



Orthofix External Fixation

Basic Considerations

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MECHANICAL CONSIDERATIONS IN FRACTURE REPAIR

The distinguished surgeon and educator, Alan Apley used to begin one of his lectures with a question: "Why do fractures heal?" And he would, after a suitable pause, give the answer: "Fractures heal because the bone is broken!" This may sound simplistic, but it is unquestionably true. Fracture of a long bone such as the tibia, triggers a series of events at the fracture site which is designed to stabilize the situation and initiate and promulgate the repair process. There are, however, certain prerequisites for the successful healing of a fracture and these may be summarized as follows (Kenwright and Richardson, 2000):

- There must be viable bone with no major defect at the fracture site.
- The surrounding soft tissues must be adequately vascularized.
- There must be no major infection
- The mechanical conditions must be appropriate for the different phases of fracture healing.

The phases of bone healing are well recognized. There is initial formation of a hematoma at the fracture site immediately following injury. This is invaded by inflammatory cells and becomes organized into granulation tissue which represents a primary callus response. A measure of **stability** is important at this early stage in order to maintain the integrity of the hematoma. Healing then proceeds by either direct (primary) bone healing, indirect (secondary) bone healing or a combination of the two, depending upon the prevailing mechanical conditions.

In **direct (primary) bone healing**, osteons cross the fracture line where the fragments are in direct contact. This kind of healing is seen following **very rigid stabilization** such as that conferred by a plate and screws, where movement between the fracture ends is virtually non-existent. The process of primary bone healing is extremely slow, and occurs without the formation of external bridging callus. Under these conditions the return to normal bone strength is very protracted since it relies upon ultimate remodelling of the bone, which is a long, drawn-out process. Union may take in excess of one year and refracture and time-related osteolysis are recognized complications.

Indirect healing predominates where there is **some degree of movement** between the bone ends, and in these circumstances, bridging external callus forms in an attempt to reduce movement between the fragments. As it develops, this external callus envelope provides excellent support, and fractures healing in this indirect manner regain strength rapidly as the external callus matures. Remodelling then occurs in a bone which can already withstand physiological loading.

EARLY EXTERNAL FIXATION

In the past, surgeons tended to reserve external skeletal fixation for the most severe types of fractures, especially those associated with extensive damage to the soft tissues. This was due largely to the type of equipment available, which at the time, was heavy, cumbersome, and difficult and time consuming to apply. Furthermore, these early external fixation devices were expected to provide a measure of rigidity similar

to that provided by internal fixation with a plate and screws which was, at the time, the treatment of choice for long bone fractures. Even the most rigid external fixation, however, will permit some minimal movement. It has been suggested that optimal primary bone healing will not be achieved if movement at the fracture site is more than 5-10 microns. Even with very rigid external fixation, this movement is often greater than 10 microns and with this type of equipment, therefore, primary bone healing will not occur. On the other hand, the devices originally available did provide a substantial measure of uncompromising rigidity which, while valuable in the early stages of fracture healing, did not encourage the formation of **external bridging callus**. It therefore followed that conventional external fixation devices did not encourage either primary bone healing, or external callus formation to best advantage, resulting in a prolongation of overall healing time and a high incidence of non-union. These features, together with the fear of pin track infection, accounted for the understandable reservations expressed by many surgeons regarding the use of external skeletal fixation.

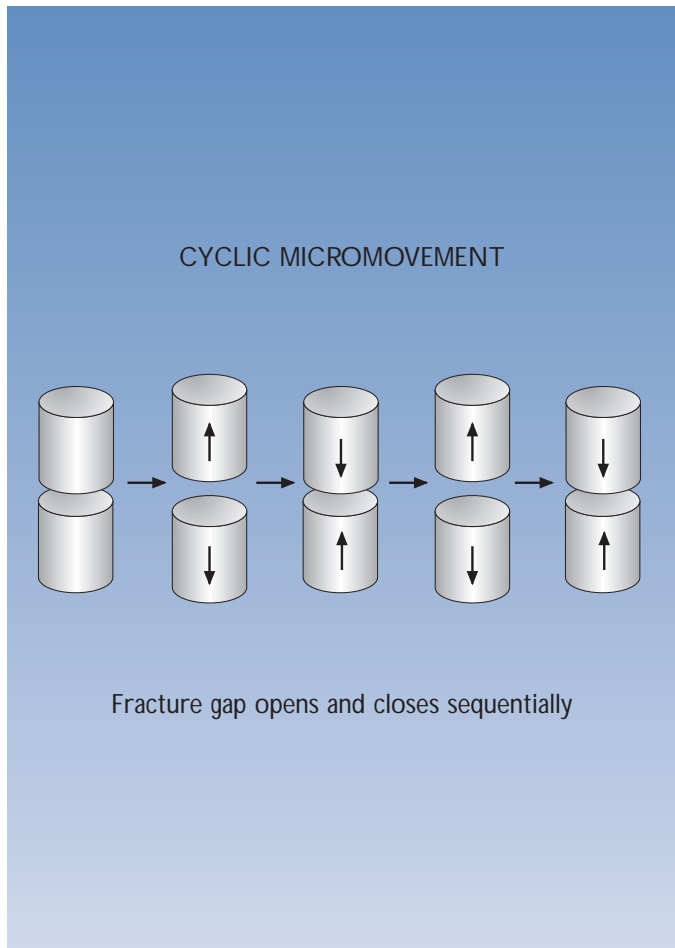
THE CONCEPT OF DYNAMIZATION

That some element of movement is necessary for external callus formation is now universally recognized. In femoral fractures treated in traction without a splint (as they used to be), macromovements occur at the fracture site in the early days after injury (Lippert 1974) and these are associated with the production of prolific amounts of external callus. Fractures treated in casts are also known to move considerably in the early days after injury and fractures of the tibia treated this way in combination with early weightbearing often heal with substantial callus formation (Sarmiento et al 1989). It is also worthy of mention that in fracture situations where there is early and continuous cyclic micromovement, as in the case of rib fractures subjected to the ebb and flow of respiratory movement, there is abundant external callus formation.

In contrast, where external fixation is used in combination with internal fixation, or where rigid internal fixation with a plate and screws is employed, movement between the bone fragments is inhibited, and external callus formation reduced or suppressed completely. As described above, external fixation itself is often fairly rigid in order to confer sufficient strength to maintain the reduction in long bone fractures and prevent the development of malunion. This rigidity tends to work against the natural stimulus for callus growth and development. As we shall see, however, external fixation does offer opportunities for the application of controlled loads to the fracture site. This ability was recognized by Giovanni De Bastiani, originally a Professor of Physiology at the University of Padua, and subsequently Professor of Orthopaedics at the University of Verona. He called it **Dynamization**.

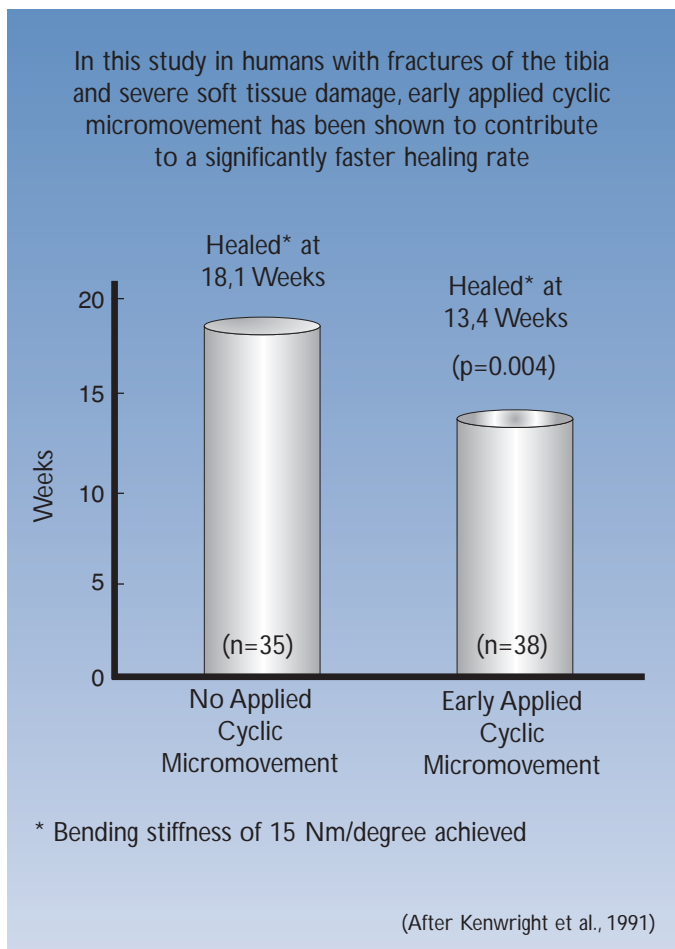
The term Dynamization was originally applied by De Bastiani to describe the transfer of a **progressive** load to the fracture site at a given point in the healing cycle. A body of experimental work now exists to suggest that different kinds of applied movement are of particular benefit at different stages in the healing process, and that the term "Dynamization" should be expanded to include all of these. The two main types of movement which fall under this category are:

- Cyclic Micromovement
- Progressive Loading

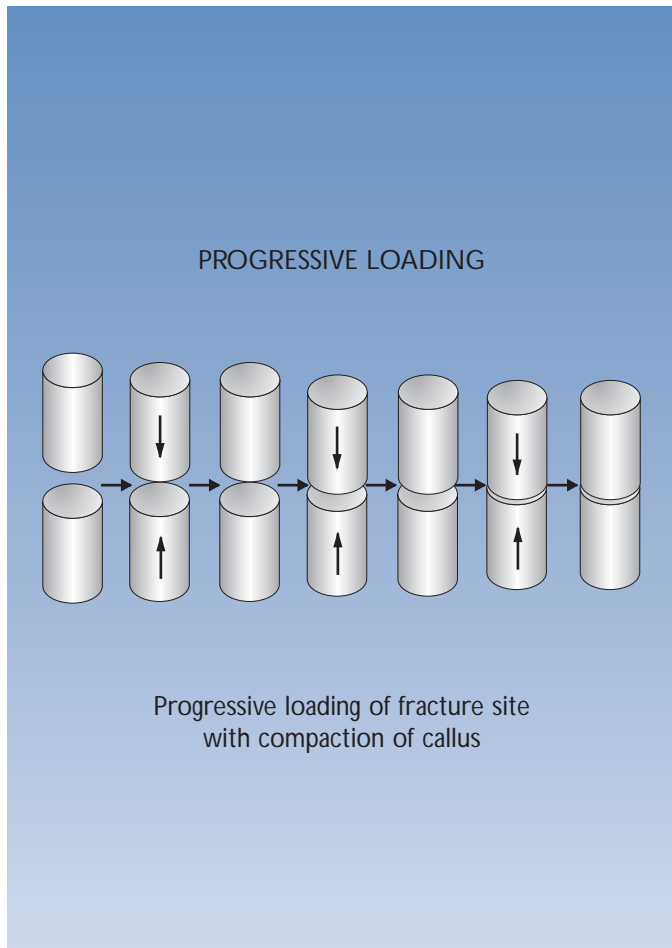


Cyclic Micromovement

In an experimental study in sheep tibia, small amounts of micromovement applied at an early stage following osteotomy have been shown to enhance external callus formation (Goodship and Kenwright 1985). This study employed short periods of axial cyclical movement (500 cycles at 30% strain, over 17 minute periods, daily), commencing soon after the injury. This, and other studies have shown that both the amount of applied strain and the timing of application of the cyclic micromovement are critical. In terms of the level of applied strain, while 30% achieved the desired result with enhanced callus formation, levels which were either too high (60%) or too low (5%) inhibited healing. As regards timing, if the application of micromovement was delayed until 6 weeks following the osteotomy, healing was inhibited.

