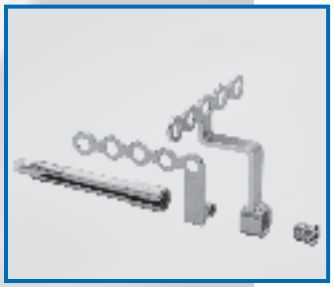
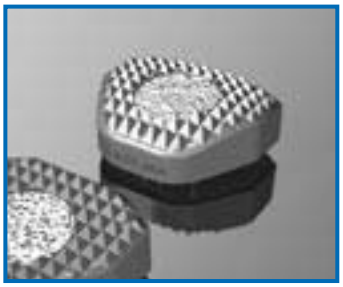
AO Development

News

New Products from AO Development





News—Number 1 | 2003

Dear Reader,

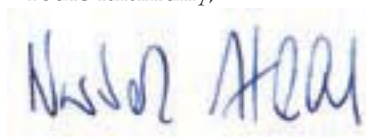
Working with surgeons from all over the world and different specialties on new developments and products is truly one of the most exciting tasks I ever have experienced. It is thrilling to watch how an idea from a motivated surgeon develops as a team effort together with researchers and engineers into a new technology. It is also very rewarding to meet new, interesting people who are dedicated to finding solutions for clinical problems. Let me encourage you to become part of this great organization and the very special AO spirit. We are always very interested in your ideas and/or comments to existing AO techniques.

In this issue of *New Products from AO Development* we have asked Rainer Schmelzeisen, MD, chairman of the AO Craniomaxillofacial Expert Group to provide us with an outlook on his specialty. Even if you are not operating in this area, I am convinced that you will find his ideas in tissue engineering and endoscopy fascinating. And hopefully, it may also make you look at the new craniomaxillofacial products with a different perspective. Within AO Development, the exchange of experiences and technologies between spine, craniomaxillofacial, general trauma, and even veterinary surgery has proven to be very fruitful.

I would like to stress that none of the articles in this brochure are a substitute for the relevant OP Technique and the AO teaching tools. Please get more detailed information on the products from your local Synthes representative.

Last but not least, a wholehearted thank you to our Synthes partners, who have supported us in different ways, and to all the contributors of this third issue, especially to the medical doctors who have also participated in the development of the described products.

Yours faithfully,



Norbert P. Haas

Contents

Rainer Schmelzeisen

News in craniomaxillofacial surgery

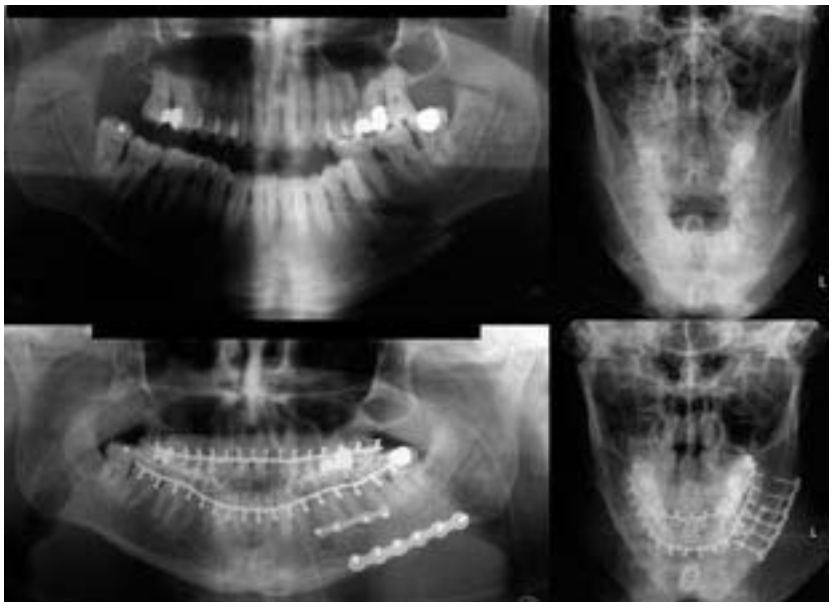
The Craniomaxillofacial Expert Group (MFEG) is working towards innovative approaches and widening the scope of products following clinical testings in craniomaxillofacial surgery.

Priorities of the group are expanding applications of implants in neurosurgery and skull base surgery, biotechnology, and new endoscopic techniques. In craniomaxillofacial trauma new techniques of endoscopic fracture reduction and plate fixation have been initialized and continuously improved. Following the presentation of a prototype for endoscopic fixation of condylar fractures at the Expert Group Meeting in 1996, the constant activity of the group in close cooperation, especially with Synthes USA and AO Development in Davos, led to a completely new set for the intraoral treatment of condylar fractures. Meanwhile, there is a worldwide need for continuing education of this new type of surgery. First steps are being undertaken for endoscopic treatment of orbital and frontal sinus injuries (Fig. 1).

Fig. 1: Control view following endoscopic-assisted reduction and fixation of a right condylar fracture.

The development of endoscopic techniques is paralleled by a widespread clinical application of locking systems in craniomaxillofacial surgery. It is expected using these systems, that act as an internal fixator, may significantly drop the complication rate (Fig. 2). These systems may have implications on the work of other Expert Groups as, for example, in hand surgery.

Fig. 2: Pre- and postoperative x-rays of a severe dislocated fracture of the left mandibular body in a 32-year-old man. Fixation with two Locked Mandible Plates (small and medium).



Establishing systems for computer-aided surgery and navigation in craniomaxillofacial surgery has been disappointing. Up to now, it has not been possible to establish tools that match the possibilities of comparable systems. Computer-aided surgery and navigation is regarded as a "door opener" for clinical research in many clinics and further attempts should be made to develop craniomaxillofacial navigation up to a state-of-the-art level in the AO.

A steady development has been achieved in biotechnology. An important event was the Biotechnology Meeting in Freiburg, held on March 28, 2003, with the Chairman Norbert Haas and the Chairmen of the MF and the Shoulder Expert Groups. More than 100 participants—internationally known scientists, producers, and surgeons—contributed to this meeting. Topics included cell proliferation, bone substitute materials, gene therapy, and growth factors. This activity is expected to increase within the AO in the future; another symposium on biotechnology and its future aspects in the AO will be held next year.

With increasing demand for specialized knowledge in areas other than implants, the MFEG will steadily involve experts of other fields in its meetings. During the last meeting of the Group in Tucson/Arizona, an internationally well-known scientist, Dr Cesar Guerrero, from Venezuela presented his outstanding experience with the application of distractors in craniomaxillofacial surgery.

Building up networks and involving specialists of non-AO specific fields will not only be the future challenge for the craniomaxillofacial group within the AO. We would regard the abbreviation AO in that environment to read as "always open", as an essential precondition to maintaining leadership in innovation and quality assurance in traumatology and reconstructive surgery.

Rainer Schmelzeisen

New craniomaxillofacial products

Maxillary Distractor

The Maxillary Distractor is a completely intraoral distractor designed to meet the clinical needs for a distraction device that can correct severe maxillary bone deficiences in both, AP and vertical, directions. It is advantageous for patients with maxillary hypoplasia, particularly cleft lip and palate patients, due to its ability to overcome the substantial soft-tissue forces around the maxilla. The Maxillary Distractor includes a posterior foot plate and an anterior foot plate, which are completely interchangeable and pinned to the body of the distractor. Overall, the Maxillary Distractor offers four distractor lengths and the ability to create 72 custom sizes with the available foot plate options.

22 mm Cranial Tube Clamp (line extension)

The Cranial Tube Clamps rapidly reattach a cranial bone flap back to the skull after a craniotomy. They provide rigid fixation to protect the brain and to encourage healing of hard and soft tissues. When used over a burr hole, the Cranial Tube Clamp also helps prevent tissue from entering or exiting the cranium, further protecting the brain and improving cosmesis. The 22 mm Clamp utilizes two 22 mm diameter discs in conjunction with a standard length tube shaft.

