

TK System

Innovations

2 | 2010

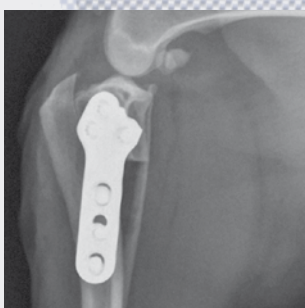
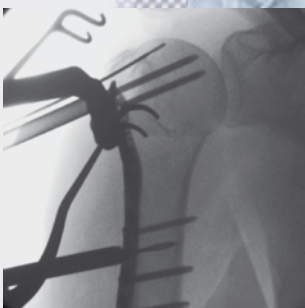
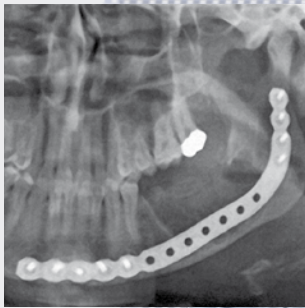
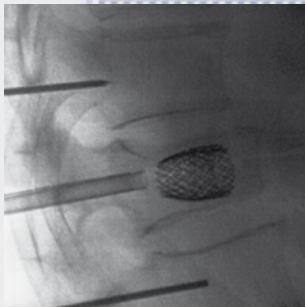


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PHOTOS ON PAGES 54–57 WERE TAKEN BY GERI KRISCHKER, ZÜRICH, SWITZERLAND

Dear reader,

We all appreciate the need for constant improvement, but then this often turns out to be a lot more complex and challenging than initially expected. The AO Foundation is currently experiencing this with the implementation of major strategic initiatives: empowerment of the specialties and regions. Compared to the scale of these processes, the changes in the TK System seem to be of a rather minor degree: besides maintaining our highly specialized Expert Groups we are also moving towards transspecialty task forces as in biomaterials, thorax, power tools, and certain technologies which are relevant for more than one specialty. All new ideas are screened for potential application in other clinical areas as the original idea was intended for. At the same time we have started to put more effort in the exact definition of the clinical problems which makes our innovation process more open to unpredicted solutions. It is impressive to see the first results.

As the TK specialties for Spine and CMF in 2010 have successfully managed to modify their structure in response to changed internal and external requirements, the TK System continues to strive for effective and streamlined approaches to innovation and development in all areas.

We are also facing new challenges caused by difficult, long, and resource-intensive regulatory approval processes. Creating another plate size, eg, a small stature version of an existing plate, can become almost as complex as developing a completely new plate. And the ever increasing regulations for clinical trials make it harder, longer, and more expensive to provide clinical evidence on new treatment options. To encourage you to help us in our quest for increased evidence in our development efforts, this issue features an article from AO Clinical Investigation and Documentation on how to perform a clinical study.

In the lead article of this issue, Roger Härtl will give you a comprehensive overview of navigation in spine surgery and its clinical benefits. The vertebral body stenting system enables augmentation of collapsed or unstable vertebral bodies in a minimally invasive, percutaneous approach, restoring height, and conserving the affected vertebral body. The low-pressure injection of high-viscosity bone cement prevents leakage. The stent allows good interdigitation with the surrounding cancellous bone structures.

Other devices we like to highlight are the Epoca glenoid components, and the 2.7/3.5 mm LCP posterolateral distal fibula. For craniomaxillofacial surgery the matrix mandible system concludes the trilogy of the matrix family of already existing solutions for midface- and neurosurgery. The veterinary LCP notched head T-plate again indicates the need for exchange between all specialties.

The column, Portrait, features Stefaan Nijs, from Belgium, who has contributed heavily to the development of several new treatment options in better anchorage of the blade plate and for the humeral nail. We like to encourage you to follow his example and to share your talents with us. You may approach the AO Foundation any time if you have an idea for the improvement of patient treatment as Stefaan Nijs did.

Once again, we would like to stress that none of the articles in this publication is a substitute for the AO's surgical techniques or the AO teaching tools. You can obtain more detailed information on these devices from the AO or the official technical guidelines and documentation.

If you have any comments or questions on the articles or the new devices, please do not hesitate to contact any one of us.

Yours faithfully,



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COMPUTER-ASSISTED SURGERY FOR SPINAL INSTRUMENTATION



Fig 1 a–b
2-D information, obtained by two infrared cameras tracking reflective beads, is converted into a 3-D representation based on the different reflective angles.

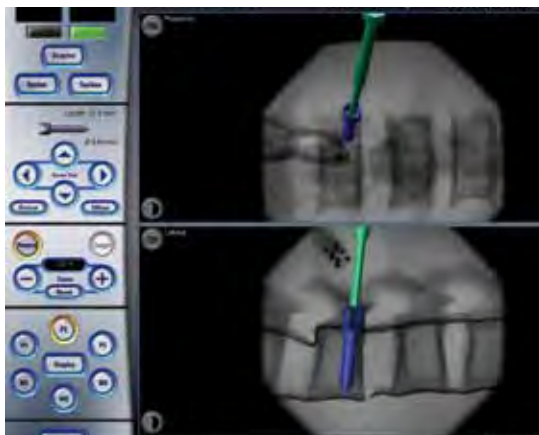


Fig 2
2-D navigation uses image-intensification-based AP and lateral images to track an instrument's position in relation to spinal anatomy.

Introduction

Spinal surgery inherently carries the potential of injury to spinal cord, nerves, and important vascular structures. There is general agreement among surgeons that imaging techniques are essential for safe and accurate placement of spinal instrumentation regardless of the complexity of spinal surgery, the anatomical region, and the level of training and comfort-level of the individual surgeon. Traditionally this has involved the use of x-ray or image intensification guidance either as a control at the end of a procedure or for active guidance throughout surgery.

Recently, stereotactic 2-D or 3-D imaging techniques have been developed and have gained acceptance in disciplines, such as cranial neurosurgery and certain orthopaedic procedures. Computer-assisted surgery (CAS) uses navigation systems to improve visibility to the surgical field and increase the accuracy of surgery and instrumentation placement by virtually linking the operated bony anatomy with pre- or intraoperative imaging studies, usually CT scans. The use of CAS has first been described for spinal instrumentation placement in the mid-1990s [1–4] and the different types of CAS have been reviewed in a recent AO publication [5]. However, CAS could potentially improve the way spinal surgery is performed. The purpose of this article is to review the basic concepts and current application of CAS within spinal surgery.

Types of computer-assisted surgery

The most basic imaging for spinal surgery consists of static AP and lateral x-rays or image intensification during surgery. In CAS a virtual representation of the surgeon's instruments are shown in relation to the patient's anatomy that is displayed on a separate computer screen. CT scans or image intensifier images are used to generate the virtual surgical reality. This surgical "GPS" requires the attachment of a reference array with reflective beads to the patient's spinal anatomy and to the surgical instrument to be tracked. The 2-D information obtained by two infrared cameras tracking these beads is converted into a 3-D representation based on the different reflective angles (Fig 1). Tracking using electromagnetic instead of infrared technology is currently being evaluated and has shown promising results [6, 7].

- 2-D navigation (2-D-nav) uses image-intensification-based AP and lateral images to track an instrument's position in relation to the spinal anatomy. It is easier to set up but provides only 2-D information (Fig 2).
- 3-D navigation (3-D-nav) uses preoperative or intraoperative CT-like scans.
 - Preoperative CT scans require matching the patient's bony anatomy with the scan which typically requires surgical exposure of

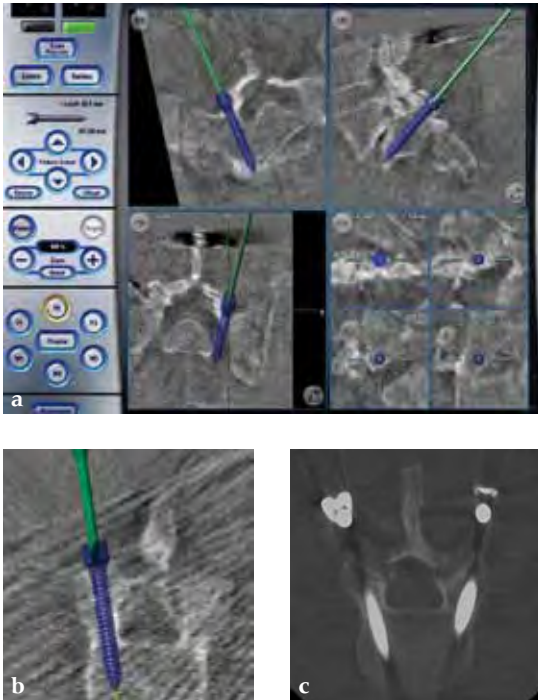


Fig 3a–c

a Intraoperative CT scans from an image-intensification-based isocentric C-arm. The software allows simulation of various diameter and length screws. **b–c** Comparison of intraoperative simulation and postoperative CT scan shows the high accuracy of CAS.

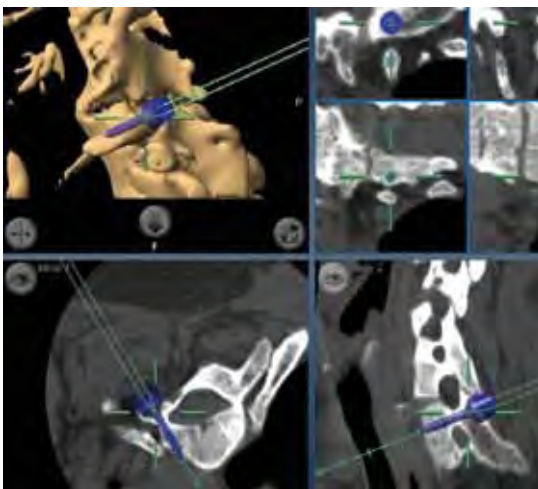


Fig 4

In this cervical deformity case extensive ossification was present and regular landmarks not available. Navigation allowed precise placement of cervical pedicle screws.

certain landmarks. Alternatively, intraoperative AP and lateral image intensification can be used to match the preoperative CT scan with the actual patient's anatomy in the operating room.

- Intraoperative CT scans can be obtained using image-intensification-based isocentric C-arms, portable cone beam CT (“O-arm”, Medtronic) or true intraoperative CT scanners (iCT). Isocentric C-arms and portable scanners offer the advantage that they can also be used as regular C-arms, however their imaging quality may be inferior to stationary CT scans (Fig 3).

Potential advantages and disadvantages of CAS

Supporters of CAS state that stereotactic navigation has the potential to:

- Improve accuracy of instrumentation placement and optimize the size of instrumentation used
- Reduce radiation exposure to surgeon and staff
- Enable less-invasive approaches through smaller access
- Allow preoperative planning of instrumentation size and trajectories and osteotomy procedures
- Allow verification of screw accuracy intraoperatively (intraoperative scanners only)
- Minimize the risks of wrong-level surgery
- Decrease reoperation rate

Potential disadvantages of CAS include:

- The learning curve associated with the technologies for the surgeon and the OR staff could be significant
- Upfront costs of the capital equipment
- Interruption of surgical “flow”
- Additional equipment and footprint in the OR
- Limited imaging quality and field of view with mobile 3-D imaging devices currently on the market.
- Potential increase in OR time
- Potential line-of-sight limitations for optical systems
- Concerns about accuracy and interference with metallic instruments using electromagnetic navigation systems

Application within spinal surgery

Within spinal surgery CAS is typically used for placement of instrumentation. A recent survey among AOSpine surgeons (see page 6) (Härtl, et al, unpublished 2010) showed that CAS is particularly helpful in three areas: complex spinal surgery, such as deformity and revision surgery; minimally invasive spinal surgery (MIS); and surgery in challenging anatomy, such as thoracic and cervical instrumentation.

Deformity and revision surgery

Placement of instrumentation in anatomy that has been distorted due to significant deformity or due to previous surgery and subsequent scarring and ossification can be difficult and is associated with an increased rate of misplacement. In these cases CAS allows precise placement of instrumentation even in the absence of regular anatomical landmarks (Fig 4).

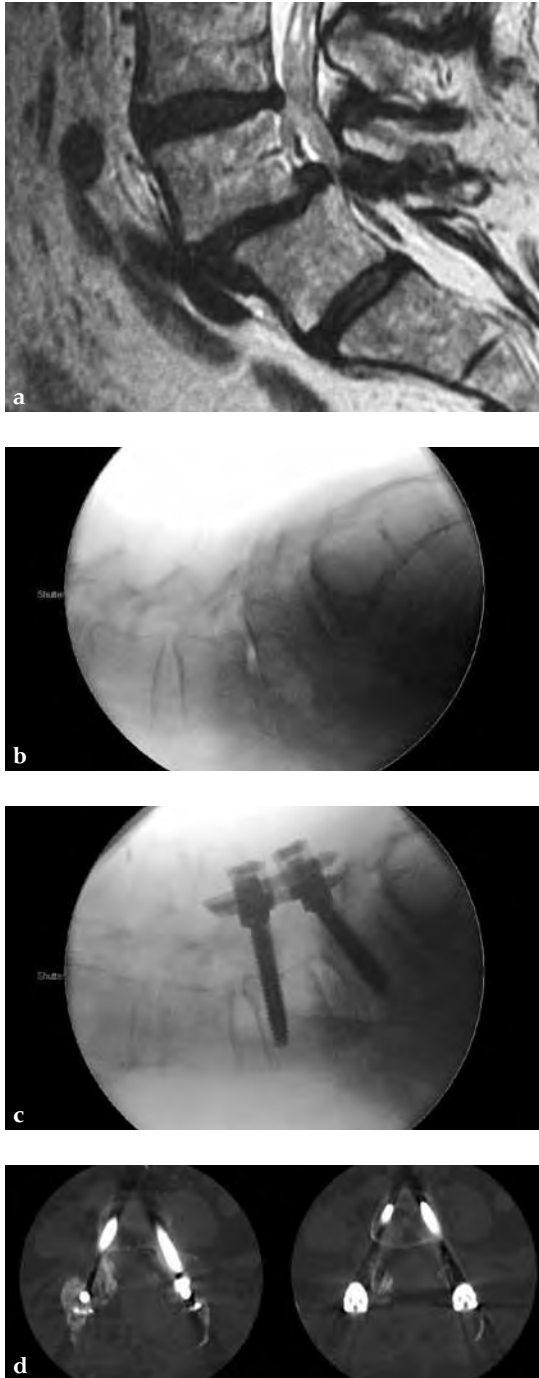


Fig 5a–d

a Preoperative MRI scan: significant spondylolisthesis in a symptomatic patient.

b Intraoperative x-ray of same patient: progression to grade II spondylolisthesis in prone position on OR table.

c Minimally invasive surgery allowed decompression, discectomy, instrumenta-

tion, and reduction in this patient through two small skin incisions with minimal blood loss.

Minimally invasive spinal surgery (MIS)

The goal of MIS is to achieve outcomes that are comparable or superior to conventional surgery but with less postoperative pain, quicker recovery, reduced blood loss, less soft-tissue damage, smaller surgical incisions and less scarring. The concept of MIS evolved out of the advancements achieved in four different surgical fields over the past years:

- Microsurgery using the microscope or endoscope
- New spinal access strategies via percutaneous or miniopen procedures
- Neuronavigation using 2- or 3-D imaging technology
- New instrumentation

Two recent clinical studies demonstrated improved screw accuracy with isocentric image-intensification-based CT navigation compared to conventional image intensification in > 300 patients undergoing minimally invasive lumbar fusion [9, 10]. Stereotactic navigation is especially useful in patients with more complex anatomy, such as significant spondylolisthesis or degenerative scoliosis. For example, the combination of microsurgery, tubular access approach, CAS and modern instrumentation technology allow decompression and reduction of lumbar spondylolisthesis and stenosis with minimal blood loss and injury to the surrounding musculature (Fig 5). Navigation can also be used to determine the best trajectory for intervertebral cage placement and for transsacral fixation [11]. In the lumbar spine it can be used to determine the length of rods and to align screws during a multilevel fusion so that the percutaneous rod placement is facilitated (Fig 6). Stereotactic navigation has also enabled the minimally invasive resection of odontoid masses via a transnasal route, which is a significant improvement when compared to conventional maximally invasive transoral surgery [12, 13] (Fig 7).

d Postoperative CT scan: accurate positioning of instrumentation. 3-D-nav allowed for optimization of screw length and diameter given the patient's anatomy.

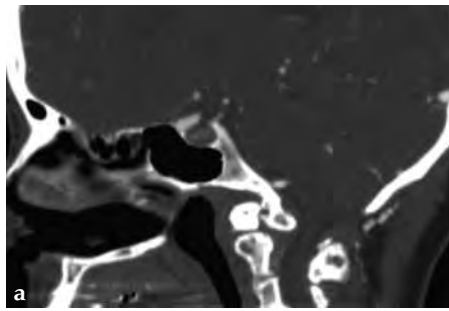
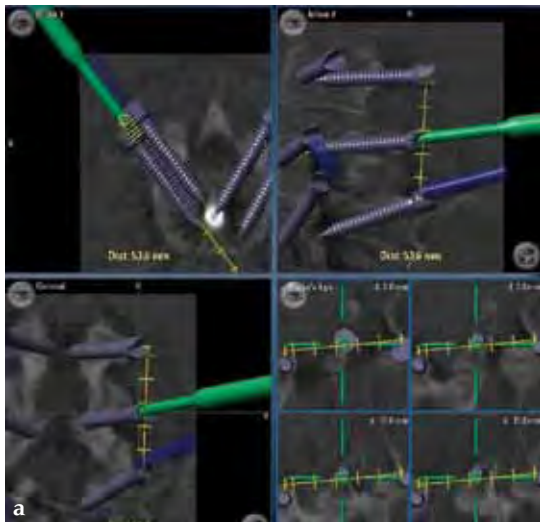


Fig 6a–b

a Intraoperative screenshot of multilevel lumbar instrumentation. By simulating multiple screws a screw angle and trajectory can be chosen that will facilitate smooth insertion of rods. Distance between screws and rod length can also be determined.

b Postoperative lateral x-ray in same patient. This case combined a lateral translumbar approach for interbody fusion L2–L4, a transsacral discectomy, instrumentation, and fusion for L4–S1 and percutaneous pedicle screw instrumentation from L2–S1 using 3-D-nav.

Fig 7a–c

a Preoperative CT scan: os odontoideum with compression of cervicomedullary junction in a symptomatic patient.

b Intraoperative view of navigated endoscope entering nose. Reference array for navigation has been attached to skull clamp.

c Postoperative CT scan: complete resection of the mass. Patient also underwent occipitocervical instrumentation and fusion.



Fig 8
T4 pedicle screw placement using 3-D-nav.

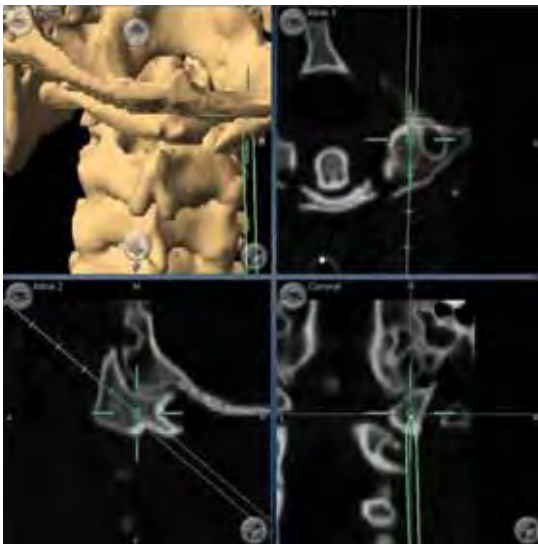


Fig 9
Unstable C1 fracture. Placement of lateral mass screw on the right using 3-D-nav.