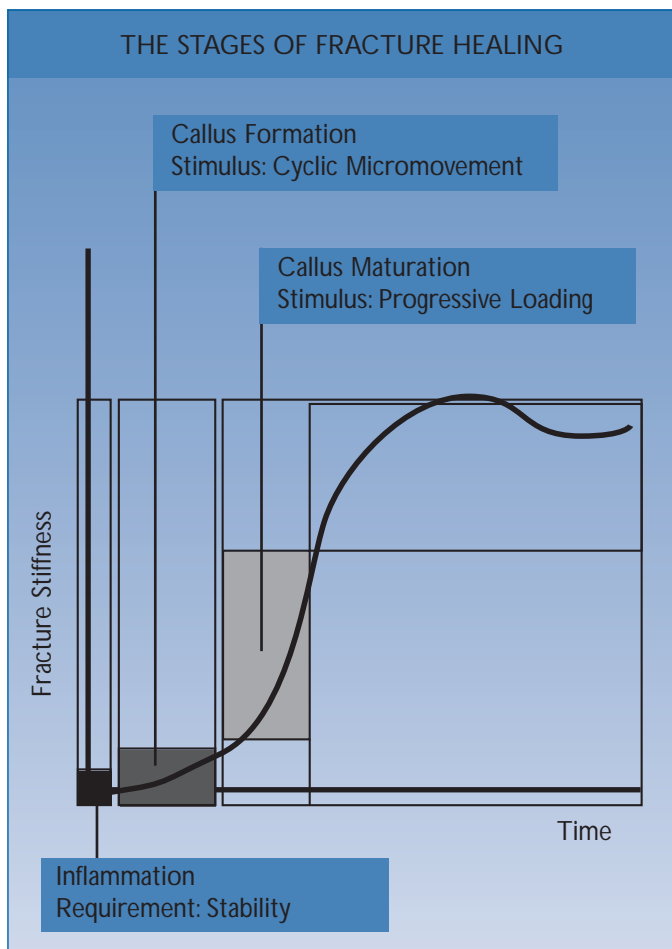


The important contribution of cyclic micromovement to overall healing has been convincingly demonstrated in a clinical study (Kenwright et al 1991). This study involved 82 patients with tibial fractures, half of whom were randomly allocated to a rigid external fixator and half to a fixator capable of supplying cyclic micromovement from day 7 following fracture. As can be seen from the graph below, fractures subjected to early cyclic micromovement healed significantly faster than those treated with a rigid fixator throughout.



Progressive Loading

It has also been shown that controlled collapse of the callus at the fracture site leads to a more rapid return of bone strength in groups of experimental fractures treated with external skeletal fixation. As described earlier, this technique was originally described in the literature as “dynamization”, but it is completely different from the controlled early cyclic micromovement discussed in the previous section. Closure of the fracture site is the result of Progressive Loading, and once bridging of calcified callus is visible across the fracture site, there is a rapid fall in cyclic micromovement (Richardson et al 1995). It is this **reduction** of micromovement which allows the survival of osteoblasts at the fracture site. Progressive loading thus aids maturation of the external callus. The way is now clear for full calcification of the callus, and phase three of the healing process is in progress.

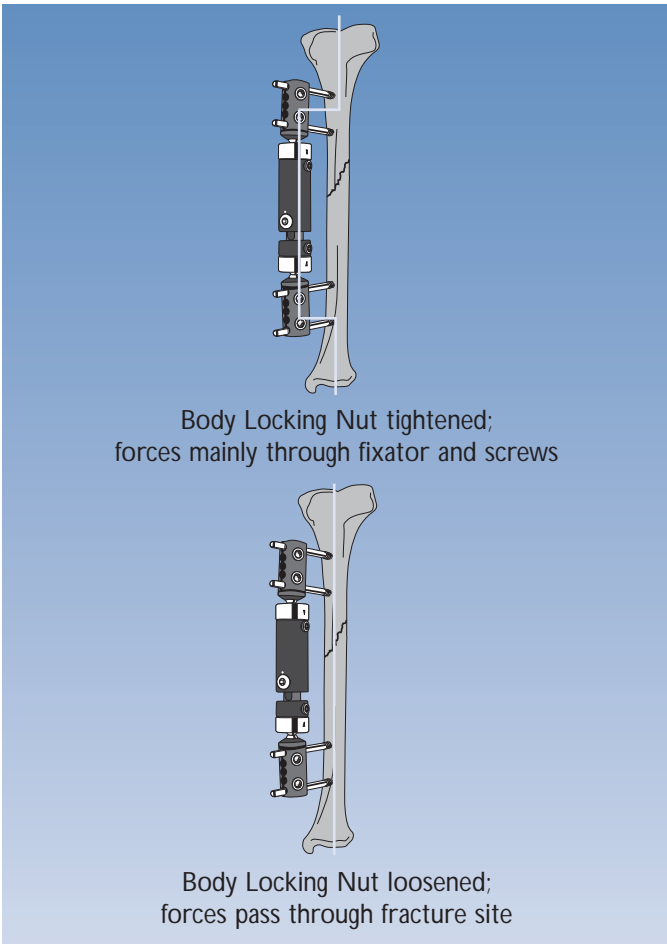


While the ideal mechanical conditions for remodelling are not fully understood at this time, it appears that some degree of loading is needed for the process to proceed effectively, thus restoring the normal mechanical properties of the bone.



The original Orthofix Dynamic Axial Fixator (10000 series), often referred to as the “DAF”, was designed by De Bastiani to allow the release of axial forces in the external frame at an appropriate point in the healing cycle, thus transferring a progressive load to the fracture site.

This was achieved by constructing the body, or barrel of the fixator in two parts, one of which could slide in an axial direction within the other. The two components of the body were locked together by tightening a Central Body Locking Nut to form a single rigid unit following initial application of the frame, and this situation maintained until the decision was made to “dynamize” the fracture.



Body Locking Nut tightened;
forces mainly through fixator and screws

Body Locking Nut loosened;
forces pass through fracture site

He recommended that this “dynamization” should occur once the presence of early callus had been detected. His background in physiology gave him the understanding that natural forces should work to advantage once callus was forming. Callus was usually first seen some 2-6 weeks after application. As we have already seen, while this technique entered the literature as “dynamization”, it was actually the process of progressive loading at the fracture site, with closure of the fracture gap.



In some very comminuted fractures, fear of dramatic fracture collapse with major shortening prevented such fractures from being “dynamized” despite x-ray evidence of the presence of callus at the fracture site. To allow such fractures to be subjected to movement without fear of collapse, the Dyna-Ring attachment was developed. This ring with its silicone cushion could be attached to the male stem of the fixator body, 2 mm below the rim of the female component. Now, with the Central Body Locking Nut loosened, 2 mm of movement at the fixator and no more, was produced on weightbearing, providing stimulus without collapse.

Initial results with the Dynamic Axial Fixator were highly encouraging and associated with a low incidence of pin track infection and a low non-union rate (De Bastiani et al 1984; Foxworthy and Pringle 1995; Wallace and Howard 1993). Since we now know that cyclic micromovement is of cardinal importance in the early stages of fracture healing, and progressive loading later, why was the original Orthofix Dynamic Axial Fixator so effective if it omitted to provide early cyclic micromovement? The answer is simple. **It did provide early cyclic micromovement as well as later progressive loading.** This was accomplished by virtue of the fact that as soon as they were able, and usually not more than a week following application of the frame, patients were encouraged to partially weightbear on their locked frame. Applying weight in this way caused minimal flexion of the screw shafts, which immediately returned to their former, unflexed state as soon as weight was removed from the affected limb as the foot left the ground. Thus walking on the locked fixator effectively delivered cyclic micromovement to the fracture site in this way.

The Development of the ProCallus Fixator

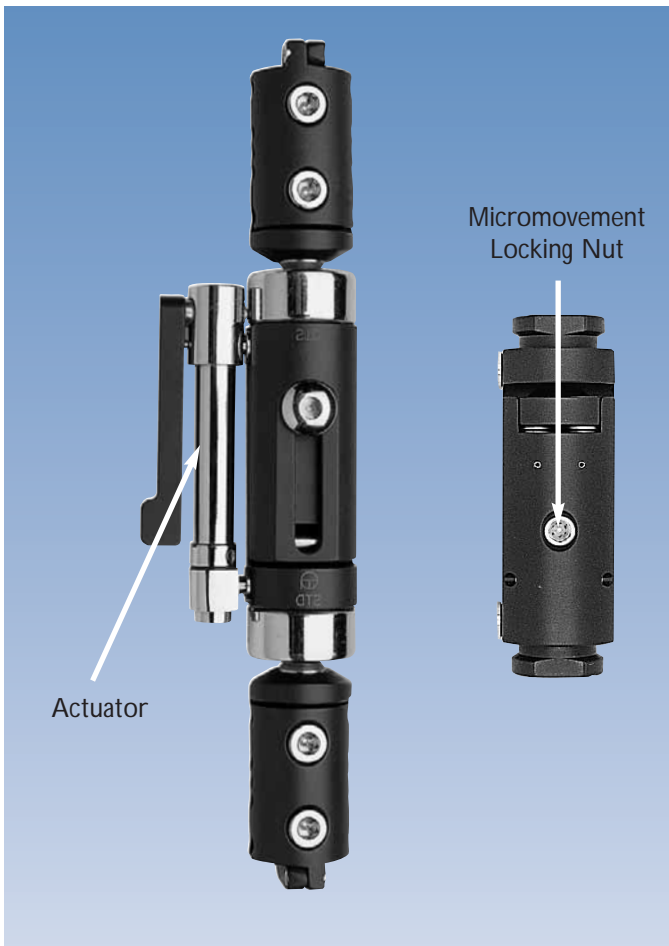
With growing understanding of the concept of Dynamization and its component parts, it was appreciated that the design of the original Dynamic Axial Fixator could be improved. Changes were incorporated both to allow cyclic micromovement to be applied at an earlier point in the healing cycle, i.e. even before the patient was capable of partial weightbearing, and to provide a more consistent and reliable form of cyclic micromovement. This was the new Orthofix ProCallus Fixator.

While the barrel is still made up of two components, they now slide one against the other in a groove, rather than fitting one inside the other. This reduces the likelihood of jamming when the **Central Body Locking Nut** is eventually loosened to allow Progressive Loading.



A spring-loaded **micromovement facility** which can function while the Central Body Locking Nut remains tightened, has been incorporated. The feet of the **Actuator** fit into the cams of the fixator. With the **Micromovement Locking Nut** loosened and the Actuator in place, moving the **lever of the Actuator** backwards and forwards to its full extent will result in 2 mm of controlled cyclic micromovement in the fixator body. The extent of movement at the fracture site will depend upon the rigidity of the system (i.e. number of screws, bone-fixator distance) and the callus and soft tissue resistance.

This means that cyclic micromovement can now be applied daily to the fracture site at a very early stage while the patient is still confined to bed and not yet able to weightbear. Once the patient can weightbear, the Actuator is removed permanently, and with the Micromovement Locking Nut loosened and the Central Body Locking Nut still tightened, weightbearing itself will provide effective cyclic micromovement at the fracture site without the risk of fracture collapse. When progressive loading of the fracture site is desired, this is achieved by loosening the Central Body Locking Nut.