Cranial Flap Tube Clamp with textured surface (line extension)

The Cranial Flap Tube Clamps with textured surface rapidly reattach a cranial bone flap back to the skull after a craniotomy. When creating craniotomies in the posterior regions of the cranium, there are areas of greater concavity on the interior surface of the cranium. Due to its higher surface roughness, the Cranial Flap Tube Clamp with textured surface enables the clamp to grip the bone more aggressively, which increases the rigidity of the fixation.

3-Point Bending Pliers

The 3-Point Bending Pliers allow bending of the Midfacial Plates 1.5 and 2.0 with center space using one pair of bending pliers only. The pliers allow bending in plane by means of the three prongs on the tip of the bender, in plane by means of the groove in the tip of the bender, and out of and by the "scissor"-like tip of the bender. The pliers cannot be used for bending plates without center space since the screw holes would be deformed.

Low Profile Neuro System

The Low Profile Neuro System offers a complete line of plates, screws, meshes, and instruments designed to close bone flaps quickly, enabling stable internal fixation and addressing especially neurosurgical problems with the lowest plate/screw profile of any self-drilling product available on the market. The Low Profile Neuro System includes all plates and meshes currently available in the Cranial System 1.3 and 1.5 as well as the new Ti Low Profile Neuro Strut Plates and the new Ti Low Profile Neuro Adaption Plates. The Low Profile Neuro System offers new Ti Low Profile Neuro Self-Drilling Cranial Screws with greater strength and an improved cruciform drive system that delivers superior blade/screw retention and off-axis stability.

Screw Replenishment Device

Restocking of modules with screws, especially with very small and short screws, is a very fiddly and time-consuming work. This screw loader is designed for easier and faster restocking of small screws into modules. It works for 1.0, 1.3, 1.5, and 2.0 mm screws.

Hex Coupling Screwdriver Handles and Blades (line extension)

Three new Hex Coupling Handles in the dimensions small, medium, and large are available. The Handles have a textured distal end, which distinguishes them from the mini-quick handles.
The new 1.0, 1.3, 1.5, and 2.0 mm Cruciform Blades with holding sleeve and Hex Coupling come in a long as well as a short version and are also usable for bioresorbables. The new Holding Sleeve features a definitive snap when the sleeve engages the screw and is easier to assemble and disassemble.

Mandible Locking Plate 2.0—Bending Templates

The Bending Template for the Mandible Locking Plate 2.0 helps contouring of the plate. The templates are manufactured out of AL1100FN1 which is an aluminium alloy well suited for this application due to its strength and ductility.

Zygomatic DCP, 4 holes with space

The Zygomatic DCP 2.0 with 4 holes and center space is a line extension of the existing 5-hole Zygomatic DCP 2.0 with the same dimensions. The new plate is more stable and offers a larger distance to bridge the fracture.

Ratcheting Screwdriver—New Handle

The new Ratcheting Screwdriver for manual insertion and placement of Synthes' 2.0 mm, 2.4 mm, and 3.0 mm maxillofacial screws features a more ergonomic handle made of standard medical grade phenolic and stainless steel. The screwdriver has three operation positions—forward ratchet, reverse ratchet, and locked. It takes Synthes' maxillofacial hex coupling blades/tapes.

In-Situ Bender/Cutter

The In-Situ Bender/Cutter provides surgeons with a simple device for heating and cutting resorbable implants in situ or away from the surgical site. The In-Situ Bender/Cutter consists of a plastic hand piece, which houses two AA batteries and a choice of three heating/cutting attachments (wide plate heating, narrow plate heating, and cutting attachment). The device is sterile-packaged.

Automated Tack Driver

The Automated Tack Driver simplifies the insertion of the Synthes 1.5 x 4 mm resorbable tacks. It also reduces the gross forces applied to the surrounding bone during insertion with the current instrumentation. The Automated Tack Driver inserts the tacks into predrilled holes via an internal, spring-powered shaft. Prior to each insertion, the spring is compressed manually by depressing the instrument tip on a sterile surface or directly on a tack itself. The insertion force can be modified intraoperatively, depending on the patient's bone quality and the surgeon's preference. The Automated Tack Driver can be disassembled without tools for postoperative cleaning.

1.5 x 3 mm Tack and Emergency Tacks for the Resorbable Tack Systems 1.5 and 2.0 (line extension)

The Synthes Resorbable Tack System provides surgeons with a means for fast and simple fixation of resorbable plates to bone in craniofacial reconstruction and fracture repair. The tacks are also indicated for use in mandibular augmentation procedures by containing bone grafts using resorbable meshes or sheets. This line extension includes 1.5 x 3 mm Tacks for thinner pediatric bone and Emergency Tacks for the Systems 1.5 and 2.0, as well as a new 2.0 mm Tack Driver with Holding Sleeve, a 2.0 mm self-retaining Holding Sleeve and three new 2.0 mm Drill Bits.

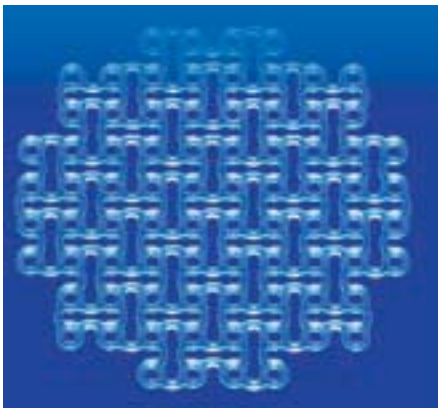
Adjustable Resorbable Tap

The implantation of resorbable screws requires predrilled screw holes and tapping with the existing Self-Drilling Taps for the Resorbable Fixation System. These taps are specific to diameter and length of each screw. The new Adjustable Resorbable Taps for the existing eleven 1.5 mm, 2.0 mm, and 2.5 mm Resorbable Cortex Screws are more versatile reducing the number of necessary taps to six.

Resorbable Screws (line extension)

The 1.5 mm Resorbable Cortex Screw line is now also available in 3 mm, 5 mm, and 8 mm length for varying bone thickness. The screws are made of 70:30 poly (L/DL-lactide) and are compatible with the existing Resorbable Plates 1.5, Meshes, and Screwdriver lades. The 1.5 x 3 mm Resorbable Cortex Screws come with new taps in mini quick and hex couplings. The 1.5 x 5 mm and 1.5 x 8 mm screws use the new Adjustable Resorbable Tap.

Resorbable Contourable Mesh Plate 1.5



The Resorbable Contourable Mesh Plates conform to the irregular shape of the skull, without folding or wrinkling during contouring, and provide temporary fixation of bone fragments or bone graft containment. Contouring is easy and possible in three dimensions. Indications are maintaining position and/or containing bony fragments, bone grafts (allograft or autograft), or bone graft substitutes or mandibular reconstructions. The mesh plates are also indicated to prevent soft-tissue prolapse at bone graft donor sites. The mesh plates are compatible with the existing Resorbable Fixation System tacks and screws; they are MRI/CT-compatible. The surgeon can choose between a round or square shape, 50 mm or 100 mm diameter, and a thickness of 0.25 mm, 0.5 mm, or 0.8 mm.

