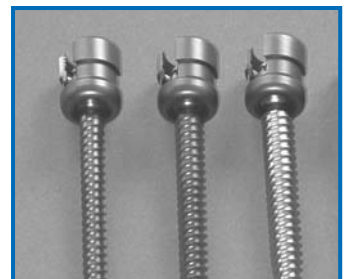
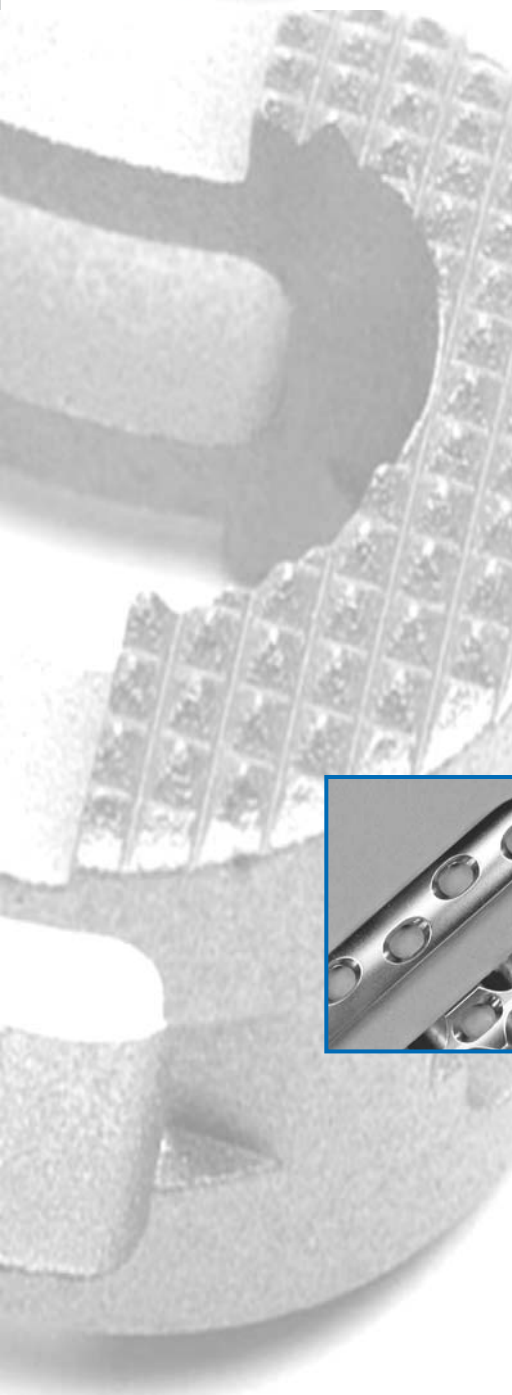




New Products from AO Development





Dear Reader,

An important feature of the implants and instruments from the AO is the choice of material. Originally, the AO concentrated on high load-bearing stainless steel, then moved on to more biocompatible titanium and today is using a variety of very different materials depending on the clinical problem. In this issue of *New Products from AO Development*, John Disegi, the chairman of the AO Material Expert Group, provides you with an insight into the characteristics of the various materials. An overview of the AO solutions in osteobiology will follow in one of the next issues.

As AO Development is a joint effort of surgeons engaged with the AO Foundation, the AO Development Institute and our industrial partners, I welcome the merger of SYNTHES-Stratec and Mathys Medical. This new global SYNTHES producer will enhance our know-how and support in development, but will also ensure the distribution of AO implants worldwide to provide you with the best techniques to treat your patients.

Since the AO is changing its screw recess from hexagonal to Stardrive®, I would like to direct your attention to the article on the test results of the AO Research Institute. The advantages in torque transmission and screw extraction have convinced the AO to make Stardrive® the new AO standard for all screws.

Once again I would like to stress that none of these articles is a substitute for the AO's OP Techniques or our AO Teaching Tools. You can obtain more detailed information on these products from the AO or your local SYNTHES® representative.

If you have any comments or questions on the articles or the new products, please do not hesitate to contact us. The AO is always interested in your feedback and is keen to involve surgeons worldwide in our joint activities in research, development and education for the benefit of the patient.

Yours faithfully,

A handwritten signature in blue ink, appearing to read 'Norbert Haas'. The signature is fluid and cursive, with the first name 'Norbert' and the last name 'Haas' clearly distinguishable.

Norbert P. Haas

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Materials used for AO implants— An overview and outlook

Introduction

AO implants are manufactured from a wide range of different materials. This article will provide you with an overview of the most commonly used materials and explain their clinical advantages.

The majority of metallic AO trauma implants are manufactured from Cr-Ni-Mo stainless steel, CP titanium, or Ti-6Al-7Nb alloy. A few cobalt-base alloys with commercial names such as L-605 and Elgiloy are also used for specialty implants. Nonmetallic implant materials include PEEK (polyetheretherketone) and resorbable polylactide polymers. Influences on specific material selection during the implant design phase include anatomical location, perceived stress limits, diagnostic imaging considerations, competitive factors, and most importantly, the capability to solve a clinical problem. Calcium sulfate, calcium phosphate, and other bioceramics used for bone grafting or as bone void fillers will not be covered in this review article.

Stainless steel

Implant quality 316L stainless steel meeting International Organization for Standardization (ISO), American Society for Testing and Materials (ASTM) and AO ASIF compositional, metallurgical, and mechanical requirements is used for a large number of fracture fixation devices. The wide combination of mechanical properties is ideal for a variety of implants. Some of the product features include:

- *Cerclage wire*—ability to twist and deform without breaking.
- *Reconstruction plates*—3-D contourability.
- *DHS*—good fatigue strength.
- *Bone screws*—excellent torsional strength and ductility.
- *Bone plates*—high strength with good ductility.

The positive attributes of implant quality 316L (ISO 5832-1) are offset by a few deficiencies

including the possibility of nickel allergy due to the 15% nickel content and considerable signal artifact during MRI that may interfere with diagnostic imaging. The use of Fast Spin Echo pulse sequence during MRI can reduce the amount of artifact obtained with stainless steel. Low-nickel implant stainless compositions that contain a maximum 0.05% nickel are emerging to address the nickel sensitivity problem. AOCID recently coordinated a literature survey at the Technical University Munich on low nickel sensitization in animals and humans and an AO Research Grant is funding a paravertebral patch test study of Ni-sensitized patients in Germany. Fortunately, the low-nickel implant alloys exhibit improved mechanical properties and corrosion resistance. Typical annealed mechanical properties are as follows:

	Low Nickel	ISO 5832-1
UTS (MPa)	1 000	590
0.2% YS (MPa)	600	250
Elong (%)	50	57
ROA (%)	70	88
Fatigue (MPa)	480	180

UTS = Ultimate Tensile Strength

YS = Yield Strength

Elong = Elongation

ROA = Reduction Of Area

Titanium

Pure titanium is considered the benchmark by which all other biomaterials are judged due to its outstanding combination of long term corrosion resistance and biocompatibility. The low amount of MR artifact and ability to be anodized for color-coded implant systems are unique properties of titanium. Pure titanium can be cold worked for added strength but the majority of trauma applications include relatively low-stressed maxillofacial, cranial, and hand implants. Its overall mechanical properties are somewhat inferior to stainless steel. A schematic of torque versus angle of rotation for titanium and stainless steel bone screws (Fig.1) highlights the lower torsional

yield strength and ductility associated with pure titanium.

