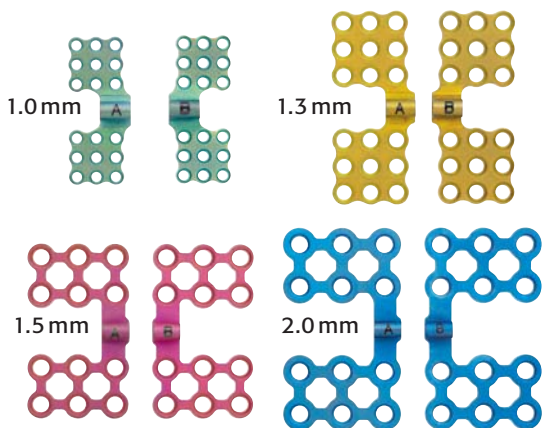


Fig 6b Mesh footplates

The BC distractor (Fig 4) uses a "B" footplate which is threaded onto the lead screw and a nonthreaded "C" footplate, which is attached over the end of the distractor body with a machine screw. When the device is activated, the "B" footplate moves along the lead screw, separating it from the "C" footplate, which remains motionless.

The AB and BC style distractor bodies are offered either with or without a universal joint attached on the activation end of the distractor body. The universal joint aids in the attachment of activation arms. All of the distractor bodies are 3.4mm in diameter and are available in various lengths from 15–30 mm.

The system includes removable activation arms, which are available in various lengths in a rigid or flexible design (Fig 5). The extension arms allow the device's point of activation to be located away from the distractor body to an area (either intraoral or percutaneous port) that is easily accessible by the activation instrument.

The extension arms can be removed once the distraction phase is completed without the need for a second surgical procedure by disengaging the outer sleeve from the inner sleeve using a removal instrument. The distractor can then be buried in the soft tissue. The possibility of inflammation or infection at the transcutaneous or transmucosal portal will be reduced, as is the social inconvenience caused by protusion of the extension arm.

Steps of a normal placement procedure are summarized as follows:

- Standard surgical incision (intraoral or submandibular)
- Assembly and fitting of the distractor
- Standard surgical osteotomy and bone mobilization
- Fixation of the distractor
- Verify bone translation via device activation
- Standard surgical closure

The patient activation screwdriver mates with the activation hex on the distractor or an extension arm. The bone is advanced by the patient in 0.7mm increments for one full rotation with the AB distractor and in 0.35mm increments for one full rotation with the BC distractor, in accordance with the rate of distraction (number of turns per day) prescribed by the surgeon. To remove the distractor a second surgical procedure is necessary.

The CMF distraction system offers multiple styles and sizes of footplates that fit either with the AB or the BC distractor bodies. The footplates are suitable for use on both sides of the mandible and are designed with different screw-hole orientations to appropriately conform to individual patient anatomy. The footplates are available in 1.5mm and 2.0mm sizes and utilize 1.5mm and 2.0mm titanium screws respectively, to attach the device to the bone (Fig 6)

To treat patients aged 12 months or younger, the new pediatric craniofacial distraction system is recommended. It has been developed using the same concept and comprises of 1.0 mm and 1.3 mm sized footplates which accept the corresponding bone screws.

Both systems are intended for single-use only.

#### New K-wires for multi-vector distractor

Furthermore, new extensions to the existing multi-vector distractor system have been developed. Now, additionally available calibrated 2.0 mm K-wires can be used to secure the device to the mandible and transmit force to move the bone. They serve as a visual guide to control insertion depth.



Fig 1a–h  
Distraction osteogenesis.

Case images courtesy of Scott P Bartlett, Philadelphia, US



### Condylar Add-On System

The reconstruction of oromandibular defects following surgical extirpation of oral cavity carcinoma presents a significant surgical challenge. Mandibular deformities and defects may result from trauma, infections, exposure to radiation, neoplasms, and congenital defects, most mandibular deformities arise as a result of ablative surgery for neoplasms. The consequential changes to the oromandibular anatomy caused by resection of the primary and regional metastases are often not only functionally disabling but also socially isolating. Therefore, a complete subsequent recovery of function as well as esthetics is exceptionally important whenever reconstruction is considered.

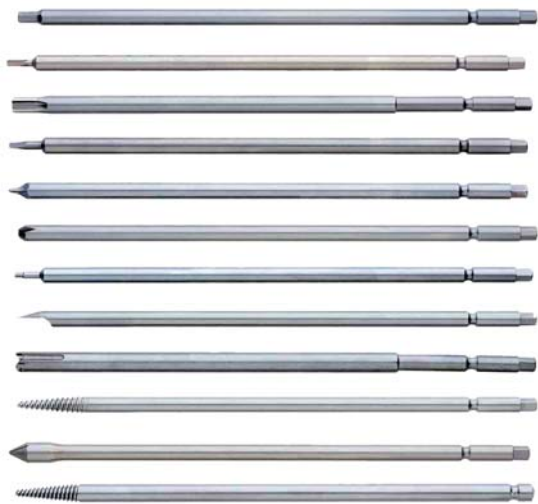
The new condylar add-on system (CAS) provides a temporary solution for reconstruction of the mandibular condyle. To achieve optimal fit in the patient's glenoid fossa, the system includes four different fixation plates that adjust the height of the condylar head on the 2.4mm mandible reconstruction in 2 mm increments. Unlike the already existing plate 2.4 with fixed condylar head, this new system's height adjustment allows it to be used on a larger number of patients.

This device is not intended for use as a permanent prosthetic device, for patients with temporomandibular joint (TMJ) disorders, or patients with traumatic injuries of the TMJ.