André Gächter

New knee products

TomoFix: Osteotomy Gap Measuring Device

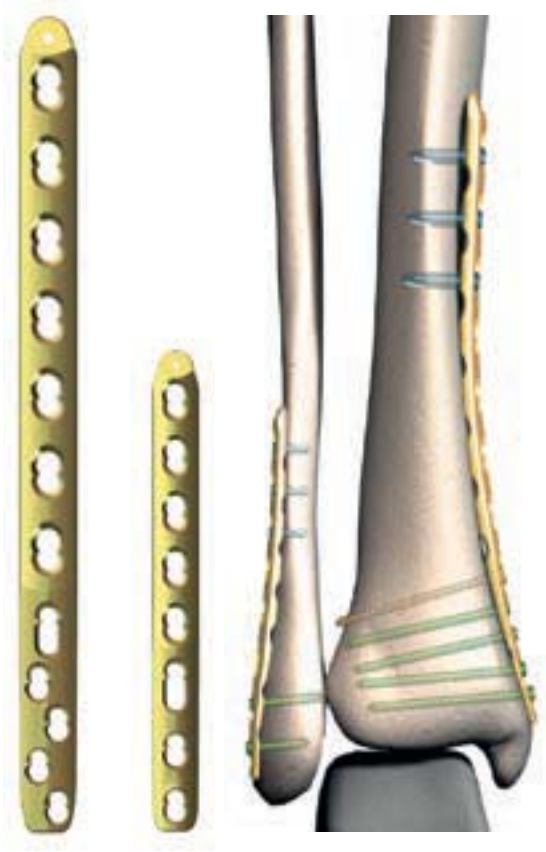
The TomoFix Gap Measuring Device enables simple measuring of the depth of the osteotomy gap and determination of the suitable chronOS block (if used).

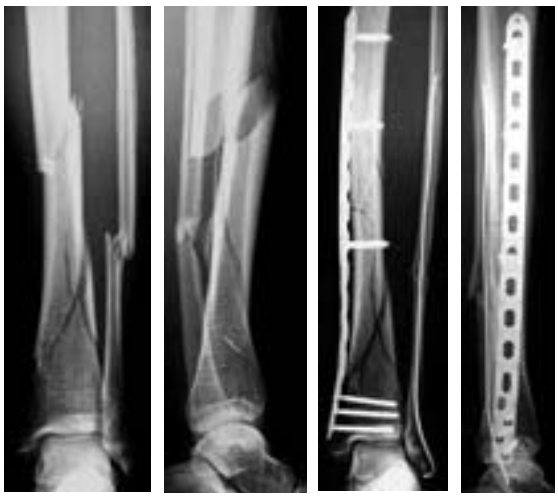
Christiaan van der Werken

New long-bone products

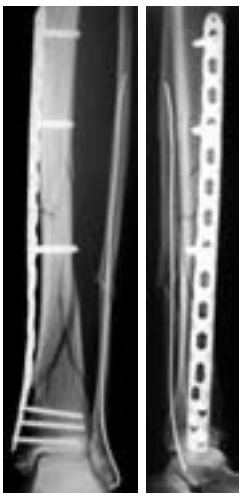
LCP Metaphyseal Plate 3.5, 4.5, and 5.0

The LCP Metaphyseal Plate is indicated for fractures in the metaphyseal areas which reach into the proximal and distal shaft of the humerus, proximal, and distal tibia as well as fibula, and proximal, and distal radius as well as ulna.
The LCP combination holes provide a choice of dynamic compression and/or angular stability in one implant. The dense net of LCP combination holes in the thinned plate area allows a closer insertion of the screws and, therefore, provides a higher purchase with better stability. The long hole helps to optimize fine-tuning of the reduction in the longitudinal axis. A bullet tip enables easier application of a minimally invasive surgical technique. The small hole is intended for temporary fixation with a K-wire. The thinned plate profile (especially designed for the distal ends) provides easy contouring of the plate and takes the peculiarities of the metaphyseal area into account. The angulation of the two outermost hole units (11°) towards the center of the thinned plate area allows a closer juxta-articular plate placement. The plate's undercuts maintain good vascularization of the periost. The LCP Metaphyseal Plate is available in stainless steel and titanium and is fully compatible with the instruments and implants of the LCP System.





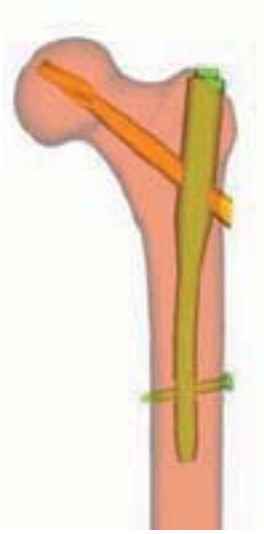
32-year-old woman, closed fracture type 42-C3 with minimal soft-tissue injury, after skiing accident. Minimally invasive plate osteosynthesis of the tibia. AP and lateral x-rays, postoperative views, and 6 weeks follow-up. Weight bearing of intially 10 kg was increased to 30 kg at 6 weeks, patient is pain free.



Ti Distal Femoral Nail (DFN): Additional Nail Lengths and 6.0 mm Ti Locking Screws

The Titanium Distal Femoral Nail (DFN) is now available in additional sizes of 180 mm, 220 mm, and 260 mm, in all diameters, to better accommodate patients' anatomy.
The existing 6.0 mm Ti Locking Screw line has been extended with sizes 30 mm, 35 mm, and 40 mm for smaller patients.

Trochanteric Fixation Nail (TFN)



The TFN is a new cannulated, intramedullary nail system. It is indicated in stable and unstable fractures of the proximal femur including pertrochanteric, intertrochanteric, basal neck fractures, as well as a combination thereof. Additionally, the long TFN is indicated in high and long subtrochanteric fractures, pertrochanteric fractures associated with an injured shaft, pathological fractures (of osteoporotic bone) in both trochanteric and diaphyseal areas, proximal or distal nonunions, malunions, and revisions.
The helical blade provides improved resistance to varus collapse and rotational control of the head-neck fracture segment. The result is superior life to cut-out versus single screw fixation and reduced bone removal versus a traditional hip screw.
The TFN is made of titanium alloy (Ti-6AI-7Nb) and available in lengths from 170 mm to 460 mm.
The TFN is, at the moment, only available in SUSA and Stratec territories.

Proximal Femoral Nail (PFN): New Aiming Arm

The new Aiming Arm for the Proximal Femoral Nail (PFN) is manufactured in carbon fibre-reinforced PEEK (Poly-Ether-Ether-Ketone) material which increases mechanical and thermal stability. The guiding distance was increased to reduce the effect of material wear. The height has been increased for longer guidance of the drill sleeves and bigger labeling.

Coupling Screw and Guide Shaft Adaptor for DHS One-Step Lag Screw

This new device allows the use of standard DHS instrumentation to implant a One-Step Lag Screw. The Guide Shaft Adaptor for DHS One-Step Lag Screw fits into the truncated hex recess of a One-Step Lag Screw. The Coupling Screw Adaptor secures the Guide Shaft Adaptor to the One-Step Lag Screw. The standard DHS wrench then fits over the assembly for insertion. The plate is placed over the inserted Lag Screw as in standard DHS technique.
The Coupling Screw and Guide Shaft Adaptor enable clinics to upgrade their DHS systems to the Synthes DHS One-Step Lag Screw without needing to purchase new instrument sets.

Ortholine: Harris Adaptor and Küntscher Adaptor

The Harris Adaptor and Küntscher Adaptor have the same function as the Hudson or Trinkle Adaptor but a different coupling mechanism for the different reamer shafts. The new adaptors permit use of Synthes Power Tools with reamers from competitors.

Quick Coupling for DHS/DCS triple reamers for Compact Air Drive/Power Drive

The new Quick Coupling for DHS/DCS triple reamers provides easier insertion, coupling, and extraction of the triple reamer shafts than the existing device.

Attachment for Acetabular and Medullary Reaming with reverse

The new attachment for acetabular and medullary reaming has the additional feature of a reverse gear.

Adaptor for Radiolucent Drive for Battery Power Line

The adaptor permits to use the Battery Reamer with the Radiolucent Drive and transforms the speed of the handpiece to the optimal speed for the Radiolucent Drive. The adaptor is directly connected to the Battery Reamer, hence no extra coupling device is needed.