Special anatomy: cervical and thoracic instrumentation

Instrumentation of the cervical and thoracic spine can entail special challenges, even with open surgery and relatively “straightforward” anatomy. Screw placement with CAS can facilitate the placement of pedicle screws with very high precision (Figs 4, 8). A recent publication has demonstrated that for thoracic pedicle screws the use of CAS resulted in reduction in operative time and improvement in screw accuracy [14]. In the cervical spine placement of pedicle screws in patients has been accomplished with higher accuracy using 3-D-nav when compared to conventional techniques [15]. In the high cervical spine it can be used for accurate instrumentation of the occiput, C1 and C2 (Fig 9) [16].

AO survey on use of navigation in spine surgery

Despite reports suggesting that CAS can improve accuracy of screw placement and decrease radiation exposure [1, 2, 14, 17–21], it has not been generally accepted among spine surgeons. The reasons for this are complex and may involve factors related to availability, training, individual experience and preference, economical factors, and many more.

A better understanding of these reasons would be essential in order to determine the current deficits of navigation and how these can be addressed. Therefore, the previous Access and Navigation Expert Group decided to perform an internet-based survey among AOSpine surgeons in order to better understand current attitudes towards spinal navigation (Härtl, et al, unpublished 2010).

678 out of 3,348 contacted spine surgeons (20%) responded to a 12-item questionnaire that assessed the experiences with CAS and their current attitudes towards its use in spine surgery (Fig 10). The results showed that while 35% of overall surgeons actually had CAS available at their institution only few used CAS routinely. Despite an even more widespread distribution of navigation systems in North America and Europe only 11% used it routinely. Surgeons performing a high volume of spinal fusions are more likely to use CAS than surgeons performing a lower volume of spinal fusions, indicating that high-volume users may have integrated CAS more effectively into their workflow. This goes against previous thoughts that navigation may be used by surgeons who are not that familiar with instrumentation and would rely on CAS to facilitate procedures in the OR. Routine users considered its accuracy, the potential of facilitating complex surgery, and the reduction in radiation exposure as the main advantages of CAS. Routine users identified the increase in OR time associated with CAS as the main reason why they did not use CAS more frequently. The lack of equipment, inadequate training, and high costs were quoted by the majority of the “non-users” as the main reasons for not using CAS. The survey also showed that 42% of surgeons felt positively about CAS and that 37% had strong and very strong positive beliefs about the benefits of navigation. Overall, neurological surgeons and surgeons with a busy MIS practice were more likely to use CAS. In summary, the survey demonstrated that the majority of responding surgeons had positive beliefs about navigation.

However, the high costs associated with CAS systems, lack of access to navigation systems, the increase in OR time, and the lack of hard scientific data supporting its clinical benefits, appear to be the main reasons why surgeons do not use CAS or do not use it more frequently.

Conclusion

The integration of CAS into spinal surgery holds great promise and (class III) clinical evidence supports its benefits especially in complex surgery, minimally invasive procedures, and for instrumentation of challenging anatomy, such as in the thoracic and cervical spine. Better designed studies and trials are needed to confirm these benefits. Overall, surgeons have positive opinions about CAS but the current technology needs to be improved in order to make CAS more user friendly and time efficient. In order to reach more surgeons the technology has to be affordable and better training opportunities must be offered. The future of CAS will include more widespread access to better imaging technologies, such as intraoperative CT scanning and the combination of CAS with different imaging modalities and possibly intraoperative functional monitoring, such as electrophysiology [22].

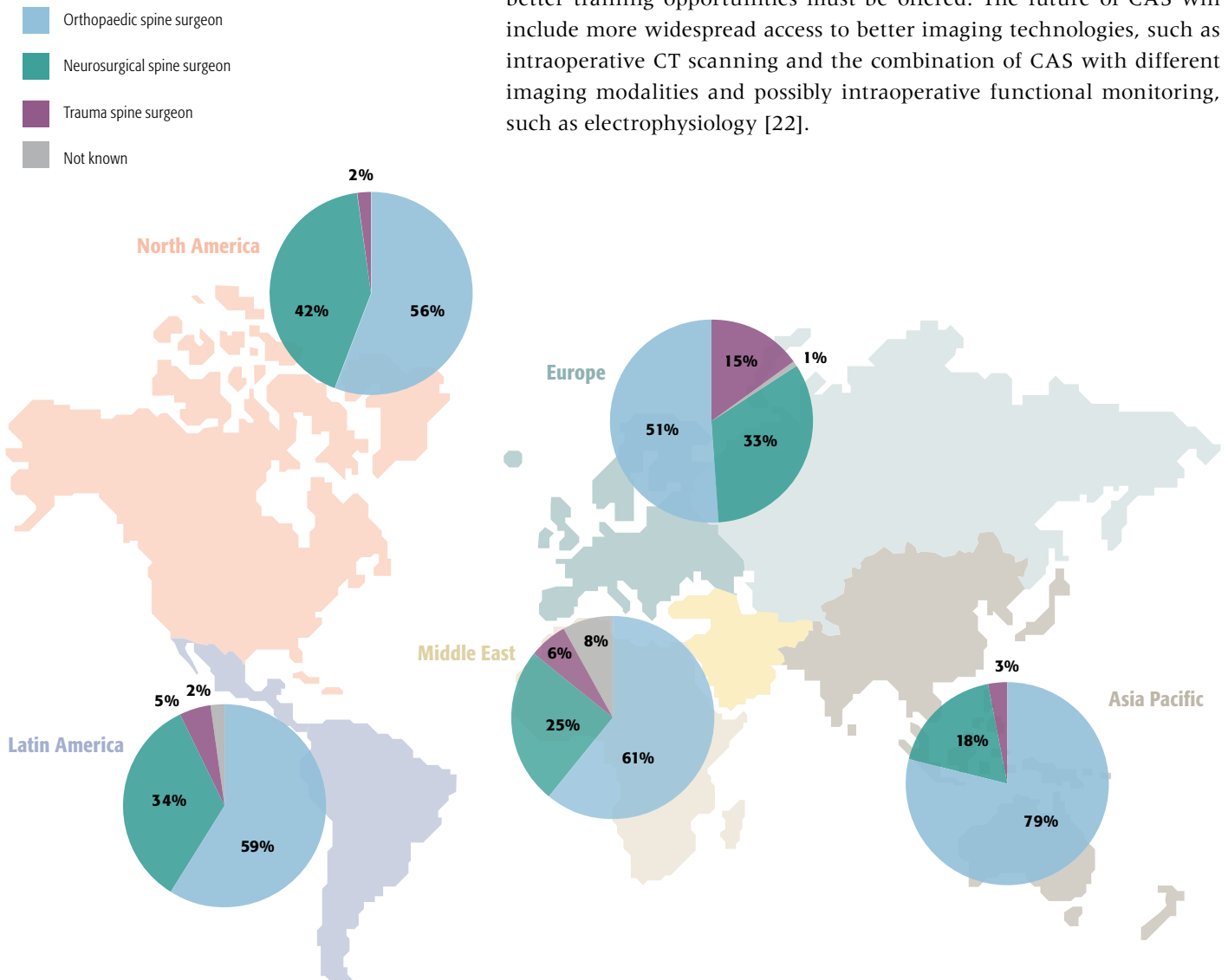


Fig 10
AO survey on use of navigation in spine surgery: distribution of subspecialty by continent.

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SPINE



Fig 1
The 4.0 mm titanium alloy rod is 50% stronger and 70% stiffer than existing 3.5 mm titanium alloy rods.



Fig 2
Polyaxial screws have 100° of angulation in all directions.

Synapse 4.0

Posterior cervical fusion (PCF) surgery is often needed when patients require treatment of some typical spinal conditions, including degenerative disc disease, spondylosis, spinal stenosis, fracture, and tumor. Additionally, it can be an essential surgical option for revisions of pseudarthrosis or failed previous surgery.

The goals of posterior cervical spine fusion surgery are to:

- Treat nerve and/or spinal cord impingement through decompression
- Achieve stabilization of spinal segments after fracture or trauma
- Correct deformity and maintain alignment

The implants and instruments available for surgery have continued to improve over time. Early techniques for posterior stabilization included use of wire or cable around affected bony structures, such as the lamina and/or spinous process. Posterior plate and screw constructs offered some additional stability and reduced potential complications, such as loosening of wiring, although screw placement and plate alignment remained difficult in many patients. The further development of multi-angle screw and rod constructs offered surgeons the advantages of stable fixation and added flexibility for optimal placement.

Comprehensive instrumentation for occipital cervical thoracic surgery

The synapse system is an enhanced set of instruments and implants, including clamps, variable-axis screws, hooks, transconnectors, transverse bars and rods, designed for posterior stabilization of the upper spine. The implants provide the flexibility required to accommodate variations in patient anatomy.

Key to achieving this flexibility is the polyaxial screw implant. With angulation in all directions, the implant accommodates the most demanding surgical constructs, without the need for favored-angled or biased screws. The locking cap utilizes a square-thread design to eliminate cross-threading during final tightening.

Synapse is available in two rod diameter sizes of 3.5 and 4.0 mm, and the new synapse 4.0 system allows for interchangeable use between both 3.5 and 4.0 mm diameter rods. This allows the surgeon to decide intraoperatively on the rod stiffness and strength, depending on the anatomy of the patient and the indication.



Fig 3
The top-loading transconnector adds torsional rigidity to the construct.

The 4.0 mm titanium alloy rod [Ti 6Al 7Nb] is 50% stronger and 70% stiffer than the existing 3.5 mm titanium alloy rods. It is ideal for surgical indications, such as:

- Crossing the occipitocervical [OC] and/or cervicothoracic [CT] junctions
- Severe trauma cases resulting in gross spinal instability
- Tumor situations where significant bone resection has destabilized the spine segments

The system includes a top-loading transconnector which attaches to the polyaxial screws to provide additional construct torsional rigidity when required.

One of the best instrumentation features of the system is the simple and efficient threaded screwdriver which eliminates screw toggle during insertion and mechanically disengages the screw to eliminate sticking of the driver in the screw recess.

The synapse system is fully compatible with the OC fusion systems to provide comprehensive instrumentation throughout the occipital cervical thoracic [OCT] region.

A 28-year-old, 109 kg man was involved in a high-speed motor vehicle collision with C7–T1 jumped facet and T1 teardrop fracture. The patient had ASIA E with motor score of 100. He had failed closed reduction in the emergency room then was taken to OR emergently for open reduction and C5–T2 posterior segmental instrumentation with synapse 4.0. The patient did well postoperatively with no evidence of collapse or failure.

Synapse 4.0 was the ideal solution to treat this injury. This was a heavy patient with a highly unstable injury at the cervicothoracic junction. Synapse 4.0 enabled stabilization of his injury with a rigid construct. It has all the benefits of the 3.5 system but is more rigid and allowed use of one system as opposed to using the 3.5 system and a 6.0 rod system with the nuances of a tapered rod. The author was able to place C5 and C6 lateral mass screws utilizing the Magerl technique and C7, T1, and T2 pedicle screws.

Case provided by Rick Bransford, Seattle, USA

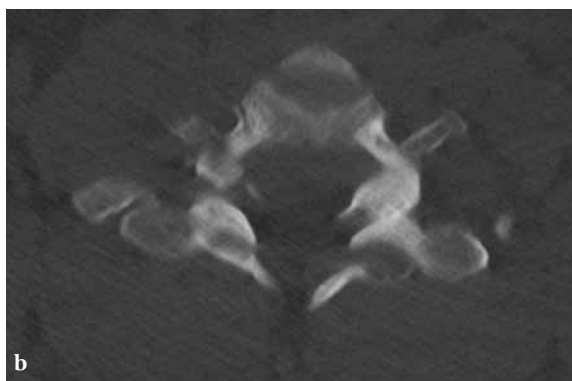
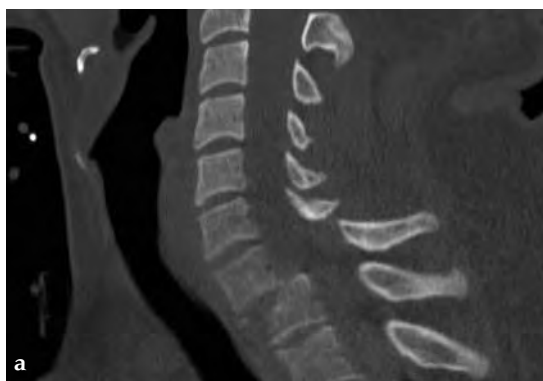


Fig 1a–b
Preoperative images.

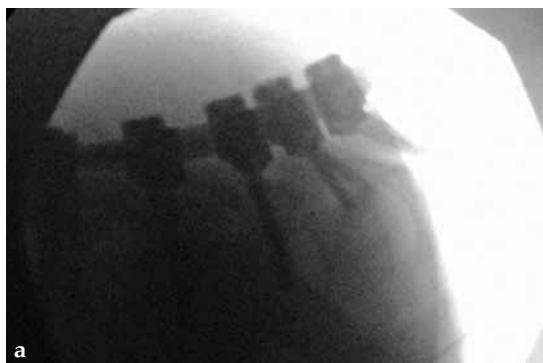


Fig 2a–b
Intraoperative images.

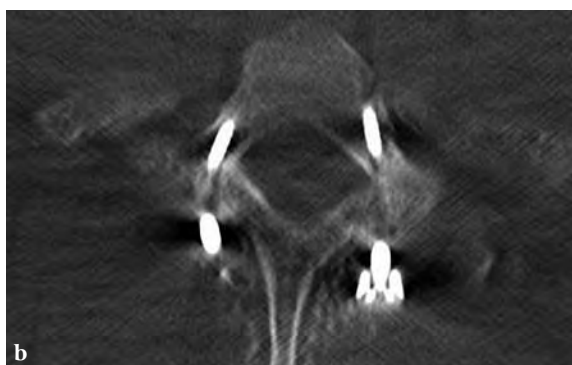


Fig 3a–b
Postoperative CT scans.

Fig 4
Postoperative x-ray.

In the US screws are only indicated from T1–T3.



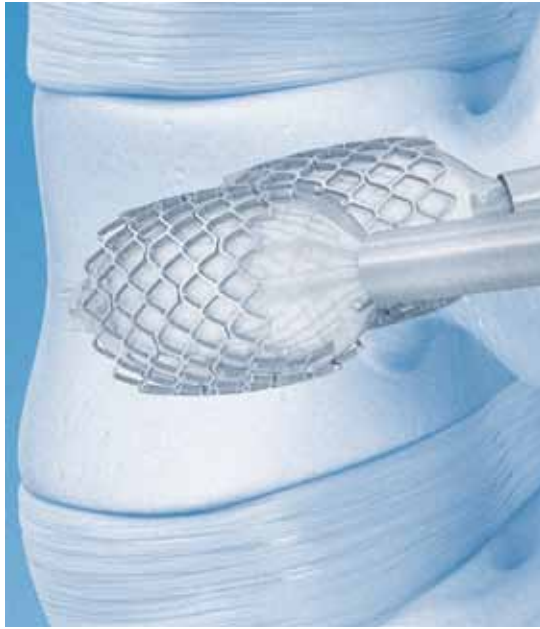


Fig 1
VBS system.



Fig 2
VBS: small, medium, large.

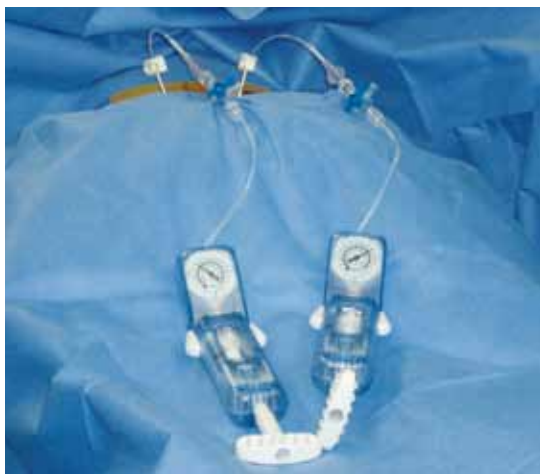


Fig 3
Expansion of the stent by hydraulic volume/pressure control.

Vertebral Body Stent (VBS)

The vertebral body stent (VBS) system is an efficient method to treat painful, traumatic, and osteoporotic compression fractures, as well as osteolytic lesions. It addresses the procedural drawbacks of common and established treatment options like vertebro- and kyphoplasty which can result in either incomplete fracture reposition or in intraoperative loss of the restored vertebral body height [1].

The VBS is an expandable metal scaffolding (ie, a stent) which can be inflated from inside a vertebral body. Stent technology has been known for two decades to treat vascular diseases [2]. In 2002 Sebastian F rderer first published the idea of implanting two balloon-expandable stents into fractured vertebral bodies [3], which has also been biomechanically assessed in comparison to simple balloon kyphoplasty [4]. The technology has been available since 2008 and has been applied in more than 4,000 levels.

VBS advantages

The surgical technique of VBS involves a unique percutaneous minimally invasive procedure where the vertebral body can be accessed posteriorly. The stents are implanted laterally on both sides of the spine. After positioning, the stents can be balloon-expanded inside the collapsed vertebral body restoring its original height and the natural curvature of the spine. The stents will remain in the created cavity and prevent the recollapse of the fractured vertebra after the balloons are deflated and removed. The remaining cavities can then be safely filled using a PMMA-based bone cement, resulting in pain relief as well as quick and easy patient mobilization [5, 6].

Instruments and stents

The new VBS small/medium/large (S/M/L) features a complete set of different stent sizes. With the available stent lengths of 13, 15, and 20 mm, it is possible to treat levels from T5 to L5 in a comprehensive range of patients' anatomies.

All instruments are sterile packed, single use, and allow para- and transpedicular access either using a guide (K-) wire or a trocar. The set includes a drill and plunger for clear intraoperative determination of the stent size. The cement injection cannula is designed with a special side opening for safe direction of the cement within the cavity.

One solution

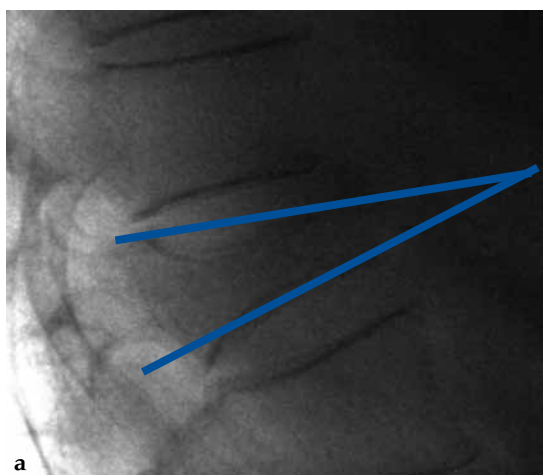
VBS S/M/L can be used with vertecem V+ which is a PMMA-based bone cement ready to use right after mixing for up to 27 minutes. This allows maximum flexibility during surgery and an optimum use of OR time.