**Figs 1a–d**  
Resection of condyle and reconstruction with condylar add-on mounted on 2.4mm reconstruction plate.

Case images courtesy of Oliver Driemel, Regensburg, DE

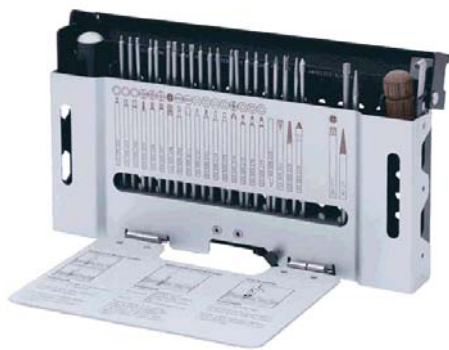


### Screw Removal Set

The necessity to explant screws and plates in various institutions using different fixation systems is not an uncommon situation in the life of a surgeon. However, having the right instrumentation in place is not always a matter of course. The new screw removal set was designed to meet these requirements. It is a compact set of screw driver blades that can be used for removal of 0.9 mm and 3.2 mm screws with various drive configurations, commonly used in CMF procedures.

The new screw removal set includes blades for the most common available drive mechanisms including:

- cruciform
- torx
- hex
- center (Square)
- clutch drive (Slotted)
- slotted
- Phillips
- THORP



An osteotome is included in the set to remove bony ingrowth around the screw head. It is designed with a hex coupling allowing use with either a screwdriver handle or with a trauma drill.

In addition, the set also contains an extractor for broken screws with shafts of 1.0–3.2 mm in diameter with a sheared off head. In smaller diameters the extractor device cuts out the bone surrounding the shaft of the screw and removes it without making contact. The internal threads then engage the screw threads and remove it without further trephining of the bone along the screw length.

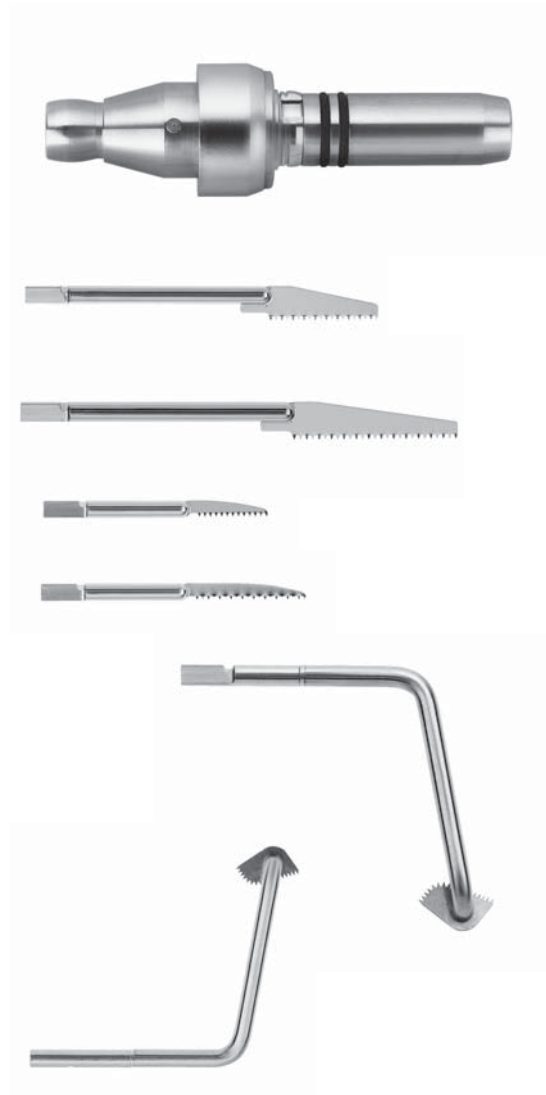
For removal of screws with damaged or stripped head, a conical threaded device (quick coupling) or stripped screw extractors (hex coupling) is inserted vertically along the long axis of screw until it engages the core of the screw. The reverse threading of the instrument will then draw the screw (counterclockwise) out of the bony fragment.

Locking pliers are available to help grab and remove screw parts close to the bone surface. As new drives are introduced to the CMF market, additional blades will be made available to complete the universal screw removal set.



Nils-Claudius Gellrich, Robert Harten, Martin Langer, Rainer Schmelzeisen, Edward B Strong

## NEW COMPREHENSIVE PRODUCTS



### Air PenDrive/Electronic Pen Drive Attachments for CMF Surgery

Both the air pen drive (APD) and electric pen drive (EPD) have proven to be reliable power tools for small and micro bone surgery. In response to requests from CMF surgeons, a number of new attachments for both systems have recently been approved.

### Adapter for intracoupling

An adapter to couple both drive systems with dental handpieces, mucotomes and hermatomes with ISO 3964 coupling geometry.

### New blades

A series of blades with shafts with elongated length (26–44 mm), as well as extra thin reciprocating saw blades for intraoral sawing.

### New blades for IBO procedures

A special set of blades with angulated shaft has been designed especially for osteotomies on the inferior border.



Case image courtesy of Martin Langer, Münster, DE

### Norian for CMF Indications

#### Norian CRS and CRS Fast Set Putty

Traumatic and surgically created defects in the craniofacial skeleton often require filling with a synthetic material for optimum clinical outcomes. Norian CRS (craniofacial repair system) and Norian CRS Fast Set Putty, offer two treatment solutions for such cases. The Norian CRS family of products is completely synthetic self-setting calcium phosphate cements which closely resemble the mineral phase of bone. Once cured, both materials have identical chemistries and are gradually resorbed and replaced with bone during the bone remodeling process. The key difference between the two formulations is in the intraoperative handling and delivery properties.

#### Norian CRS

Norian CRS is an injectable form of the cement which is mixed in the operating room using an automated mixing system. Once mixed, that material is transferred to a delivery syringe and injected into its intended site via a needle. These features make Norian CRS ideal for cases where delivery to a remote or deep site is necessary.

#### Norian CRS Fast Set Putty

Norian Fast Set Putty is a more rapidly setting version of the product (sets in 3–6 minutes) which also has greater viscosity. These features give the product enhanced moldability and contourability once placed in the surgical site. Norian Fast Set Putty comes packaged in two components; a cup containing a sterile powder (calcium phosphate) and a vial containing sterile solution (dilute sodium phosphate). The two components are combined and mixed by hand using the spatula included. After mixing for 45–90 seconds, the material is ready to be delivered to the site.