5.0 mm Steinmann Pins with central thread

The additional 5.0 mm Steinmann Pins with central thread in 225 mm, 250 mm, 275 mm, and 300 mm length are indicated for knee or ankle fusions in obese patients or injuries with severe swelling. The pins are part of the Large External Fixator Set.

Dankward Höntzsch

51-year-old man, AP and lateral x-rays, pre- and postoperative.

Adjustable Large External Fixator

The Adjustable Large External Fixator is indicated for fractures of the tibia and femur, joint bridges, and osteotomies. Its pivoting T-clamp and convergent pin slots allow for fixation of shaft fractures as well as of tibial pilon and plateau fractures. The radiolucent, pre-assembled fixator is applied to the bone using a minimum of four Schanz screws through two pin clamps. The body of the Adjustable Large External Fixator is of radiolucent fibre-reinforced PEEK. The overall length ranges from 295 mm to 354 mm depending on clamps and distractor travel. The pin placement for the innermost pins ranges from 132 mm to 215 mm. It features two spring-loaded 6-position pin clamps. ML/AP angulation, torsion of 45° in each direction and gross (45 mm) and fine (35 mm) distraction/compression. The Adjustable Large External Fixator is equipped with new Reduction Handles, a 5 mm Combination T-Wrench, and a 9 mm Combination Wrench.

6.5 mm Cannulated Screws

The 6.5 mm Cannulated Screw is a line extension of the existing 7.3 mm Cannulated Screw for use in patients with smaller bones, such as smaller, elderly females and adolescents. It makes it easier to fit three screws in the femoral neck, and, furthermore, it fits better through the metaphyseal holes in some plates. The 6.5 mm Cannulated Screw is used with a 2.8 mm Guide Wire. The 6.5 mm Cannulated Screw is available in lengths of 16 mm and 32 mm as well as with different thread lengths. The cutting flute has been shortened. It is made of 316L and TAN.

2.8 mm Guide Wire for 7.3 mm Cannulated Screws

The longer, 450 mm threaded Guide Wire for the 7.3 mm Cannulated Screw set is advantageous for procedures in obese patients with more than the usual amount of soft tissues—especially in pelvic injuries.

6.5 mm Cancellous Bone Screws with 24 mm thread length

The 6.5 mm Cancellous Bone Screw with a 24 mm thread provides surgeons with an additional option for stable fixation of metaphyseal fractures and joint fusions. These screws improve screw hold in the far fragment (in case of a fracture) or far bone (in case of a joint fusion) when a 16 mm thread is too short and a 6.5 mm Cancellous Screw with 32 mm thread would cross the fracture line or joint (in cases of arthrodesis).

3.5 mm Locking Screws (line extension)

The 3.5 mm Locking Screw line extension is an addition to the Small Fragment LCP set. It provides longer length ranging from 65 mm to 95 mm for use in metadiaphyseal areas. The screws feature a T15 Stardrive™ head, locking threads, and are self-tapping. For more information about the change to Stardrive—as the new AO standard—see page 10 in News 1/2001.

LC-DCP 2.0 and LC-DCP 2.7 (line extension)

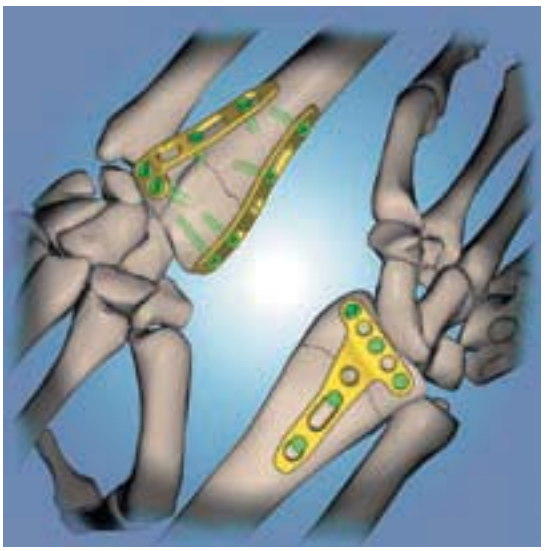
The LC-DCP Plates 2.0 and 2.7 are intended for treating fractures, osteotomies, and replantation of small bones, including hand, ankle, and foot, as well as long-bone fractures in the veterinary patients—canines and felines. The LC-DCP line is extended by the 5-hole and 7-hole LC-DCP 2.0 as well as the 5-hole and 7-hole through 12-hole LC-DCP 2.7. Additionally, the LC-DCP 2.7 incorporates rounded, chamfered edges to aid in percutaneous placement and to decrease the risk of soft-tissue irritation.

Jesse B. Jupiter

New hand products

Locking Distal Radius System 2.4

The Locking Distal Radius System 2.4 consists of the new plates: LCP T-Plate 2.4, LCP Radial Column Plate 2.4, LCP L-Plate 2.4, LCP Distal Radius Plate 2.4, dorsal (π-Plate), LCP Volar Plate 2.4, and LCP Volar Buttress Plate 2.4. The 2.4 mm Locking Head Screw, self-tapping, the 2.4 mm Cortex Screw, self-tapping—both with Stardrive recess—and special instruments complete the new system. This variety of plates allows fragment-specific treatment of all patterns of distal radial fractures. Indications are simple and displaced extraarticular and intraarticular distal radial fractures and corrective osteotomies of the distal radius. All implants are manufactured in Ti15Mo resulting in excellent bending properties and resistance to fatigue failure, allowing reverse bending. The edges of all plates are chamfered to reduce sharp edges that could contribute to irritation of tendons. Surfaces are polished to minimize tissue adhesion. The distal arms provide a smooth gliding surface for the tendons. Different plate lengths are offered to avoid cutting. The angular stability of the construct allows treatment of osteoporotic bone.



AP and lateral x-rays of a reversed Barton fracture 23-B3 in a 34-year-old woman after fall on outstretched hand. 3-months follow-up.

Hans Zwipp

New ankle and foot products

Modular Foot Set: Additional plates, screws, and instruments

The Modular Foot Set is indicated for osteotomies, fusions, replantations, and fracture repair of the foot. The following devices are additions to the existing implants and instruments of the Modular Foot Set.

Newly designed 4-hole and 6-hole LC-DCP 2.7 to address larger foot (midfoot) fractures, osteotomies, fusions, and replantations. The standard DCU part of the hole allows for 14–80° of angulation with a limited contact undersurface to preserve the periostium. The rounded edges aid in percutaneous placement and reduce soft-tissue irritation. The Hind/Midfoot Plates 2.7 are indicated for calcaneal-cuboid fusions and lateral column lengthening. A thin 1.2 mm profile thickness is utilized to minimize soft-tissue irritation.

The 6.5 mm Cancellous Bone Screw with large core diameter is indicated for triple arthrodesis (fusion of the calcaneus, talus, navicular and cuboid) and hind/midfoot fusions of the injured foot in diabetic patients. It is a fully threaded bone screw with a cancellous thread pitch. The core diameter is 4.0 mm, the range is 60–110 mm in 5 mm increments.

A Sharp Hook with small Taper features a stronger and more robust tip

Jones fracture with pseudarthrosis in a 58-year-old man. Fixation with a 4-hole LC-DCP 2.7 whereby dynamic compression was achieved using 3.5 mm screws.

James B. Hunter

New pediatric products

90° Toddler Osteotomy Plate

The 90° Toddler Osteotomy Plate 4 mm displacement with 38 mm blade length offers pediatric surgeons greater flexibility when performing intertrochanteric femoral osteotomies. The design of this Angled Blade Plate is identical to the existing 8 mm displacement with 38 mm blade length. The technique for insertion is the same.

6-year-old boy with Legg-Calvé-Perthes disease, pre- and postoperative x-rays.