References

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A 78-year-old man with back pain after a simple fall. An MRI showed a subacute fracture with a collapsed vertebral body of L1. A VBS was used for height restoration. The patient was pain-free immediately after the intervention.

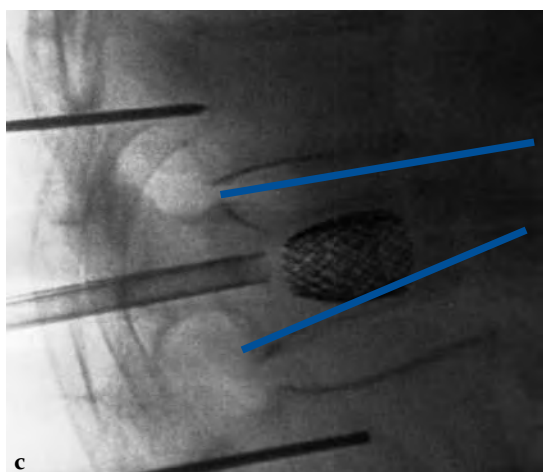
Case provided by Paul Heini, Bern, Switzerland



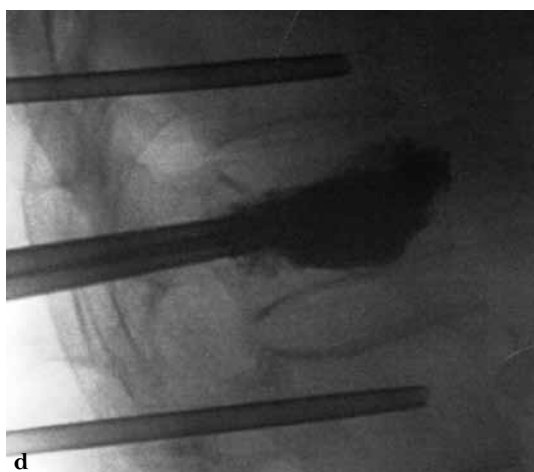
a
Vertebral body when the patient is in prone position.



b
After stent placement.

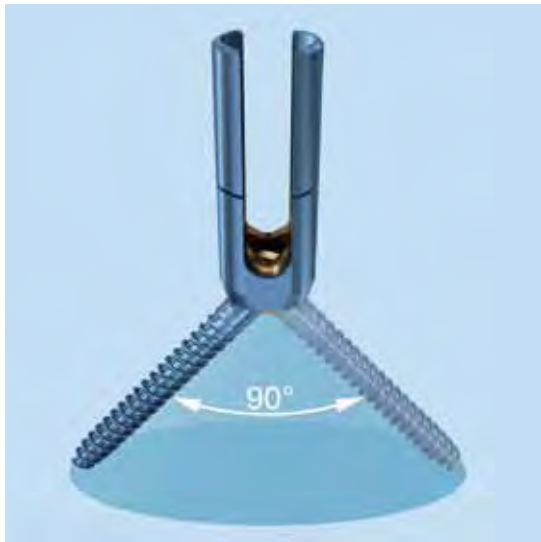


c
Full expansion of the stent after removal of the balloon, obvious height gain.



d
After cement injections, the cement infiltrates the surrounding bone and provides definitive mechanical stability.

Fig 1a–d
Intraoperative images.



Universal Reduction Screws (URS) in the Treatment of Deformities

The indication for surgery of an idiopathic scoliosis according to Cobb should be a thoracic spine of more than 50° and lumbar spine of more than 45°. In these cases surgery is necessary, leading to the correction and stabilization of the spine by implant systems. Surgical management of scoliosis is generally intended to prevent further progression of the deformity [1].

Nowadays in modern instrumentation systems, more anchors are used to connect the rod and the spine. This allows individual segmental rotation, resulting in better correction and less frequent implant failures [2]. Segmental pedicle screw constructs are considered the gold standard for deformity correction today [3].

Universal reduction screws (URS) are polyaxial pedicle screws with extended tabs, enabling rod reduction without the use of reduction instruments. The tabs can be broken off after rod reduction. The screw heads allow for a polyaxial adjustment of 90° around 360°. The locking cap of the URS is designed as a two-step locking cap. The outer part of the locking cap captures the rod and locks the polyaxiality of the screw, while the inner part of the locking cap locks the rod in place. The individual fixation of the polyaxiality and the rod allows for segmental derotation as well as parallel compression and distraction.

Rod reduction and curve correction will be performed by reducing the locking cap within the extended tabs. As soon as the rod is fully reduced by the locking cap, the rod can be derotated to correct the deformity according to the Cotrel-Dubousset technique [4, 5]. To fine-tune the deformity reduction and to reduce the prominence of the rib hump, individual vertebral bodies can be segmentally rotated with the help of derotation tubes. After final tightening of the screws, the extended tabs are broken off the screw at their indented break-off line.

References

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**A 23-year-old man with neurogenic kyphoscoliosis,
Cobb angle: 120°.
Fusion of T7–S1 with universal reduction screws.
Duration of surgery: 4.5 hours.**

Case provided by Cornelius Wimmer, Vogtareuth, Germany

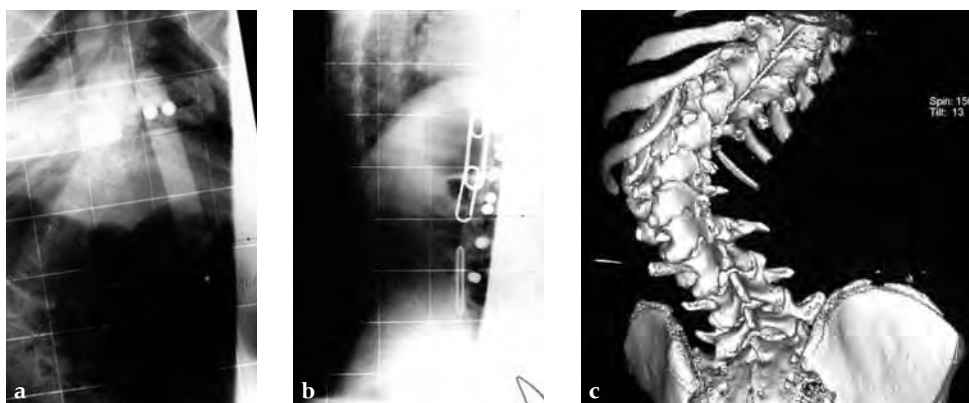


Fig 1a–c
a–b Preoperative x-rays.
c 3-D CT scan.



Fig 2
Intraoperative picture.

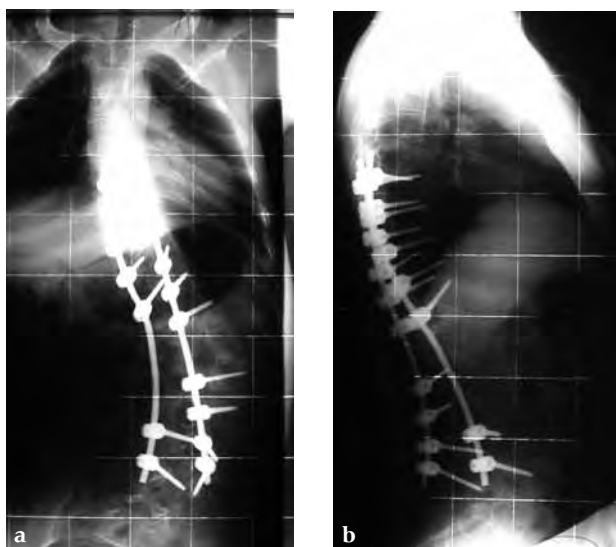


Fig 3a–b
Postoperative x-rays.



Fig 4
X-ray 1 year postoperatively.

Norbert Südkamp, Stefaan Nijs, Ralph Hertel

TRAUMA UPPER EXTREMITY



Fig 1
3.5 mm LCP superior clavicle.



Fig 2
3.5 mm LCP superior anterior clavicle.



Fig 3
3.5 mm LCP superior clavicle.



Fig 4
3.5 mm LCP superior anterior clavicle.

3.5 mm LCP Superior Clavicle

The 3.5 mm LCP clavicle plate system is indicated for fixation of fractures, malunions, nonunions, and osteotomies of the clavicle. It is part of the 3.5 mm LCP clavicle set which consists of the already available 3.5 mm LCP superior anterior clavicle plate and the future 3.5 mm LCP anterior clavicle plate.

The existing 3.5 mm LCP superior anterior clavicle was designed to fit on the superior end laterally and twist midshaft to fit anteriorly on the medial aspect. The new 3.5 mm LCP superior clavicle plate design has removed the twist in the plate. A lateral bow was put in the plate to enhance plate fit. The flat superior design allows more flexibility in placement. A K-wire hole was added to the distal end of the plate as a plate holder. Notches in the plate facilitate easier contouring that may be required in some cases. Diverging and cross-hatching screw pattern in the lateral end increase fixation strength.

The 3.5 mm LCP superior clavicle comes in left and right versions and are available in lengths of 6-, 7-, and 8-hole plates with or without lateral extension. The plates use 3.5 mm locking screws in the shaft and feature 2.7 mm locking screws in the lateral extension, also allowing for an increased number of screw positions laterally.

To ensure an anatomical fit, 49 bones from the University of Tennessee collection (a modern collection of bones, with the earliest specimen from 1981) were scanned spanning all age groups and sexes. The majority were younger, male specimens, mimicking expected patient population.

Surgery is straightforward as in most cases no or only minor additional contouring of the plate is required thus minimizing surgery time.

A 22-year-old man sustained an open clavicle fracture after a motorcycle injury.

Case provided by Harry A Hoyen III, Cleveland, USA

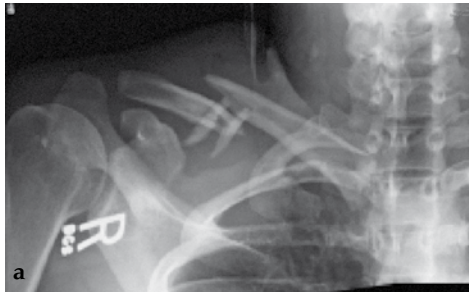


Fig 1a–b
Preoperative x-rays.

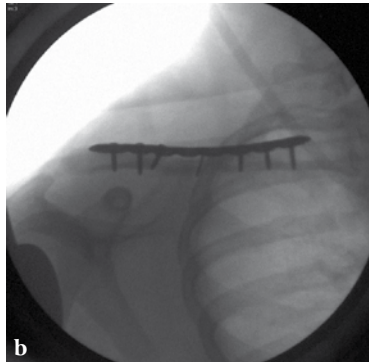
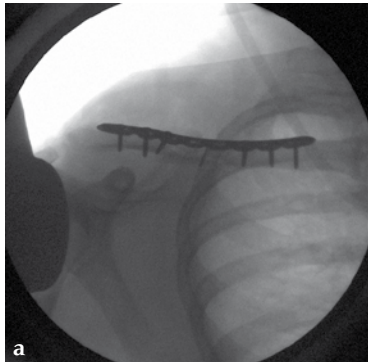


Fig 2a–b
Postoperative images.

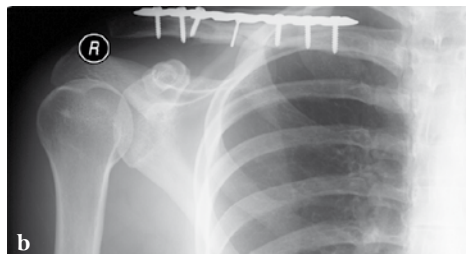
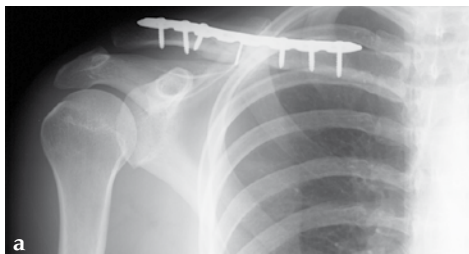


Fig 3a–b
X-rays taken 3 months postoperatively.



3.5 mm LCP Percutaneous Aiming System for PHILOS

PHILOS is usually implanted through the deltopectoral approach which implicates a long incision and extensive soft-tissue retraction to reach the anatomy of interest. The less-invasive transdeltoid approach is more soft-tissue friendly and gives a better view of the greater tubercle.

The 3.5 mm LCP percutaneous aiming system for PHILOS offers the possibility to insert the PHILOS plate through the transdeltoid approach and to insert the shaft screws percutaneously enabling a less-invasive application of PHILOS.

The system consists of a sleeve system and an aiming arm. It is used analogously to the existing PHILOS aiming instruments and other aiming systems. The aiming arm is radiolucent to allow control under image intensifier. Locking as well as cortex screws can be used through the device. Compression achieved by cortex screws in the shaft may lead to plate tension. The device has to be locked to the plate at both ends to ensure the plate–device alignment.

A safe zone is defined to protect the axillary nerve (screw holes near the axillary nerve are not accessible through the device). Therefore, the elongated plate hole is not accessible through the aiming arm due to the protected nerve zone. However, by abduction of the arm after fixation, these screw holes become accessible.

Overall, the 3.5 mm LCP percutaneous aiming system facilitates plate insertion as well as positioning and adjustment.

A 76-year-old woman suffered a low-energy fall at home.

Case provided by Stefaan Nijs, Leuven, Belgium



Fig 1
Preoperative x-ray.



Fig 2
PHILOS plate mounted on guiding arm, with suture augmentation in place.



Fig 3
Preliminary fixation and percutaneous reduction with bone elevator.



Fig 4
Intraoperative view.

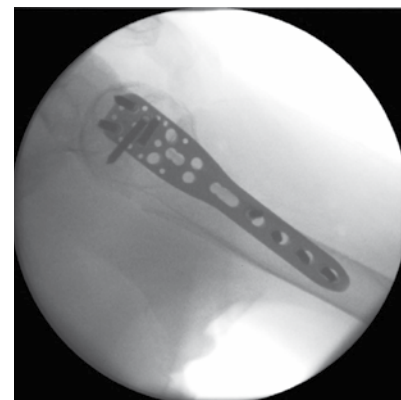


Fig 5
Intraoperative view of final result.



Fig 6
Postoperative view.
Note the minimally
invasive approach.

Fig 7
Postoperative
result.





Epoca Glenoid Components

Reconstruction of the osseous geometry of the shoulder is as important as the soft-tissue balancing. Using the Epoca prosthesis' customized medial and posterior offset adjustment features, anatomical reconstruction of the proximal humerus is achieved. The glenoid component is used in painful and/or severely deformed joints. In case of major loss of cartilage and excessive retroversion, reorientation is essential to reestablish normal joint kinematics.

The Epoca glenoid component was designed to facilitate a normal glenohumeral range of motion. Reduction of the size and its special geometry allows an increased range of motion. Its beveled rim maximizes the articulation surface area whilst simultaneously reducing the risk of impingement and excessive rim loading. Unlike the subchondral bone plate, the glenoid and humeral cartilage surfaces have similar contours. Congruence, a measure of conformity between two surfaces, is defined as the difference between the radius of curvature of the humeral head and the glenoid. The closer this difference is to zero, the more congruent the joint will be. The gleno-head surfaces of the Epoca system are congruent. This radial match enhances joint stability, muscular efficiency, and compliments the centering function of the rotator cuff. This congruence, in conjunction with the convex posterior surface of the glenoid component, promotes even stress distribution in subchondral bone and reduces polyethylene wear. The convex posterior surface additionally reduces the risk of the so-called "rocking horse effect". This is further enhanced by Epoca's two pegs, which are situated far apart from one another to facilitate stable fixation in the cement mantle. Peg anchorage can be further enhanced using the shell screws.



The Epoca shell screws are specifically designed hollow screws that are firmly anchored into the bone allowing long-term in- and ongrowth. The intraosseous interface allows correct monitoring of the long-term bony anchorage. The pegs of the glenoid implant are cemented into the shell screws, which contain the bone cement, and prevent it flowing into the bone cavity. This keeps the cement at the bony surface and in the screws, making possible future revisions easier.

The glenoid implants are manufactured in Switzerland from UHMW polyethylene to ISO 5834. Progressive glenoid sizes are available from 42–54 mm in 2 mm increments for individual adaptation. The shell screws are manufactured from titanium. A precise, low-profile, and easy-to-handle instrumentation makes the system convenient to use.

Case 1: A 60-year-old man with an omarthrose of the left shoulder joint. Epoca consisting of uncemented resurfacing head and glenoid component used.

Case provided by Norbert Südkamp, Freiburg, Germany



Fig 1a-c
Preoperative x-rays.

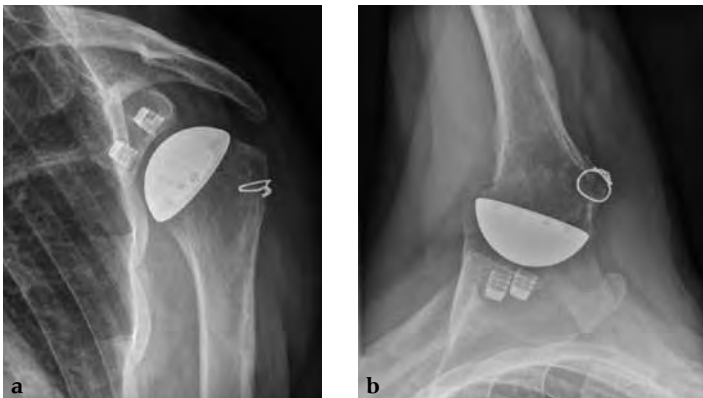


Fig 2a-b
X-rays 4 weeks postoperatively.



Fig 3a-d
Functional result 4 weeks postoperatively.

Case 2: A 78-year-old man.

Case provided by Ralph Hertel, Bern, Switzerland



Fig 1a–c
Primary osteoarthritis with large inferior osteophyte.

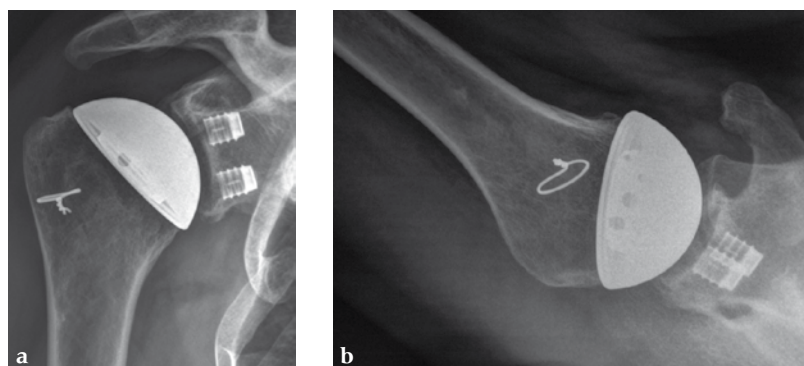
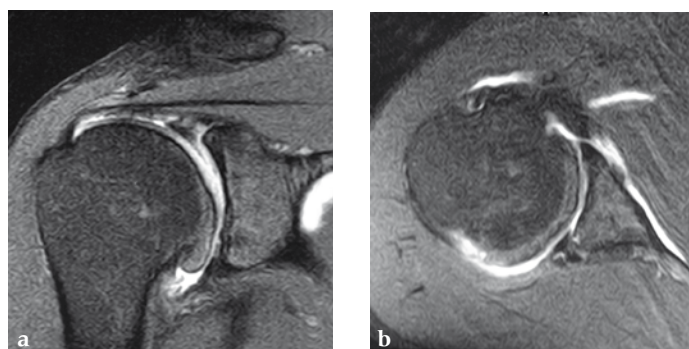


Fig 2a–b
Total shoulder arthroplasty with resurfacing head and hybrid glenoid.