#### Features and benefits

The Norian CRS line of products hardens in a warm and wet environment, reducing the need to control moisture at the surgical site. The materials undergo in situ isothermal hardening, thereby eliminating thermal injury to the surrounding tissues. Both materials also achieve maximum compressive stress values which exceed that of native cancellous bone after 24 hours of hardening.



Automatic mixer for Norian CRS.



Norian CRS Fast Set Putty components.



**Delivery of Norian CRS into a simulated cranial defect.**



**Norian CRS Fast Set Putty being applied to a cranial defect.**

### Clinical success

Norian CRS has been in clinical use for nearly a decade, with a large number of patients successfully treated by the use of this product. The more recently developed Norian CRS Fast Set Putty has also enjoyed widespread clinical success while expanding treatment options available to surgeons.

### Clinical indications

Both Norian CRS and Norian CRS Fast Set Putty are indicated for filling or repairing craniofacial defects and craniotomy cuts with a surface area no larger than 25 cm<sup>2</sup>. These materials are also indicated for the restoration or augmentation of bony contours of the craniofacial skeleton, including the fronto-orbital, malar, and mental areas. Both products are not intended for use in the spine, and should not be used in the presence of infection.

Clinical procedures appropriate for the use of Norian CRS products include:

- Cranioplasty
- Cranial recontouring
- Cranial flap augmentation
- Augmentation genioplasty
- Onlay grafting
- Skull base defect repair

The application of the Norian products in layers is not recommended. Furthermore, they should not be used against an open sinus.

### Basic science

The Norian CRS bone cements consist of a carbonated apatite that more closely resembles the mineral phase of bone than hydroxyapatite. Hydroxyapatite is commonly thought of as the mineral phase of bone. However, it is the mineral dahllite that actually comprises 60–70% of total dry bone weight. Dahllite has higher carbonate content (4–6%) than hydroxyapatite (0%). Therefore, as carbonated apatites with a carbon content of 5%, the Norian CRS products more closely resemble the composition of natural bone.

### Matrix Neuro System

The new matrix neuro plate and screw system offers a complete line of screws, plates, meshes as well as new instrumentation designed for neurosurgical fixation. It is intended for use in selective trauma of the midface and craniofacial skeleton, craniofacial surgery, and reconstructive procedures. It can also be used for selective orthognatic surgery of the maxilla and chin. Its main strength revolves around its concept of improved self-drilling low profile neuro screws which can be used in a range of plate strengths.

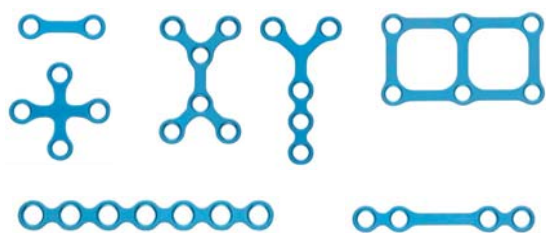


Fig 1

### Implants

In order to meet the need for low profile in neurosurgical applications broad matrix neuro plates are 0.4mm thick, which is significantly less than the currently existing low profile system. Still they provide maximum strength being comparable in bar stiffness. Full selections of titanium plates such as 2-hole and 4-hole dog bone, y-plate and box plate and burr hole covers are available (Fig 1).

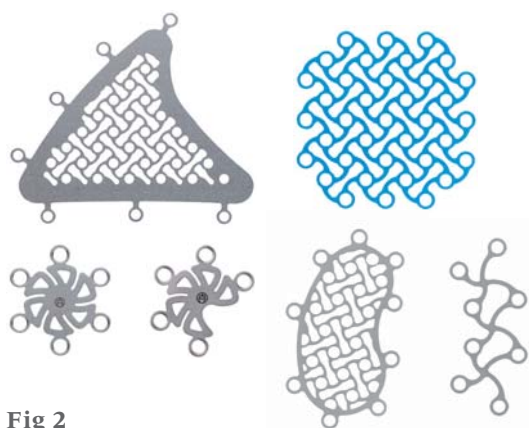


Fig 2

The matrix neuro contourable mesh is available in a variety of shapes and sizes to meet the needs of the individual patient. In addition to the malleable mesh another more rigid version is available. Both versions are 0.4mm thick. The unique design allows screw placement through either side of the mesh. It is color-coded based on strength characteristic. Specialty shapes, such as strut mesh, temporal mesh, and the mastoid mesh are available as well (Fig 2).



Fig 3

The matrix neuro self-drilling screws have a unique thread design for rapid screw starting and significant lower insertion torque almost instantaneously starting with bone contact (Fig 3). They have a deep recess cross-drive for improved retention and resistance to pull-out. The screws are available in 3 mm, 4 mm, and 5 mm lengths (1.55 mm in diameter—emergency screws in 1.85 mm are available). They provide a fast closure of bone flaps and rapid fixation of cranial fractures. The overall plate/screw profile of the matrix neuro system is 0.5 mm.



Fig 4

The matrix neuro system includes newly designed instrumentation such as screwdriver blades, mesh cutters, plate benders and plate holders (Fig 4). It is available with an especially designed modular graphic case, which is stackable, providing a flexible and convenient means of storage. Addressing the need for quick and easy access of instruments and implants the drawers feature an improved movement and the screw holding insert is made of metal instead of plastic (Fig 5).

### The Matrix System

The matrix neuro set is the first part of the new matrix system, a new plating platform for internal fixation of the craniomaxillofacial skeleton—addressing neuro, craniofacial, mandibular, and orthognatic surgery. Its main characteristic feature is that all screws work with all plates within each matrix system. Furthermore, only one blade is needed for all screws within each matrix system. Along with a streamlined instrumentation the matrix systems offer significant consolidation of the sets combined with improved ease of use quality. The matrix neuro system will be followed by respective systems for midface (see page 2) and mandible with all systems being consistent in color-coding and case design.