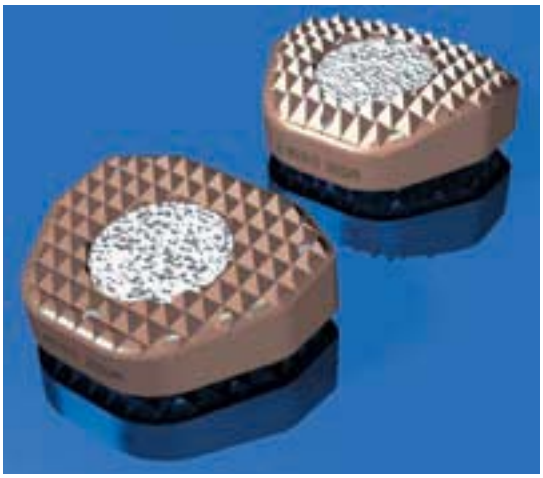
Paul W. Pavlov

New spine products

Cervios / Vertebral Spacer-CR

The Vertebral Spacer-CR is a radiolucent cage system made out of PEEK Optima designed for use in interbody procedures from C3 through C7. The spacer has a trapezoidal footprint which is 12 mm AP x 15 mm ML, the heights vary from 5 mm through 12 mm. The Vertebral Spacer-CR is available in three different sagittal profiles: convex, lordotic, and parallel. A central canal for autograft or osteoconductive, and maybe in future osteoinductive, materials allows fusion to occur through the implant. The teeth on the surface minimize migration.

Cervios^{chronOS} / Vertebral Spacer-CR^{chronOS}



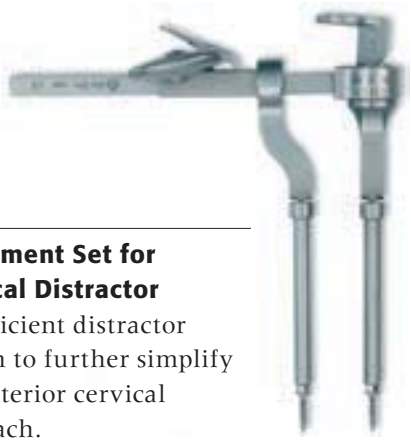
Interbody fusion procedures involve the use of bone grafts and bone replacement materials to encourage bony fusion. Studies have shown that the success rate of fusion depends on the intraoperative packing of the interbody fusion implant with the bone substitute. Therefore, the AO offers the Cervios/Vertebral Spacer CR as prefilled cages with chronOS to complement or even replace painful bone graft harvesting from the iliac crest.
ChronOS is a resorbable ceramic (β-TCP) bone substitute which is fully synthetic and has an interconnective open porosity. In-vivo studies have demonstrated its osteoconductive behavior and later resorption within 32 weeks.

Included in the Cervios instrument set are:

Packing Block
Is used for filling the empty Cervios cage with bone graft.

Cancellous Bone Impactor
Used with Packing Block to impact bone graft tightly into the empty Cervios cage.

Holder for Implants and Trial Implants
Permits simple attachment of trial implants and cages.



Instrument Set for Cervical Distractor
An efficient distractor system to further simplify the anterior cervical approach.

SynCage-LR

SynCage-LR is intended for use in the lumbar spine to facilitate fusion of two adjacent vertebrae. Indications are lumbar and lumbosacral pathologies which may require anterior segmental arthrodesis, including degenerative disc disease and instability, revision surgery for failed decompression syndrome or pseudarthrosis, and reduced spondylolisthesis.
The design of the SynCage-LR features convex superior and inferior surfaces which mimic the natural endplate curvature. Its wedge-shaped body design helps to restore the natural lordotic curvature of the spine and to restore the disc height. The surfaces feature large holes for bony in-growth or chronOS prefilling mass. The pattern of the holes and the large contact surface of the implant with the anatomical contour of the endplate interface serve to reduce the risk of subsidence and to transfer load to the strong peripheral bone of the vertebral body. The SynCage-LR is radiolucent and made out of PEEK Optima. It is available in five heights and two footprints. For the L5–S1 segment a special wedge angle, the SynCage-LSR, is available. An additional posterior fixation increases the biomechanical situation significantly.

Distractors
Usable for straight approach and to ease the access to the lumbosacral intervertebral space.

Trial Implants
Permit precise selection of the implant size and can also serve to open the disc space.

Trial Implant Holder
Provides a secure grasp of the trial implants in order to allow a safe in-situ manipulation.

Cancellous Bone Impactors and Packing Blocks
Enable easy filling and packaging of the implant with bone graft material.

Vertebral Spacer PR (PLIVIOS)

The Vertebral Spacer PR is a radiolucent spacer system designed for use in interbody procedures for L1 through L5. The footprint is 8 x 22 mm and comes in 7, 9, 11, 13, 15, and 17 mm heights. This narrow width allows for a smaller window to be created, by a partial laminectomy, lateral to the spinal cord without compromising the facet joints and structural stability of that vertebral level.
The spacer is made out of PEEK Optima, a radiolucent, biocompatible, inert polymer material. It has a rectangular footprint and convex cranial/caudal surfaces to match the vertebral endplate geometry. The implant has a scaffold-like structure which reduces the overall amount of synthetic material needed. A central hole allows the use of allograft. The Vertebral Spacer PR contains two radio-opaque pins for proper placement under fluoroscopy and recognition in follow-up evaluations.

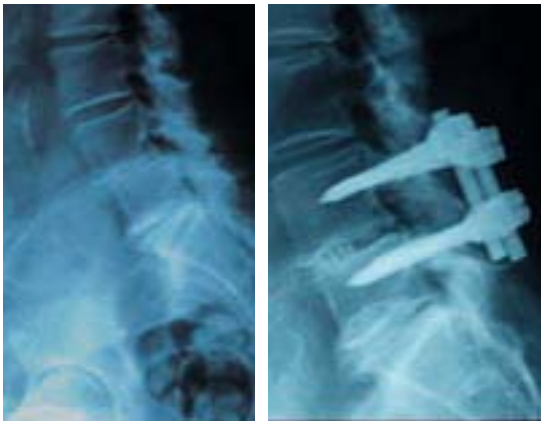
64-year-old woman, lateral, pre- and postoperative x-rays.

Vertebral Spacer TR (TRAVIOS)

The Vertebral Spacer TR is a radiolucent cage system designed for use in transforaminal lumbar interbody fusion procedures from L1 through L5. The material is PEEK Optima, a biocompatible inert polymer. It enables adequate compression of autograft in and around the implant, thus assuring better stress distribution and load sharing, providing an optimal environment for biological fusion.

The Vertebral Spacer TR has a kidney-shaped footprint. The cranial/caudal surface is convex in the medial lateral direction to provide optimal interface with the lumbar vertebral endplate geometry. The implant has two central holes to receive autograft or other osteo-inductive material and to allow fusion to occur through the implant.

Pre- and postoperative x-rays, lateral view.

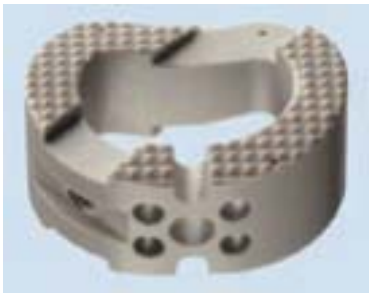


VISIOS—Vertebral Spacer AR

VISIOS is a radiolucent anterior lumbar intervertebral spacer indicated for procedures L1 through S1. The VISIOS cage can be inserted through an anterior, anterolateral or lateral approach. The posterior curvature enables optimal anatomical adaptation. A large central aperture allows good bone ingrowth. The wedge-shaped convex design permits restoration of lordosis and conformity with the endplate geometry. VISIOS is available in five different heights for adaptation to the natural disc height. An additional posterior fixation is recommended.

For VISIOS, specific instruments have been designed.

- Holder for VISIOS
- Distractor for VISIOS
- Packing Block for VISIOS
- Cancellous Bone Impactor for VISIOS



31-year-old man, lateral, pre- and postoperative x-rays.