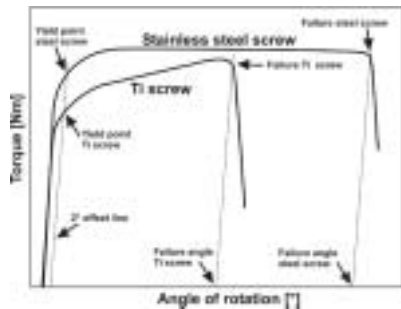


Fig. 1: Torque versus angle of rotation for stainless steel and titanium bone screws.

Titanium alloys

α + β titanium alloys such as Ti-6Al-7Nb offer increased strength for highly stressed AO implants such as cannulated and solid IM nails, universal spine clamps, LISS plates, thoracolumbar rods, and cannulated screws. They offer improved strength but less tensile and bending ductility when compared to pure titanium. Ti-15Mo is a relatively new β titanium alloy with moderate strength, high ductility, and excellent notch sensitivity. Mechanical property studies have been performed with various Ti Grade 4 and Ti-15Mo plates in order to compare the reverse bending properties. Reverse bend testing (n=3) was performed with a series of annealed Ti Grade 4 and beta annealed Ti-15Mo plates according to ISO 7801. The reverse bend test setup is highlighted in Figure 2.

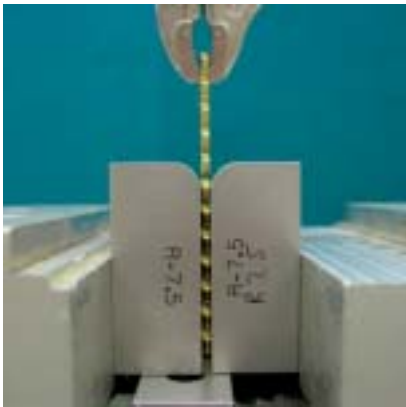


Fig.2: Reverse bend testing.

	Mean number of bends	
	Ti Grade 4	Ti-15Mo
Locking reconstruction	11 ± 3	32 ± 5
Universal fracture	4 ± 0	10 ± 2
2.0 Locking	19 ± 3	56 ± 4

The reverse bend fracture resistance of the Ti-15Mo plates was improved by a factor of 2.5-3X when compared to Ti Grade 4 plates. Enhanced reverse bending performance represents an important clinical advantage during intra-operative plate contouring.

PEEK

PEEK is an advanced thermoplastic polymer that is available as an implantable material. Special synthesis methods and processing precautions control the composition, uniformity, and internal cleanliness. Current applications include vertebral spacers, spiked washers, and other implants are under development.

PEEK offers good mechanical properties (100 MPa YS; 20% elongation; 170 MPa flexural strength) and radiolucency. PEEK spiked washers are formulated with 6% barium sulfate for radiopacity as a replacement for the polyoxymethylene (POM) C spiked washer with stainless steel reinforcement ring. Unconventional machining and cleaning procedures are required to provide noncontaminated surfaces during fabrication operations. PEEK mechanical properties will not be degraded during steam autoclaving, ETO, or gamma sterilization.



Fig. 3:PEEK vertebral spacers.

Resorbable polylactide

The generalized chemical formula for polylactide polymer is $(C_3H_4O_2)_n$. Various isomers known as L-lactide, D-lactide, and DL-lactide refer to the structural orientation of the polymer. Isomers can be differentiated on the basis of their specific optical rotation. Amorphous (noncrystalline) 70:30 L/DL-polylactide is the primary stereoisomer used for mid-face and cranial resorbable plates, screws, and burr hole covers. The in vivo degradation mechanism is well-documented in the literature.



Handling operations are critical since polylactide granules are supplied in inert gas purged foil packs, stored at a low temperature, vacuum dried at a high temperature, and

transferred under inert gas cover to injection molding or compression molding equipment.

Resorbable polymers are ideal for craniofacial implants because of their small mass and the low applied stress. Their excellent vascularity and 4–6 week fracture healing timeframe are favorable clinical factors. Material improvements such as higher strength and faster resorption rate plus improved implant designs will offer expanded opportunities in the future for resorbable polymers.

Surface modification

Implant surface interactions are primarily responsible for biological response and have a pronounced effect on the clinical performance of trauma products. Ongoing research by the AO Research Institute has identified the importance of metallic implant surface microtopography on the cellular reactions that are obtained. Movement between implant surface and soft tissue may cause fibrous capsule formation around a liquid filled void on stainless steel. The liquid phase allows buildup of cellular detritus, fretting debris, and possible infection. Capsule formation is not observed on titanium implants. Recent findings in Davos indicate that there is a strong correlation between lack of fine micro-roughness and the presence of a liquid filled void. Results have supported the hypothesis that stainless steel void formation is due to lack of microtopography and the inability of cells to adhere to surface discontinuities.

Other surface modifications for implants include low friction anodizing to improve the fretting and galling resistance of titanium. Bulk coatings include HA to encourage biological fixation and antiseptic or antibiotic antibacterial films. Osteoinductive additives such as BMP-2, IGF-1, and TGF- β 1 will be applied to implant surfaces in the future to control specific biological functions.

Future developments

Substantial efforts have been made by many research groups to develop metallic foams that provide low stiffness, stable bony ingrowth, structural support, and delivery of bone forming compounds (Fig. 4).

Long-range developments are also under investigation to explore advanced material technologies such as:

- Nonmagnetic amorphous metals with high strength and good wear properties.
- Titanium shape memory alloys that do not contain nickel.
- Nanotechnology processing to produce CP titanium with strength levels that exceed Ti-6Al-7Nb.
- Novel titanium alloys that demonstrate an ultralow elastic modulus, extremely high strength, and super plasticity due to a dislocation-free plastic deformation mechanism.

Potential clinical applications for these new materials include implants with low apparent density for osteoporotic bone, improved MR or CT imaging, *in vivo* shape memory activation, and better resistance to fatigue fracture.