The recommended protocol for use of the ProCallus fixator is given below:

A Protocol for Phased Dynamization

DESIGNED TO PROVIDE AN OPTIMAL STIMULUS FOR THE DEVELOPING CALLUS AT THE CRUCIAL STAGES OF THE HEALING CYCLE			
Time from Injury	Healing Stage	Physiological Requirements	Fixator Mode
Day 1-7	Inflammation: <i>Patient bed-bound or non-weightbearing</i>	Stability	<ul style="list-style-type: none"> • Central Body Locking Nut TIGHTENED • Micromovement Locking Nut TIGHTENED
Starting at some time between day 1 and 7 and continuing until week 3-6	Callus Formation: (a) <i>Patient non-weightbearing or partially weightbearing up to 20Kg</i> (b) <i>Partial weightbearing 20Kg or more, to full weightbearing</i>	Cyclic Micromovement <ul style="list-style-type: none"> • Actively administered using the Actuator • On weightbearing 	<ul style="list-style-type: none"> • Central Body Locking Nut TIGHTENED • Micromovement Locking Nut LOOSENED Actuator used for 10 minutes daily (one full cycle every 2 seconds) for 2-3 weeks, or until partial weightbearing 20Kg. ACTUATOR MUST BE REMOVED AFTER EACH TREATMENT SESSION Actuator is not used once patient is weightbearing 20Kg, and should be removed permanently at this point.
Week 3-6 onwards	Callus Maturation: <i>Clinical evidence of fracture stability; partial weightbearing 20Kg, up to full weightbearing</i>	Progressive Loading	<ul style="list-style-type: none"> • Central Body Locking Nut LOOSENED



Dynamization with the XCaliber Fixator

The XCaliber fixator is supplied with either a static or a dynamic compression-distraction unit. The static unit permits simple compression or distraction of the fracture only. The dynamic unit is spring-loaded and when the patient weightbears with the central body locking nut of the fixator loosened, cyclic micromovement is applied to the fracture site. Progressive loading may then be applied to the fracture at the appropriate time by removing the dynamic compression-distraction unit.

The development and refinement of the Orthofix External Fixation System described above illustrates the basic Orthofix Philosophy which has governed the design and development of all its products. In a single sentence this may be described as “**respect for, and enhancement of the natural physiological process of fracture healing**”. The manner in which this is achieved is detailed below:

Minimal disturbance of the fracture site and excellent stability in the initial period following fracture

- The screws are placed in the bone on either side of and well away from the fracture site.
- The Orthofix provides a degree of stiffness comparable with that of the double-frame Hoffmann-Vidal Fixator (Aro and Chao 2000), controlling lateral bending and torque forces during the initial phase of treatment. This stability derives in part from alignment of the body of the fixator with the long axis of the bone to be treated, partly through the inherent rigidity of the device and the screws, and partly as a result of screw geometry. The ability to lock the body in the rigid mode, allowing early mobilization and weightbearing, encourages bone metabolism.

The net result is to permit organization of the hematoma to proceed under the most favorable conditions possible and to allow the initial external callus collar to form.

Stimulation of the production of external bridging callus and its subsequent maturation, by the application of effective mechanical stimuli to the fracture site at appropriate points in the healing cycle

The minimizing of complications by an understanding of, and respect for bone biology

The major problems with external fixation, which have prevented it from replacing internal fixation in many indications, are pin track infection and pin loosening. The design of the Orthofix screws is a major feature of the system and plays an important role in the prevention of pin-associated problems. This topic is dealt with separately below.

Shorter Learning Curve: Ease of Application; Ease of Removal

Finally, mention must be made of the ease and rapidity with which the Orthofix can be applied and removed. This is particularly germane to the situation in the Emergency Room, where multiple trauma cases are regularly encountered. The ProCallus Fixator is applied in minutes (average 20-30 minutes after familiarization with the technique) and this implies shorter periods of anesthesia in these severely compromised patients. Since the screws are conical in shape, they can be removed with ease as an out-patient procedure without the need for general or local anesthesia.

IN TRAUMA

1. Fractures of the Long Bones

While initially developed for the routine treatment of fractures of the long bones of the upper and lower limbs, few would now regard external fixation as the treatment of choice for simple fractures of the tibia or femur. In these situations, intramedullary nailing is universally regarded as the standard procedure. Since external fixation does not interfere with the fracture site, it was, and still is in many instances, recommended for use in association with open fractures of the tibia and femur. Even here, intramedullary nailing has in recent years become more ubiquitous, and is frequently used to treat Grade II open fractures with acceptable results. The treatment of Grade III open fractures, however, remains for the most part the domain of external fixation. Intramedullary nailing of tibial fractures does not always produce ideal results, as there is a high incidence of chronic residual knee pain and disability reported in the literature (Court-Brown et al 1997; Dogra et al 2002; Skoog et al 2001; Wallace and Howard 1993).

The most significant contribution provided by external fixation in general, and Orthofix external fixation in particular in the trauma setting, however, is in the treatment of **polytrauma** patients with femoral fractures. Here, speed is of the essence, since it is well recognized that if femoral fractures in these patients are not stabilized within the first 24 hours following injury, mortality and morbidity rates are very high. The speed with which an Orthofix fixator can be applied under these circumstances has had a major impact on survival rates in polytrauma (Brug et al 2000).

2. Articular and Periarticular Fractures

Open reduction and internal fixation (ORIF) with plates and screws is still widely practiced in the treatment of fractures in and around joints. In high energy fractures this approach has frequently been plagued by the development of deep infection and necrosis of the tissues overlying the hardware and has, on occasion, resulted in amputation of the affected limb. This is a totally unacceptable state of affairs, and there is currently a major trend towards the use of minimally invasive techniques to restore joint anatomy, coupled with the provision of excellent stability, and the option of early joint mobilization.

Orthofix monolateral external fixation is able to provide all of these features through modular attachments to the standard range of devices, in conjunction with use of the Orthofix Fragment Fixation System (see p. 45) which enables percutaneous reconstruction of joint surfaces. Since joint bridging is rarely required, joint function can often be preserved throughout the treatment period. In instances where joint bridging is inevitable, e.g. in highly comminuted fractures of the distal tibia, the wrist or the elbow, devices can be unlocked to permit controlled joint movement at a suitable point in the treatment programme.

These fractures can also be treated using the Orthofix Sheffield Ring Fixator in conjunction with the Fragment Fixation System, where indicated.

3. Pelvic Fractures

Pelvic fractures are life-threatening situations. In the presence of anterior instability, whether or not this is accompanied by posterior instability, anterior stabilization must be achieved as quickly as possible, in order to reduce pelvic volume and contain bleeding. The Orthofix Link System was designed for rapid application in these circumstances (see Manual 8 "Pelvic Applications").

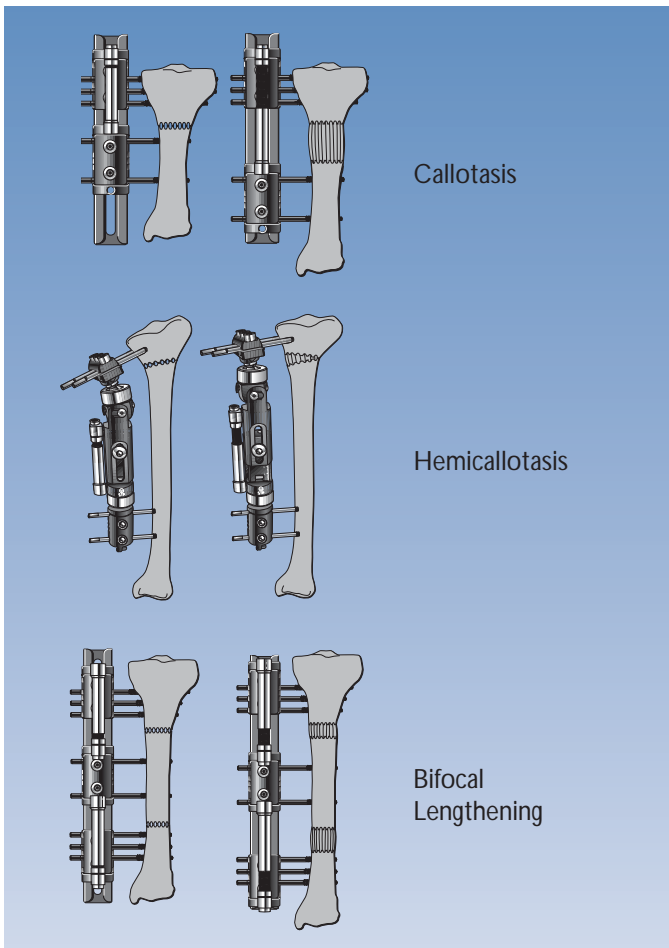
4. Fractures of the Small Bones of the Hand and Foot

Fractures of the metacarpals and metatarsals, and the phalanges of the hands and feet are particularly amenable to treatment with the Orthofix range of mini-devices designed specifically for this purpose (see Manual 9 "Treatment of Fractures and Deformities in Small Bones").

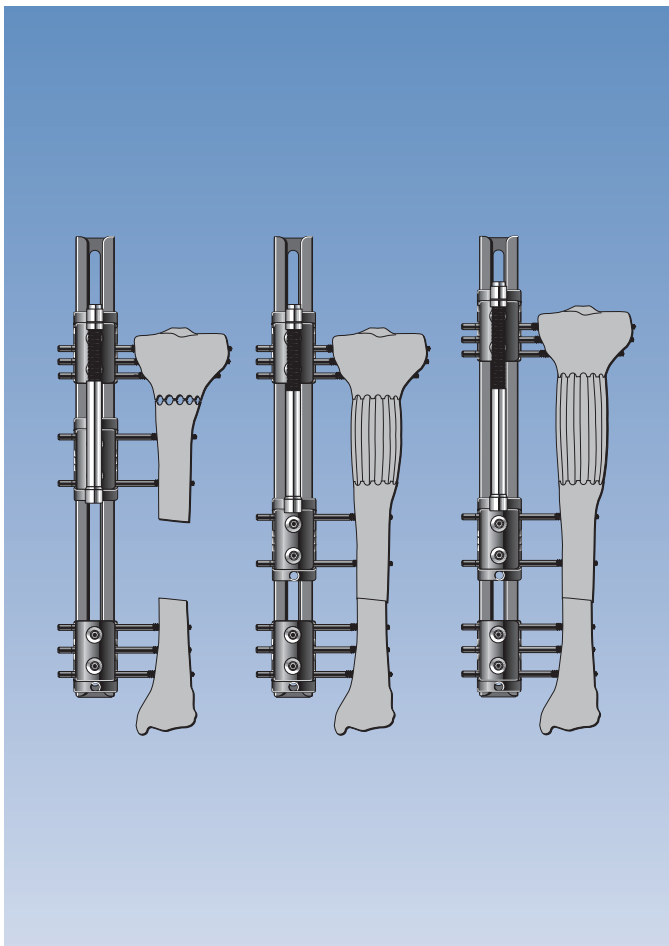
IN ORTHOPAEDICS AND LIMB RECONSTRUCTION

1. Techniques Involving Callus Manipulation

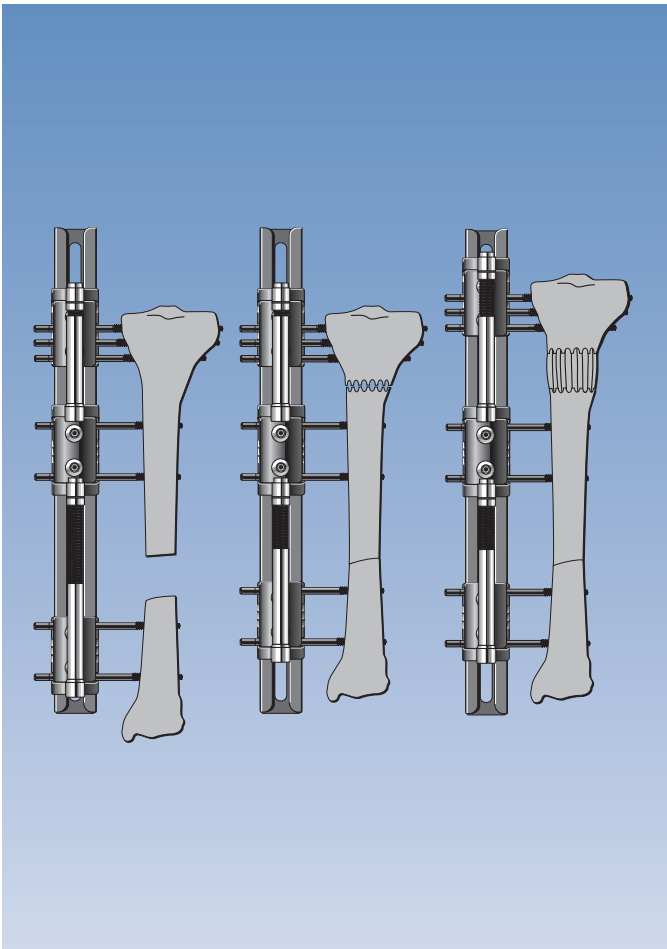
When a bone is artificially fractured by intention, the fracture site (**osteotomy**), will form callus as the healing process proceeds, and this plastic, developing callus can be manipulated to achieve a variety of objectives. Orthofix external fixators can be used to lengthen the callus mass (and hence the bone) by a process of slow, symmetrical distraction (**callotasis**), or by slow, asymmetrical distraction (**hemicallotasis**), to correct a deformity. These procedures provide opportunities for multilevel surgery. Thus lengthening of a limb can be carried out at two levels simultaneously (**bifocal lengthening**).