SynMesh—Additional sizes and instruments

The SynMesh system is indicated for use as a vertebral body replacement device in thoracolumbar spine (T1 through L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma. This modular system allows building of the most appropriate construct to address the defect and patient's anatomy. The SynMesh system is to be used with Synthes supplemental internal fixation systems, eg, VentroFix or USS.

This update features 36 additional mesh heights and additional instruments.

Convex End Rings

The Convex End Rings enable locking the end ring to the mesh with the new low-profile 2.0 mm or 3.0 mm Locking Screw.

2.0 mm and 3.0 mm Locking Screw, low profile, titanium

The low-profile 2.0 mm and 3.0 mm Locking Screw are used to secure the new Convex End Rings to the mesh footprints.

Implant Holder, large and small with tips

The Implant Holder improves secure handling of the mesh and distributes the impaction forces over a larger area, reducing implant deformation during insertion.

Forked Impactors

The Forked Impactors enable better maneuvering of the SynMesh construct into its final position. Three designs are available: angle lateral, angle superior, and straight.

Corpectomy Caliper

The Corpectomy Caliper measures the size of the defect to determine the size of the implant needed. It has long arms to measure the defect through deep surgical incisions.

SynCore Insert Trimmer

The Insert Trimmer is to be used with SynCore, which are cancellous bone inserts, to fill the interior of the SynMesh Spacer. The inserts can be stacked and/or trimmed to the desired lengths.

39-year-old woman, pathological fracture in L1 due to metastasis of breast cancer, MRIs and x-rays, Synmesh combined with Ventrofix.

Additional ACF Spacer instruments— FRA instruments are incorporated in the Cervios system

The Anterior Cervical Fusion (ACF) instruments are designed to facilitate ACF procedures utilizing a modified Smith Robinson Technique. The existing Synthes™ ACF Spacer instrument set has been enlarged to improve discetomy and endplate preparation, which are key elements for successful biological fusion.

ACF Cervical Disc Shaver
Facilitates the removal of the larger fragments of the nucleus pulposus and cartilaginous endplate. It will lessen the OR time required for performing cervical discetomy and blood loss of the patient.

ACF Rasp
Permits removal of cartilaginous tissue from the cervical endplates to expose bleeding bone and assists preparation of the cervical vertebral endplates without damaging the subchondral bone.

ACF Detachable Trial Spacer
The new trial spacers are detachable and available in parallel, lordotic, and convex geometries to permit the selection of the most appropriate implant and height so that restoration of disc height can be maintained.

ACF Spacer Implant Holder
Securely grips the ACF implant for controlled insertion by employing a new speednut locking mechanism. The handle enables impaction of the implant with a hammer.

ACF Graft Packing Block
Used in conjunction with the existing graft packer to facilitate packing osteoinductive material into the central canal in cervical spacers.

Additional PLIF instruments— FRA instruments are incorporated in PLIVIOS set

The Posterior Lumbar Interbody Fusion (PLIF) instruments allow for a posterior approach, a complete discectomy and implant insertion under distraction. Trial Spacers permit the selection of the most appropriate height so that restoration of disc height can be maintained.

Graft Funnel
The Graft Funnel enables better placement of autograft or allograft in the anterior and medial aspect of the vertebral disc space.

Graft Pusher
The Graft Pusher facilitates in the delivery of autograft or allograft with the use of the Graft Funnel.

PLIF Spreader, 7 mm
The PLIF Spreader has the same overall height as the implant and ensures accurate sizing and distraction.

PLIF Trial Spacer
The PLIF Trial Spacer has the same overall height as the implant and ensures accurate sizing and appropriate implant selection.

PLIF Detachable Trial Spacers
The Detachable Trial Spacers have the same geometry and height as the PLIF implants. They ensure accurate sizing and appropriate implant selection. Distraction can be achieved without worrying about compressing the dural sac. Once the Detachable Trial Spacer has been positioned, the dural sac can then slide over the top of the spacer, while implant insertion occurs on the contralateral side.

Intervertebral Disc Shavers
The Intervertebral Disc Shaver allows the surgeon to break-up the nucleus pulposus in a fast and efficient manner, while also beginning to scrape off the cartilaginous layer of the vertebral endplate.

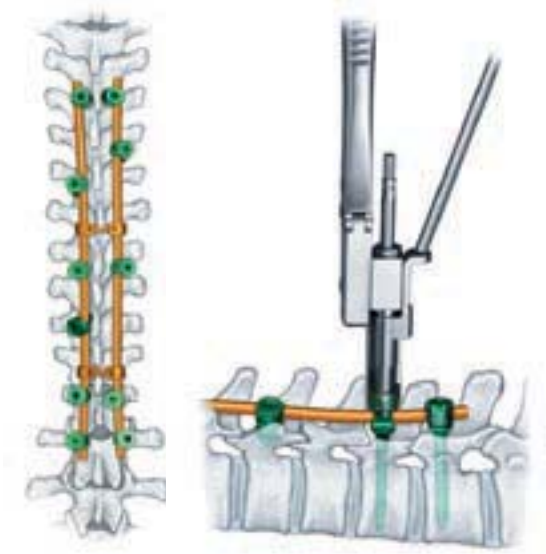
Intervertebral Disc Excisors
Facilitates removal of nucleus pulposus from the intervertebral disc space.

Bone Rasp, Straight, 8 mm width /
Bone Curette, straight, 5.5 mm width, 140 mm length /
Bone Curette, reverse angle, 5.5 mm width, 140 mm length

All three instruments facilitate removal of nucleus pulposus and the cartilaginous layer of the endplates to expose bleeding bone. Endplate preparation can be achieved without damaging the subchondral bone.

Dual-Opening Universal Spine System (USS)

The Dual-Opening USS is a stand-alone system designed to treat deformities in the thoracic, lumbar, and sacral spine using the technique of segmental translation. It incorporates the dual-opening features of the Small Stature USS system with screws and hooks applied to a 6.0 mm rod.

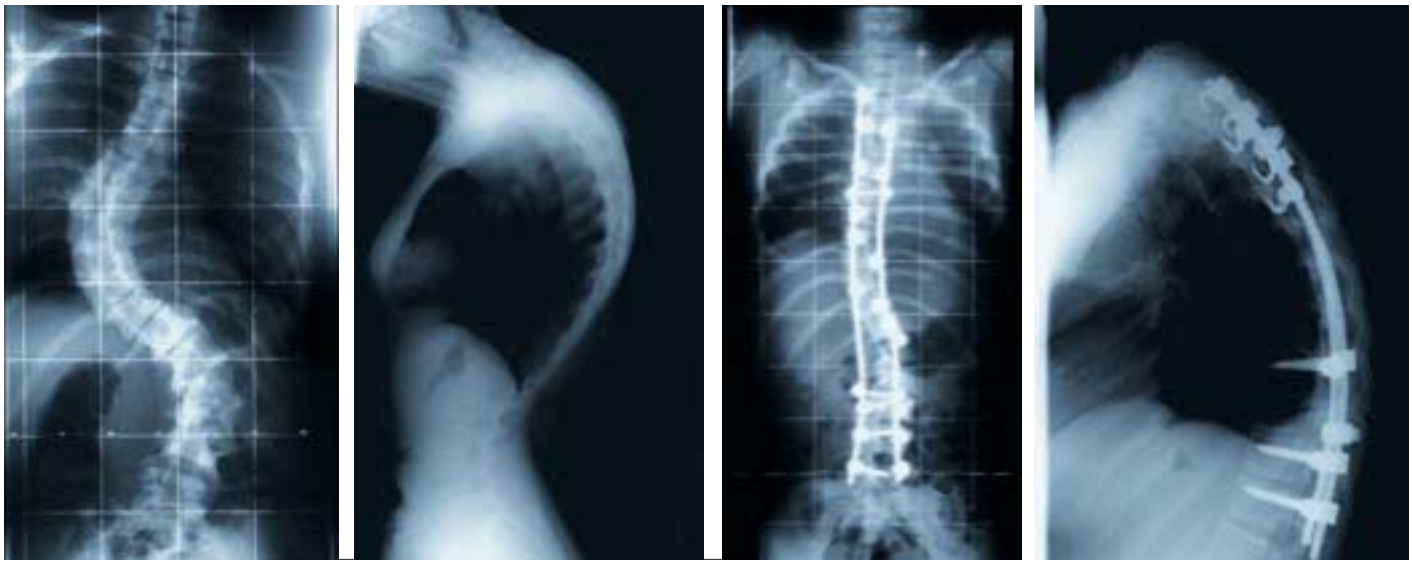


The new hook designs for pedicle, lamina (small, medium, and large), thoracic lamina, angled lamina, tall body lamina (small, medium, and large), and transverse process (left and right) are available for standard side loading and for front loading when using a transverse bar.