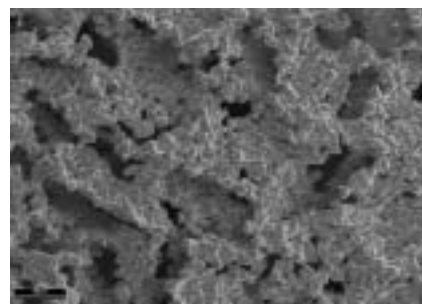


Fig. 4: Example of titanium foam structure.

Conclusion

Successful integration of implant materials for AO implant applications is the result of close cooperation between clinicians, research scientists, material specialists, product development designers, and manufacturing engineers. Clinical feedback especially through the medical AO Expert Groups is crucial to understand the advantages, disadvantages, and limitations of conventional and advanced biomaterials. Active participation within the ISO and ASTM implant committees ensures that high quality AO material standards will be maintained on a worldwide basis. Full manufacturing support by the producers is needed to determine processing response and cost-effective manufacturing strategies for new implant materials. This team effort within the AO is responsible for providing surgical implants with improved properties and superior clinical performance.

John Disegi, Chairman, AO ASIF Materials Expert Group (MAEG), can be contacted at disegij@synthes.com for further implant material information.

New foot and ankle products

Calcaneal Locking Plate

The Calcaneal Locking Plates are designed to address complex fractures and osteotomies of the calcaneus, including, but not limited to extraarticular, intraarticular, joint depression, tongue type and severely comminuted fractures. The plates are applied to the lateral side. The plate has 15 threaded holes, which accept 2.7 mm and 3.5 mm Cortex Screws as well as 3.5 mm Locking Screws. The numerous holes enable versatility and provide options to address multiple fragments and fracture patterns. It provides a fixed angle construct and a buttress to the articular surface of the calcaneus. The distal end of the plate has two bendable tabs to give support for the anterior process and plantar fragments. The plate is available in two sizes, short and large, and comes in a left and a right version. At the moment, the plate is available in stainless steel. A version in a special kind of titanium with 15% molybdenum is under development.

Several new instruments were developed for the convenient use of this plate:

Tab Bender Pliers for Calcaneal Locking Plate

The Tab Bending Pliers are used to bend the two tabs located on the Calcaneal Locking Plates. The surgeons now have the ability to safely contour the tabs of the plate in-situ for better anatomical fit.

2.8 mm Threaded Drill Guide

Guides a 2.8 mm drill bit perpendicular to the plate to ensure proper mating of the 3.5 mm Locking Screw and plate hole threads.

Threaded Plate Holders

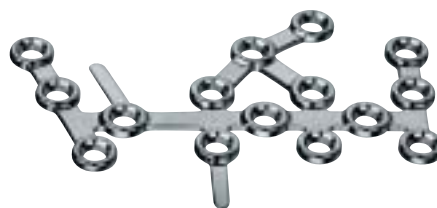
Aids to position the plate to the bone and may also be used for in-situ bending to achieve a better plate fit.

Calcaneal Locking Plate Cutter

Facilitates precise hole/tab removal without creating upward facing burrs.

Bending Template

A Bending Template provides a visual aid for 3-D contouring.



New pelvic products



Percutaneous Guiding System

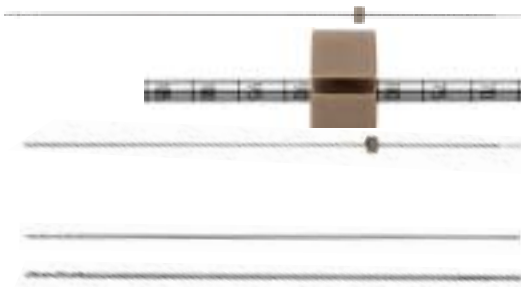
The Percutaneous Guiding System is a set of instruments that allows percutaneous placement of long screws in the pelvic area and other body regions. It allows easy and accurate drilling and screw insertion. The Percutaneous Guiding Instrument protects the soft tissues and guides Drill Bits, Screwdriver and Screw to the bone and can be secured to the bone with a K-Wire.

Percutaneous Guiding Instrument



A bullet nose eases insertion of the guide. The slender shape of the guide protects the soft tissue. The V-shape gives sufficient control to the Drill Bit and guides the screw to the drilled hole. It allows greater flexibility than the tubular drill sleeves. The use of oscillating drills is recommended. A K-Wire hole allows K-Wire fixation of the guide to the bony surface. The instrument is 220 mm long.

Drill Bit, diameter 2.5 mm, with length measurement



The Drill Bit with coupling for a Jacobs Chuck allows drilling near the Percutaneous Guiding Instrument. Laser marks on the Drill Bit and a plastic ring facilitate direct reading of the drilling depth.

Drill Bit, diameter 3.5 mm, with length measurement

The Drill Bit 3.5 mm enables predrilling of a gliding hole.

Screwdriver, diameter 2.5 mm, self-holding

The extra long self-holding Screwdriver is especially designed for using 3.5 mm Pelvic Cortex Screws. This combination also helps apply percutaneous screws in other body regions.

The set also contains a Cleaning Brush for the K-Wire hole, a Sterilizing Tray, an Insert for Screws and a Lid to enable proper storage of the instruments.



New long-bone products

Minimal Invasive Percutaneous Osteosynthesis (MIPO) Instruments

MIPO Instruments are designed to facilitate reduction and to minimize devascularization of fracture fragments by minimizing soft tissue stripping.

The Reduction Instruments are placed in the distal and proximal end of the fracture. Due to direct application of forces to the bone, the instruments allow better manipulation of the bone fragments and therefore facilitate reduction of the fracture.

Soft Tissue Retractor

The Soft Tissue Retractor prepares a cavity for subsequent, percutaneous insertion of a plate. It is inserted percutaneously through a small incision and separates the soft tissues from the periosteum. The Soft Tissue Retractor is available in a version for Small and one for Large Fragments.



Large Fragment Manipulator

The Large Fragment Manipulator with threaded rods (diameter 5.0 mm) features a self-drilling tip, standard tip, and round cannulated tip as well as a K-Wire and cannulated drill. The threaded, cannulated rod with a round tip allows a guided, unicortical application.



Small Fragment Manipulator

The Small Fragment Manipulator with threaded rods (diameter 3.0 mm) features a self-drilling tip and a standard tip.

Plate Holder

The Plate Holder facilitates the handling of the plate insertion (Plate Handle for LCP and LC-DCP Manipulator). The specific handle is used with different plate clamps and enables plate insertion of the LCP and LC-DCP Narrow, LCP and LC-DCP (4.5/5.0 dimension, broad and narrow) as well as LCP and LC-DCP (3.5 dimension).

An externally mountable template can be used to indicate the holes of the plate for subsequent screw.



Coaxial Clamp

The Coaxial Clamp enables axial reduction of bone fracture fragments through a small skin incision via the axial sliding mechanism of its forceps. It is therefore a major improvement on conventional reduction forceps, which are insufficient for use in less invasive surgery due to their scissor-like opening mechanism.