Where a bony defect exists in the shaft of a long bone, the callotasis technique can often avoid the need for an extensive autologous bone graft with its attendant morbidity at the donor site, and the uncertainty of ultimate success. Instead, an osteotomy can be performed at a suitable point in the bone (ideally in the metaphyseal region) and once callus has begun to form at the osteotomy site, the segment of bone separated by the osteotomy can be dragged slowly in the appropriate direction to fill the gap, with callus forming behind it. This is the technique of **bone transport**.

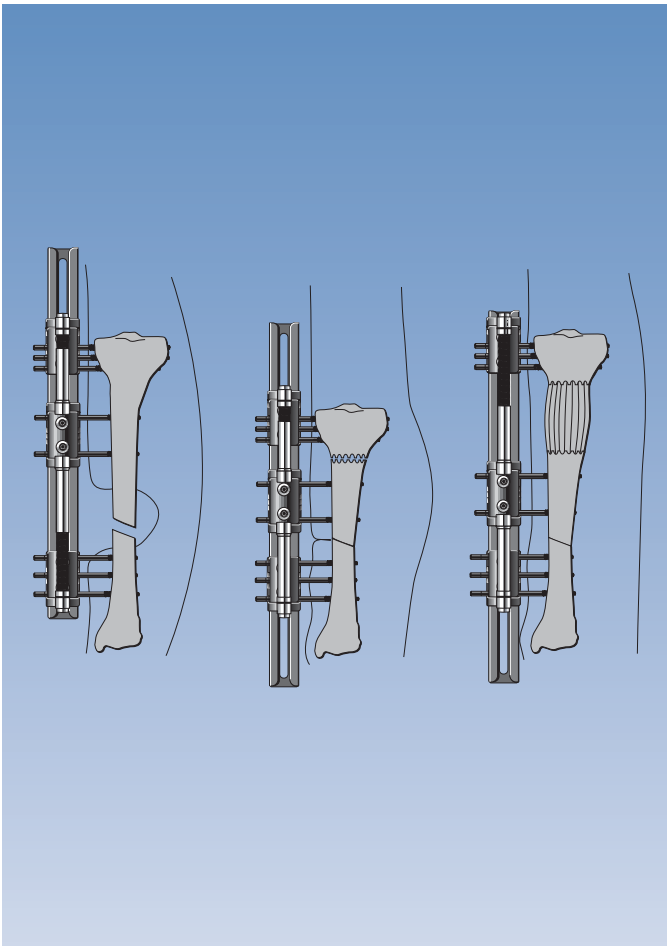


Where they are not too large, some gaps may be closed immediately at operation resulting in a shorter limb. Length can then be restored at a later date, following osteotomy and callotasis at a distant site in the limb (**the Compression-Distraction Procedure** - Saleh and Rees 1995).



Where there is bone damage associated with major soft tissue loss, bone grafts, accompanied by transfer of extensive muscle flaps and skin grafts, will frequently produce a final result which is cosmetically unacceptable.

This can be avoided by resection of a segment of bone immediately beneath the soft tissue defect, with closure of the resulting bony defect. Some of the bone removed may be diseased, but the method may also call for the removal of some healthy bone. This is because the amount of bone resected must be sufficient to allow the remaining soft tissues to cover the defect without the need to import tissues from other sites. The shortened limb may then subsequently be restored to its full length by osteotomy and callotasis at a distant site (Giebel 1991, 1992).



In these callus-manipulating techniques, certain principles must be adhered to for a successful result:

WAITING PERIOD

- A suitable **waiting period** must be observed following execution of the osteotomy to ensure that sufficient callus will have formed within the osteotomy gap before distraction is commenced.

RATE OF DISTRACTION

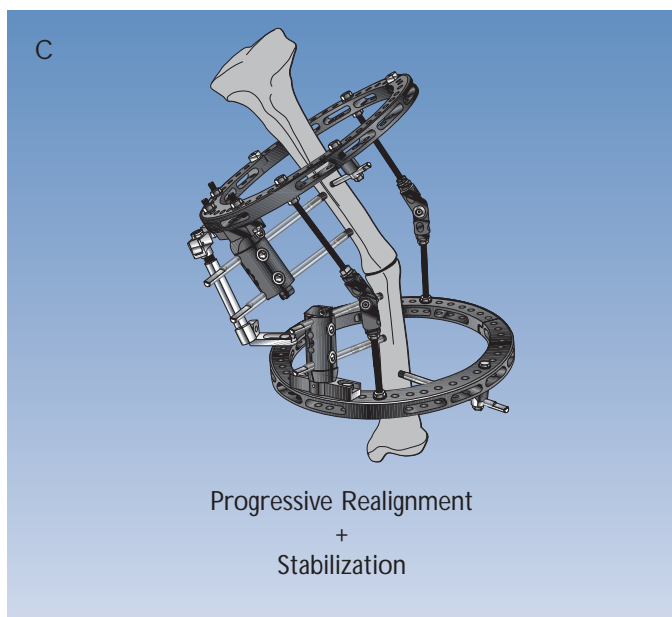
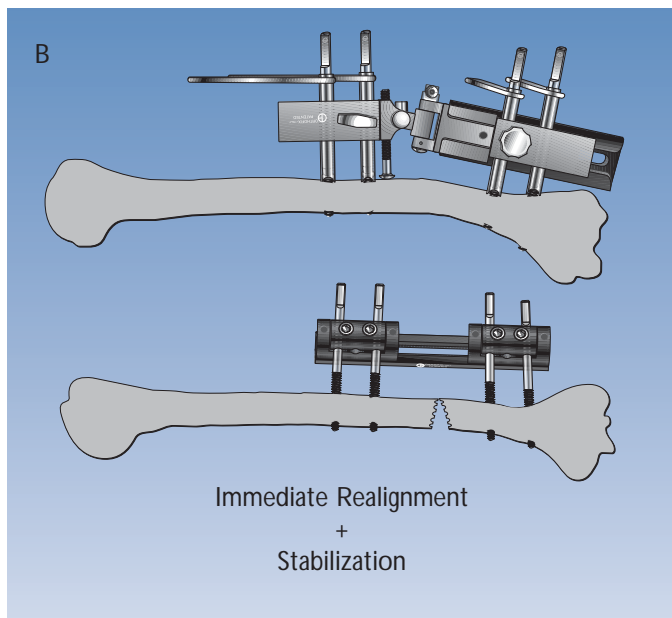
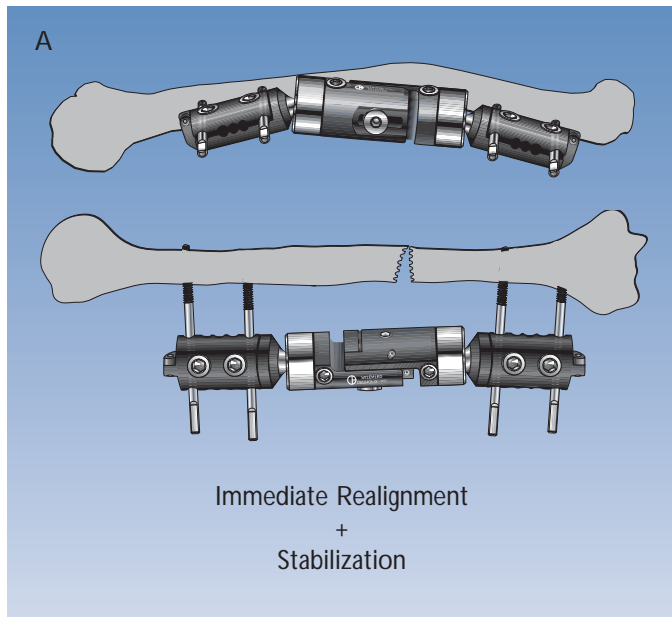
- The **rate of callus distraction** is critical, and when carried out at a single site, is 1 mm per day at the bone, usually delivered at a rate of 0.25 mm every 6 hours. The geometry of the frame will dictate the actual rate of distraction at the fixator to achieve this. The quality of the callus must be carefully monitored by serial x-rays and the distraction rate may need to be adjusted accordingly.

NEUTRALIZATION PERIOD

- Once the desired length has been achieved, or transport completed, a **neutralization period** approximately equivalent in length to the distraction period is observed, during which the length of the callus column is maintained in a stable condition until **bony consolidation** has occurred. All of these concepts are discussed in detail in the appropriate Manuals.

DYNAMIZATION

- Three complete cortices should be evident (i.e. three out of four, when an AP and an oblique view are considered), prior to the institution of dynamization. If, however, the Dyna-Ring is used, dynamization may be commenced at an earlier time point, since, it will prevent the newly formed segment from collapsing. Many surgeons are now using the Dyna-Ring as soon as distraction has been completed.



2. Non-Union

Orthofix external fixation has been shown to have wide application in the treatment of all forms of non-union, hypertrophic, atrophic or infected. In any form of non-union, the same broad principles of treatment apply, and these are:

- **Realignment**
- **Stabilization**
- **Stimulation**

Monolateral frames can be used for the realignment of an angulated non-union where immediate on-table correction can be carried out safely. Here, articulating ball-joints can assist in the correction procedure (A) or, where the Limb Reconstruction System is used, this can be accomplished using the Acute Correction Templates (B) (see Manual 11 “The Limb Reconstruction System - part B: Correction of Deformities”). Where there is a danger of neurological sequelae with immediate correction, e.g. damage to the peroneal nerve during correction of a valgus tibia, progressive correction of angulation is indicated, and this may be achieved following surgery using the Sheffield Ring System (C) (see Manual 12 “The Ring Fixation System - part C: The Sheffield Ring Fixator - Limb Reconstruction and Complex Trauma”).

Orthofix frames provide an excellent means of stabilization following realignment. Since the screws or wires are inserted well away from the fracture site, they are ideal in infected cases where other forms of stabilization, such as a plate or an intramedullary nail would be contraindicated. They further allow the fracture to be controlled by compression, neutralization or distraction (ligamentotaxis).

It is not uncommon for a bony defect to be associated with the treatment of a non-union, e.g. where infected bone has been removed, or a congenital pseudarthrosis or tumour excised. In these situations, bone grafting may now often be avoided by the technique of bone transport, which can be effected using either the Limb Reconstruction System or the Sheffield Ring System (see Manual 11 “The Limb Reconstruction System - part B: Correction of Deformities” and Manual 12 “The Ring Fixation System - part C: The Sheffield Ring Fixator - Limb Reconstruction and Complex Trauma”).

Orthofix Monolateral frames allow conversion from rigid to dynamic or elastic fixation providing a potent means of mechanical stimulation when indicated, while the inherent stability of all of the frames is complementary to other forms of stimulation which may be used, such as bone grafting, or electrical stimulation.