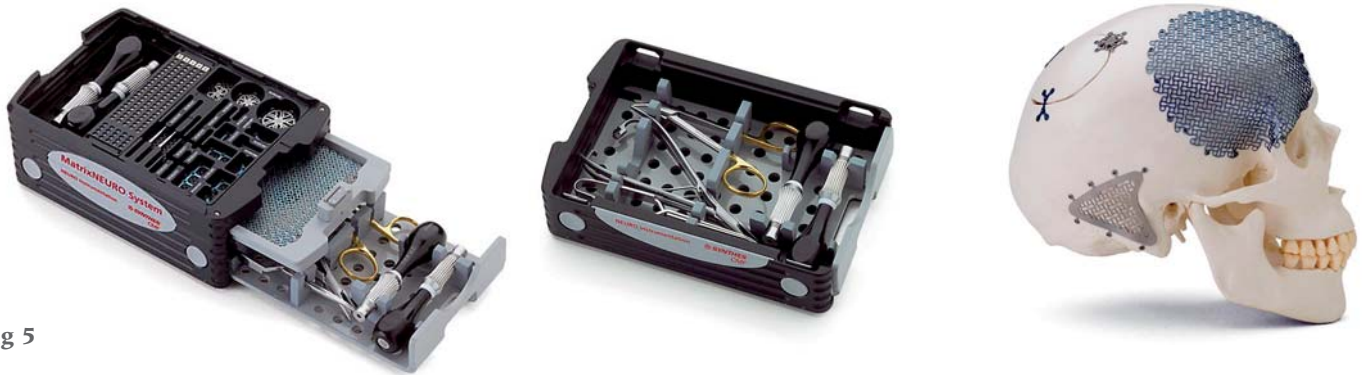


Fig 5



Pictures of anatomy lab.

Jesse Jupiter, Martin Langer

## PRODUCT DEVELOPMENT IN TRAUMA RELEVANT TO CMF



### LCP Volar Column Distal Radius Plate 2.4

The LCP volar column distal radius plate (VCP) 2.4 is indicated for fixation of complex intra- and extraarticular fractures, and especially for highly comminuted fractures, as well as corrective osteotomies of the distal radius.

The implant design is based upon a concept by Rikli and Regazzoni, who identified the structural columns of the distal radius and the need to not only reduce the articular components but also provide support for both the radial and ulnar sides equally.

The LCP VCP is anatomically contoured for the distal radius and has a low profile, which implies less overall implant bulk, minimizing soft-tissue irritation. It provides multiple screw options in the head of the plate (8- and 9-hole head configurations) to better support the articular surface and to address fracture fragments individually. A 3-screw cluster addresses the radial styloid. Four screws support the ulnar column.

The plate shaft is available in 3-, 4-, and 5-hole versions and accepts 2.4/2.7 mm cortex or 2.4 mm locking head screws.

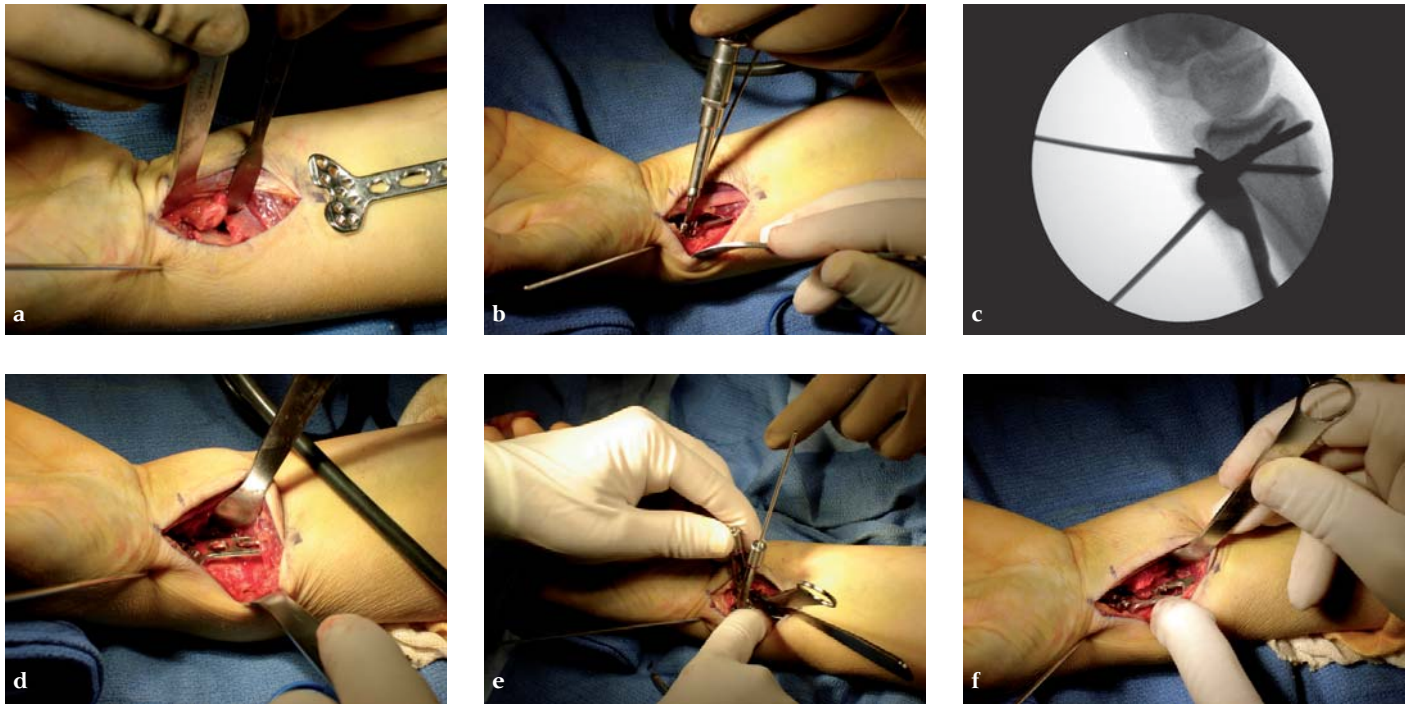
The LCP VCP provides the option to use mini drill guides and standard threaded drill guides to confirm screw trajectory options.