The screws feature the dual-opening design and a dual core thread design which includes two core diameters within each screw to improve bony purchase: a cortical thread at the screw bend, and a cancellous thread at

the screw tip. The available screw diameters are 4.2, 5.2, 6.2, 7.0, 8.0, and 9.0 mm, with lengths from 25 mm to 80 mm.
Other new implants are collars (standard and grooved to match transverse bars), a 12-point nut, and new transverse bars in lengths of 15, 20, and 25 mm. All implants are offered in both Titanium and Stainless Steel. The Dual-Opening USS features several new instruments: Hook Holding Forceps, Rod Introduction Pliers (Persuader), Distraction Clip, Socket Wrench, Holding Sleeve for Socket Wrench, and Collar Positioner.

16-year-old woman with progressive kyphoscoliosis (scoliotic double curve: preoperative thoracic 78° and lumbar 68°; postoperative 38° and 30°); posterior instrumentation with pedicle screws in L1 to L5 and pedicle, lamina and transverse process hooks in T2 to T10 after anterior release.



New instruments for Pediatric (small stature) Universal Spine System (USS)

Screwdriver 4.0 mm
with T-Handle

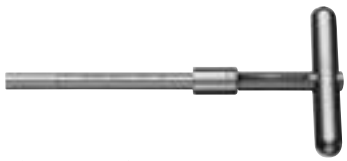
Support for Rod Introduction Pliers

Sleeve Positioner for USS
Pediatric Sleeves

Socket Wrench
for 12-point nut
with L-Handle

Depth Gauge for Pedicle Screws
4.2 to 9.0 mm

USS Pediatric
Rod Introduction Pliers



Socket Wrench 5.0 mm
with T-Handle

Holding Sleeve for Fillister Head
Screws

Sleeve Pusher

Pedicle Preparation instruments

The Pedicle Preparation instruments are used in the preparation of the vertebral body for screw insertion. All instruments are compatible with dual core screws in the Universal Spine System Variable Axis Screw and Click´X Systems.

Palm Handled Ratchet

The Palm Handled Ratchet has a 6 mm hex quick disconnect attachment for insertion of taps and pedicle markers.

Large Handled Awl

The Large Handled Awl is used to puncture the proximal cortical layer of the vertebral body and has a large oval-shaped handle. The Awl enables easy insertion of 8.0 mm and 9.0 mm dual core screws due to its large tip.

Large Handle Curved Probe

The Large Handle Curved Probe is used to create a hole for screw insertion. It has a large handle, bent distal end, and a gold coated (titanium nitrate) tip for easy visibility in the surgical field.

Quick Release Probe Shaft

The Quick Release Probe Shaft is used with a quick release handle to probe the pedicle for screw insertion. The Probe Shaft has a rib on it that allows identification of AP and lateral views. After probing, the shaft is uncoupled from the handle and left in the hole for identification on x-ray or fluoroscopy.

Pedicle Marker, beaded

The beaded Pedicle Marker identifies the dimension and direction of the pedicle hole after probing. The beads correspond with specific lengths along the shaft so that depths can be determined in lateral views.

Taps for Dual Core Screws

The Taps for Dual Core Screws enable tapping a pedicle screw hole prior to screw insertion using a handle with 6 mm hex quick disconnect. The Taps are available solid or cannulated.

Extraction instruments for damaged Click´X Locking Caps

The Extraction instruments for damaged Click´X Locking Caps enable removal of a damaged hex-drive Click´X locking cap. With the clamping mechanism of the extractor the locking cap is firmly held and can easily be removed.

SynFrame Retractor Holder

The SynFrame Retractor Holder is free adjustable and features a catch mechanism.

Mathias Müller

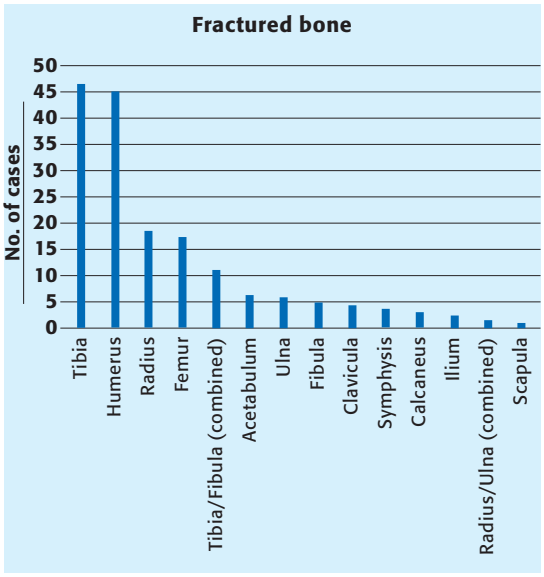
Early clinical experience with the LCP 3.5/4.5 systems

The aim of this prospective study was to systematically document the results of the first applications of the LCP system in routine clinical practice for a broad spectrum of indications. From March 2000 to February 2001 144 patients with 169 fractures were treated with the LCP system at six European trauma centers and at one American center. Patient recruitment was distributed across the individual centers as follows:

Kantonsspital Chur	39 patients
Kantonsspital Fribourg	37 patients
Wilhelminenspital Wien	24 patients
Hospital for Special Surgery New York	20 patients
Kantonsspital Aarau	9 patients
Spital Davos	8 patients
Kantonsspital Luzern	7 patients

The patient sample was comprised of 67 women and 77 men aged between 11 and 93 years. The period from accident to operation was 62 days on average (minimum 0 and maximum 917 days).

Graph—Spectrum of indications



For this study, a follow-up rate of 88.2% was achieved. Five patients died before fracture healing was concluded without there being any recognizable link between the cause of death and the implant. One year after the operation, 130 fractures had gone on to complete and uneventful healing. For 19 patients a total of 27 unexpected "adverse events" were documented.

Table—Documented "adverse events"

Adverse events	No. of cases
Delayed or nonunion	5
Loss of reduction	1
Loosening of implant	1
Loosening of implant & loss of reduction	4
Breakage of implant	4
Infection	2
Postoperative nerve palsy	2
Refracture (2nd fracture close to implant)	4
Implant-related pain	2
Osteonecrosis	2

The complications documented were of various degrees of severity and corresponded to a complication rate of 12.6%. None of these complications was determined to be "purely implant-related". Instead, eight of the 18 revision operations were the consequence of technical inadequacies during the operation, or the stability of the osteosynthesis was overestimated by the surgeon. The infection rate (2/151 of the fractures followed-up) is low (1.5%) for this heterogeneous patient sample that included numerous open fractures and many revision operations on patients who had already been operated on repeatedly (1.5%); this is especially true for the rate of secondary cancellous bone grafts (1.5%).