The Coaxial Clamp consists of a Sliding Mechanism and various Arms that can be attached onto the Sliding Mechanism.



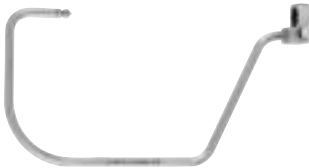
Sliding Mechanism

Any arm can be attached to the Sliding Mechanism according to the needs of the surgeon. It provides the axial closing mechanism of the sliding forceps.

Subcutaneous Arm



The Subcutaneous Arm is used to reduce long-bone fracture elements. The arm can be placed subcutaneously on the fractures' fragments through a small skin incision.



Percutaneous Arm

The forceps' ends can be inserted through small skin incisions (percutaneously). A spiked disc can be put on the Percutaneous Arm tip in case of poor bone quality to prevent any damage to the bone.

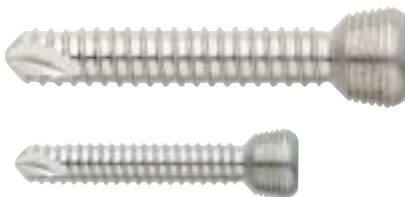


Pelvic Arm

The Pelvic Arm is indicated for pelvic surgeries. The instrument is placed into the body either through a standard or a minimally invasive approach.

Christiaan van der Werken

4.0 mm Stardrive Locking Screws



The new 4.0 mm Stardrive Locking Screw features a T25 Stardrive head, locking threads, and is self-tapping. Available lengths are 14 mm up to 90 mm.

The introduction of the 4.0 mm Stardrive Locking Screw is another milestone to provide the Stardrive design in locking screws.

For more information about the change to Stardrive—as the new AO Standard—see page 10 in News 1/2001.

5.0 mm Stardrive Locking Screws



The new 5.0 mm Stardrive Locking Screw features a T25 Stardrive head, locking threads, and is self-tapping. Available lengths are 14 mm up to 90 mm.

The introduction of the 5.0 mm Stardrive Locking Screw further extends the range of locking screws with a T25 Stardrive head.

For more information about the change to Stardrive—as the new AO Standard—see page 10 in News 1/2001.

3.5 mm Titanium Locking Screws—Additional Lengths

The 3.5 mm Titanium Locking Screw features a T15 Stardrive head, locking threads and is self-tapping. The screws are now also available in lengths from 65 mm to 95 mm.

The additional lengths widen the existing indications for use in the meta-diaphyseal region through their longer length.



Example for treatment of distal lower leg fracture with 3.5 LCP System



Fig. 1

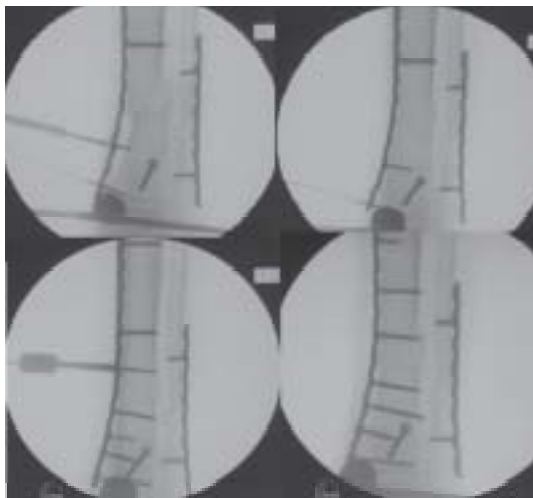


Fig. 2



Fig. 3

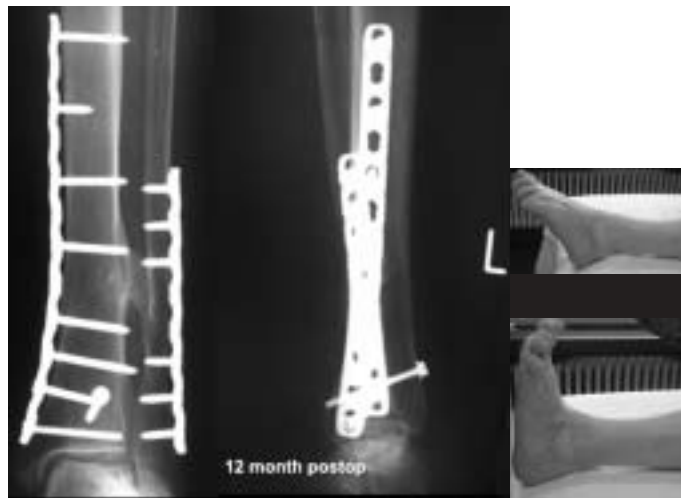


Fig. 4

The 73-year-old female patient suffered a distal fracture of the lower leg, in a road traffic accident (Fig. 1). With the soft tissue parts heavily swollen, first of all transfixion of the ankle joint took place. Once the soft tissue situation had settled down, definitive osteosynthesis was carried out after a few days.

First of all, bridging osteosynthesis (ORIF) was carried out on the fibula with a 3.5 LCP, an external fixator. Prebending and percutaneous introduction of a prebend 3.5 LCP (12-hole) from the medium malleolus in a proximal direction, on the distal tibia. Fixation of the implant on the shaft with a Head Locking Screw (Fig. 2a) was followed by repositioning of the joint block by means of a Cortex Screw (Fig. 2b). After that, merely completion of fixation with further Head Locking Screws inserted percutaneously (Fig. 2c,d). Early postoperative check-up (Fig. 3) and illustration of healing after 12 months with good functional results (Fig. 4).

Stardrive Screwdriver, T25, self-retaining, 245 mm



A new Screwdriver was developed for the Stardrive Screws.

Stardrive Screwdriver Shaft, T25, 165 mm



A Screwdriver with a shorter Shaft was developed for the Stardrive Screws.



K-Wire Box

The K-Wire Box is a tool that enables storage, washing and sterilization of K-Wires together with the tools. It is very useful during surgery as it offers all the necessary K-Wires without needing much space. The K-Wire Box consists of a base for up to 12 different containers for K-Wires. There are 19 different, transparent containers, depending on the length and diameter of the K-Wires.

David Helfet

Instruments for Over-Insertion of the Helical Blade for Trochanteric Fixation Nail (TFN)



The TFN is a new cannulated, intramedullary nail system. Its use is indicated in stable and unstable fractures of the proximal femur including pertrochanteric, intertrochanteric, and basal neck fractures, as well as a combination thereof.

The Helical Blade provides improved resistance to varus collapse and rotational control of the head-neck fracture segment.

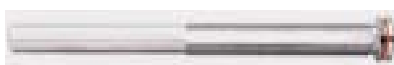
In certain clinical situations, the Helical Blade may be inserted beyond the lateral cortex of the femur. The Over-Insertion Instruments should only be used when more than five millimetres of interfragmentary compression is necessary. The lateral aspect of the Helical Blade will be flush with the lateral cortex.