The LCP VCP 2.4 comes in left and right versions. All plates are available in stainless steel and titanium. Overall, the system consists of 40 different plates, making it the most complete set for distal radius fractures available.

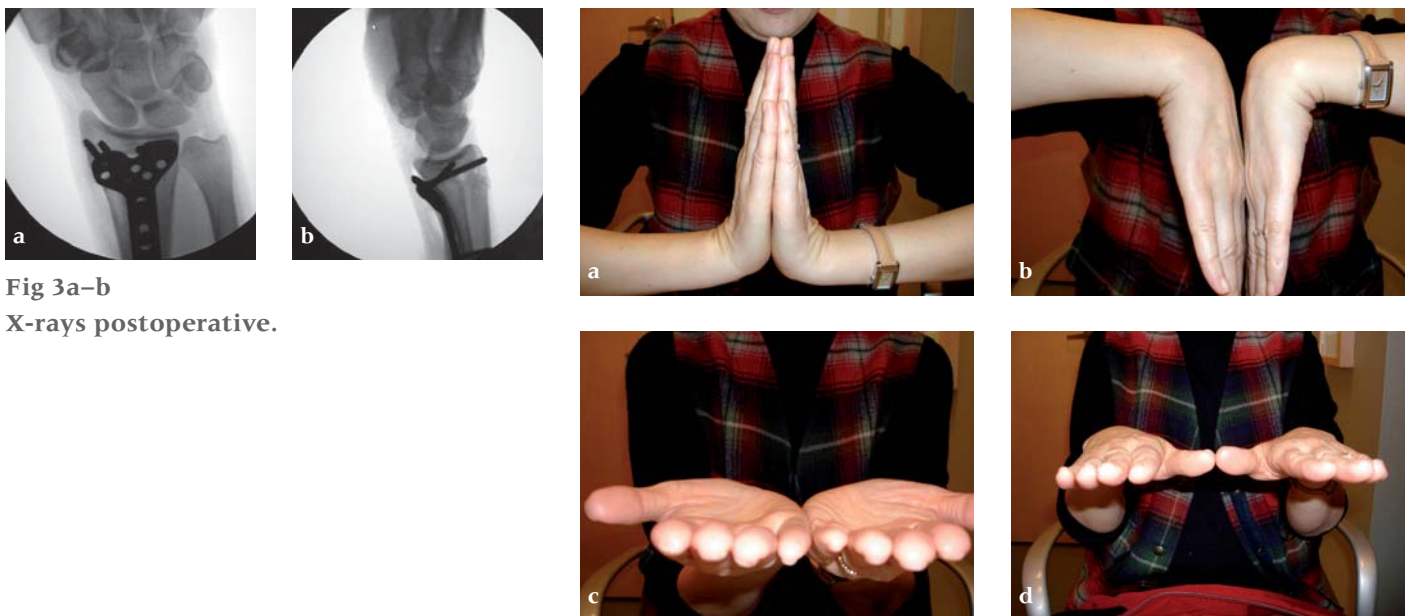
### 28-year-old woman.



Fig 1a–b  
X-rays preoperative.



**Fig 2a-f**  
Step-by-step operative procedure.



**Fig 3a-b**  
X-rays postoperative.

**Fig 4a-d**  
Full motion recovery.

Case provided by Jesse Jupiter, Boston

Sabine Goldhahn

## NEWS FROM AO CLINICAL INVESTIGATION AND DOCUMENTATION (AOCID)

### Final Results from the International Randomized-Controlled Trial on Condylar Neck Fractures

Fractures of the mandibular condyle are common and account for 9–45 % of all mandibular fractures. However, to date it could not be shown which treatment options lead to the best functional results and the lowest number of complications. Therefore, a randomized controlled trial on condylar neck fractures has been conducted by AO Clinical Investigation (AOCID) to investigate the functional outcome and evaluate possible complications.

The primary objective of this study was to show whether there is an improved functional outcome in a patient group with mono- or bilateral condylar neck fractures treated with endoscope-assisted transoral open reduction and fixation (ENDO group) versus a patient group surgically-treated without endoscopic assistance (ORIF group).

#### Patient recruitment

#### Treatment allocation

#### Follow-up visits

8–10 weeks

1 year

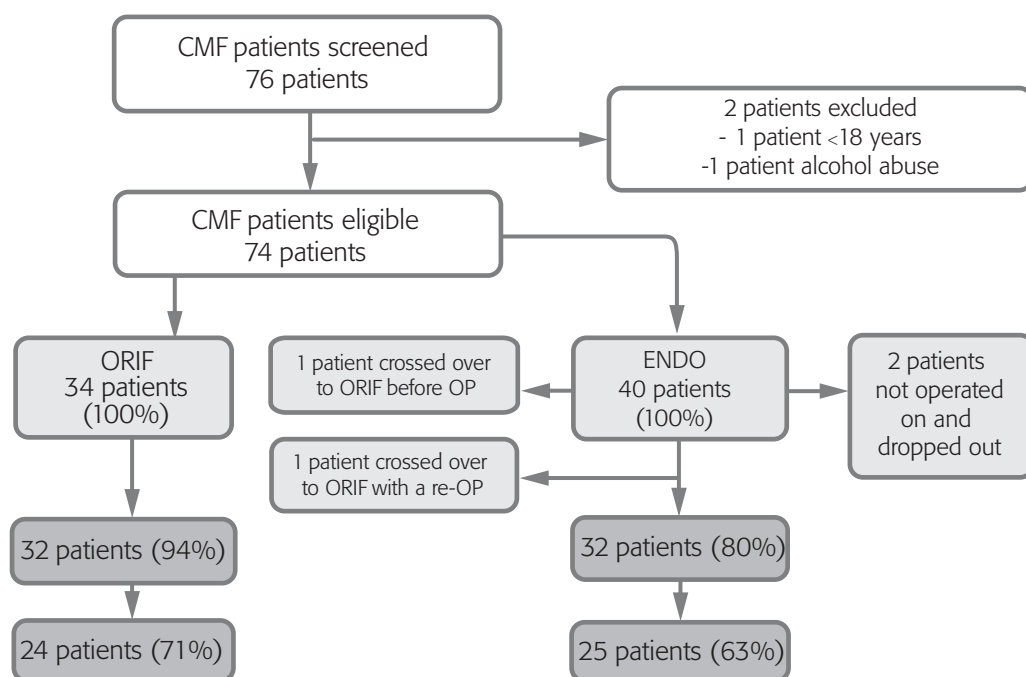
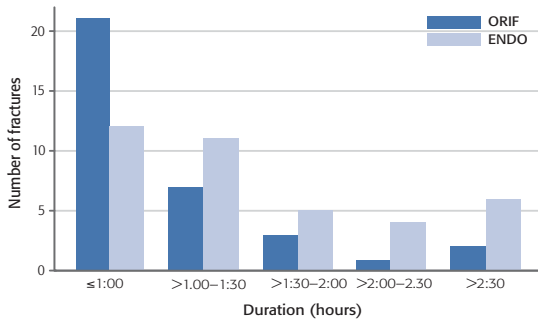