Case 3: A 59-year-old man.

Case provided by Ralph Hertel, Bern, Switzerland

Fig 1a–b
Primary osteoarthritis with increased retroversion of the glenoid.

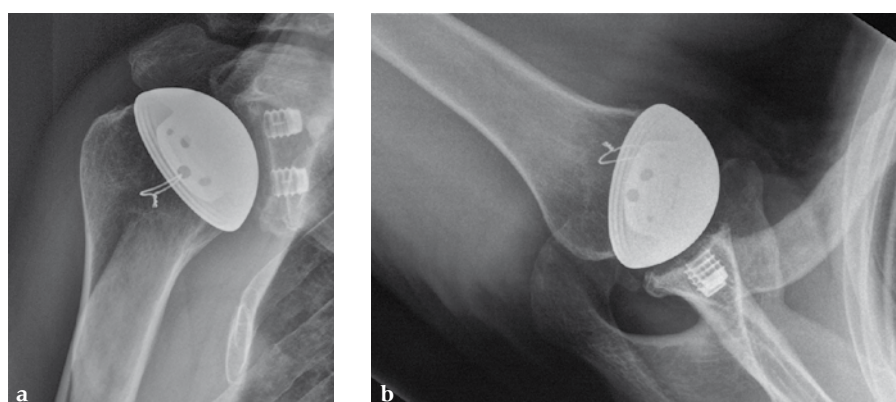
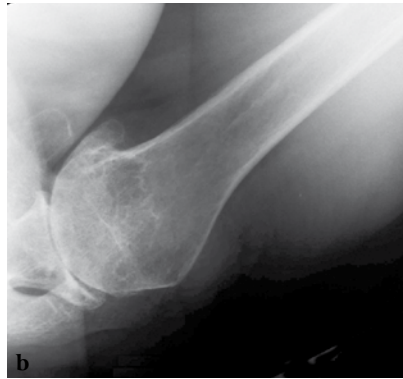


Fig 2a–b
Total shoulder arthroplasty with resurfacing head and hybrid glenoid.



Case 4: A 74-year-old woman.

Case provided by Ralph Hertel, Bern, Switzerland

Fig 1a–b
Secondary osteoarthritis resulting from multi-directional instability with mainly posterior component.

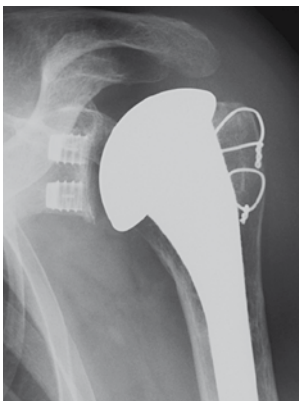


Fig 2
Total shoulder arthroplasty with pressfit shaft and hybrid glenoid.

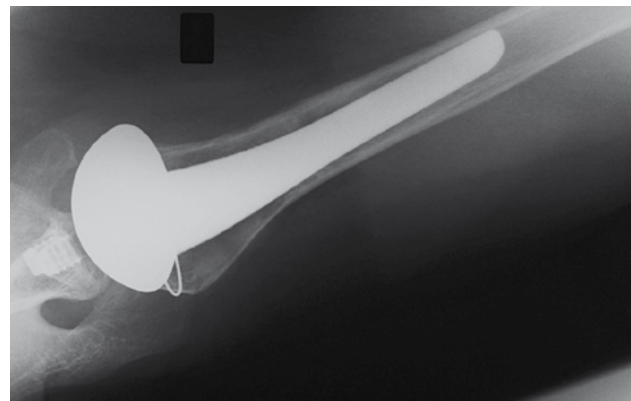


Fig 3
The humeral head is well centered over the glenoid and aligned with the scapula.

Case 5: A 71-year-old woman.

Case provided by
Ralph Hertel, Bern, Switzerland



Fig 1a–b
Primary osteoarthritis with B1 glenoid.

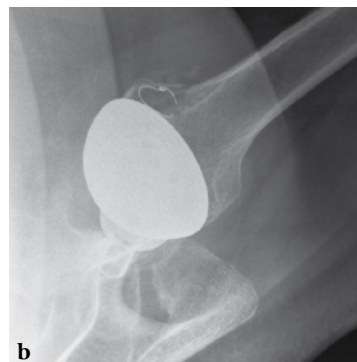


Fig 2a–b
Total shoulder arthroplasty with resurfacing head and hybrid glenoid.



Fig 1
Epoca revision set.

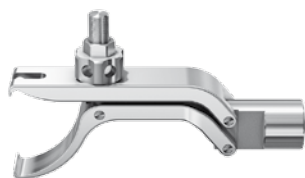


Fig 2
Articulated head extractor.



Fig 3
Articulated eccentric extractor.



Fig 4
Conical extraction screw for shell screw and metalback peg removal.



Fig 5
Trail stems for extra-long stem implants.

Epoca Revision Set

The Epoca revision instruments are intended for removal and revision of Epoca shoulder system implants. Due to the increased number of shoulder arthroplasty cases, the revision cases have also increased. The extent to which a component must be removed during revision surgery depends on the mode of failure, eg, glenoid erosion, glenoid component loosening, insufficient reduction and fixation of tuberosities, instability, infection, and component malpositioning.

Revision shoulder arthroplasty cases have been recognized to be among the most difficult in shoulder surgery, therefore specific instruments for implant extraction/removal as well as for the reimplantation of long or extra-long humeral stem implants have been designed. The set includes several new instruments as well as existing instruments needed for revision surgery.

The set consists of the articulated head extractor which fits comfortably around the largest head, the articulated eccentric extractor which grasps the eccentric and extracts it out of the stem implant, a stem extractor, a conical extraction screw for shell screw and metalback peg removal, a carbide drill bit and drill sleeve for drill suction device for metalback removal, a short reaming rod for humerus reamers, and trial stems for long and extra-long stem implants.

Furthermore, the system is completed with existing instruments for removal and revision, such as chisels, osteotomies, and awl.

A completely assembled prosthesis—head, eccentric, shaft—was subjected to an axial pull-out test with the extraction instruments. The results showed a necessary pull-out force of around 3,000 N (two tests: forces recorded were 2,926 N and 2,909 N). The head extractor did not show plastic deformation until an axial force of 8,323 N, the eccentric extractor at 7,107 N (second measurement 6,764 N), and the connection screw of the stem extractor at 7,126 N (second measurement 5,195 N). The test results indicate that the instruments sustain damage at a much higher force compared to the force required to disassemble the prosthesis, thus ensuring instrument efficacy.

Douglas Campbell

TRAUMA HAND



1.8 mm VA Locking Buttress Pins

The 1.8 mm variable angle (VA) locking buttress pins are used for fixation of complex intra- and extraarticular fractures and osteotomies of the distal radius and other small bones. They are part of the VA-LCP distal radius system.

The VA locking head with T8 StarDrive recess allows the pin to lock up to 15° off-axis in any variable angle locking hole, or on-axis in any locking hole to provide angular stability at angles determined by the surgeon. The 1.8 mm diameter shaft is smooth and nonthreaded with a blunt, rounded tip which enables easy insertion and provides buttressing for the subchondral bone of complex and comminuted fractures. The rounded tip lowers tendon irritation when penetrating the far cortex. It also draws the surgeon's attention to the principles of angular stability, where it is unnecessary for a locking screw or buttress pin to breach the far cortex at all. Leaving the tip of a locking screw or buttress pin just underneath the far cortex provides equal stability to engaging the far cortex with screw threads, particularly in osteopenic bone, thereby removing any risk of tendon irritation or injury. 4 mm of "neck threads" in the shaft aid in backing out the pin for easy removal.

The pins are available in titanium and stainless steel in lengths of 8–30 mm.



2.4 mm VA-LCP Two-Column Volar Distal Radius (Narrow), for Small Stature

The 2.4 mm variable angle LCP distal radius system is indicated for fixation of complex intra- and extraarticular fractures and osteotomies of the distal radius. The variable angle technology enhances fragment-specific fracture fixation by providing the flexibility to lock screws in trajectories that diverge up to 15° from the central axis of the plate hole. The plates are precontoured to match the anatomy of the volar distal radius. Variable angle locking holes in the head of the plate enable placement of the screws at the most appropriate position to create a locking construct which will support the articular surface and reduce the need for bone graft.

The system consists of the 2.4 mm variable angle LCP two-column volar distal radius and the 2.4 mm variable angle LCP volar extraarticular distal radius plates. Both plate types use 2.4/2.7 mm cortex or 2.4 mm locking screws in the plate shaft, and 2.4 mm variable angle locking screws in the head of the plate. The variable angle locking screws are available from 8–30 mm.

The 2.4 mm variable angle LCP two-column volar distal radius system has been expanded by the addition of a small stature version in particular for narrow radii of small-statured patients because the current 6-hole version may be too wide for this group of patients. The middle holes in the plate head have been merged, the plate angle lowered from 25–20°, the corners made rounder on radial and ulnar edges, and the divergent predefined screw angles increased. The narrow plate also comes in a left and right version with four different shaft lengths (42–72 mm / 2–5 holes) and two corresponding guide blocks. The plates are available in stainless steel or titanium, sterile, and nonsterile. A trial implant allows determination of correct plate size in regions with sterile implants only. This trial implant may be fixed temporarily through K-wire holes.

The design of the 2.4 mm variable angle LCP two-column volar distal radius plate reflects the need to reconstruct and stabilize the load-bearing radial and, more importantly, intermediate columns of the distal radius, as well as the sigmoid notch (which forms part of the distal radioulnar joint). As such, it provides stability to the areas of the radius shown to be biomechanically crucial in force transmission, as well as to the distal part of the forearm rotation mechanism.

A young woman, 1,5 m tall, 45 kg, sustained a very distal C1.1 fracture of the distal radius.

Case provided by Martin Langer, Münster, Germany



Fig 1
Intraoperative view showing reposition of the radiocarpal joint with the K-wire.



Fig 2
Stabilization of the radiocarpal articular surface with one single 2.4 mm screw at the level of the watershed line, and narrow plate below the watershed line.



Fig 3a–c Postoperative x-rays showing comparison of plate alternatives.

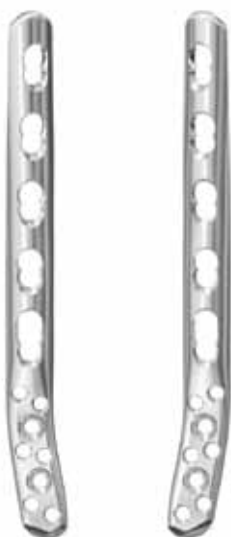
a Four-hole small.

b Four-hole.

c Five-hole.

Michael J Gardner, Philip Kregor

TRAUMA LOWER EXTREMITY



2.7/3.5 mm LCP Posterolateral Distal Fibula

Treating unstable ankle fractures successfully requires anatomical reduction and stabilization of the distal fibula. This involves restoring accurate length, alignment, and rotation. Often this may be complicated by comminution, osteoporotic bone, and associated syndesmotic instability. Laterally-based-placed fibular plates do not allow for buttressing of the common posterior or posterolateral fracture spike of the distal fragment, and positioning of the plate is directly subcutaneous to the incision, which is often through thin or compromised skin. Using standard small fragment implants provides limited options for distal fixation.

The 2.7/3.5 mm LCP posterolateral distal fibula addresses these issues by offering a precontoured, thin but stronger plate which assists with anatomical reduction to restore joint congruency. It is indicated for fractures, osteotomies, and nonunions of the metaphyseal and diaphyseal region of the distal fibula, especially in osteopenic bone.

The LCP posterolateral distal fibula plate offers six round locking holes and two coaxial holes distally which accept 2.4 and 2.7 mm locking and cortex screws to provide multiple screw options. The distal holes are slightly divergent to help prevent screw pullout. The coaxial hole accepts both locking and cortex screws and its recess for screw heads minimizes screw-head prominence by allowing the screws to sit more flush with the plate, creating a low-profile construct. Its posterolateral position allows it to be placed deep to the peroneal muscles, minimizing the risk of wound healing problems due to prominence. A 2.7 mm lag screw may be placed through the distal screw cluster, and a syndesmotic screw may also be placed through the plate.

The anatomically precontoured plate shaft is only 2.25 mm thick yet substantially stronger than the one-third tubular plate. The combination holes in the shaft accept 3.5 mm locking screws, 3.5 mm cortex screws, and 4.0 mm cancellous bone screws.

The plate comes in left and right versions and is available in lengths from 77–233 mm (3, 4, 5, 6, 7, 9, 11, 13, and 15 holes). It is offered in stainless steel and titanium, sterile, and nonsterile.



A 56-year-old man slipped and fell, sustaining a fracture dislocation of the ankle. His fibula was stabilized with a posterolateral plate. The construct included several nonlocking screws in the diaphysis, and multiple 2.7 mm locking screws in the distal fibula. As with most Weber B fracture patterns, a lag screw was possible from posterior to anterior through the plate. Finally, intraoperatively the patient was found to have a syndesmotomic injury, and after reduction, a syndesmotomic screw was placed through the plate.

Case provided by Michael J Gardner, St Louis, USA



Fig 1a–b
Preoperative x-rays.



Fig 2a–b
X-rays 3.5 months postoperatively.

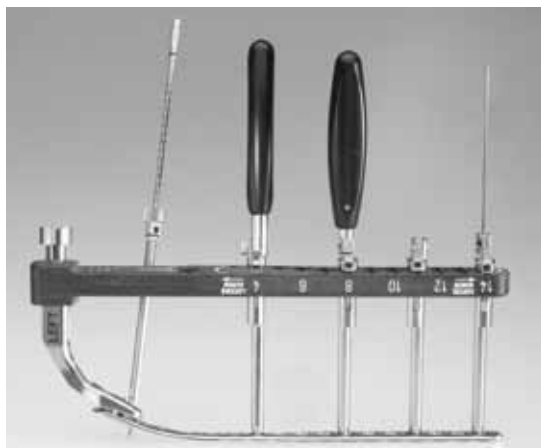


Long Ratched Stagbeetle Forceps

The stagbeetle clamp is a small fragment variant of the Weber clamp (pointed reduction clamp), one of the most commonly used and helpful tools for the surgeon.

When used properly, precise fracture reduction is possible with minimal soft-tissue damage. However, a relatively common problem using the stagbeetle clamp is that the distance between the two points may be too great to allow the ratchets to engage.

The new forceps is identical to the standard clamp, but has a longer ratchet to increase its working range.



LCP Small Fragment Percutaneous Instrument Set

The LCP small fragment percutaneous instrument set is intended to be used with the LCP low-bend medial distal tibia plate and any future small-fragment plates in need of an aiming arm. Surgeons can currently place screws in the diaphyseal portion of the plate, however, it is not an efficient process.

The LCP small fragment percutaneous instrument set consists of a comprehensive series of aiming arms, insertion handles, and instrumentation to facilitate percutaneous, subcutaneous/submuscular insertion of various plates to allow minimally invasive surgery for reduced soft-tissue damage. It may also reduce image intensifier exposure and time in the OR because the arm targets the holes and facilitates screw insertion.

The set enables aiming for all three positions of the combination hole (locking, neutral, and compression). The instruments snap into the aiming arms for quick assembly and removal. Color coding helps easy identification of compatible instruments. The aiming arm is made of carbon fiber for radiolucency. The insertion handle attachment point provides three points of fixation when connected to the plate.

Mario Gasparri

THORAX



Fig 1
New caliper.



Fig 2
Old caliper.

Caliper

The new universal caliper is designed for easy readability, durability, and compact size. In comparison with the currently available flat caliper this device also offers improved handling capabilities yet is easier to clean. The calibrated markings are etched in black on an off-white arm extension, which has a square shape and is etched on all four sides. The extensions arm is made of radel (polyphenylsulfone (PPSU)) for better durability. It is intended for various areas of thoracic surgery, ie, with the sternal fixation system and the matrix rib system.

Michael Blauth, René Attal

TRAUMA INTRAMEDULLARY NAILING

PFNA Enhancements

Introduction

The PFNA in its short and long version is indicated for pertrochanteric fractures, intertrochanteric fractures, and high subtrochanteric fractures. In addition the long version is indicated for low and extended subtrochanteric fractures, ipsilateral trochanteric fractures, segmental fractures of the femur, and pathological fractures. Several components of the PFNA system have been improved to enable intraoperative compression, and facilitate insertion and cleaning.

Blade

The design has been changed to allow intraoperative compression and to improve the strength of the blade also with respect to implant removal. The current insertion/extraction instrument can be used with the new blade and vice versa because the interface is exactly the same. The new blade can be used with the existing stainless steel insertion handle, or with the existing radiolucent insertion handle.

The blade comes in lengths of 75–130 mm in 5 mm increments and is available in titanium and stainless steel. New blade lengths of 75, 125, and 130 mm offer more options to better fit the patient's anatomy.

The compression instrument is screwed into the blade through the protection sleeve. Then the buttress nut is turned counterclockwise to move the protection sleeve backwards until it pushes towards the compression instrument. Under image intensifier control, the buttress nut is turned counterclockwise achieving intraoperative compression and closing the fracture gap.

End caps and screwdriver StarDrive

The end caps, available with extensions of 0, 5, 10, or 15 mm in titanium and stainless steel now have a StarDrive T40 recess and are intended for use with a new screwdriver. This new T40 screwdriver has a ball tip which allows angulation of the instrument in relation to the nail/end cap. This facilitates insertion of the end cap over guide wire with hook and is an advantage compared to the current straight T40 screwdriver.

Aiming arm

The new aiming arm is made of PEEK carbon fiber which is easier to clean. It can be used for locking of standard and short nails which reduces the number of instruments needed. The self-holding feature of the protection sleeve makes the handling easier. The new aiming arm is compatible with the existing and new insertion handles.



Fig 1
New PFNA blade design.



Fig 2
Compression instrument.



Fig 3
End caps with T40 recess.



Fig 4
StarDrive T40 for new end caps.



Fig 5
Aiming arm.



Fig 6
Insertion handle.



Fig 7
Guide-wire aiming device.

Insertion handle

Compared to the existing radiolucent handle the new design is slimmer, allowing smaller incisions and therefore reducing potential interference with the pelvis and soft tissues. The handle is radiolucent which provides for good visibility on x-rays. The integrated positioning aids lateral-orientation-facilitated guide-wire positioning and insertion.

The new insertion handle is compatible with the existing instruments and implants.

Guide-wire aiming device

This new device facilitates guide-wire positioning and insertion. It is attached to the aiming arm using the connecting screw for PFNA. The C-arm is rotated in AP view until any two orientation lines are symmetrical to the protection sleeve. The midline in between these two orientation lines predicts the location of the guide wire and PFNA blade. The insertion depth of the nail is adapted until the midline is centered in the femoral head. The C-arm may be readjusted to make sure that two lines are symmetrical to the sleeve.