Indications are 31-A1 and 31-A2 fractures—excluding 31-A3 (reverse obliquity fracture)—done in all appropriate fracture patterns to achieve maximum compression at the time of surgery, minimizing the subsequent dynamization by the Blade with postoperative weight bearing, thereby creating a more stable fracture-implant construct at the time of surgery.

Note: Clinically and in osteoporotic cadavers in the lab, pull-out of the blade from the head via axial compression using the compression nut has not occurred.

A Counterbore was added to the central hole of the Buttress/Compression Nut to allow the Blade Guide Sleeve to be fully inserted to the level of the lateral cortex.

The TFN is, at the moment, only available in Synthes USA and Stratec territories.



New spine products

New SynCages for Interbody Fusion

All new SynCage implants have a porous surface for better contact bone adhesion.

SynCage-Open

The SynCage-Open is an ideal implant for patients with nonosteoporotic vertebral bodies. It has been specially designed for use in interbody procedures from L1-S1. The design of the SynCage-Open is a fusion of the TIS and SynCage implants.

The cranial/caudal surface is convex in the sagittal plane to provide optimum interface with the endplate geometry.

The implant has a central canal and four lateral windows to receive autograft or other osteoconductive material to allow fusion to occur through the implant.

The outer ring of the implant has been designed to withstand the compressive loads on the outer portion of the vertebral bodies.

The SynCage-Open is available in an anterior, lateral and anterolateral version. All implants come in heights from 9 mm to 21 mm.



SynCage-Curved

The SynCage-Curved as an alternative to the Vertebral Spacer-TR (see page 15 in News 1-2003) enables surgeons to choose between a polymer and a titanium implant.

The SynCage-Curved has been designed as a scaffold, with central and lateral canals to allow for bone to grow from endplate to endplate, through the implant. The cranial/caudal surface is convex in the medial lateral direction to provide optimum interface with the endplate geometry.

The SynCage-Curved is available in heights from 7 mm to 17 mm.



SynCage-Small

The SynCage-Small is a titanium cage system designed for use in interbody procedures from C3 through C7.

The surface areas of the cranial and caudal surface have been redesigned to increase the surface area of the implant by 20% compared to the existing SynCage-C.

The SynCage-Small is available with three different sagittal profiles (parallel, convex, and lordotic) that provide the surgeon with a variety of cranial/caudal implant surfaces that may be required due to varying anatomy and to discectomy technique.

The SynCage-Small is available in heights from 5 mm to 12 mm.

The implant has central and lateral canals to receive autograft or other osteoconductive material to allow fusion to occur through the implant, from endplate to endplate. With the opening of this central canal, the outer ring of the implant has been designed to withstand the compressive loads felt on the outer portion of the vertebral bodies.





SynCage-Narrow

The SynCage-Narrow is a metallic version of the Vertebral Spacer-PR (see page 14 in News 1-2003). It is designed with saw-tooth teeth, similar to those existing on the PLIF allograft and Vertebral Spacer-PR implants, on the cranial and caudal surfaces thereby increasing its resistance to expulsion compared to the existing Contact Fusion Cage. The surfaces are convex to match the geometry of the vertebral endplates.

The SynCage-Narrow is designed with a width of 8 mm for all heights from 7 mm to 17 mm.

Because of this narrow, constant width and the flat insertion technique, only a small window has to be created by a partial laminectomy, lateral to the spinal cord, which does not compromise the facet joints and structural stability of that vertebral level.

Because the SynCage-Narrow is manufactured from a titanium alloy (TAN), less material is necessary and, therefore, it can be designed with lateral windows for fusion, giving the implant a more scaffold-like structure. Together with the central hole, the implant can receive autograft and allow fusion to occur through and around the implant. This SynCage-Narrow is, at the moment, only available in SUSA territories.



Click'X Rod, Curved

For the Click'X System, the Click'X Curved Rods with diameter 6.0 mm are now also available in shorter lengths of 45 mm and 55 mm. They are made of pure titanium (TiCp).



SynFrame Auxiliary Instrument—Long and Wide Retractors

The SynFrame Standard Access and Retractor System enables small incisions and significantly reduces tissue damage and blood loss.

New retractors have been developed to offer surgeons a wider range of options for patients with excessive soft tissue:

The new Long Retractors are 200 mm to 220 mm long and 23 mm wide.

The new Wide Retractors are 50 mm wide and 100 mm to 180 mm long.

Together with the existing Rib Retractor, Small Two-Piece Holding Ring (240 mm), Adjustable Ring Extensions, and Holder for Optics, they will be included in a new set, called SynFrame Auxiliary Instruments.

Cavity Creation System

The Cavity Creation System addresses the need to access the vertebral body transpedicularly and bilaterally. It is indicated for vertebral body compression fractures and features a disposable approach set and a reusable curette set. With these instruments, a cavity can be created that allows for a low-pressure delivery of filler material, reducing the risk of cement and marrow extravasation.

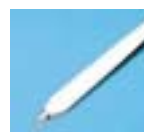
The Cavity Creation System requires fewer steps than existing systems when accessing a vertebral body. This reduces operative time and offers an easier procedure for the surgeon.

The instruments for Cavity Creation are, at the moment, only available in SUSa territories.



Cavity Creation Disposable Approach Kit Awl-Tipped Probe, 220 mm

The Awl-Tipped Probe establishes the entry point and trajectory into a bony site, and guides the Working Cannula into position.



Handle, Awl-Tipped Probe

The Handle features a latch design for easy assembly with the Awl-Tipped Probe.



Working Cannula, 5 mm, threaded

The Cannula threads maintain the surgical path and protect soft tissue while controlling the advance and removal of the Cannula.



Handle, Working Cannula

The Handle enables a simple snap on/snap off assembly with the Working Cannula.



Cannula Tamp, 4 mm OD

The Cannula Tamp features a basic loop design that allows easy manipulation in the Cannula.



Cavity Creation Curette Set Hinged Tip Curettes, 8 mm to 20 mm

The Hinged Tip Curettes are the most unique feature, providing a new mechanism for creating a void within the vertebral body. It deploys when the handle knob is turned. When deployed, the Curette is rotated and translated to create a cavity.



Cavity Creation Curette Set Graphic Case





Instruments for Universal Spine System (USS) Dual Opening for Deformities

Three existing instruments of the USS have been improved:

Rod Introduction Pliers (Persuader)

The improved Rod Introduction Pliers feature a sleeve holder that can be disassembled and has better cleaning properties.

Sleeve Positioner

The improved Sleeve Positioner features a sleeve holder that can be disassembled and has better cleaning properties.

Hook Positioner for USS Dual Opening Hooks

The new Hook Positioner for USS Dual Opening Hooks has improved the fit of both lamina and pedicle hooks.