Fig 1

Recruitment and follow-up chart of the study patients.



**Fig 2**  
Duration of operation as categorized by specific time intervals.

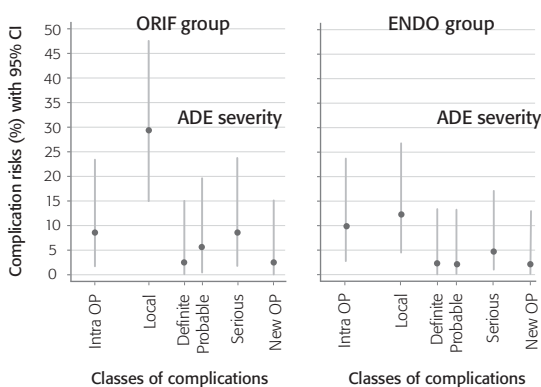
The study was of adult patients with the above mentioned fractures presenting one or more of the following conditions: inclination of the condyle  $> 30^\circ$ , severe dislocation, severe functional disturbances, severe pain upon palpation or movement, and/or vertical shortening of the condyle. Seven hospitals from five countries participated in the trial.

34 patients in the ORIF group with a mean age of 33 years and 40 patients in the ENDO group with a mean age of 32 years were included. At the 8–12 week follow-up (FU) examination, 32 patients were examined in both the ORIF and ENDO group, corresponding to FU rates of 94% and 80%, respectively. At 1 year, the FU-rates were 71% ( $n=24$ ) in the ORIF group and 63% ( $n=25$ ) in the ENDO group.

Patients in the ORIF group were operated median 33 minutes faster than in the ENDO group ( $P=.003$ ). There were no differences between the groups for the asymmetric Helkimo dysfunction score (A-HDS), clinical dysfunction index, anamnestic dysfunction index, and index for occlusion and articulation disturbance, as well as the patient-assessed functional outcome. However, at the 8–12-week FU, patients in the ENDO group had significantly less important alterations of the facial physiognomy than those in the ORIF group ( $P=.001$ ). The investigator-rated cosmetic outcome was significantly worse in the ORIF group at both FUs ( $P<.001$ ). At 8–12 weeks, the patient-evaluated cosmetic outcome was also worse in the ORIF group ( $P=.053$ ).

Overall, patients with bilateral fractures ( $n=12$ ) were more likely to yield worse scores for the A-HDS compared to unilateral fracture patients at the 8–12-week FU examination ( $P=.012$ ). They also had more moderate or severe symptoms than patients with a unilateral fracture at this initial FU ( $P=.002$ ).

For three patients from the ORIF group and five patients from the ENDO group, intraoperative complications were described. Ten patients from the ORIF group and five patients from the ENDO group suffered from at least one postoperative complication, where the overall number of complications reported for the ORIF and ENDO group were eleven and six, respectively. Among other postoperative complications, one case of implant breakage and two superficial infections were described in the ORIF group, and three cases of swelling occurred in the ENDO group.



ADE = adverse device effect  
IntraOP = intraoperative complications  
Local = all local complications  
Definite and Probable = relation to surgical treatment  
Serious = serious adverse events  
New OP = patients underwent a new operation

**Fig 3**  
Complication risks for both treatment groups.

Two cases from each of the ENDO and ORIF groups were regarded as having facial nerve damage immediately after surgery; the palsy in one of the ENDO patients was described as Bell's palsy. At the 8–12 week FU, five additional cases of facial nerve damage were described in the ORIF group, where three of them did not recover at this FU period.

The estimated risk for experiencing at least one intraoperative complication was 8.8% in the ORIF group and 10% in the ENDO group, which was lower compared to the estimated risk for experiencing at least one postoperative complication in either treatment group (ie, 29.4% and 12.5% in the ORIF and ENDO group, respectively); these results were not statistically significant.

To summarize, patients may benefit from better cosmetic results and fewer complications when ORIF is assisted by endoscopy in condylar neck fractures.