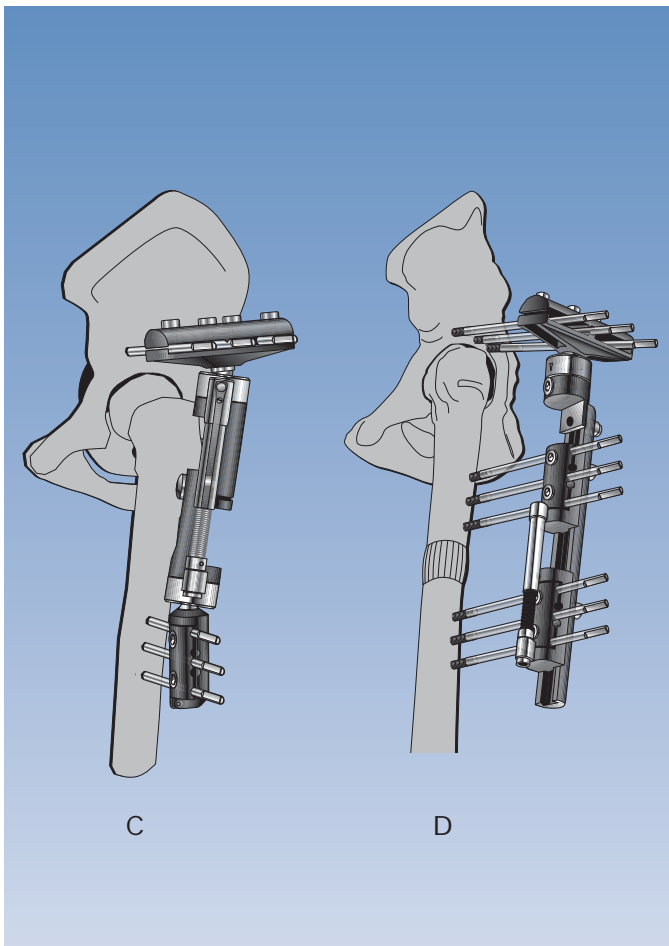
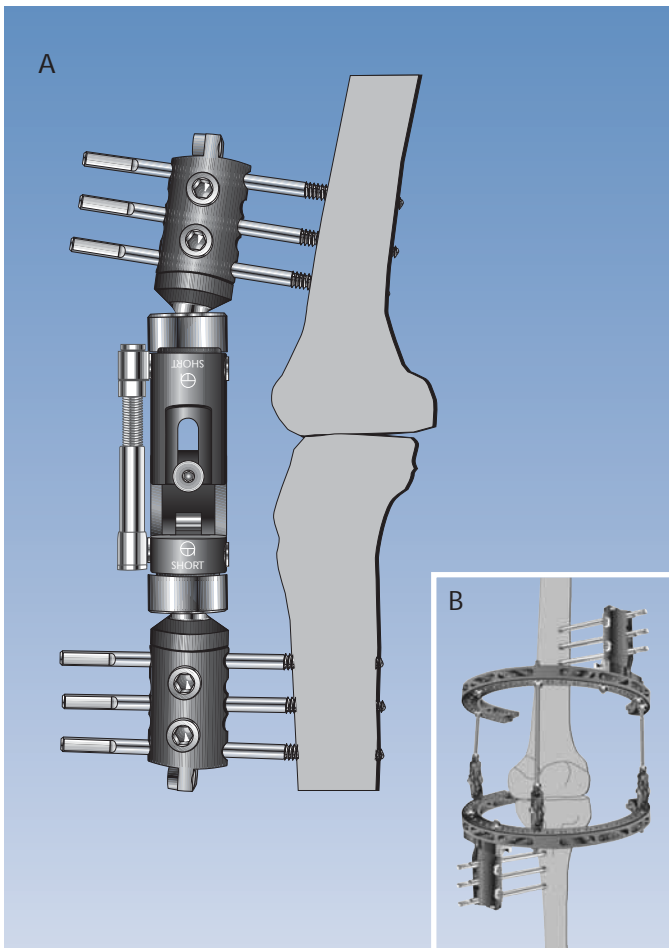
It can thus be appreciated that for many non-unions, Orthofix external fixation can provide all the elements of a definitive treatment programme.

3. Arthrodesis (Joint Fusion)

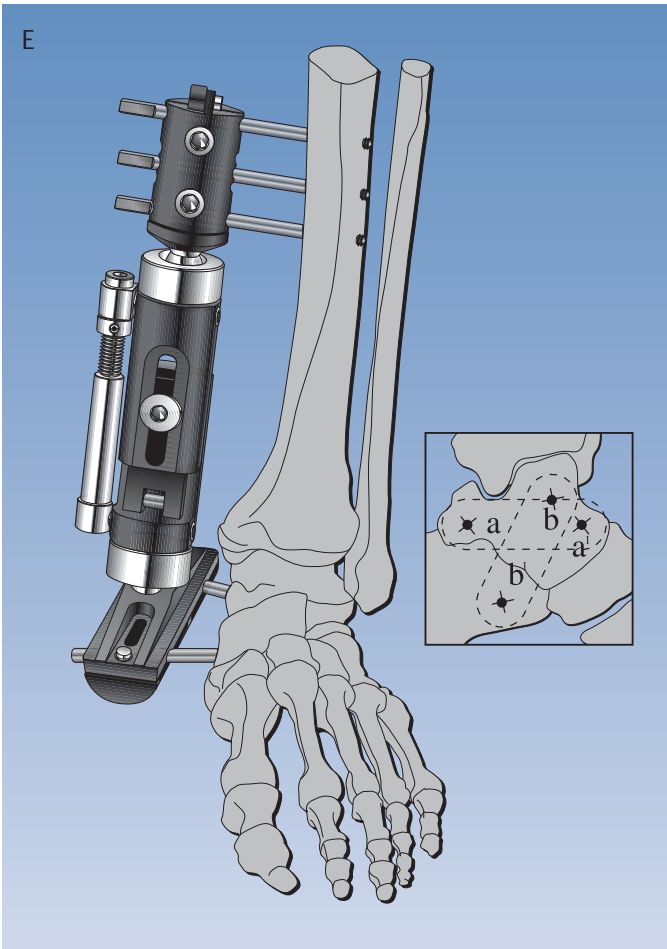
Arthrodesis is an uncommon procedure in the knee or hip due to the excellent results which generally derive from primary or even secondary arthroplasty. In these joints, therefore, it is usually a last resort, where other options are no longer available. It is a more common procedure in the ankle, however, where the results of arthroplasty have been generally disappointing.

Where **knee** arthrodesis is contemplated, e.g. for major trauma with bone loss, or following removal of a joint prosthesis, compression between opposing surfaces can be achieved using either a monolateral Orthofix external fixator, or the Sheffield Ring System. A single ProCallus fixator applied anteriorly (A), or two fixators, one placed anteriorly and one laterally can be used, or an all-screw Sheffield Ring System (B).

With either type of frame, stabilization and arthrodesis in a position of 15° of flexion is possible.

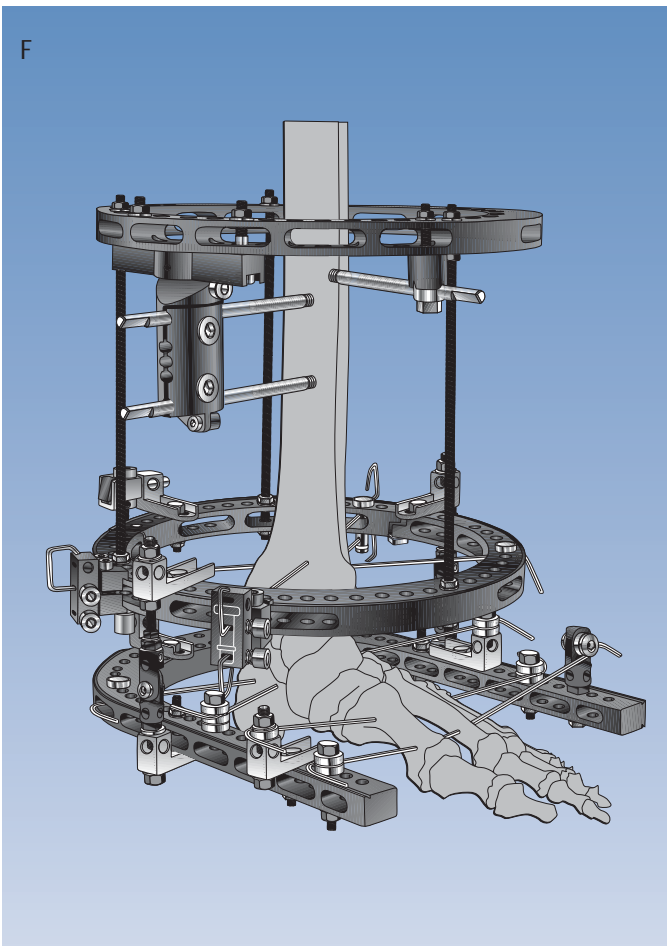


In the **hip**, monolateral fixation is indicated, and this is conveniently performed using a ProCallus fixator with the Trauma Garches Clamp as a modular attachment. Three screws are inserted through this clamp into the pelvis, with three screws inserted into the proximal femur through a standard straight ProCallus clamp (C). If hip fusion in conjunction with femoral lengthening is contemplated, the Trauma Garches Clamp may be attached to the Limb Reconstruction System (D).



In the ankle, arthrodesis is an accepted treatment for severe and debilitating arthritis. Compression arthrodesis may be achieved with either internal or external fixation, but with internal techniques involving open reduction and the insertion of plates non-union rates of up to 26% have been reported (Holt et al 1991; Kirkpatrick et al 1991; Mears et al 1991). In addition, internal fixation is contraindicated in the presence of infection. Here, as in the knee, either monolateral or ring fixation may be used.

Where there is good bone quality, a medially placed ProCallus with a Torbay Garches Clamp or T-Clamp distally, can be used. The distal screws are inserted into the talus for tibio-talar fusion, or into the talus and calcaneum for subtalar/tibio-talar double fusion (E).



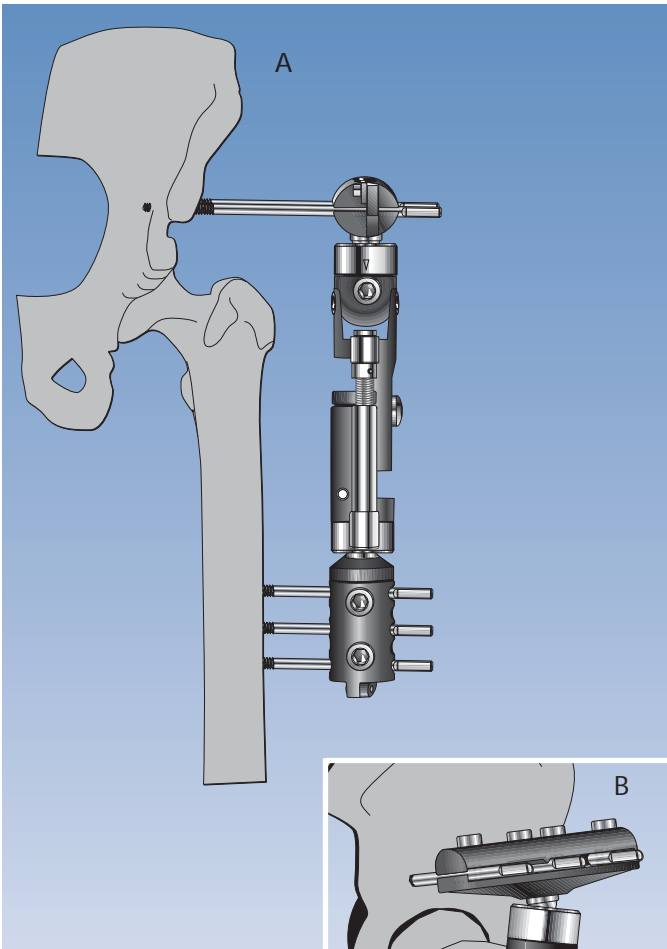
Where bone quality is poor, and the anatomy in the region distorted, circular fixation with the Sheffield Ring Fixator extended to the foot will provide even, long term support. Limited joint exposure and debridement is needed, and post-operative adjustment of alignment is possible.

The frame can be further extended proximally with additional osteotomies of the tibia and fibula for the correction of any length discrepancy (F).