Click'X Spondylolisthesis Dual Core Pedicle Screws

To offer the same screw portfolio in the Click'X Spondylolisthesis Dual Core Pedicle Screws Set as with the Click'X Set, the diameters 5.2 mm, 8.0 mm, and 9.0 mm were added. All new screws are available in lengths from 30 mm to 65 mm.

Furthermore, missing screws of 30 mm, 35 mm, and 65 mm in the existing diameters 6.2 mm and 7.0 mm were added.

Transpedicular Schanz Screw with double thread for Spondylolisthesis Reduction, with Dual Core

As an addition to the Universal Spine System, Transpedicular Schanz Screws with double thread for Spondylolisthesis reduction are added with Dual Core. The new screws are offered in titanium alloy (TAN) and stainless steel in diameters 6.2 mm and 7.0 mm, with thread lengths of 40 mm, 45 mm, and 50 mm.



New veterinary products

5.5 mm Broad LC-DCP

The use of the 5.5 mm Broad LC-DCP is indicated in treating equine long bone fractures. The plate features the limited contact—dynamic compression plate design—and is made of stainless steel. It is 5.7 mm thick, 16 mm wide, and available in lengths from 178 mm (10 holes) up to 322 mm (18 holes). The existing 5.5 mm Cortex Screws can be used with this plate.

The significantly increased stiffness in the LC-DCP construct should result in less micromotion at the arthrodesis site and therefore less cyclic fatigue and delayed fusion. The design affords a more uniform cross section that should reduce stress concentration at the screw holes.



5.5 mm Cortex Screw—Additional Lengths

This existing 5.5 mm Cortex Screws are now also available in lengths of 54 mm and 58 mm. This line extension provides the veterinary surgeon with more options in treating equine long bone fractures, especially in combination with the new 5.5 mm Broad LC-DCP.



3-year-old thoroughbred. Dorsopalmar and latero-medial radiographic views of a metacarpophalangeal arthrodesis performed with a prototype 5.5 mm LC-DCP. The arthrodesis was necessary, because the animal suffered a breakdown injury during a race.

Proximal Femoral Nail (PFN) study

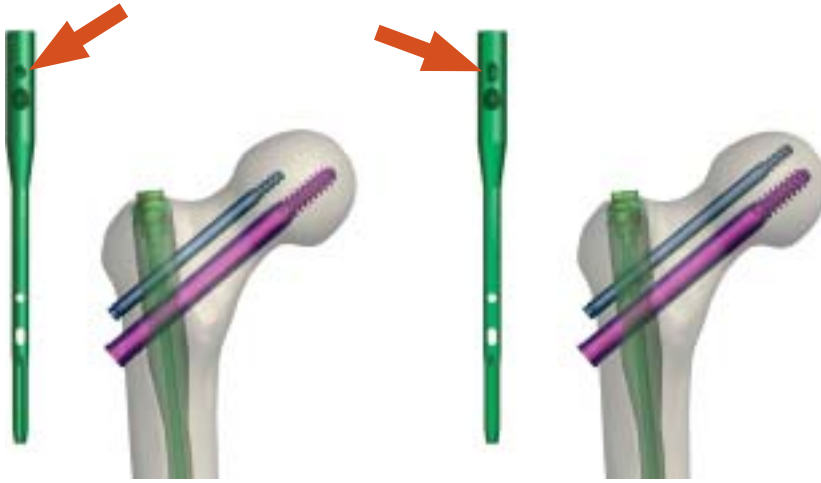


Fig. 1: Left: Standard PFN. Right: modified PFN for the study with slotted hole for the antirotation pin.

Treatment of unstable trochanteric fractures with the PFN has shown low implant-related complication rates in several clinical studies. The PFN has an extra hip pin to prevent rotation of the head neck fragment and an improved nail design with grooves to reduce the stress levels in the bone at the distal end of the nail. However, in rare cases, this hip pin resulted in two complications—medial migration and cut-out.

The initial step to reduce the risk of migration and cut-out was to modify the design of the hip pin and it now includes a small lateral shoulder that prevents excessive medialization. Then, in an attempt to further improve the clinical results, an in-depth investigation of the biomechanical situation was carried out. It was hypothesized that the pin can migrate when the pin rather than the femoral neck screw takes over the main physiological load. A modified PFN (mPFN) was developed, with an oval hole in the nail, instead of a round one, through which the hip pin is inserted. Under load-bearing conditions, the antirotational function of the hip pin is maintained whilst at the same time this design ensures that the load is taken over by the femoral neck screw.



Fig. 2: 87-year-old female patient 3 months after implantation of a mPFN.

A multicenter observational study was initiated under the lead of AOCID to investigate the handling of the mPFN, the stability and strength of the construct, the incidence and type of implant-related complications, and whether the new concept functioned in clinical practice.

In six European teaching hospitals, 250 patients with unstable trochanteric fractures were included and treated with the mPFN. Prospective documentation and data collection were performed for 3 months postoperatively. During this period, patients were followed up at 6 weeks and at 3 months. At each visit, details about the patient, implant, the actual surgery, postoperative complications, recovery and x-rays were documented. Besides the clinical examination, AP and lateral x-rays of the fractured hip were taken. The x-rays were evaluated for fracture reduction, femoral neck screw and hip pin position, consolidation, tendency to telescoping or collapse, loss of parallelism, migration and cut-out.

The study showed that the handling was equivalent to that of the regular PFN. No breakage of the nail at the side of the oval hole was documented. The cut-out risk was practically, but not completely, eliminated if reduction of the fracture and position of fixation were adequate. Medial migration was no longer documented.

However, several complications related to surgical technique, resulting in excessive lateralisation of the pin, were reported.

In conclusion, this study showed that the new concept with the oval hole in the intramedullary nail of the modified PFN works in clinical practice but does not improve the clinical results. Much more important to the clinical outcome is proper fracture reduction and correct selection and positioning of the implants. Consequently, it was decided not to implement this design modification.

Stardrive® recess compared to hexagonal recess— A finite element analysis

Situation

The Stardrive® is the new AO screw drive connection. This drive has several advantages when compared to the conventional HEX drive (see also TK News 1/02, p. 10). The Stardrive® is also used in locked screws. The drive diameter of the Stardrive® is larger than the HEX drive, while the HEX drive is deeper. The influence of these parameters on the stresses in the transition zone between the head and the body of the screw, which is the weakest region of any screw, was not predictable. The AO Research Institute performed a mathematical analysis of the situation.

Goal

To compare the von-Mises-stresses in the transition zone between the screw head and the screw body for the two screw drive designs.

Method

A Finite Element Analysis using the ABAQUS Software was carried out. Two models with up to 250,000 elements and linear elastic material properties were analyzed under a bending and a torsion load.