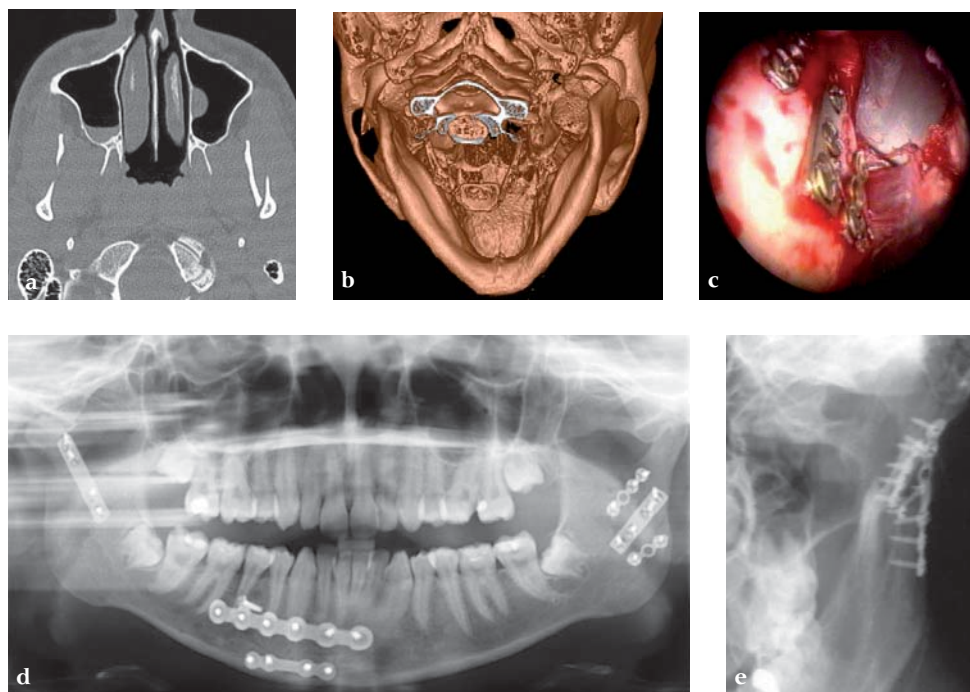


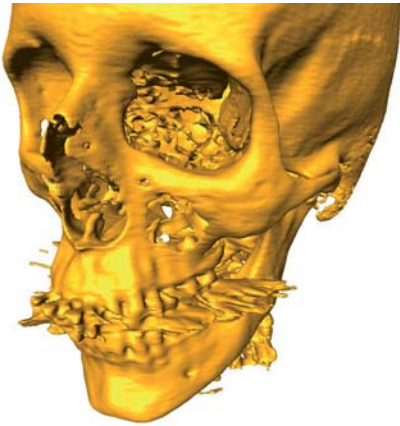
Fig 4a–e Endoscopic fixation of condyle fracture.

Case images courtesy of Rainer Schmelzeisen, Freiburg, DE

Lukas Kamer, Thomas Heldstab, Ricco Soder, Thomas Kaup, Hansrudi Noser

## NEWS FROM THE AO DEVELOPMENT INSTITUTE (ADI)

### Improving Anatomy and Fabrication of Medical Rapid Prototyping Models



**Fig 1** CT imaging drawbacks: 3-D CT reconstruction with partial volume averaging within the orbital region and scatter artefacts and imprecise rendering of dental structures.



**Fig 2** MRP color 3-D printing of CT data using semi-automated threshold (grey) and manual segmentation procedures (orange), matched with Xtreme CT data of the correspondent dental plaster cast (blue).

Medical rapid prototyping (MRP) is an established diagnostic aid in CMF surgery. Supporting the clinician in related image data handling and by providing a solution for less expensive manufacturing would make this technology more widely available in clinical routine procedures.

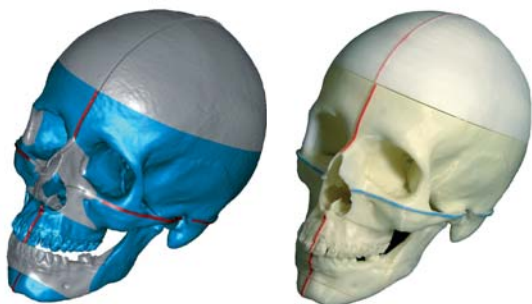
#### Introduction

MRP comprises the production of physical 3-D models based on computed volumetric image data for medical purposes. The production pipeline for MRP usually consists of CT-image data acquisition, segmentation and 3-D visualization and MRP manufacturing. Typical MRP techniques are stereolithography, selective laser sintering, fused deposition modeling and 3-D printing technologies.

In the past, the quality of MRP was compromised by artefact generation occurring in all stages of the production pipeline. Fortunately, image data obtained from the latest generation of rapid CT scanners, image processing, visualization and MRP techniques significantly reduce the risk for undesired artefacts such as stair step or motion artefacts. Nevertheless, within the skull the bony orbit and the dental region there are two critical anatomical areas where automated 3-D rendering is still of unsatisfactory quality. Limited CT scan resolution creates 'holes' in regions with thin bony structures due to partial volume averaging, and renders dental structures imprecise. Unwanted scattering artefacts are created by metallic dental restorations. Subsequently, the quality of MRP modeling is reduced in a similar way (Fig 1). In the following, enhanced medical image computing techniques aiming to improve MRP for CMF surgery are presented.

#### Improving anatomy

The bony orbit can be rendered more accurately by additional but time-consuming manual segmentation procedures (Fig 2). Improved visualization of dental structures is obtained by using very accurate scanning procedures of dental plaster casts (eg, laser- or cone beam based Xtreme CT-scanning).



**Fig 3** Special CAD computing techniques such as Boolean operations for facilitated preoperative planning, eg, for the definition of Frankfort and symmetry plane or osteotomies; 3-D computer model (left) and its MRP model based on fused deposition modeling (right).



**Fig 4** MRP elastic modeling of the nose and left eye.

### Improving preoperative planning and handling

Additional computer-aided design (CAD) techniques may be applied to enhance and/or facilitate preoperative planning. The midline of the face and Frankfort plane may be outlined and osteotomies delineated to form refixable segments, thus sparing time-consuming drilling for separation of the segments (Fig 3). MRP models of soft tissue can be separately segmented and printed using an elastic material (Fig 4).