4. Arthrodiatasis (Articulated Joint Distraction)

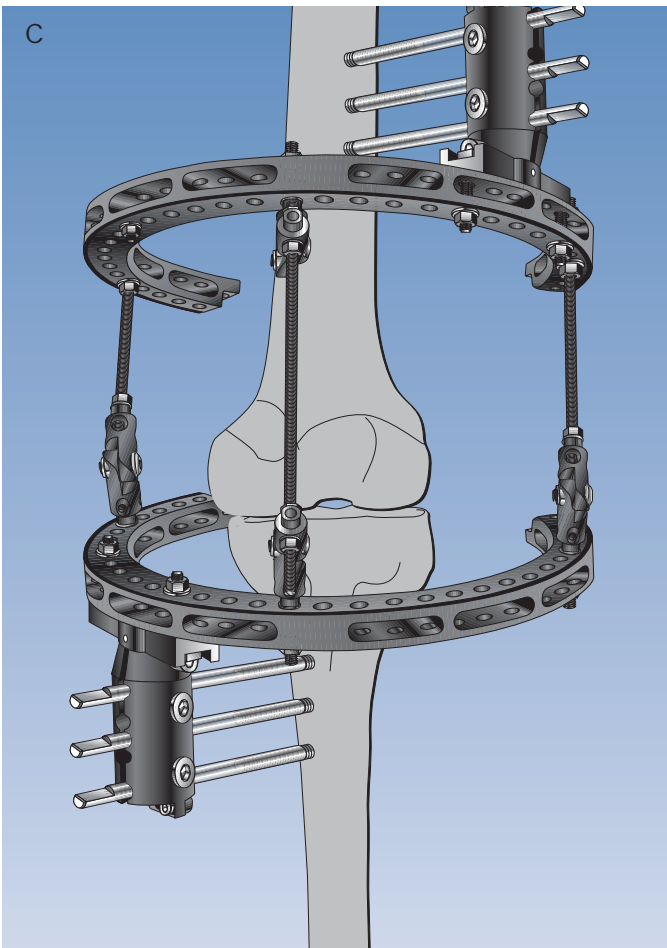
Arthrodiatasis is a technique unique to external fixation. Developed initially for the conservative treatment of osteoarthritis of the hip, it allows off-loading of body and /or muscle forces and distraction of a joint space with an external fixator while preserving or re-establishing joint movement in one plane by the addition of a hinge. These measures are designed to restore synovial circulation and encourage repair of articular cartilage. Encouraging results have been described using Orthofix external fixation for arthrodiatasis of the hip (Aldegheri et al 1994).

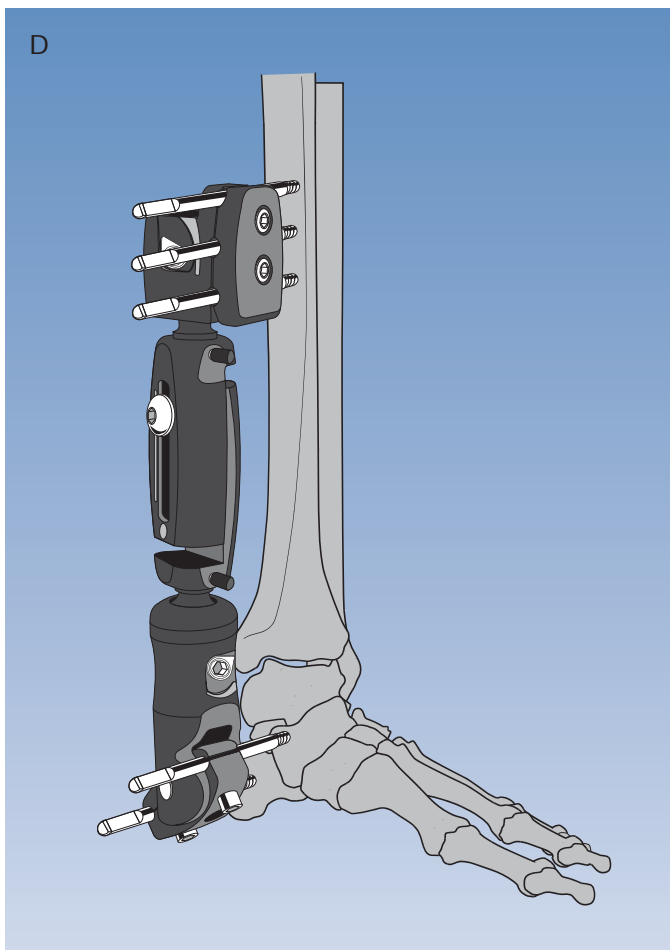
Here the ProCallus fixator is used in conjunction with the articulated body for the hip and a T-Clamp (A) or Trauma Garches Clamp (B) for the pelvic screws. (For full details of the operative technique in the hip, see Manual 4 “Arthrodiatasis - Articulated Joint Distraction”).



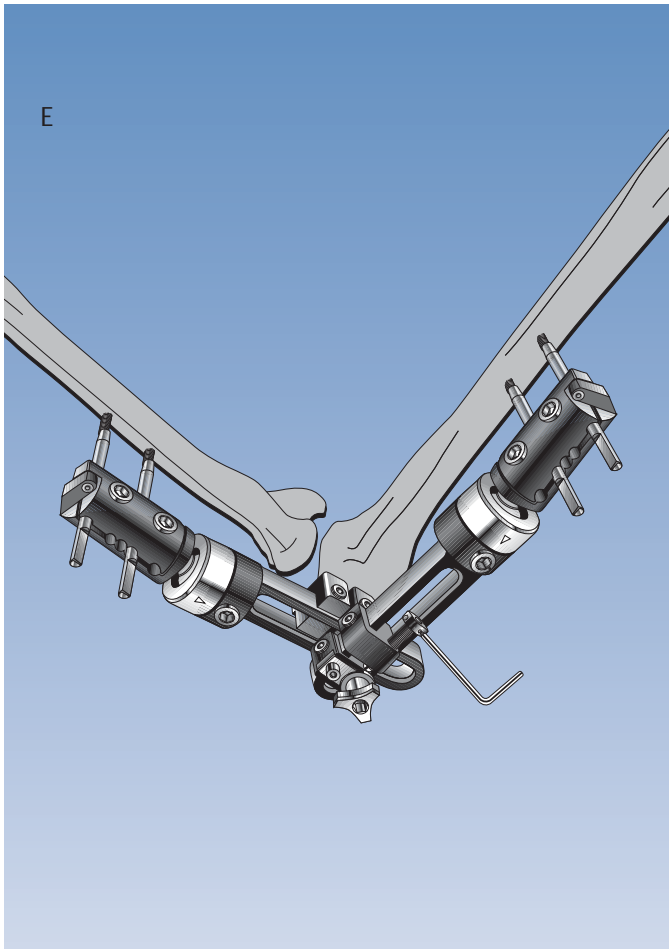
In the knee and ankle, articulated distraction can be used to correct joint contracture. The picture opposite shows a Sheffield Ring Fixator being used for this purpose in the knee (C). The hinges are placed slightly anterior to the centre of rotation of the knee, and correction achieved using a posterior motor after 3-5 mm of joint distraction.

At the ankle, the technique is used with the Sheffield Ring Fixator for the correction of equinovarus and cavo-varus deformities. A pushing system between the tibia and hindfoot and hindfoot and forefoot is used to distract the joints and achieve partial correction, after which the motors and hinges are changed to pull up on the foot. For a full description of the surgical technique see Manual 12 “The Ring Fixation System - part C: The Sheffield Ring Fixator - Limb Reconstruction and Complex Trauma”.

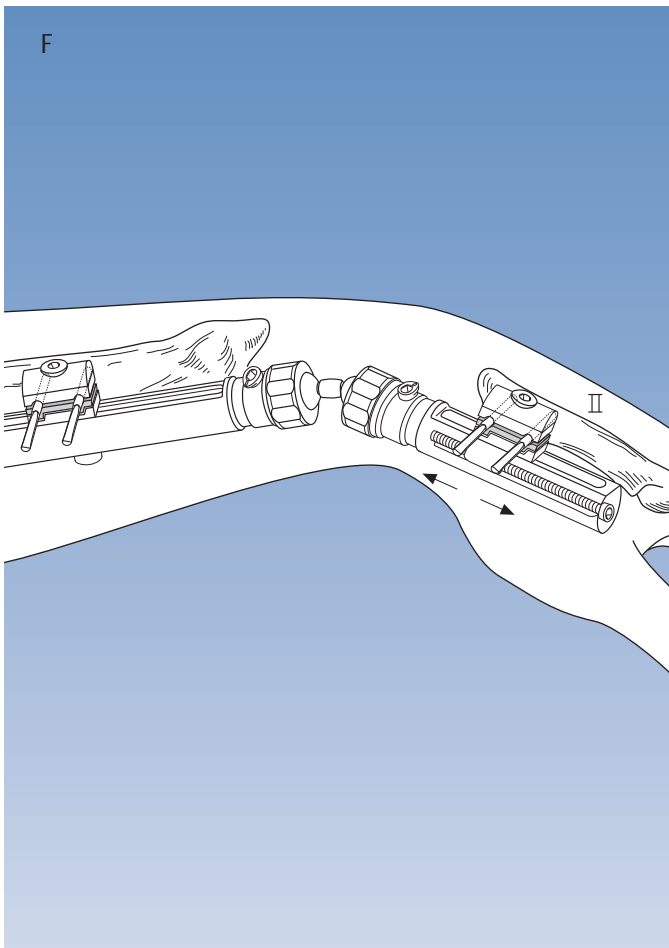




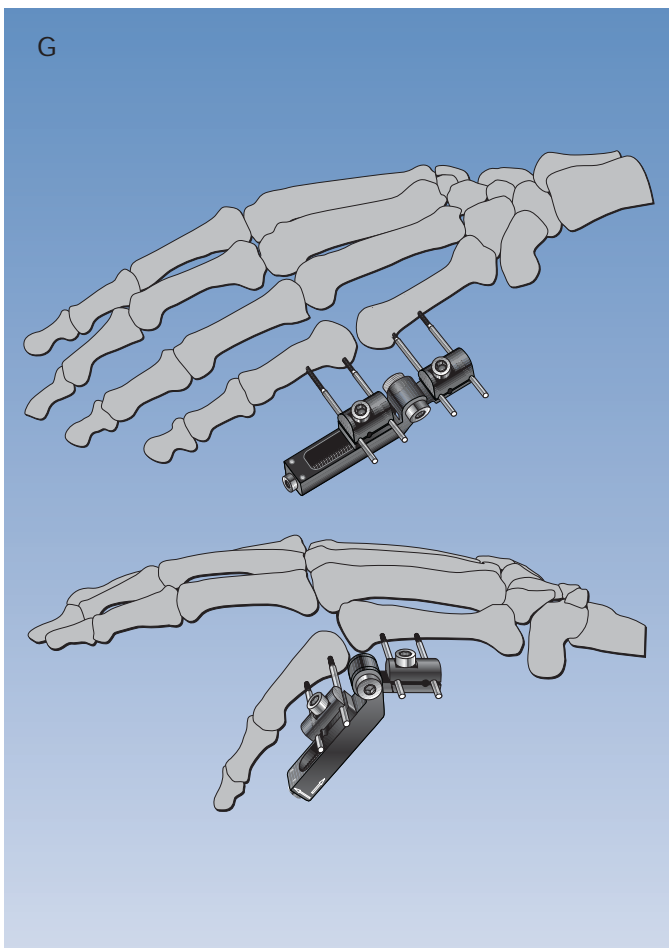
In the ankle, use of the technique has also been described in association with Orthofix monolateral external fixation of severe tibial plafond fractures (Bonar and Marsh 1993, 1994; Marsh 2000). Here it is used during surgery to distract the talus from the ankle mortise to assist in the reduction of the distal tibia. The distraction is normally reduced after this has been done. The assembly used may be either the ProCallus fixator with the Radiolucent Ankle Clamp distally, or the XCaliber Ankle Fixator (D) shown opposite. Distraction of the joint space is achieved in either case by means of the compression-distraction unit.