Results

The maximum von-Mises-stresses in the transition zone of the Stardrive® screw are 4% lower under bending and 8% lower under a torsion load than those in the HEX drive screw. The main reason for this result is the depth of the drive. In the case of a locked screw, the screw head is supported by the surrounding plate. For the Stardrive® design the weakest diameter lies in the supported area inside the head, but for the HEX drive design, the drive reaches into the unsupported area of the transition zone and thus the weakest diameter lies in the unsupported area.

Conclusion

Despite the geometrical differences of the drive, a locking head screw with Stardrive recess offers at least the same resistance to bending and torsion loads than a locking head screw with hexagonal recess.



Fig 1: Stress distribution in a locked screw with HEX drive under bending load.



Fig 2: Stress distribution in a locked screw with Stardrive® under bending load.

AO Development Institute –Ten years of successful cooperation between surgeons, researchers and engineers

Research projects that result in new concepts and principles often require new technologies, implants and instruments. To better cope with these technical needs S. M. Perren, R. Frigg and H. Wyss conceived a new engineering group under the creative leadership of R. Frigg with the goal of implementing research ideas and developing basic and possibly risky projects with a far-reaching and extended horizon.

In general, such projects do not respond directly to the perceived day-to-day needs of the surgeons but originate from novel ideas, thus allowing for unexpected basic progress and leadership supplementing the conventional product development of the manufacturers. The following examples demonstrate the basic philosophy of the ADI and its close collaboration with leading surgeons, the AO Research Institute (ARI), AOTK and with the product development departments of the manufacturers.



Fig 1: The LISS system with threaded conical locking.

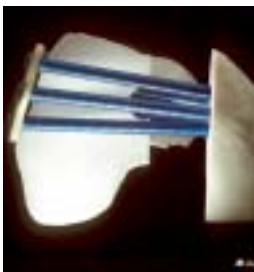


Fig. 2: Angular locking of metaphyseal fixation of LISS.



Fig. 3: Proximal humerus locked pin and screw fixation.

From PC-Fix to MIPO

One of the first projects of the ADI was to develop technologies that were in line with the new balance of mechanics and biology as required by the 'biological internal fixation' approach. It was an essentially new approach to internal fixation that combined fracture stabilization with care for the biological aspects of not only the soft tissues but also of bone. Research had shown that the potential for living bone to unite solidly, very quickly, and reliably was not being fully exploited by the existing compression technology. Compression technology was thus supplemented by a new approach to internal fixation.

In ARI research, the new principle of the internal fixator had resulted in the so-called Point Contact Fixator (PC-Fix). The PC-Fix produced by the ADI served as proof of concept for animal studies. Its technology combined optimal biology with flexible fixation to stimulate prompt bone formation. The interlocking of screws within plates allowed minimization of the 'bone to implant' contact area that was previously identified as deleteri-

ous to the blood supply. ARI studies and clinical experience also provided proof of better infection resistance. An important advantage of this technology was that the screws made of CP titanium did not show a single failure on application out of more than 2,000 locked screws clinically used. The principle of interlocking removed the need for axial preloading of the screws (now 'threaded bolts'). The problem was that removing the locked conical connection between the 'plate' and screw required a new locking mechanism. The ADI developed the conical threaded interlocking system that resolved this problem completely (Fig. 1). Thus, it was possible to develop a simple internal fixator for maxillofacial surgery for fresh fractures that supplemented the existing MF-locked system for defect application.

The next step of ADI development was the creation of the LISS (Less Invasive Stabilization System), which replaced angled blade fixation of metaphyseal fractures, allowing minimally invasive procedures with 'blind' insertion of the screws. It is a fact that angular stability of the screws (Fig. 2) not only solves many problems of metaphyseal anchorage (eg. LISS) but is especially important in epiphyseal comminution where it opens up totally new horizons as in the new developments relating to proximal humerus fractures (Fig. 3). In preparation for the new technology, unicortical, self-drilling screws were developed in a combined effort of the ARI and ADI that resulted in a basic change in AO philosophy towards self-cutting bone screws. The ADI contributed fundamentally to the newly developed self-tapping technology of the AO. It also defined the new shape of shallow threads of some special screws (such as LISS, new Schanz, LCP) that allowed the core diameter to be increased with successful improvement of flexural stiffness and of the resistance to lateral loading, which is especially important in cancellous bone, while maintaining resistance to axial pull-out. Thus, the basic technology for MIPO (Minimally Invasive Percutaneous Osteosynthesis)

(Fig. 4) was born—Locking allowed elevated application, foregoing the need for precise shaping that blind application would not allow, which meant that preshaped implants could be used. The ADI contributions mentioned are originating technologies of today's clinically successful LCP (Locked Compression Plate) and the like.

As already mentioned, MIPO is a basic technology that offers interesting and important aspects. Together with a special working group of the AOTK, collinear reduction (Fig. 5) has been developed by the ADI. Although collinear reduction is an essential ingredient of MIPO, it has the potential for much wider application. In maxillofacial surgery, applying MIPO techniques required endoscopic procedures that were studied and developed in collaboration.

Blades and screws

The ADI also developed the new Schanz screw, combining radial preloading as a new ARI-born principle with self-drilling and self-tapping. The application of the new Schanz screw consisted of very simple insertion of this self-drilling threaded bolt, eliminating much of the 'fiddly work' such as drilling, tapping, and length measurement required for conventional technology. The new technology was not only much simpler but provided precise seating of the thread by minimizing the exposure to wiggling and losing track of the hole buried deep within the soft tissues. The preloaded interface minimized the loosening of the Schanz screws that was often seen with conventional technology.

Many other developments of the ADI are currently in routine use in clinical applications of internal fixation. One of these examples is the spiral blade, which has revolutionized the anchorage of medullary nails, eg, in the proximal femur. The first prototypes of the novel and successful Universal Spine System (USS) were also developed at the ADI, but because of very early transfer to Stratec's product development, the ADI contribution is not well recognized today (Fig. 6).

Flexible nails and helical implants

In medullary nailing, the problem of approach is usually that the point of insertion depends on the shape of the nail that in turn must fit the medullary canal after final in-

sertion. If it were possible to allow insertion of a deformable nail that could be stiffened once inserted to provide resistance to load, a much wider choice of insertion points (eg, avoiding damage to the rotator cuff) would be available (Fig. 7). The proximal humerus and the femur are good examples of this—The FLEXNAIL developed by the ADI allows avoidance of damage to the rotator cuff in proximal humerus fractures. In femur fractures, the FLEXNAIL also allows much easier insertion at the lateral aspect of the trochanter instead of the 'fossa piriformis'. The HELICAL NAIL (Fig. 8), another novel basic principle developed with the help of ADI, achieves the goal of easier surgical insertion (Fig. 9). The principle of helical implants as published in the *Injury Supplement* led to the development of the HELICAL NAIL and the helical plate (HUMFIX Fig. 10). The former is now in the final stage of product development, but the latter has not yet received the attention it clearly deserves.