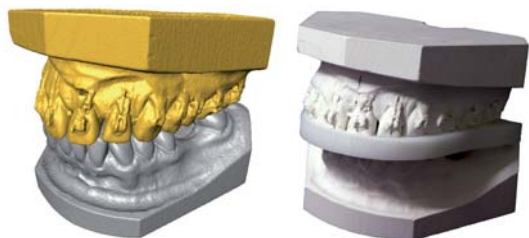
MRP manufacturing of surgical guides may be applied to transfer preoperative computer-aided planning from the computer screen to the intraoperative situation, helpful in ascertaining the correct intraoperative position and used eg, in orthognathic surgery (Fig 5). For the production of accurate dental guides it is important to avoid standard CT-image patient data due to limited image resolution and metal artefact generation.

### Identifying the remaining key problem

MRP offers a wide range of applications and has proved to be very useful in CMF surgery and other medical specialties. With the advent of the latest generation of CT scanning technology, image processing and RP techniques, most of the disadvantages associated with MRP modeling may be excluded.

However, the ADI has identified high production costs as the remaining key problem for clinical applications. Such MRP models are prototypes, generating a small turnover compared to industrial applications, and since (ii) RP machines, specialized software, equipment, processes and software are costly and not normally at the disposal of clinicians or industrial suppliers. These additional expenses are frequently not covered by the health insurance.

As a result the ADI has formed a taskforce in order to address this problem and to discuss with surgeons with the intention of offering an affordable MRP service, tailored to the needs of CMF surgeons.

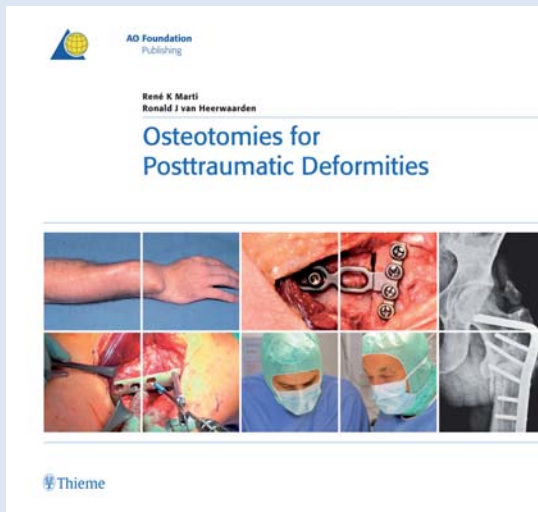


**Fig 5** Xtreme CT scanning of dental plaster casts produces very accurate 3-D computer models (left). Corresponding plaster cast and MRP surgical guide produced by CAD processing (right).

For interested clinicians and for more information please contact  
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Cristina Lusti

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## Osteotomies for Posttraumatic Deformities

René K Marti, Ronald J van Heerwaarden

An international group of renowned surgeons present an outstanding hands-on approach to perform correction osteotomies in posttraumatic deformities from the clavicle to the foot.

Most of the content is based on case presentations and each case provides step-by-step descriptions of case history, planning, surgical approach, osteotomy, fixation, rehabilitation, and finally pitfalls and pearls. Hundreds of full-color pictures, precise illustrations, and x-rays demonstrate the significant steps in deformity corrections. Long-term follow-ups demonstrate the efficacy of osteotomies in the treatment of malunions.

In the principles preceding the case presentations relevant theoretical information on posttraumatic deformities and osteotomies, indications, operative techniques, and fixation methods, as well as the formation of a surgical plan is provided.

This book should convince creative orthopedic and trauma surgeons to consider joint-preserving techniques in the treatment of posttraumatic deformities and arthritis.

Edward Ellis III

## PORTRAIT OF RISTO KONTIO



Risto Kyosti Kontio is a specialist maxillofacial surgeon in the department of oral and maxillofacial surgery at the Helsinki University Hospital, Finland. He joined the AOTK (CMF) as a medical member last year.

Risto grew up in the rural environment of Joutsa. This municipality of his motherland Finland is located in the province of Western Finland and at that time had a population of around 4000. However, it covers an area of 656.45 km<sup>2</sup> of which 165.12 km<sup>2</sup> is water.

To enter the world of medical care, Risto moved to the capital and became a registered dental practitioner at the University of Helsinki in 1979. He was trained in the departments of maxillofacial surgery, orthopedics, and ENT surgery to become a medical doctor in 1993 and later a specialist maxillofacial surgeon in 1998.

Having achieved his education, he decided to move on and gained practical experience at City Hospital, Porvoo, Finland and at the Peradenya University Hospital, Sri Lanka. However, he soon returned to Helsinki, where he still resides and works with his highly respected Professor of maxillofacial surgery, Christian Lindqvist, at the University of Helsinki. Under his guidance Risto conducted large studies on the reconstruction of orbital wall fractures both experimentally and clinically and published the results as his academic dissertation in 2006.

Risto has always enjoyed the teaching aspects of his work and consequently became a member of the AO Faculty in 1998 at the CMF Principles Course in Davos. Since then he has lectured at various AO educational activities and proudly directed an AO Principles Course in Porvoo, Finland in 2006.

Risto is happily married with Ulla and the couple is blessed with four children, Ilari, Riikka, Sirke and Karri. As a true Scandinavian many of his recreational activities involve winter sports, of which he especially likes skiing. In their rare spare time, the family members escape to their little shack in the rural outskirts. However, they also enjoy metropolitan experiences and thus the whole family has been seen at a punk rock show in New York City lately.



Helsinki University Hospital, department of oral and maxillofacial surgery

Edward Ellis III

## CERTIFICATE OF MERIT

In Madrid, Beat Hammer from Aarau, Switzerland, was awarded with the AO Certificate of Merit. This prize is periodically awarded by the AOTKs to surgeons who significantly support the work of the Expert Groups. This time the AOTK (CMF) honored Prof Hammer's major efforts in improving canthal fixation with titanium wire. The awarding ceremony took place on the occasion of an AO Course in Madrid, Spain.



**From left to right: Beat Hammer with MDEG member Carl-Peter Cornelius, Course Chairman Gregorio Sanchez-Aniceto, CMFEG member Scott P Bartlett.**

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