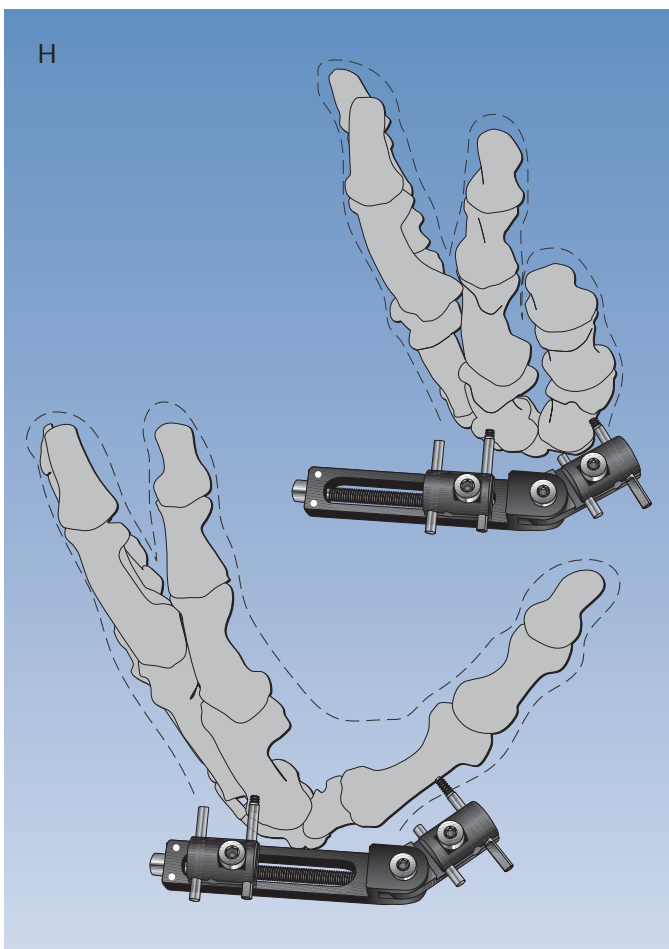
Use of the technique in the upper limb has also been described. Here the primary objective is the treatment of joint stiffness in the elbow, the wrist and the joints of the hand (Pennig 2000). In the elbow, the Orthofix elbow fixator is used to lengthen the shortened ligaments and fibrotic capsule and to disimpact humero-ulnar and humero-radial joint surfaces prior to mobilization (E).



For the stiff wrist, the Pennig Dynamic Wrist Fixator with a compression-distraction module on the metacarpal side and a gliding module on the radial side is used (F). With the fixator applied, distraction may normally be carried out intra-operatively, with the object of achieving a joint space twice the normal width. Redistraction may be carried out after a few days, and the joint is mobilized by unlocking the distal ball-joint.



For long-standing stiffness in the metacarpophalangeal and interphalangeal joints, a horizontal axis articulated MiniRail may be used (G). This shows articulated distraction of the fifth metacarpophalangeal joint. For details of this technique see Quick Reference Guide 14, parts A and B and the MiniRail Brochure.



5. Soft Tissue Correction

The treatment of joint contractures and stiff joints by arthrodiastasis described above, all involve an element of soft tissue correction since ligaments and capsules have shortened secondary to a primary joint problem. There exist situations, however, where the soft tissue contracture represents the primary problem, and here too, Orthofix external fixation is valuable. One of the commonest examples of its use in this context is in soft tissue contracture of the first web space in the hand following severe burns. The figure opposite (H) shows a vertical axis articulated MiniRail being used for this purpose.

MONOLATERAL FIXATORS

These fixators are normally applied to one side of the affected limb with their long axis aligned with the long axis of the bone segment. The exception is the Pelvic Fixator which is applied to the iliac bones in a transverse fashion to stabilize the pelvis, but is described in this section because of its monoplanar design.

Fixators with Ball-Joints

Fixators with ball-joints are used primarily in acute trauma. Ball-joints afford the facility to make final adjustments to the position of the fracture after application of the frame. In some instances they also permit mobilization of a joint where this has been bridged by the fixator. Not all the ball-joints in the Orthofix family of fixators are identical in design. All of them, however, incorporate a cam and bush system which when tightened stabilizes the position of the bone screws in relation to the body of the fixator. The devices included in this section are:

1. **The ProCallus Fixator**
2. **The XCaliber Fixator**
3. **The Small Blue DAF (31000 series)**
4. **The Pennig Dynamic Wrist Fixator**
5. **The Radiolucent Wrist Fixator**
6. **The Elbow Fixator**
7. **The Pelvic Fixator**
8. **The Pennig MiniFixator**

1. The ProCallus Fixator and its Modular Attachments

Key Features:

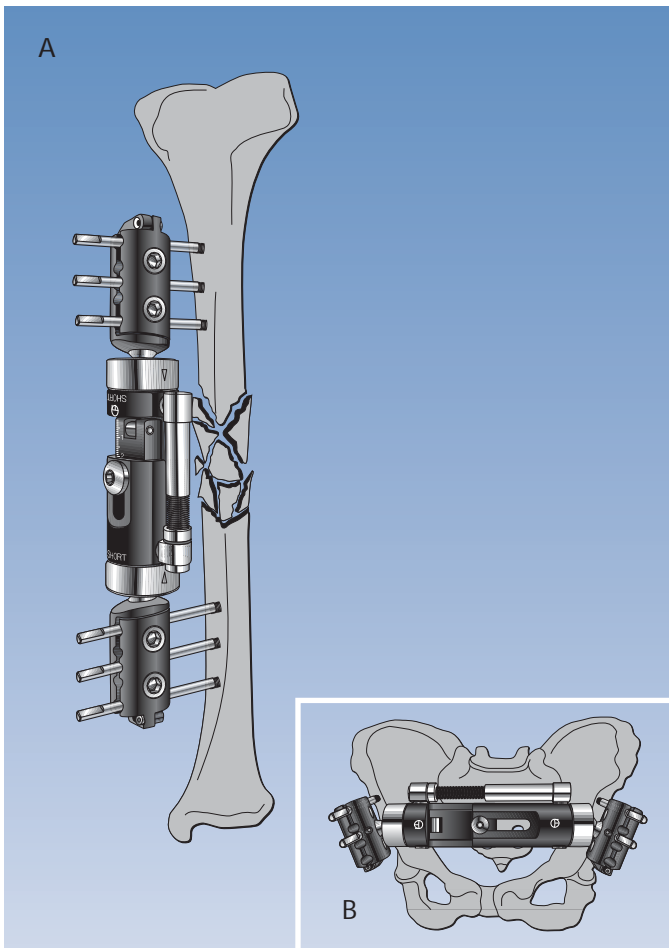
This is the basic monolateral fixator. It incorporates a range of distinguishing features which include:

- Ball-jointed clamps which articulate with the body of the fixator and permit final reduction after application of the frame. The clamps have five screw seats;
- Hinged clamp covers which can be tightened on either the screw guides or the screws themselves, thus obviating the need to use an additional template;
- A micromovement facility which can be activated either manually by means of an Actuator, or by weightbearing;
- A sliding telescopic body, activated by loosening a Central Body Locking Nut, for the application of a progressive load to the fracture site;
- The ability to accept a range of other ball-jointed modules in place of the standard bone screw clamps, and several non ball-jointed modules attached in different ways, to increase the versatility of the device.

Principal Uses:

The ProCallus is used with straight clamps (A) or a straight clamp and a T-clamp to treat fractures of the shafts or the metaphyses of the long bones (femur, tibia, humerus). It can be used with two T-clamps for anterior stabilization of the pelvis (B).

When loosened, the ProCallus ball-joint allows 36° of movement in all planes. It is tightened by means of a steel cam and an aluminium bush, both of which components are single-use only.



Assembling the Ball-Joints of the ProCallus Fixator for attachment of the clamps or other ball-jointed modules

Assembly of the ball-joints of the ProCallus Fixator is described in detail since the same steps must be followed for attachment of any of the ball-jointed modules to the fixator

- Insert one cam into the body of the device with the dot facing the adjacent clamp site.

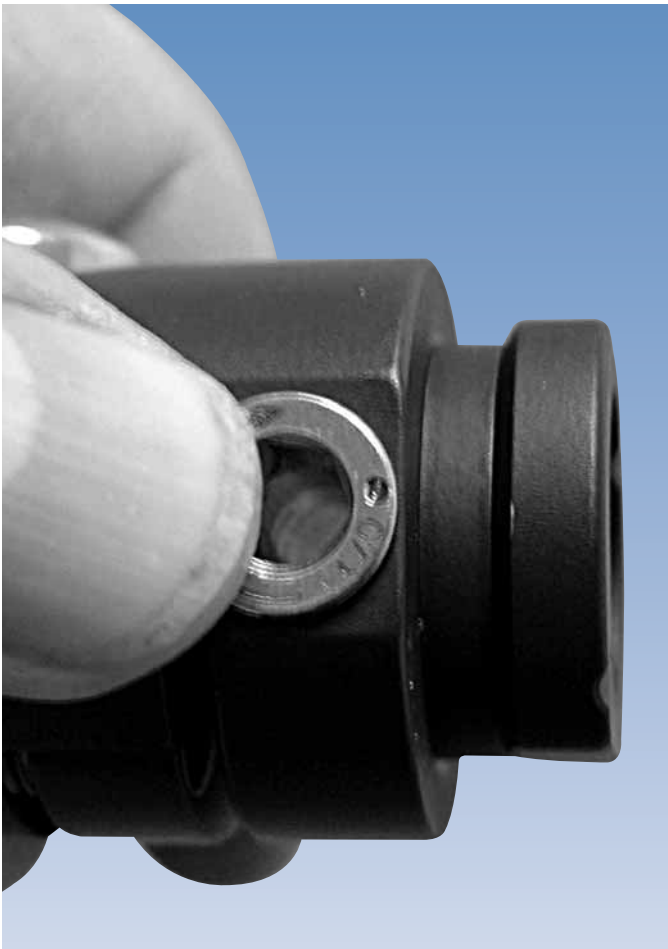
NOTE: The two Allen wrench fitting points must be positioned on the same side.



- Insert the bush with its groove facing the cam.



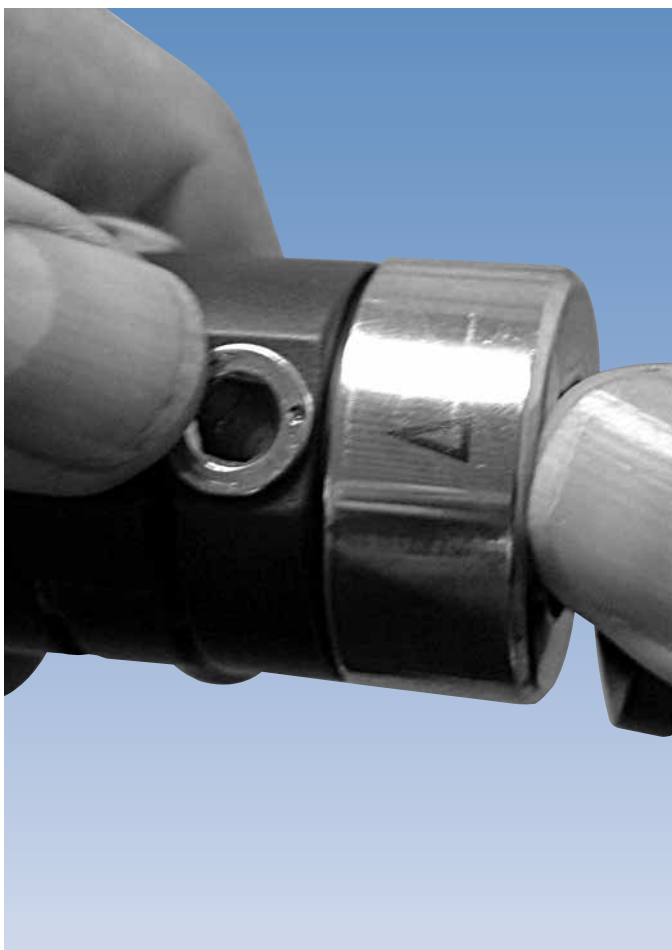
- Rotate the bush with the finger to ensure that the cam is seated in its groove.