The guide-wire aiming device can be attached to the existing aiming arms and also to the new aiming arms.

Locking screw for distal locking

Locking screws for distal locking are now available: either 5.0 mm locking screw, self-tapping in lengths of 28–100 mm, or 5.0 mm locking screw with StarDrive recess in lengths of 26–100 mm.

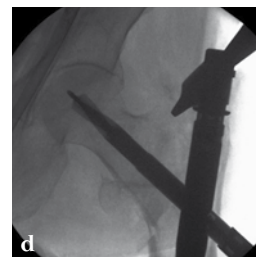
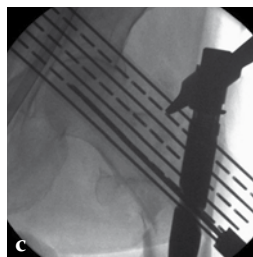
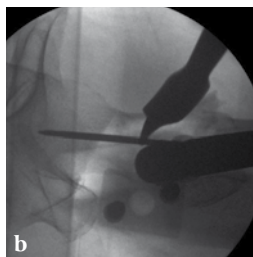


Fig 8a–d Use of the guide-wire aiming device in an 87-year-old woman.

- Clinical picture of the whole aiming and insertion construct.
- After closed and minimally invasive open reduction with a Hohmann retractor pushing on the anterior aspect of the femoral neck for better axial alignment, the guide-wire aiming device has been mounted to the aiming arm and helps to identify the optimal position of the guide wire in the femoral head.
- The K-wire runs parallel to the chosen line of the aiming device. In AP projection the tip of the blade should be positioned in the center of the femoral head.
- In AP projection the tip of the blade should be positioned in the center of the femoral head, in lateral projection the blade should run parallel to and in middle of the neck and also end dead center of the femoral head. The distance of the tip of the blade to the joint should be approximately 10 mm. No pre-drilling is recommended in osteoporotic bone.

Compression feature used intraoperatively.

Case provided by Michael Blauth, Innsbruck, Austria



Fig 1
Preoperative x-ray.



Fig 2a-b
Intraoperative compression images.

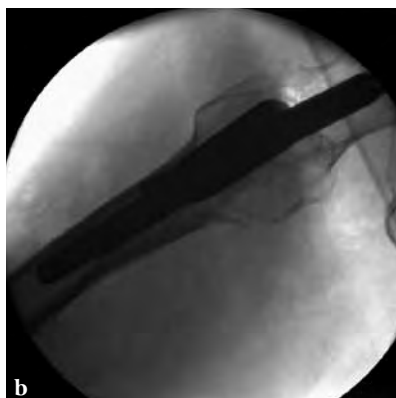


Fig 3a-b
Immediately postoperative AP
and lateral images.



Fig 4a-b
Postoperative AP and lateral x-rays.

Theddy Slongo

PEDIATRIC

**End Caps, Small, for TEN and STEN**

Elastic stable intramedullary nailing (ESIN) has become the method of choice for internal fixation of femoral and tibial shaft fractures in children of 4–14 years of age. In the lower extremity, ESIN treatment may be complicated by loss of reduction following push-out of the nails at the entry site, especially in unstable femoral shaft fractures. The rate of this complication—nail migration with subsequent soft-tissue and skin irritation—was reported to be as high as 5–12% until end caps became available, which lock the nails at the entry point. The use of end caps avoids postoperative instability, even in heavier, older patients, and with unstable fracture types. To maximize stability of ESIN-instrumented unstable fractures, end caps require properly placed nails that are correctly bent. It is essential to cut the nails to a correct length at the entry site to ensure adequate anchoring of the nails in the caps and anchoring of the cap in the cortical bone respectively. The end caps are equipped with a self-cutting device and are put over the cut ends of the nails like a hollow screw that is fixed in the cortical bone at the nail entry site. A special bevelled impactor is mandatory for the final nail positioning. The position of the nail inside the end cap can easily be visualized since the caps are semiradiolucent. The end caps also protect the soft tissues from the cut nail ends, and improve retrieval because the cap facilitates nail placement and creates a space around the nail ends for the extraction pliers. Only one small, extra instrument, the driver for the caps, is required.

Following the positive experiences with the end caps, there is also a need for small end caps. On the one hand there has been a request for a safer and more comfortable stabilization of clavicle fractures, on the other hand there has been a request for a safer stabilization of problematic forearm fractures in older children.

Biomechanical studies performed at AO Foundation show that end caps increase the push-out force six times over that of conventionally inserted nails. A clinical study run by the Department of Pediatric Surgery in Bern demonstrated the clinical efficacy.

Additional small-sized end caps (pink) in titanium and stainless steel for use with 1.5–2.5 mm diameter STEN and TEN have now been added to the existing size end caps (green) for 3.0–4.0 mm STEN and TEN.

Case 1: Transverse forearm, shaft fracture (22-D/4.1), 9-year-old girl.

Case provided by Theddy Slongo, Bern, Switzerland



Fig 1a–b
Preoperative x-rays show transverse forearm, shaft fracture.



Fig 2a–b
Postoperative x-rays show good alignment. Because of the potential instability, small end caps were used.



Fig 3a–b
Six months postoperatively there is correct alignment, length, and good full consolidation; nails were removed after this control without any problems.

Case 2: Oblique forearm, shaft fracture (22-D/5.1) with end caps, 11-year-old boy.

Case provided by Theddy Slongo, Bern, Switzerland



Fig 1a–b
Preoperative x-rays show an oblique, unstable forearm, shaft fracture.



Fig 2a–b
Postoperative x-rays show good alignment. Small end caps were used because of the potential instability; in this case the new technique with distal ulnar entry point was performed.



Fig 3a–b
Six months postoperatively, x-rays show correct alignment, length, and good full consolidation. Nails were removed without any problems after this control.

Michiel Verhofstad, Christian Matula

BIOMATERIALS



Fig 1
Norian drillable material.



Fig 2
Norian drillable.



Fig 3
Norian drillable mixer.



Fig 4
Norian drillable
syringe.

Norian Drillable

Norian drillable is a synthetic ceramic, injectable, moldable, and bio-compatible bone-void filler indicated for tibial plateau, distal radius, calcaneal, and intertrochanteric fractures.

Norian drillable is a calcium-phosphate-based bone-void filler, based on the same ceramic phase as Norian SRS. It has been enhanced with the addition of chopped fibers as a reinforcing phase, and sodium hyaluronate as a flow promoter. The bioabsorbable polymer fibers, which comprise approximately 2% by weight of the cured material, are degraded in the body by hydrolysis, lose their strength in approximately 4 months, and are eliminated over time. The ceramic component is slowly remodeled over a period of years, at a rate depending on the metabolic activity of the host bone. When fully cured, the composition formed closely approximates the mineral phase of bone.

Norian drillable is intended to be placed into bony voids either before or after final fracture fixation. It allows drilling, tapping, and screw placement through the filler at any time even after the setting process is completed ("reduce → fill → fix"). Of course, Norian drillable can also be used after completion of the osteosynthesis in the same way as conventional Norian SRS ("reduce → fix → fill"). Once the material is set, it acts as a temporary medium that provides mechanical support during the healing process. This is of particular relevance in elderly patients with metaphyseal fractures with bone loss, eg, due to impaction. Please note that the screws should not be placed near the edge of the cement as this may cause a fracture of the bone-void filler.

Norian drillable can be delivered either as an injectable paste that is mixed with an automatic mixer or as a fast-set putty which is manually mixed with a cup and spatula. Both are available in amounts of 3.5 and 10 cc.

Norian drillable as injectable paste is prepared outside the sterile field with a mechanical rotary mixer and injected via a sterile syringe and needle. After mixing, the material forms a smooth, viscous paste that remains injectable for approximately 5 minutes at 18–23°C / 64–73°F. At body temperature (37°C / 98.6°F), Norian drillable begins to harden after 2 minutes and sets in approximately 10 minutes. If a tourniquet is used, the hardening is delayed, but can be enhanced using warm saline. Norian drillable reaches its ultimate compressive strength in 24 hours.

Norian drillable as fast-set putty is supplied in two containers: the mixing cup holds sterile powder and the solution syringe holds the liquid mixing solution. The moldable putty is mixed by hand with cup and spatula supplied in the kit within the sterile field and delivered by hand



Fig 5a–b
Fibers.

or another instrument. After mixing, the resultant putty material can be manipulated for 2 minutes at 18–23°C / 64–73°F. At body temperature (37°C / 98.6°F), Norian drillable fast-set putty begins to harden after 2 minutes of implantation and sets in approximately 3–6 minutes. Norian drillable fast-set putty reaches its ultimate compressive strength in 24 hours.

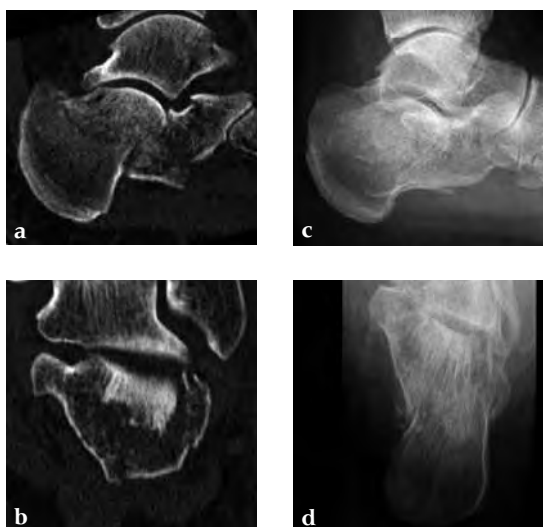


Fig 1a–d
Preoperative CT
scans and x-rays.

Case 1: A 70-year-old man sustained a Sanders IIA fracture of his left calcaneus. After open reduction a gap was left due to impaction of the osteoporotic metaphyseal bone. To support preliminary maintenance of the primary reduction a block of calcium phosphate was introduced beneath the posterior facet. The rest of the gap was filled with Norian drillable. After hardening plate osteosynthesis was performed. Two screws were placed through the fiber-enhanced calcium phosphate. Weight bearing was started 6 weeks later. After 6 months the fracture was healed without secondary loss of reduction. Note that at that time the degradation of the void filler is visible.

Case provided by Michiel Verhofstad, Tilburg, The Netherlands

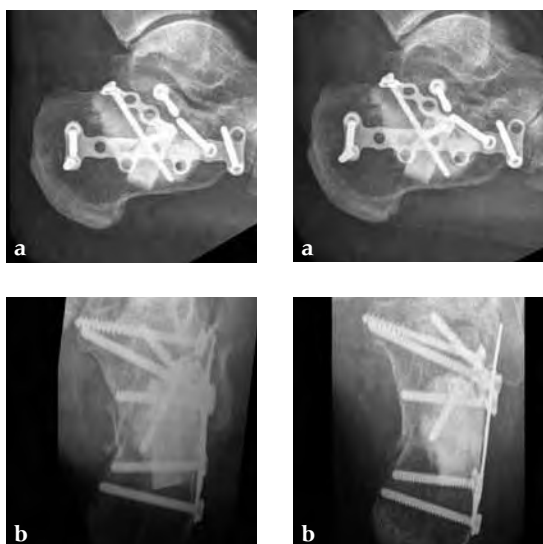


Fig 2a–b
Immediately post-
operative x-rays.

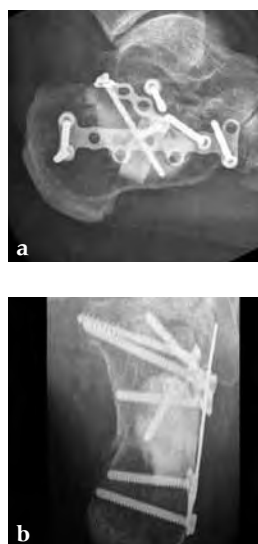


Fig 3a–b
X-rays 6 weeks
postoperatively.



Fig 4a–b
X-rays 6 months
postoperatively.

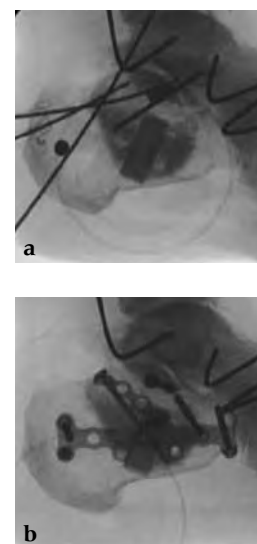


Fig 5a–b
Intraoperative image
intensification.

Case 2: A 38-year-old man sustained a lateral tibia plateau fracture (Müller AO Classification 41-B.3/Schatzker type II). After opening the lateral wedge, the osteochondral fragment was reduced and maintained with two K-wires. A gap beneath this fragment was left. Subsequently, a 3.2 mm hole was drilled in the lateral wedge using an inside-out technique. Then the lateral fragment was reduced. A 3-hole buttress plate, followed by two subchondral compression screws were used for final fracture fixation. Finally, Norian drillable was injected in the gap through the predrilled hole. Weight bearing was started after 6 weeks. At 6 months the fracture had healed anatomically and the patient was complaint-free.

Case provided by Michiel Verhofstad, Tilburg, The Netherlands

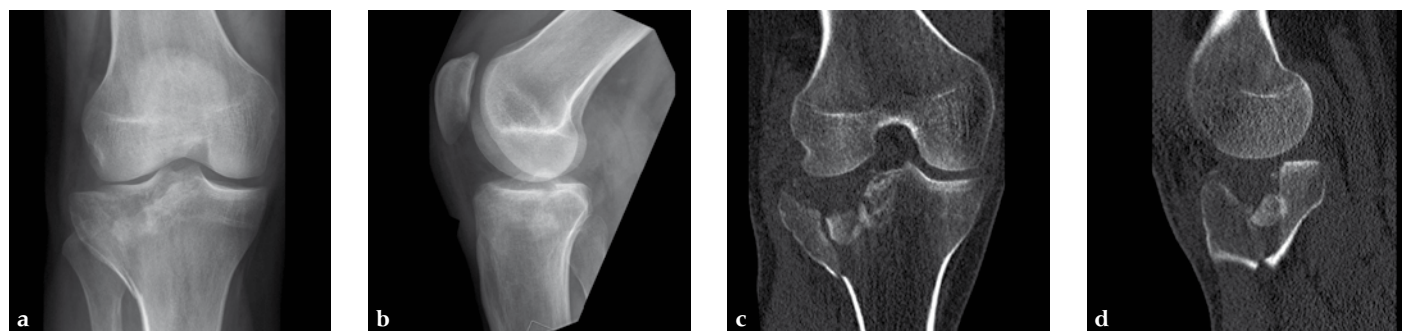


Fig 1a–d
Preoperative x-rays and CT scans.

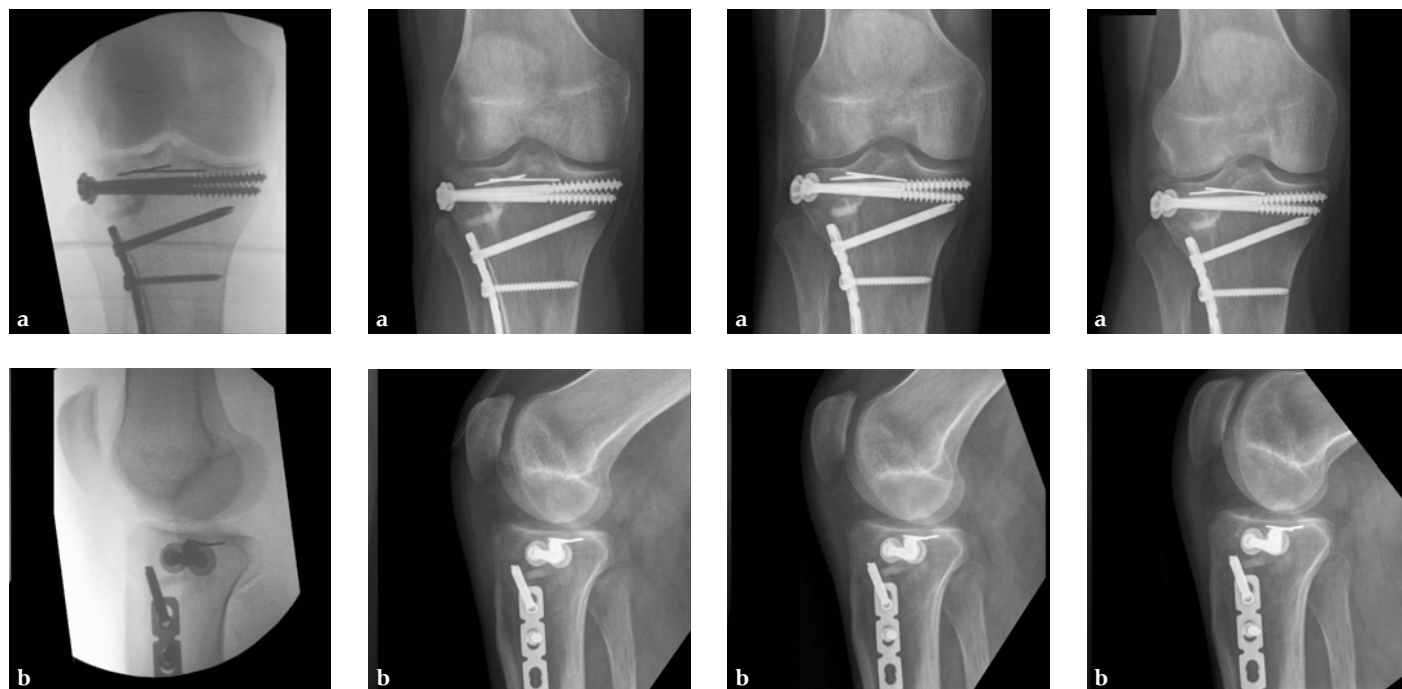


Fig 2a–b
Intraoperative images.

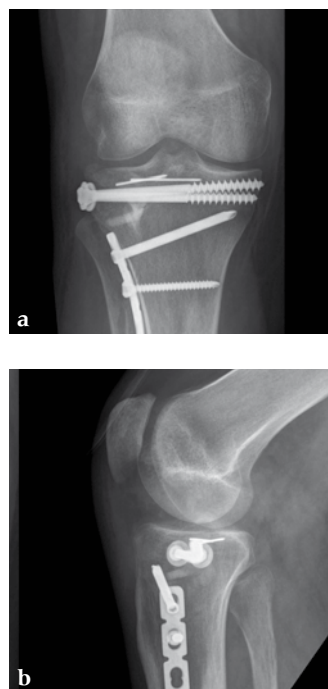


Fig 3a–b
X-rays 6 weeks postoperatively.

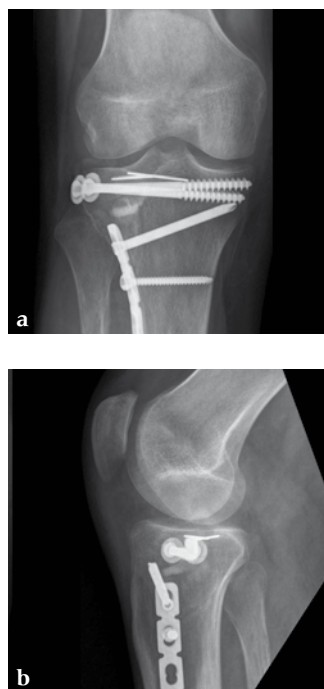


Fig 4a–b
X-rays 3 months postoperatively.