The LCP system with its different types of screws and a very broad range of applications is of necessity associated with the hidden risks of error during operative planning and during operative intervention. The surgeons emphasized that, thanks to the possibility of fracture bridging fixation, the advantages of the LCP system lie especially in

- its good purchase in osteoporotic bone;
- the stable angle fixation of small, unstable fragments;
- the reduction of primary cancellous bone grafting.

Sylwester Gogolewski

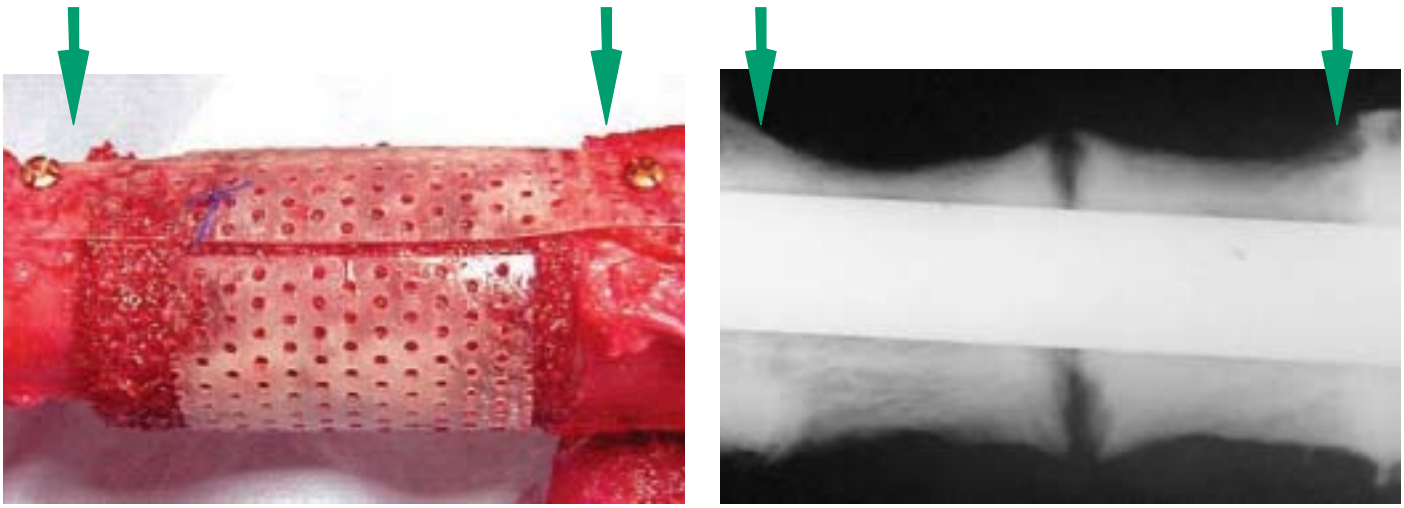
Bioresorbable polylactide mesh implants in the treatment of critical-size bone defects

Bone defects above a "critical size" do not heal spontaneously. Autogenous cancellous bone grafts are used to promote healing of such defects. Surrounding bone graft packed in the defect with bioresorbable microporous membranes can additionally facilitate healing.

In the maxillofacial skeleton, microporous membranes are used to regenerate the large orbital and facial defects and critical-size defects of the mandible. While the microporous polylactide membranes, often in combination with bone graft, function effectively in the maxillofacial skeleton, it is prerequisite to use perforated membranes—meshes in combination with bone graft—for the treatment of critical-size segmental defects of long bones. In the sheep model, the critical size 4 and 7 cm long segmental defects in the tibia were packed with autogenous cancellous bone graft and surrounded with nonperforated and/or perforated polylactide meshes. The implants had a single-tube and/or a tube-in-tube configuration. In all cases where nonperforated membranes were used to treat bone defects, there was a nonunion at 16 weeks. Bone healing was only observed in the defects filled with bone graft and covered with perforated membranes, suggesting that the presence of perforations improves bone graft reconstitution. Despite a higher graft volume contained in defects covered with the single-tube perforated membranes than those implanted with the perforated tube-in-tube membranes, the healing was more efficacious in the latter case. The implant consisting of the tube-in-tube membranes allows for a significant reduction of the amount of bone graft to be used and for the formation of the "neo-cortex" with well-defined thickness.

The primary functions of polymeric meshes in the healing of bone defects above the "critical size" are: optimizing the contact between the soft tissues and bone graft to avoid its excessive resorption; allowing adequate graft vascularization—nutrition from the surrounding soft tissue; maintaining the graft in the required location; and providing a substrate for osteogenic cells. The interface between the soft tissues and bone graft seems to be a predominant factor that determines graft survival and functionality. The perforated polymeric membranes may provide such an interface.

It is worth mentioning that in experimental animals and in a limited number of clinical



Bone healing in a 4 cm long critical-size segmental defect in the sheep tibia implanted with porous 3-D scaffold from poly(L/DL-lactide) 80/20% impregnated with bone marrow at 4 months post-implantation. Arrows indicate the ends of the scaffold.

cases it is possible to use 3-D porous polylactide scaffold impregnated with marrow blood instead of autogenous cancellous bone graft. In both cases, the healing of the defects is comparable.

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TK Recognition Prize 2002

The AO honored Phil Kregor, MD, Nashville, Tenn., with the TK Recognition Prize 2002 for his outstanding contributions in the clinical application, teaching, and dissemination of the Less Invasive Stabilization System (LISS). LISS is an anatomical preshaped internal fixator which can be applied in a minimally invasive technique indicated for fractures of the distal femur and the proximal tibia.

Phil Kregor receives certificate from Norbert Haas.

Thomas Rüedi

Portrait of Dr. med. Christoph Sommer

Christoph Sommer is a highly devoted and skilled general surgeon with a special interest in the management of the injured patient as a whole. He has been involved in the clinical testing of the new Locking Compression Plate (LCP) from the very beginning as one of the principal investigators. Within a short time he has accumulated a large number of challenging cases—every one of which was carefully planned, meticulously performed, and documented with intra- and postoperative photographs and an over 90% follow-up. Thanks to his extremely conscientious work, Christoph has presented not only highly successful results, but has also critically and honestly discussed complications to illustrate potential pitfalls of the new principles. Christoph Sommer has therefore been a regular participant and speaker at the LCP User Meetings in Berlin, where personal experiences were regularly exchanged.
His vast experience and many of his personal cases have been integrated in the new interactive CD-ROM "AO Teaching Series—LCP" of which he is a co-author.

Christoph Sommer was born in December 1959 and grew up in the mountainous eastern part of Switzerland. He has a broad medical postgraduate education including pathology, internal medicine, and general surgery. He spent one year in the UK as a visceral surgeon and one year at the Trauma Unit of Prof. Otmar Trentz at the University of Zurich. For three years he has been a consultant at the Dept. of Surgery, Kantonsspital Chur, where he also did most of his surgical training. Having attended numerous national and international AO courses he is presently a chairman of the Davos Principles Courses. He is an instructor for the Swiss ATLS courses and holds the European title for Traumatology (EBQS Trauma).

Besides his dedication to surgery, Christoph is an avid skier, mountaineer, competition rock climber and has successfully taken part in climbing the Daulaghiri in the Himalaya. This passion for the mountains is shared by his two sons and daughter—all three ranking amongst the best climbers in Switzerland and even in Europe. On top of his clinical and outdoor engagements Christoph has also published a number of key articles and book chapters.

New products from AO International

AO Teaching Series—LCP (Locking Compression Plate)

AO—your partner in education

Our mission is to advance knowledge transfer and professional practice for the improvement of learning within the international AO community. This interactive CD-ROM, edited by Michael Wagner, MD, is the first of the new AO Teaching Series. Content layout is similar to the most commonly used software programs. Simply choose your topic of interest from hierarchical menus. Download illustrations and animations for teaching courses. Regular updates are planned for AO faculty via downloads from a restricted Web site.
The AO Teaching Series is there to make your life easier.

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