External fixators—pinless, articulating and disposable

Some of the developments of ADI with substantial potential have not yet achieved wide clinical acceptance. An example of this is the PINLESS. This newly developed external fixator eliminates the need for fixation (Fig. 11) through the bone. The conventional technology of external fixation requires that the pins connecting the rod to bone are anchored within the bone. Such fixation has two essential drawbacks—Once drilled, the position and inclination of the pins in relation to the bone cannot be modified without drilling a new hole. The PINLESS is anchored only at the bone surface using the principle of pointed forceps. Anchorage is achieved without iatrogenic bone damage and application should be easy and/or easily modifiable. Furthermore, the change from preliminary external fixation to final medullary nailing is safer with PINLESS than conventional external fixators because no holes providing access from pin track to medullary cavity are drilled. Another advantage is that the PINLESS forceps can be used for temporary or short duration reduction (for example, the tendency of short proximal tibial fractures towards retrocurvation may be countered). The PINLESS has not yet seen the widespread application that its potential deserves.

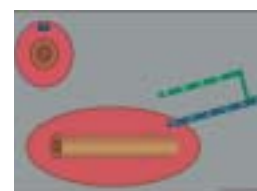


Fig. 4: MIPO (Minimally Invasive Percutaneous Osteosynthesis). It also allows for the use of pre-shaped implants.



Fig. 5: Collinear reduction.

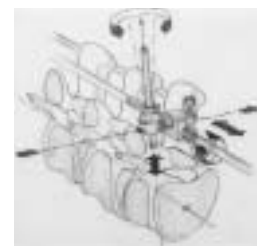


Fig. 6: The Universal Spine System (USS) originated in the ADI.



Fig. 7: FLEXNAIL humerus. Avoids lesions of the rotator cuff.



Fig. 8: HELICAL NAIL. A fundamentally new principle.



Fig. 9: HELICAL NAIL. Allows a surgically easier lateral insertion.



Fig. 10: Helical plate HUMFIX.



Fig. 11: PINLESS external fixator.

Another device that is not yet widely in use is the FLEXAFIX. It is an external fixator for the wrist that allows not only extension and flexion but also ab- and adduction during postoperative exercising. In this case, the clinical advantage of the new development that was brought about by a collaborative effort of ARI and ADI has not yet been perceived. A further development of the ADI that at that time was not realized was a very simple external fixator system, DISPOFIX, which could be produced at minimal cost for use in developing countries. It is now obvious that the ADI was too early, and it is rewarding to see that this type of development is finding practical application.

Biodegradable implants

Using the progress made by the ARI in biodegradable implant materials, the ADI has developed a set of plates and screws for maxillofacial application and anchors for general applications. The problem to be solved was that in maxillofacial surgery the tendency is to use small implants but many of them. The removal of such implants needs an extensive surgical approach. As such implants are not likely to be subject to high functional loads, biodegradable materials such as the new generation developed by the ARI are finding an interesting and important application.

ADI as a partner

In addition to the type of developments mentioned, the ADI supports AO teaching, providing the infrastructure of the courses in Davos and abroad but also organizing dedicated workshops and seminars on new technology. The ADI is an essential partner of the AOTK-System and is represented in all Expert Groups. These activities, together with the engineering support provided worldwide to creative surgeons, inherently escape public attention.

Over the past ten years, the ADI has contributed to fundamental progress in close collaboration with the ARI, AOTK and the product development departments of the manufacturers and last, but certainly not least, the collaboration of many highly motivated surgeons who cannot be quoted individually here. Some important recent new techniques that assure success of the AO group as the leader in the trauma field have evolved from the ADI. Its contribution is often hidden but nonetheless of basic importance. As can be expected, some developments fail, some still await recognition and some tend to be overlooked even though the impressive series of basic contributions are essential to the AO Foundation.

Heather Cain, Robert D. Fraser, Beat Lechmann

Portrait of Christopher Cain, M.D.



Dr Christopher Cain is one of Australia's principal authorities on surgery for spinal disorders. Trained as an orthopedic surgeon in Adelaide, where he obtained his MD for a thesis on the effect of surgery on the blood supply to the spinal cord, Chris' practice has been devoted to the spine for more than 10 years. He spent 12 months working with John

Webb in Nottingham, UK, before joining the Spinal Unit at the Royal Adelaide Hospital to work with David Hall and Robert Fraser.

Chris was the driving force behind the establishment of the Adelaide Spine Clinic, leading to its recognition as an AO International Spine Centre for the training of AO Fellows. He has been a devoted disciple of AO principles and technology and is a regular lecturer and instructor at AO Spine Courses internationally with a key involvement in AO Oceania.

With hard work and dedication, Chris has amassed an extensive and unique surgical experience, dealing with the complete range of spinal disorders in all age groups. His surgical skill mirrors his ability as a lecturer, being highly organized and thorough, pre-

cise, technically exact, and forward thinking. Chris expanded his background with the biomechanical principles of spinal disorders more than ten years ago. As a young surgeon, he was involved in the development of the USS, its instruments, and teaching elements as an active member of the team headed by Max Aebi and John Webb. It is these qualities that led to his involvement in the redesign of the SynCage and its accompanying instrumentation. With his contribution, the SynCage philosophy has been continued and led to the radiolucent solution in which current clinical requirements have been incorporated. There are strong concepts in the development progress, which were initiated by Chris, in which his clinical and biomechanical experience play a major role.

Chris shows the same discipline, dedication, and integrity that has placed him near the forefront of his specialty field in his life outside of spinal surgery. He has a saying that one should not complain about something unless one is willing to be part of the solution. This philosophy led him to join the AMA (Australian Medical Association) where in a very short time he has become vice president of the South Australian Branch as well as being invited onto several federal executive com-

mittees, including the Medical Professional Indemnity Taskforce. In May of 2003, he was awarded the AMA President's Award by Dr Kerryn Phelps for work conducted in relation to this Taskforce. He has also been on the executive of both state and federal committees for AOA (Australian Association of Orthopaedic Surgeons).

Married to Heather and with two children, Chris somehow manages to find time to enjoy family and sporting pursuits. He still finds time to play tennis and squash weekly and regularly completes a weights program, without the need for a personal trainer required by many who lack the self-discipline. He has worked hard at his sport and plays to win!

Despite all of his professional extracurricular activities he is a keen DIY person, who at the moment is making built-in cupboards and desks for a new study (some would say not far removed from orthopedics). He has a broad range of interests including wine, travel, and his two teenage children.

He is also a follower of Australian Rules Football, supporting the "Adelaide Crows" in the national competition whenever the opportunity arises.

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