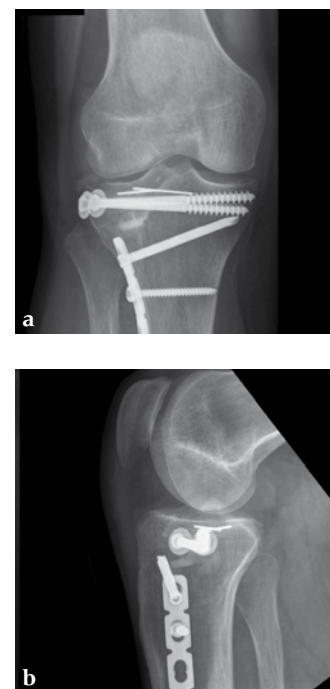


Fig 5a–b
X-rays 6 months postoperatively.

Resection of orbital lymphangioma in a 29-year-old woman.

Case provided by Christian Matula,
Wien, Austria

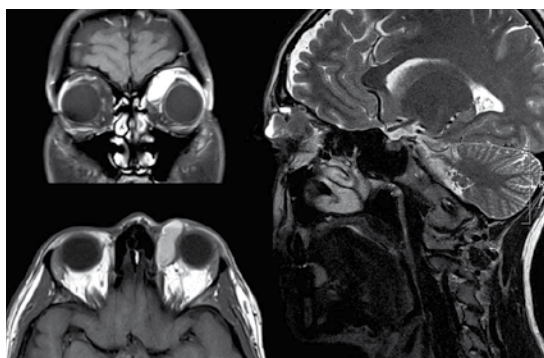


Fig 1
Preoperative images.

Norian Reinforced

Just like its sibling for trauma indications, the new Norian reinforced is a moldable, biocompatible, calcium-phosphate bone cement with added reinforced fibers that sets at body temperature. It is indicated for repairing or filling craniofacial defects and craniotomy cuts with a surface area no larger than 25 cm². Other indications include the restoration or augmentation of bony contours of the craniofacial skeleton (including the frontoorbital, malar, and mental areas), such as burr-hole voids and other craniofacial defects.

Although calcium phosphate cements have been used for some time as a treatment for cranial defects with easy administration via injection or manual placement, the occasional experience of early fragmentation and failure to set have led surgeons to refrain from using it in many cases. The vast majority of failures tend to occur early in the initial setting time, especially as an effect of dural pulsations. In order to address this reinforcing fibers and a sodium hyaluronate-based solution were added to the formula of the existing Norian CRS. The fibers, consisting of a 82:18 polylactide:glycolide copolymer, reinforce the ceramic when setting at body temperature and result in a resistance against cracking during the setting phase, whereas the sodium hyaluronate solution has been added in order to enhance mixing and handling properties.

Norian reinforced is not intended for use in the spine and should not be used in the presence of active or suspected infection. Just like the former Norian CRS there are two available delivery forms: Norian reinforced is an injectable paste that is mixed with an automatic mixer, Norian reinforced fast-set putty is manually mixed with a cup and spatula.

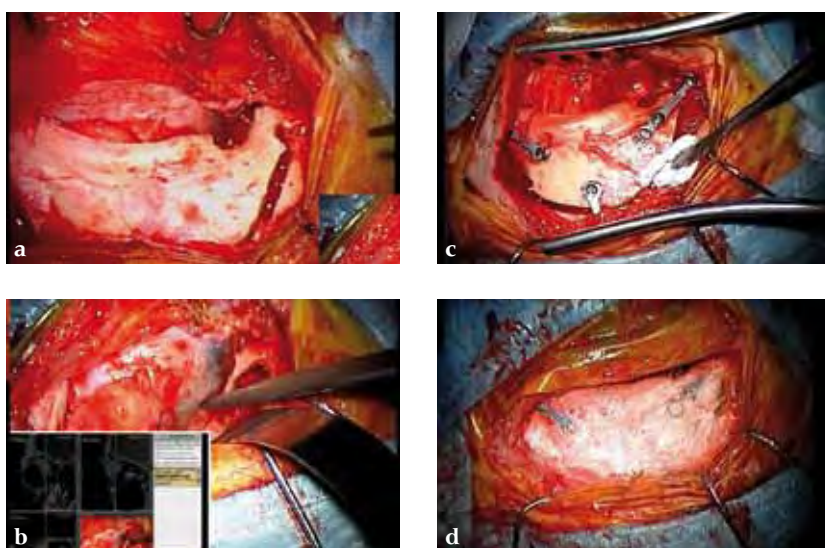


Fig 2a–d
Intraoperative images.

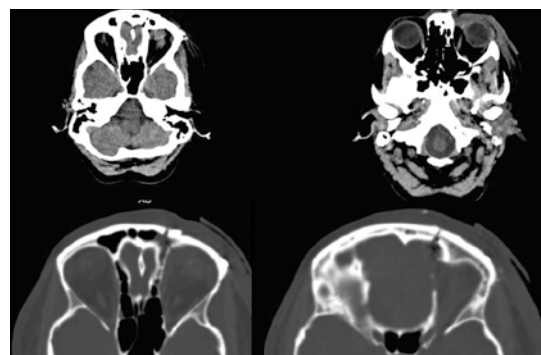


Fig 3
Postoperative images.

Daniel Buchbinder, Carl-Peter Cornelius, Scott P Bartlett

CRANIOMAXILLOFACIAL

Matrix Mandible System

The new matrix mandible system completes the family of previously developed craniomaxillofacial (CMF) matrix systems which are available for midface and neuro procedures, as well as an additional system focusing on orbital fracture repair.

The matrix mandible set follows the well-received mandible modular fixation system, yet responding to surgical feedback and need for a new consolidated set. It addresses the limitations and technical challenges for expanding into new technologies that could be seen in the old MLP/unilock 2.0 and LRP/unilock 2.4 systems due to their different designs and specific (noninterchangeable) instrumentation.

The new matrix mandible plate and screw system is intended for oral, maxillofacial surgery, trauma, reconstructive surgery, and orthognathic surgery related to the lower jaw, an anatomical structure which covers a fair amount of the daily procedures for CMF surgeons but also bears huge challenges for the developers of the system due to its complex biomechanical situation.

The main features of the system are:

- All screw diameters work with all plates
- A full set of new standardized instrumentation
- A single screwdriver blade can be used for all screws
- Improved screw/blade retention and reduced cam-out
- Off-axis screw insertion up to 15°
- Rounded “soft-tissue friendly” plate profiles
- Reduced inventory for hospitals without compromising clinical solutions

Plates

The plates in the system offer a conical locking technology for reliable screw-to-plate retention. All plates have rounded profiles and edges and an improved “angle plate” design to reduce stress in critical areas. The following plate thicknesses are available: 1.0, 1.25, and 1.5 mm (silver), and 2.0 mm (light blue) plates for trauma cases. (Malleable versions of the 1.0 mm plates are also available for load-sharing applications (color code: green-grey). For reconstructive purposes the range of plate thicknesses goes from 2.0 and 2.5 mm (light blue) to 2.8 mm (gold) with significantly improved fatigue strength. All plates are made from commercially pure titanium.



a



b

Fig 1a–b
Matrix mandible system.

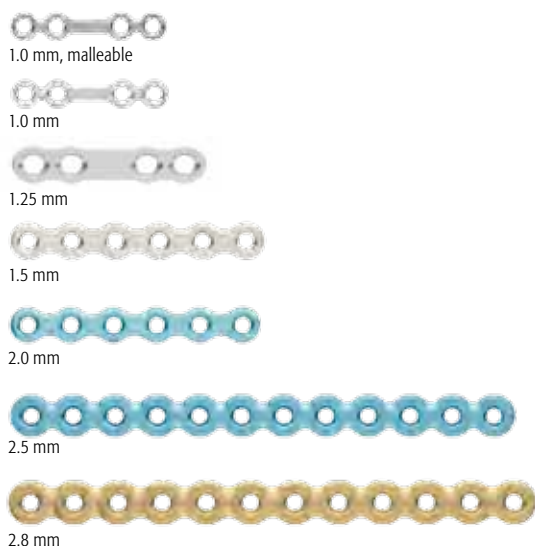


Fig 2
Plates.

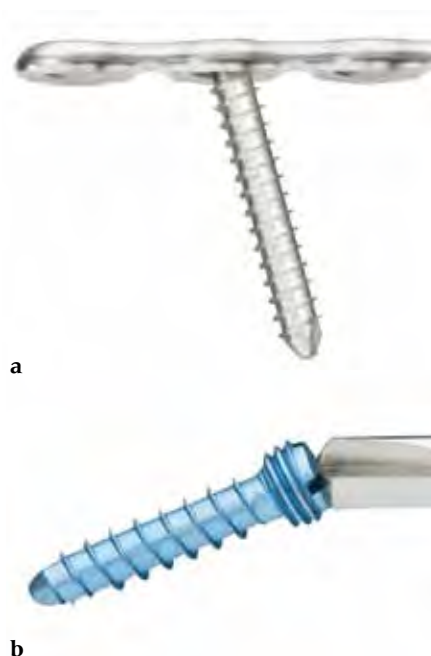


Fig 3a–b
Screws.

Screws

In keeping with the idea of the previously released matrix systems, all screw diameters in the set can be used with all the plates in the system. However, it is recommended to use those screws with the same color coding as the respective plate. 2.0, 2.4 and 2.9 mm diameter screws as well as 2.7 mm emergency (rescue) screws are available. All screws have a self-tapping tip with the 2.0 and 2.4 mm made available both with a locking or a nonlocking screw head design.

Depending on the size of the plate selected, a screw angulation of 10–15° and off-axis screw insertion up to 15° (screw-to-blade axis) can be achieved. All screws are made from titanium alloy.

Instrumentation

A specially designed set of instruments has been developed to achieve maximum efficacy with the implants in the system. Besides the feature that a single screwdriver blade can be used for all screws, new bending pliers for all plates and fixed-angle bending irons have also been developed. Furthermore diamond rasps have been added to the cutters to allow for easy on-site deburring of the cut edge of the plate.

Additionally available

The matrix mandible system will also provide the basis for future developments to continuously ensure state-of-the-art patient care. A few successful devices from older systems have been updated and integrated into the system already, ie, prebent tension plates for oblique line fractures and the condylar add-on system (see TK News 2/08). Another new plate which was based on the matrix mandible platform is the preformed (anatomical) reconstruction plate (see page 44).



Fig 4a–b
Cutting pliers with deburr
feature.



Fig 1
Intraoral situation showing exposed reconstruction plate and exposed edge of native mandible.

Case 1: A 47-year-old man transferred to the author's hospital approximately 10 days following the resection of a large, benign, locally aggressive odontogenic tumor of the mandible. He was primarily reconstructed with a locking reconstruction plate. The plate dehiscd and the patient was unable to eat or swallow leading to his emergent admission to the author's hospital for reconstruction of his mandible with a composite vascularized flap (fibula). The initial internal hardware was removed and a 2.5 mm matrix mandible locking reconstruction plate contoured and applied to the remaining mandibular rami to aid in the reconstruction of the subtotal mandibular defect.

Case provided by Daniel Buchbinder, New York, USA



Fig 2
Preoperative situation.

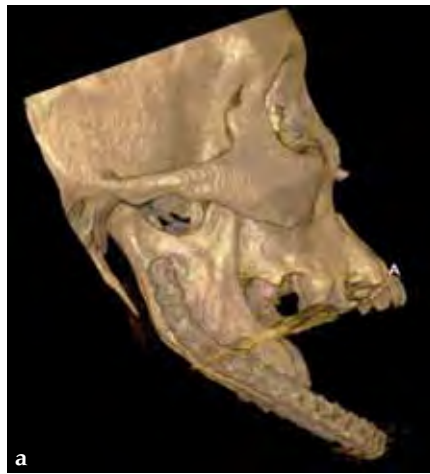


Fig 3 a–b
Initial plate from lateral and submental vertex views.



Fig 4
After removal of the reconstruction plate, a new 2.5 mm mandible matrix reconstruction plate is contoured to restore the continuity of the mandible.



Fig 5
A fibula osteocutaneous flap is harvested to reconstruct the mandible.



Fig 6
The fibula flap is contoured and inset to restore mandibular continuity and the skin paddle is used to restore the intraoral soft-tissue defect.



Fig 7a-b
Postoperative 3-D CT scans from lateral and submental vertex views.



Fig 8
Postoperative situation in frontal view demonstrating use of plate with good symmetry and projection of neo-arch and excellent alignment with maxillary dental arch.



Fig 1
Preformed reconstruction plate.



Fig 2
Set module.



Fig 3
Plate with screw module indicating the right screws for ramus, body, and symphysis.

Matrix Mandible System—Preformed Reconstruction Plate

One of the biggest challenges in mandibular reconstructive procedures is the bending of the large (or heavy) reconstruction plates. Not only can this become a time-consuming process, the bending tools can also introduce stress into the plate and even leave marks. Oftentimes this can lead to reduced fatigue life of the implant. The new preformed reconstruction plate was designed based on the matrix mandible system's 2.5 mm (light blue) plates to overcome the effects of plate fatigue due to overinstrumentation.

The preformed plates provide a 3-D shape which is based on the statistical analysis of mandible models obtained from over 2,000 CT scans, originating from various adult populations in collaboration with Marc C Metzger (Freiburg, Germany) who had already played a crucial part in developing the preformed orbital plate from the matrix orbit system.

The plates are available in three sizes: small, medium, and large with each plate offering a section of increased strength in the body and angle regions. The anatomical shape of the preformed reconstruction plates also allows for transoral application, ie, in combination with transbuccal instrumentation and/or the 90° screwdriver. The minimal intraoperative bending that is required preserves the optimal threaded-hole shape, especially in the preformed sections. These features result in a plate with increased fatigue life compared to standard reconstruction plates, thus reducing the risk of plate failure.

The preformed mandible reconstruction plates are intended for use in oral and maxillofacial surgery, trauma, and reconstructive surgery. This includes primary mandibular reconstruction, comminuted fractures, and temporary bridging until delayed secondary reconstruction, including fractures in edentulous and atrophic mandibles, and unstable fractures. They are 2.5 mm thick and are made from pure titanium. They can be used with the light blue locking screws (2.4 mm) from the matrix mandible system. Anatomically preformed sizers facilitate the correct plate size selection in the OR.



Fig 4
Sizer.

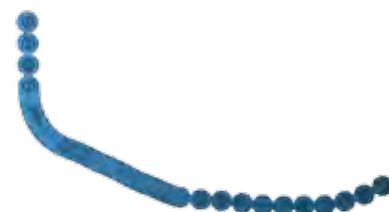


Fig 5
Bending template.

Case 1: A 27-year-old woman with an odontogenic myxoma in the left mandible. The preformed reconstruction plate was inserted prior to the tumor resection using a transoral approach with only a small additional transbuccal incision. To date the patient is free of symptoms with no signs of hypoaesthesia of the mandible and no signs of relapse. After another relapse-free period dental implants are planned for oral rehabilitation.

Case provided by Christoph Pautke, München, Germany

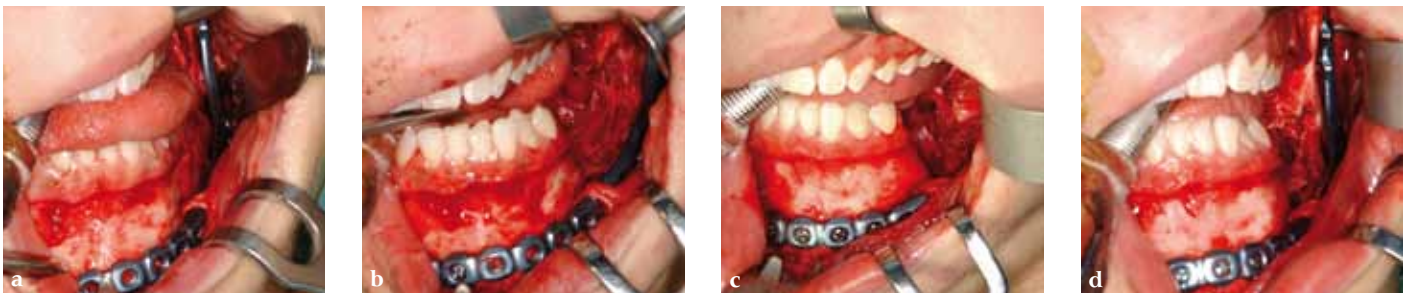


Fig 1 a–d
Transoral application of preformed reconstruction plate before tumor dissection.

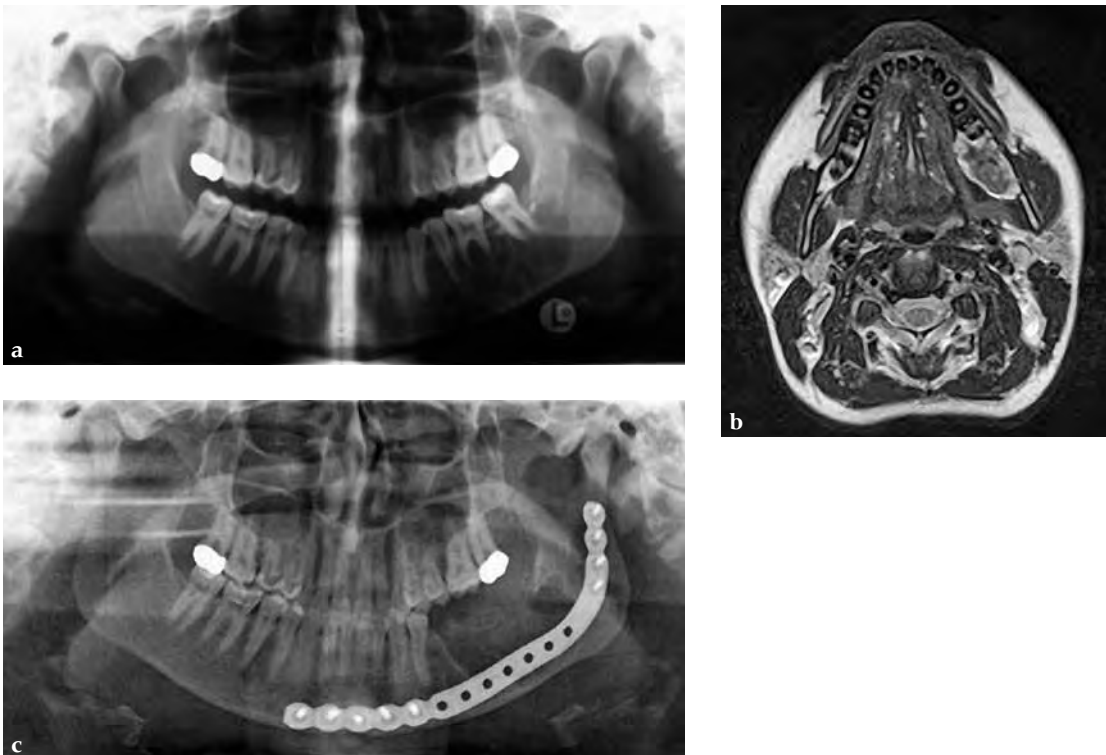


Fig 2
a–b Preoperative radiograph and MRI.
c Postoperative radiograph.



Fig 1
Implant, sizer, and template on surgical field.

Case 2: A 65-year-old man suffering from an oral cancer in the anterolateral floor of the mouth with infiltration of the right mandible. The preformed reconstruction plate was applied to the lateral surface of the hemimandible prior to en bloc tumor resection, including a bone segment via extended submandibular access. The missing bone was replaced with a revascularized scapula border in combination with a soft-tissue parascapular flap. The patient has had no recurrence 1.5 years postoperatively.

Case provided by Carl-Peter Cornelius, München, Germany

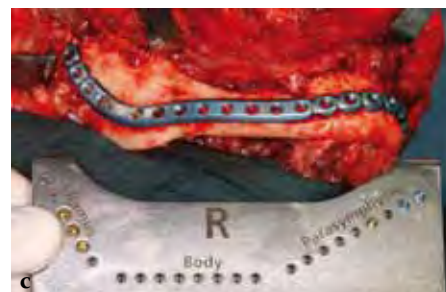


Fig 2a–c
Determining the correct implant size with the sizer and preliminary fixation.

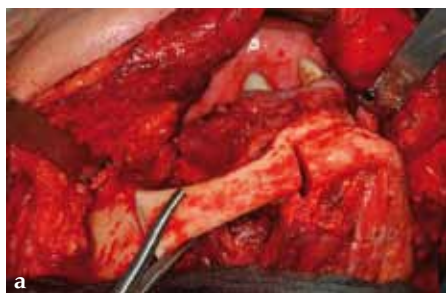


Fig 3a–c
En bloc resection of the mandible body segment with the overlying soft tissues of the floor of the mouth.

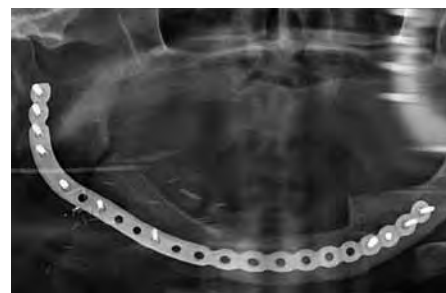


Fig 4
Primary fixation of implant, serving as a load-bearing bridge over the bone gap.

Fig 5
Reconstruction with revascularized scapular border composite flap.

Fig 6
Panoramic x-ray 1.5 years postoperatively.



Curvilinear Distractor

The new curvilinear distraction system is an internal distraction osteogenesis device that gradually advances the mandible along a curved trajectory of distraction. It addresses the clinical need for an internal mandible distractor that lengthens the mandible in both vertical and horizontal planes. It can be speculated that simultaneous expansion of the mandible in two vectors also results in a significantly increased retroglossal airway and therefore is of particular benefit in very severe cases of mandibular hypoplasia [1].

The system features various curved distractors which are fixed to the mandible with either locking or nonlocking 2.0 mm bone screws. All the distractors accept removable, flexible, or rigid extension arms from the CMF distraction system (see TK News 2/08) which move the point of activation to a location that is easily accessible with the activation instrument. The extension arms can be removed during the consolidation phase without a surgical procedure.

The distractor track is 35 mm long and can be cut to the desired length by the surgeon to accommodate individual patient needs. The underside of the track is etched to indicate the location where to cut to achieve the desired length. The end of the track is crimped to create a functional stop to prevent the distractor assembly from separating when fully distracted.

The curvilinear distractor is offered in left and right assemblies in several different radii of curvature, including 30, 40, 50, 70, and 100 mm. The distraction radius corresponds to the distance in millimeters from the center of a circle to the outer circumference of the circle. A smaller radius results in a tighter curvature of distraction as opposed to a larger radius which is closer to a straight path of distraction. The distractor is also offered in a straight version.

Curvilinear distractor bending templates are available for preoperative planning. They can be used with anatomical bone models to perform model surgery. The bending templates translate along the curved track. They are available in each radius and are helpful for:

- Selecting the appropriate radius of the distraction for an individual patient
- Determining the location of the osteotomy and placement of the device and screws
- Determining the amount of advancement necessary
- Bending the footplates and cutting the distractor track to the appropriate length

One full rotation of the activation instrument equals 1.0 mm of distraction. A minimum of 1.0 mm of distraction per day (one half turn twice daily) is recommended to prevent premature consolidation. In young patients, a rate of 1.5 to 2.0 mm per day may be considered.

The curvilinear distraction system is intended for use as a bone stabilizer and lengthening (and/or) transport device for correction of congenital deficiencies or posttraumatic defects of the mandibular body and ramus where gradual bone distraction is required.

The system is intended for use in either adult or pediatric patients over 1 year old. It is intended for single use only.

Reference

1 Looby J, Schendel S, Lorenz H, et al (2009) Airway analysis: with bilateral distraction of the infant mandible. *J Craniofac Surg*; 20(5):1341–1346.



Multiplanar mandibular with curvilinear distractor in a 16-month-old girl with Treacher Collins syndrome to improve mandibular and airway morphology and achieve tracheostomy removal.

Case provided by Derek Steinbacher and Scott P Bartlett, Philadelphia, USA

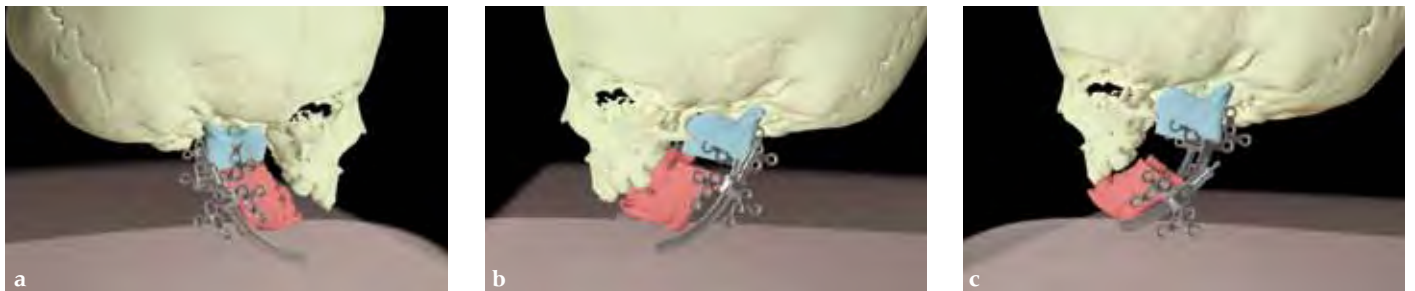


Fig 1a–c
Proposed curvilinear surgical plan.



a
Immediately after
distractor placement.



b
During distraction.



c
At completion of
distraction.

Fig 2 a-c
Lateral facial x-rays.



Fig 3a-b
Pre- and postdistraction 3-D CT scans
demonstrating curvilinear lengthening
of the mandible.



Fig 4
Predistraction.



Fig 5
During distraction.



Fig 6
Postdistraction. Note
significant improvement
in mandibular position
with closure of open bite
deformity.



Fig 7a-c
Lateral and frontal
views 6 months after
removal of the device.

Randy J Boudrieau, Brian Beale

VETERINARY



VET LCP Notched Head T-Plate

The VET LCP notched head T-plates are indicated for metaphyseal fractures of long bones in toy through to small-sized dog breeds, and cats. Its primary usefulness, however, is for the commonly observed distal radial and ulnar fractures in toy and miniature dog breeds. These fractures typically occur only 1–2 cm from the distal end of the bone. These fractures in the toy and miniature dog breeds require rigid fixation as there is reduced vascularity in their distal radius, resulting in an increased incidence of delayed and nonunions [1]. Because of the fracture location resulting in a small distal bone fragment, there is only sufficient room to place two screws with a T-plate design. The notch in the T-plate allows independent contouring of the plate at this level, facilitating its placement in the area of the radial groove adjacent to the articulation (for the extensor carpi radialis muscle tendon). The ability to place two locked screws at this level also enables a more secure fixation. Finally, the combination hole of this LCP allows standard screw fixation to be applied, where the fracture site can be compressed by loading the screw in the dynamic compression unit portion of the hole, thus increasing the fracture stability. Secondly, angulation of a screw also may be performed in the dynamic compression unit hole so as to avoid the fracture line. Locking screws subsequently may be applied in the threaded portion of the remaining combination holes, as indicated.

These plates have exactly the same design as the LCP condylar plates for use in humans. They are available in three sizes, 2.0, 2.4, and 2.7 mm. All three sizes feature seven combination holes in the shaft and two locking holes in the plate head. The plates may be cut in order to obtain the desired length. The low profile of the plates with rounded edges and a highly polished surface minimizes soft-tissue irritation (for example, under the extensor tendons of the distal radius). The plates can easily be bent or cut with the respective instrumentation.

Reference

I Welch JA, Boudrieau RJ, Déjardin LM, et al (1997) The intraosseous blood supply of the canine radius: implications for healing of distal fractures in small dogs. *Vet Surg*; 26(1):57–61.

A 1-year-old female Yorkshire Terrier (1.7 kg) fractured the right distal radius and ulna (similar to a Colles fracture in humans).

Case provided by Randy J Boudrieau,
North Grafton, USA



Fig 1a–b
Craniocaudal and lateral x-rays of the right radius and ulna preoperatively. A distal oblique radial fracture is observed.



Fig 2a–c
a–b Craniocaudal and lateral postoperative x-rays of the right radius and ulna.
c Shows the slight (~1 mm) craniocaudal malalignment of the fracture reduction (arrow).



Fig 3
Lateral x-ray 8 weeks postoperatively of the distal radius, centered on the area of the fracture. The fracture has healed.



Open reduction and internal fixation was performed using a 7-hole 2.0 mm VET LCP notched head T-plate (a 7-hole plate was cut to eliminate the proximal two combination holes). The fracture was reduced and the distal bone fragment secured with two locking screws; the notch in the T-plate allowed independent contouring of this portion of the plate adjacent to the articulation. Compression was then applied across the fracture by loading one screw (second screw-hole proximal to the fracture); a second standard screw was then secured adjacent to the fracture (angled away/proximal to the fracture). The remaining screws were placed in a locked fashion. Despite the attempt at anatomical reduction, a slight (~1 mm) step was observed in the craniocaudal reduction (Fig 2). No fixation was applied to the ulna. A soft, padded bandage was applied to the forelimb (distal to the elbow joint) for minimal support and to control swelling.

The dog was discharged from the hospital 2 days postoperatively with instructions for strict exercise restriction; the dog was ambulatory on all four limbs at this time, although lame on the right forelimb. The bandage was to be removed in about 5–7 days. The dog did very well and was reevaluated 8 weeks postoperatively, at which time x-rays revealed a healed radius and atrophic ulna (Fig 3—the ulnar atrophy is the norm in the canine for this repair in these small dog breeds). The dog was fully ambulatory and without lameness at this time; however, there was a slight decrease in full flexion at the antebrachio-carpal joint—again, this is the norm with this repair due to the surgical dissection and plate placement under the extensor tendons, which does not cause any functional deficit in the dog. The dog was gradually returned to full activity over the ensuing 2 weeks. It is recommended that these dogs not be allowed to jump from heights (eg, bed, chair) as they are at increased risk for this fracture, regarding the opposite limb in this patient.



TPLO 3.5 mm Small Stature

Cranial cruciate ligament (CrCL) injury is the most common cause of hind-limb lameness in the dog. This injury is frequently treated with the tibial plateau leveling osteotomy (TPLO). The TPLO procedure dynamically stabilizes the knee by eliminating cranial tibial subluxation during the weight-bearing phase of locomotion. The slope of the dog's tibial plateau is much greater than its human counterpart, which results in increased loads on the canine CrCL. Unlike ACL injury in humans, many canine CrCL tears start as a partial tear and progress to a complete tear due to degenerative changes occurring in the ligament.

The TPLO system is indicated for osteotomies of the canine proximal tibia and combines plates with a basic instrumentation set. The plates are pre-contoured to match the anatomic configuration of the medial aspect of the proximal tibia with a limited-contact design and optimal screw placement in the proximal region of the tibia. The plates are available in left and right configurations and feature locking-screw technology.

Until recently, the plates were available in three different profiles: 2.7, 3.5, and 3.5 mm broad. Now, a 3.5 mm plate for small stature was added to the system for use in heavy, but small-boned dogs (ie, bull terriers, bulldogs). The plates and screws are available in stainless steel. The TPLO plates can accommodate locking or cortical screws that correspond to the size of the plate used.

The TPLO 3.5 mm small stature is placed on the medial surface of the tibia. The plate fits very proximally and just distal to the articular surface. In addition, the neck of the plate sits directly over the osteotomy cut. The screw size and pattern provides sufficient strength in the candidate canine's tibia. The locking holes are appropriately angled so that the screws will not impinge into the joint or the osteotomy when the plate is applied with proper technique. The head of the plate is also designed to accommodate the placement of a positioning jig.

TPLO is used to treat complete and partial CrCL tears. Early treatment of partial CrCL tears by TPLO has been shown to protect the remaining fibers of the CrCL and reduce the chance of future osteoarthritis and meniscal injury. The osteotomy typically is healed within 8 weeks and return to function can begin progressively after evidence of x-ray healing. The long-term prognosis is excellent.

Case 1: A 4-year-old, female, spayed, 33 kg English bulldog had a CrCL tear and a medial patellar luxation. The small stature 3.5 mm TPLO plate was perfect for this dog due to the small profile of the bone and the need to use a heavier plate (3.5 vs a 2.7 mm). In the past, veterinary surgeons have been forced to either squeeze the standard TPLO 3.5 mm plate on the bone or use an undersized TPLO 2.7 mm plate. In this patient, the shorter and smaller profile head of the small stature TPLO 3.5 mm was perfect.

Case provided by Brian Beale, Houston, USA



Fig 1a–b
Preoperative
images.

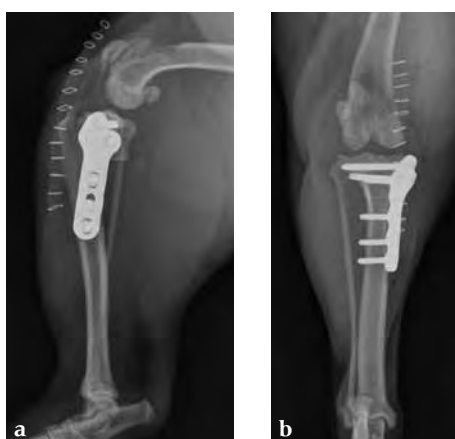


Fig 2a–b
Postoperative
images.

Case 2: An 8-year-old, female, spayed, 24 kg Australian cattle dog. This breed has short stocky legs and is very energetic and strong. The added strength of the 3.5 mm plate over the TPLO 2.7 mm plate was an advantage. The smaller head profile and shorter length of the TPLO 3.5 mm small stature plate allowed it to fit nicely on this patient.

Case provided by Brian Beale, Houston, USA



Fig 1 a–b
Preoperative
images.



Fig 2a–b
Postoperative
images.



Fig 3a–b
Images taken
7 weeks postop-
eratively.

Beate Hanson, Diarmuid De Faoite

PRACTICAL TIPS ON HOW TO PERFORM A STUDY



The publication that results from a study is just the tip of the iceberg. It is the visible end-product of many phases which have contributed to a study's success. While it is impossible to completely cover everything in one article, the following points are some practical tips derived from AO Clinical Investigation and Documentation's (AOCID) long experience in the conduct of clinical trials. The planning and study design stage is absolutely critical which is why it is the only section highlighted and presented as a step-by-step process.

Planning and study design

1. Do preliminary research

Find out more about the topic that interests you (eg, search on PubMed, the Cochrane Library, hold discussions with your colleagues, consult professional forums, etc). Ensure your idea has not already been tried.

2. Consider the purpose of your study

What is the rationale for conducting your study? Why was the new implant developed and what is its added value? What makes the new technique more beneficial for your patient compared to the standard approach? Can you find a way to compare A to show it's better than B? If you think of your idea as being simply "interesting to look at" then you should seriously reconsider it. Another possible question to ponder is what possible results from the trial are likely to change clinical practice/improve patients' lives?

3. Plan your clinical question carefully

Your clinical question will determine how good your study is, so define it very precisely. It is the bedrock upon which your study's success will be built. The PICOT acronym (Patient, Intervention, Control, Outcomes, and Timing) is a very helpful scaffold upon which to start building your research. For example, if you have a diagnostic question you might consider the following PICOT factors:

<i>Patient</i>	– Which patient group? Consider patient characteristics that may affect outcomes.
<i>Intervention</i>	– Define the diagnostic procedure of interest (eg, a new technology).
<i>Control</i>	– Is there a gold standard? If necessary, you have to define the control group to which the intervention group will be compared.
<i>Outcomes</i>	– Be specific and aim for the most important outcomes (eg, nonunion, major complications, death, etc).
<i>Timing</i>	– How long will the study last? How many follow-up visits and when?



4. Find an acceptable study design

Decide on this very carefully once all the necessary information is to hand. Let your clinical question and resources guide your choice of study design.

5. Sample size and feasibility

A sample size of 500 patients in an indication where you see 20 patients yearly is not going to work. Be aware of Lasagna's law which states that the number of patients available to join a trial drops by approximately 90% the day a trial begins, only to reappear as soon as the study is over. Remember that some fracture types are rare. Be prepared for such studies to only recruit small numbers of patients and for their recruitment to be painfully slow.

Two to five years follow-up is a very difficult task. Once healed, injured patients often do not return to their doctor so in most cases you will have to chase them up.

6. Implement a study-design freeze at an early stage

Don't have the design questioned at every instance. Good clinical practice dictates that you cannot change a study design once the first patient has been recruited.

7. Clearly define everything in the study protocol

This is an essential document which allows you to ensure uniformity for all the investigators and sites involved in the study.

8. Don't make your inclusion criteria too restrictive

Obviously you need to exclude certain types of patients but be careful that you do not shut out those who may still be acceptable for the study's purposes. Broad exclusion categories such as "active systemic infection" should be more exactly defined to help widen the net of eligible study participants.

Some general points to remember

Have clear communication with stakeholders throughout the study process

At AOCID, in addition to the regular updates through meetings and personal contact, we send out a newsletter for each study approximately three times per year to ensure that all the stakeholders are aware of how things are progressing. Provide information on the number of patients included and the follow-up rates for each site.

Define roles, and trust in the other's expertise

The principal clinical investigator (PCI) is the expert in the operating room but the clinical (or contract) research organization (CRO) is the expert in the planning and conduct of the study. A mutual respect for one another's competencies helps the process.



Regulatory problems with the medical device approval process

The approval process can vary from country to country and lead to bottlenecks in the study. Do not assume your planned national timeline will hold true for international studies.

Do not forget to get informed consent

There are intrinsic elements to trauma studies which make obtaining informed consent difficult. You may be faced with unconscious patients, or find it difficult to explain the study as the patients are in pain. Similarly, it may be hard to obtain consent as patients could be whisked into the operating room within a short time after admission. Prepare for this and make allowances in the study protocol, eg, by allowing proxy consent if appropriate.

Comorbidities

Consider your patient cohort carefully as comorbidities can play a negative role in follow-up rates. For example, mortality rates of approximately 30% in elderly patients with hip fractures will naturally lead to low follow-up rates.

Rehabilitation protocol

Be aware of the effect that this can have on outcomes. Ensure that the same standardized procedures are in place in all participating centers.

Outcome

Respect cultural differences if you perform a study in different countries

Use only patient-assessed scores that have been cross-culturally adapted and validated. Do not translate scores yourself for clinical use.

Avoid selection bias

Consider the population you would like to make inferences about and whether your sample size is truly representative of it. Not all conclusions may be transferable to other population groups. If there is a possible selection bias it is essential that this is also reported (eg, conducting a study in the military among young, healthy males).

Do not be shy about reporting complications

Knowledge of complications is very important to the improvement of patient care. So try to shake off the feeling that comprehensive and complete reporting of complications will handicap your chances of publication, reflect badly on your surgical skills, etc. In the end, it will assist many more patients and help to avoid future adverse events.

Regulatory

Find out and follow the legal framework in place

Remember that there is no clinical study without ethic committee approval and the patient's informed consent.

Ensure your clinical study has been entered into a registry

It's a prerequisite for publication in many journals these days. The best-known is probably www.clinicaltrials.gov but there are other registries, such as www.anzctr.org.au which are also acceptable.

Get agreement from all parties before proceeding with ethic committee submission

Bear in mind that there is a cost to submitting and resubmitting to ethic committees. For example, the cost of submitting to a German ethic committee is generally around € 1,500. You may have to apply to several such committees and their processes can vary—even within the same country.

At the clinic

Make sure your study center personnel are adequately trained

The initiation of a study is crucial. Ensure that all material is available and that enough time is given to train all the relevant personnel. Get them to “buy into” the study from the very start so that they are actively screening patients for recruitment in their daily clinical practice.

Early monitoring may save you future headaches

A first monitoring visit/check after only a few patients have been recruited can help to identify and correct systematic mistakes at an early stage, thereby saving a lot of time later on.

Try to anticipate issues and head them off

For example, be aware that less experienced staff members at your center will probably require closer support and more training and supervision than others.

Keep your database constantly clean

This means ensuring that there is ongoing monitoring, ongoing data checks, etc.

Data management

Have adequate procedures in place to ensure data quality. Do not wait until tomorrow to reply to a request if you can do so today.

Don't be afraid to delegate

You're most likely working full-time and are in the OR most of the time. If your center can afford it, consider having a study nurse to manage your study documentation and data for you. AOCID has had very good experience with this arrangement.

Final report

Define clear timelines

Remember that with so many actors involved the review and approval process can take a long time—which can be frustrating when you are so near your goal.

Finally, share your work with the world!

Do not forget to celebrate your achievements. Submit your manuscript to a journal, go to conferences and share your new knowledge with the scientific community.

For more information on conducting clinical studies and information about AOCID's services, please visit www.aofoundation.org/cid or write to us: aocid@aofoundation.org.



Tim Pohlemann

TK INNOVATION PRIZE AWARDED FOR THE PLAYGROUND



Fig 1
Paul Manson, Romano Matthys-Mark, Emanuel Gautier, and Tim Pohlemann at the awards ceremony.



Fig 2
Romano Matthys-Mark.



Fig 3
Innovation Team.
Claas Albers, Urs Schlegel, Dieter Wahl, Peter Däscher, Romano Matthys-Mark.

The TK Innovation Prize was awarded at the Trustees meeting to Emanuel Gautier and the ARI Innovations Team, lead by Romano Matthys-Mark, for the development of the Playground.

The Playground is a technical parcours for orthopaedic trauma surgeons with a focus on surgical skills. It is an innovative, clever way to enhance knowledge about the underlying principles by enabling surgeons to get a “feeling” for various surgical techniques. It enhances the educational offerings of the AO Foundation with a component that is very unique and practical.

The driving forces behind this concept and its implementation are Emanuel Gautier, Fribourg, Switzerland, Romano Matthys-Mark, Davos, Switzerland, and parts of the ARI Innovations Group.

Emanuel Gautier is a former AO Fellow at the ARI with Stephan Perren (1980–1983, 1985). He trained with Reinhold Ganz, Thomas Rüedi, Hans-Beat Burch, and Arnold Huggler. Since 1996, he is the co-Head of the Department of Orthopaedic Surgery at the Kantonsspital Fribourg, Switzerland. Besides many other things, he is a renowned specialist for pelvic and acetabular fractures. Emanuel Gautier is an explorer, always wondering, questioning, and interested in the principles and background.

Romano Matthys-Mark is AO “home-grown”. He joined the AO at the age of 22 after his university degree and has been with the AO Development Institute and the AO Research Institute for 16 years. Currently, he is the group leader of the Innovations Team.

From the Innovations Team, the following individuals have contributed greatly and were also honoured: Urs Schlegel, Dieter Wahl, Peter Däscher, AO Foundation, and Peter Toggwiler, who works for the Academy for Medical Training and Simulation (AMTS), Bern.

It is worth mentioning that Emanuel Gautier donated his prize money to support Jim Harrison’s project in Malawi.



Fig 4
Playground in action.

Pol Rommens

PORTRAIT



Fig 1
Stefaan Nijs, MD.

The AO should be grateful to have Dr Stefaan Nijs as one of their most active and engaged members of the young generation.

Stefaan was born in Belgium on May 11, 1969, is married to Ilse Pauwels, and is father of three sons: Jef, Lowie, and Jul. Stefaan studied medicine at the Catholic University of Leuven between 1987 and 1994. He then trained as a general surgeon at the University Hospital Gasthuisberg of the same University between 1994 and 2000. Between 2000 and 2001, Stefaan was resident at the Department of Trauma Surgery at the University Hospital of the Johannes Gutenberg University of Mainz, Germany. He returned to Leuven in 2001 to become a staff member of the Department of Trauma Surgery. He was supervisor till 2003 and has been adjunct Head of Department since then. In 2003 he successfully completed a postgraduate study of hospital management. Stefaan successfully defended his doctoral thesis on “The rotator cuff insufficient shoulder in trauma patients” in February 2010. Stefaan’s favorite hobbies are watching premier league football with his sons and listening to heavy metal music.



Fig 2
Stefaan and son, Jul.

Stefaan started a national and international career early in service for trauma care. He began his “AO career” with the basic course in Bochum in 1998, the advanced course in Davos in the same year, and the course for peripheral osteosyntheses in Oberdorf in 2001. He became the second President of the Belgian Trauma Society in 1997, and national delegate for Belgium in the European Society for Trauma and Emergency Surgery (ESTES), and its Congress President in Brussels, in May 2010. His special professional interest is in shoulder and elbow surgery. In recent years Stefaan has organized an anatomical specimen workshop on approaches in shoulder and elbow trauma surgery in cooperation with the Institute of Anatomy at his University. He has given more than 500 presentations of which more than 300 have been at international congresses, workshops, and seminars. In 2006 he was awarded a research grant from the Robert Mathys Foundation for his project “Biomechanical evaluation of stability of different systems for tuberosity fixation in fracture shoulder arthroplasty”. He was involved in several AO development projects, such as the dynamic hip screw blade and the X-mas tree humeral nail.

Stefaan is clever, adroit, and a particularly indefatigable surgeon and teacher. He is a humble and honest person with a critical, experienced view on problems of the care of our injured patients. With his thorough analyses, Stefaan is an opinion leader in the field of trauma care in upper extremity surgery. Whenever you meet him on one of his trips, you will hear an experienced and engaged surgical speaker with considered and elaborated views on actual problems in trauma care. With his driven lectures, surgery, and clinical research, Stefaan thoroughly supports AO in its core activities. We are very glad to have him as a member of our AO family!

Tim Pohlemann, Christoph Nötzli

4TH AO EXPERTS' SYMPOSIUM ON INTRAMEDULLARY NAILING AND PLATING

The 4th AO Experts' Symposium in the AO Asia Pacific region took place in Shanghai on June 22–23, 2010. The symposium was jointly organized by the TK System and AO Asia Pacific, and was chaired by Bingfang Zeng, local chairman, and Tadashi Tanaka, AO Asia Pacific President. Surgeons from several countries of the Asia Pacific region exchanged their clinical experiences in locking compression plate systems and the expert intramedullary nail family. Clinical issues, problem fractures, complications, and limitations of the existing techniques were discussed followed by case presentations of the participants. The main findings are summarized here by anatomical region.

Proximal humerus

In the proximal humerus, reduction must achieve direct contact between the fragments on the medial cortex in any type of fixation to avoid varus malalignment and to avoid implant failure in the long term. As the approach for a plate fixation is from the lateral side and the approach for a nail through the rotator cuff, the manipulation of fragments in the medial column is challenging and good instrumentation to support its restoration needs to be developed. Additionally the next generations of implants should provide options to “reach” the fragments on the medial side and hold them in their optimal position. In any case the blood supply in the medial column needs to be carefully preserved/reconstructed to allow optimal healing in this very sensitive region and the involve-

Fig 1
Discussions at the
4th AO Experts' Symposium.



ment of vascular surgeons should be considered. It was agreed that nails have limited indications in the proximal humerus, but have their place in the hands of experts, even in C1 fractures. It was agreed that the improvement of the surgical techniques with additional instrumentation is more important than the improvement of implants in the proximal humerus and the development should be enforced in this direction.

Proximal femur and neck

Trochanteric split fractures are observed at a higher rate in the Asia Pacific region compared to the rest of the world. This region's specific problem has to be addressed by appropriate treatment strategies. In the proximal femur nailing procedures have grown remarkably and replaced to a certain extent dynamic hip screw plating. After a learning curve in the surgical community and also the development of new generations of nails, the complication rates could be reduced to approximately the same level as with dynamic hip screw plating. If the entry point of the nail is through or nearby a fracture line the opening needs to be made very carefully holding the fragments together by temporary fixation in good reduction to avoid further displacement of the fragments after nail insertion. With all fixation methods the correct placement of the blade or screw in the neck is crucial to provide good purchase and enough stability. Most surgeons would prefer nailing in subtrochanteric and intertrochanteric fractures, but depending on the fracture pattern would also use plating. The importance of good anatomical reduction was pointed out and there is a high demand for improved instruments and techniques to facilitate this procedure.

Distal femur and knee

In the distal femur and knee joint vascular damage cannot be ignored and compartment syndrome can cause real problems even if it seems not to be severe. Additionally the risk of infection is higher than in other areas of the body. To avoid problems with the healing process both risks have to be carefully considered and minimized. With fractures near the joint CT scanning is nowadays routinely used in Asian hospitals. A specific plate should be considered for the distal medial femur. In complex fractures the fracture reduction and keeping the reduction is still an issue. Again, specifically designed instruments for reduc-

tion and additional anatomically shaped implants for specific fracture types are still not available and further development is needed.

Proximal tibia

In the proximal tibia the variability of the bone is quite remarkable and the fit of the anatomically shaped plates in some cases compromises the soft tissue. Reduction and maintaining reduction after fixation is still a challenge. Buttress plating to keep the reduction in the posterior parts has to be enforced and specific plates should be developed accordingly. The use of an interlocking plate as an external fixator in cases with soft-tissue damage was discussed. Single-use external fixators appropriately shaped like an external LISS might be considered as a solution. Modular attachments to such fixators could facilitate joint reconstruction. Nailing in the subarticular area is very challenging and the reduction has to be done perfectly before nail insertion. Nailing in those cases is for experts only. Nevertheless, nailing might be advantageous in cases with a compartment syndrome as no incisions are needed in the involved and/or damaged soft tissues. Additional instruments for fracture reduction and to maintain reduction during implant fixation are needed. Infections and bad soft-tissue conditions may lead to prolonged healing or even to soft-tissue necrosis and severe damage including salvage procedures, bone transportation, or the like. The management of such cases is very difficult and not only physically, but also psychologically challenging for the patient as well as the surgeon.

Distal tibia

In the distal tibia soft-tissue conditions must be considered carefully. Approaches and fracture treatment must be chosen accordingly. Infections, soft-tissue necrosis, compartment syndrome, and other soft-tissue complications require careful management of the healing process. Fractures in the pilon need to be perfectly reduced and the fixation must maintain reduction over a long period of time. Reducing and fixing fibula fractures with plating is recommended to provide additional stability, although the primary treatment is done with nailing in the tibia. The distal tibia is still an area with high complication rates, even if many options for the fracture treatment are available using the numerous plates developed especially for around the ankle joint.



Fig 2
Book-prize winner Chou Ying Chao, Chang-Gung Memorial Hospital, Taiwan, China.



Fig 3
Book-prize winner Xiang Ming, Sichuan Orthopedic Hospital, China.

Book prize for interesting case presentation

Three book prizes were awarded to:

1. **Chou Ying Chao**, Chang-Gung Memorial Hospital, Taiwan, China
2. **Xiang Ming**, Sichuan Orthopedic Hospital, China
3. **Tang Xin**, Dalian Affiliated Hospital of Dalian Medical University, China

Summary

The AO Experts' Symposia are an excellent forum to analyze problems. While some problems are due to implants and some due to the surgeon, open discussion of such mistakes helps to decrease the overall failure rate in the future. The Symposia are part of the success control in the TK milestone concept which allows analysis of problems at an early stage. The screening of clinical problems helps to expand or limit the indications, triggers further developments, and enforces education by identifying tips and tricks as well as possible dangers.

There is still a lot to do in the following areas of development and education:

- Assessment: soft-tissue damage/conditions, amount of visualization of the fracture/bone, planning
- Reduction: improvement of instrumentation needed to support reduction, temporary fixation, and fixation
- Stabilization: region-specific fit of anatomical implants, region-specific problems/complications



Fig 4
Participants of the 4th AO Experts' Symposium.

Clinton Miner

AOTRAUMA EUROPE: MASTERS COURSE PROGRAM 2011



AOTrauma has been listening to you and your colleagues through our Lifelong Learning interviews around the globe, focus groups, surveys, and course feedback. Your message is clear. Your CME needs include masters level, anatomically focused seminars, and anatomical specimen workshops meeting the highest academic standards. In 2011 we are adding these 1- to 2-day focused CME activities to the already very successful national courses that are planned. This concept is also being considered for our Davos 2011 program in the form of a “build your own course format”.

You will first see these new masters-level programs offered by AOTrauma Europe (AOTEU) for 2011. We will initially offer five anatomical specimen workshops, each focused on an anatomical area and five seminars, each focused on a specific topic or indication. These events will provide you with the opportunity to examine complex clinical problems, best practices, and ground-breaking interventions with some of the surgical leaders in the field.

The AOTEU Masters Program for 2011 includes special topic seminars and anatomical specimen workshops that include:

- Trauma of the proximal humerus
- Intramedullary nailing
- Periprosthetic fractures
- Geriatric fractures
- Upper extremities
- Foot and ankle
- Osteotomies around the knee

Registration will be limited to allow for more discussion, extensive hands-on experience, and personal interaction with the expert faculty. The short, intensive format allows for an in-depth experience of discussion, debate, and practice.

For more details visit www.aotrauma.org

Emanuel Gautier, Chairperson AOTrauma Europe Education
Steve Schelkun, Chairperson AOTrauma Education Commission
Michael Wagner, Chairperson AOTrauma International Board



Michael Fawcett

NEWS FROM AOSPINE



Fig 1
EBSJ.



Fig 2
Jens Chapman, Editor-in-Chief and Scientific Editor-in-Chief, EBSJ.

Evidence-Based Spine-Care Journal (EBSJ) is a cutting-edge journal dedicated to finding, describing, and developing the highest quality evidence. This peer-reviewed journal sets the stage for evidence-based practice and will influence the future of spine surgery for years to come. EBSJ focuses on comparative studies of effectiveness and seeks to stimulate further areas of high-quality, spine-related research.

While EBSJ is a new journal, it has evolved from the Evidence Based Spine Surgery Journal (EBSS) that was published for 5 years. The main difference between EBSS and EBSJ is: EBSS summarized findings based on advances found in current literature, whereas EBSJ publishes original research articles.

Q&A with Jens Chapman—Editor-in-Chief and Scientific Editor-in-Chief of the Evidence-Based Spine-Care Journal (EBSJ).

What was it like for you as Editor-in-Chief to experience the launch of a new journal?

Creating a new journal was most exciting. As with any new venture in a large organization, such as the AO, there were inertia and some difficulties to overcome. But people were incredibly helpful. Over the 2 years that it took to finally launch this journal, we realized repeatedly how tremendously powerful the AO is and what amazing spirit exists within the community that helped make this project come together. The difficulties were minor—people not wanting to support it initially and people having different ideas. The challenge was to get everyone on the same page but in the end we made it happen.

What do you think makes EBSJ so attractive as a scientific journal, knowing that many members that read EBSJ will already be subscribing to other academic journals, such as Spine?

With EBSJ, our emphasis is clearly on a high-standard production. All graphs and abstracts that accompany submissions are consistently produced in-house. The assistance we offer on the graphics, statistics, and layout issues lowers significantly the threshold for publishing an article. We always ask for the source data of the information supplied and are therefore very much in the know that the data being used is of as high quality as possible. Good data is the key to high scientific value.

The resulting articles are condensed, with concise and point-driven information. Key facts are represented in a practical and abbreviated format, making them easy to read for people with busy schedules. Counterpoints are placed at the end of the article to allow for rapid critical review by the reader.

One of the journal's features is a more efficient production model with specific guidelines for submissions.

Why has this methodology been adopted?

Most journals have a very lengthy and opaque process of submission and reviews. It often takes 6 months or longer to get information back on what is happening with the submitted articles. All journals have a submission process, but most of them are slow and inefficient when it comes to assigning follow-on tasks. EBSJ's submission process is more efficient, the reason being multifactorial:

1. We speed up the submission process by guaranteeing a 30-day review cycle.
2. Our guidelines specify a limited number of words, so that authors concentrate on the essential facts right from the start.
3. All submissions receive a complete and expedited methodology review that points out and analyzes strengths and weaknesses of the article. This is done by PhD reviewers who concentrate on ensuring quality information and follow tight production time lines.
4. The PhD reviewers then pass the articles to clinicians for a second round of reviews. This peer-review completes the submission cycle.

The resulting end-product is therefore more systematic and information driven. Authors can, throughout the review cycle, check the status of their submissions on our submissions website.

Are you getting enough submissions for articles?

And who can actually submit an article?

Being a new journal, we are having some challenges with getting enough submissions; which is the single most critical point as the journal lives off quality submissions. Any medical doctor, PhD, or healthcare professional in the area of spine is invited to submit an article.

Why should people submit to EBSJ?

EBSJ's submission guidelines make it easy for authors to get their concepts across, no matter what country they are from and what language they speak. Not only do we offer support when it comes to article presentation, but we also provide language experts for those who would otherwise be unable to submit to scientific journals, due to the language barrier.

Become an author and benefit

- Share your expertise with 5,000 AOSpine members and contribute to the global-knowledge base for the spine-care community as well as supporting your colleagues.
- EBSJ encourages authors and researchers across the globe to learn about research quality and reporting by providing constructive feedback on study methods and clinical review by respected experts in the field.
- High-quality standards exert the most influence on our professional credibility and how we are reimbursed.
- Our streamlined manuscript format makes effective use of the author's time and concisely presents pertinent information.
- We provide quick turn-around for publication decisions: 4–6 weeks.
- A unique opportunity to be published in early 2011.

Interested authors should contact ebsj@aospine.org for more information.

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