- Turn the cam so that its dot is facing the open end of the fixator. Now hold the cam in place with the thumb.



- Take up the ball-jointed clamp (or any other ball-jointed module it is desired to attach to the ProCallus fixator) and line up body and clamp (note squared sides). The dot on the cam should point towards the clamp. Insert body into clamp (bayonet-type locking).



- Using slight pressure, rotate the collar through 90° to line up its arrow with the dot on the cam. The ring then closes with a click.



- Repeat the procedure for the second ball-jointed clamp, ensuring that when starting, the Allen wrench fitting point of this cam is facing the same direction as that of the first cam.



- At this point both the ball-joints are in the loosened state. Locking the cams will prevent free movement of the ball-joints. Tightening of the ball-joints is done first with an Allen key. Always ensure that the hexagonal end of the Allen key fully enters the socket of the cam. The Allen key should always be held at its end when in use, to take maximum advantage of the lever arm.



- Final locking of the cam should always be performed with the appropriate torque wrench which must be turned IN A CLOCKWISE DIRECTION ONLY. A click indicates that the correct torque has been applied. Do not use the torque wrench for tightening any other screws. Any attempt to UNLOCK the cam or any screw, using the torque wrench, will damage its gearing.
- The torque wrench is pre-set at a specific value, which is 15 Nm \pm 0.5 for the 31000 Range (Small Blue DAF) and 27 Nm \pm 1 for the 90000 Range (ProCallus). This value should be checked at least every two years or any time the instrument becomes damaged, by returning it to the local authorized representative.

Note: When using the torque wrench, ensure that the wrench is completely inserted into the cam.

Cams and bushes wear with use. If the fixator is reused, cams and bushes should be replaced. If on tightening with the torque wrench, the dot on the cam moves more than 170° from the arrow on the collar of the clamp, both cam and bush must be replaced.

The Modular Attachments for the ProCallus Fixator

Ball-Jointed Attachments

The following modular ball-jointed attachments can be used with the ProCallus in place of the straight clamp or T-clamp, and the indications for which they are used is described.

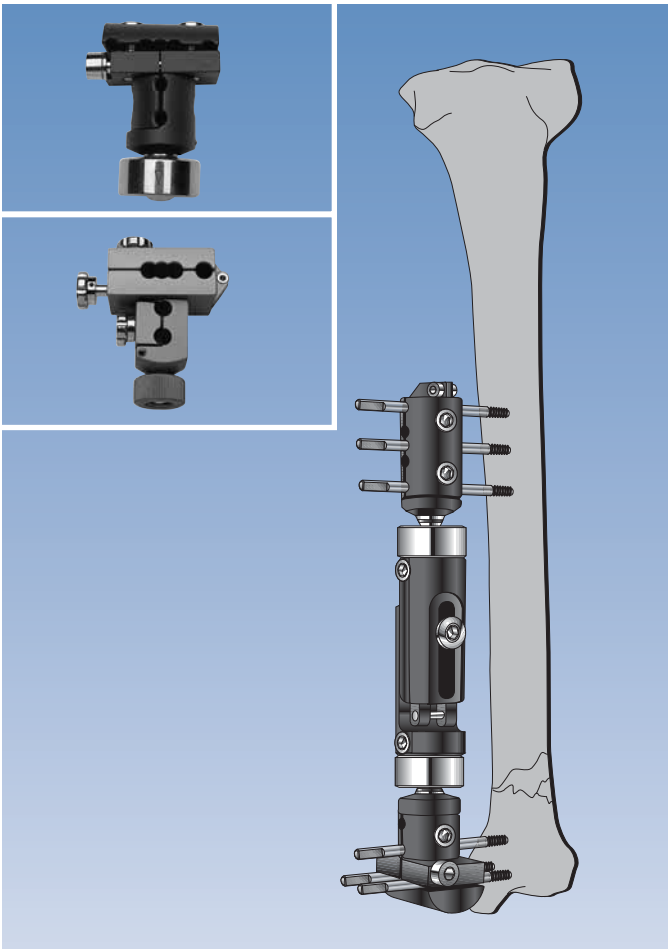
The Metaphyseal Clamp

The metaphyseal clamp allows screw placement in both epiphyseal and metaphyseal areas in a biplanar configuration. It consists of two parts:

- a component with four seats for horizontal placement of screws in the epiphyseal region of the bone.
- a component with two seats for vertical placement of screws in the meta-diaphyseal region of the bone. This portion can be rotated and locked in a desired position to permit screw placement in the center of the bone where there is superior bone stock.

The configuration of screw seats in the clamp takes account of the relative positions of the diaphyseal and metaphyseal axes of the bone. The clamp is applied using a dedicated template which is then replaced with the definitive device.

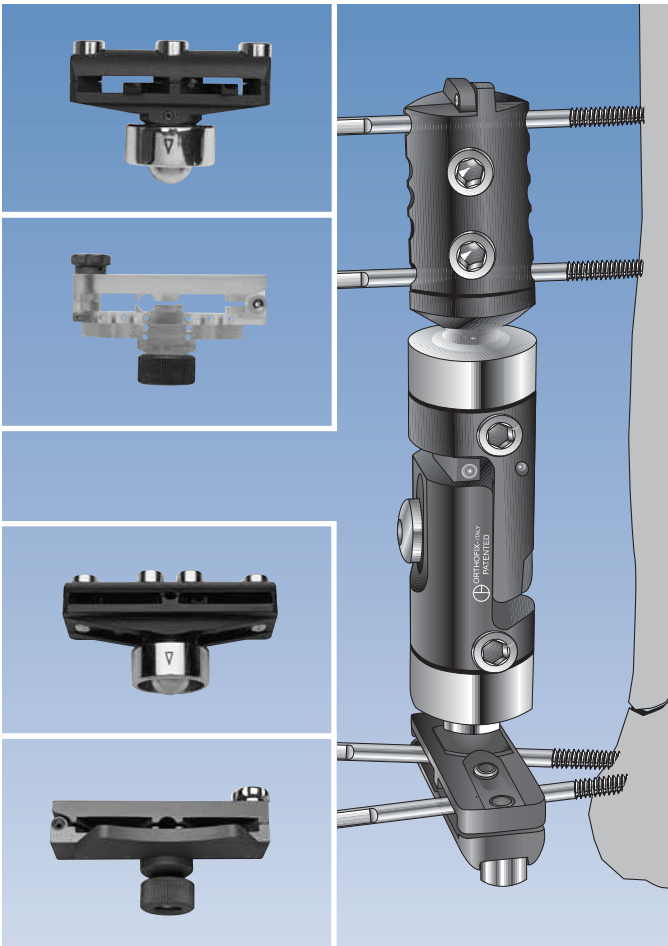
Uses: In articular and periarticular fractures of the distal femur and proximal and distal tibia, where there is sufficient space to allow application of the horizontal screws and at least one of the vertical screws.

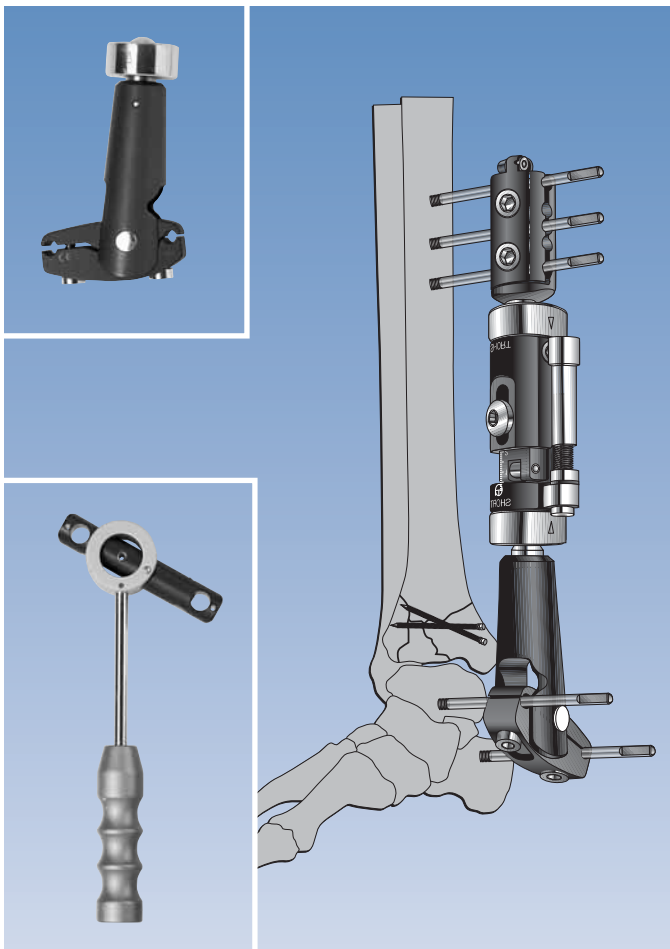


The Torbay Garches and Trauma Garches Clamps

These clamps allow introduction of screws into the epiphyseal region of long bones in a convergent fashion in the horizontal plane. Both are elongated T-clamps with two outer swivelling screw seats and one intermediate, fixed screw seat. The Trauma Garches is a heavier duty clamp. Each clamp is applied with a dedicated template, which for the Torbay Garches clamp is radiolucent.

Uses: In articular and periarticular fractures of the distal femur and proximal and distal tibia, where there is limited space; in association with the self-aligning body (see below) for the correction of deformity of the distal femur and the proximal and distal tibia. The Trauma Garches clamp can also be used for fusion of the hip (see Manual 5 "Arthrodesis").

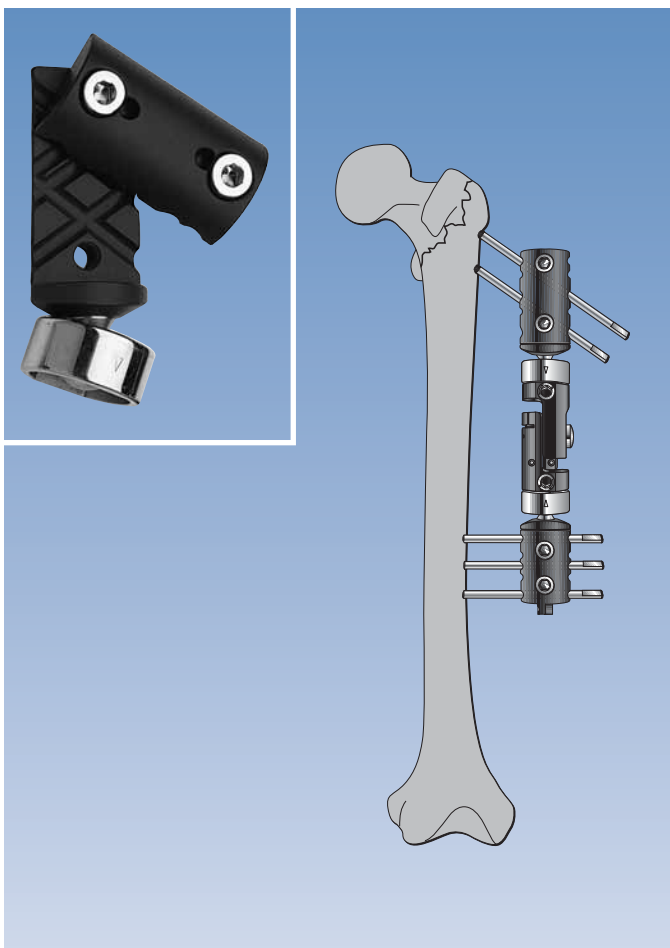




The Radiolucent Ankle Clamp

With this module, screws are inserted into the talus and the calcaneum. Introduction of these screws is facilitated by a radiolucent ankle pin guide. The radiolucent module itself allows clear visualization of the fracture site. The module can be unlocked to permit supervised dorsiflexion and plantar flexion if and when desired.

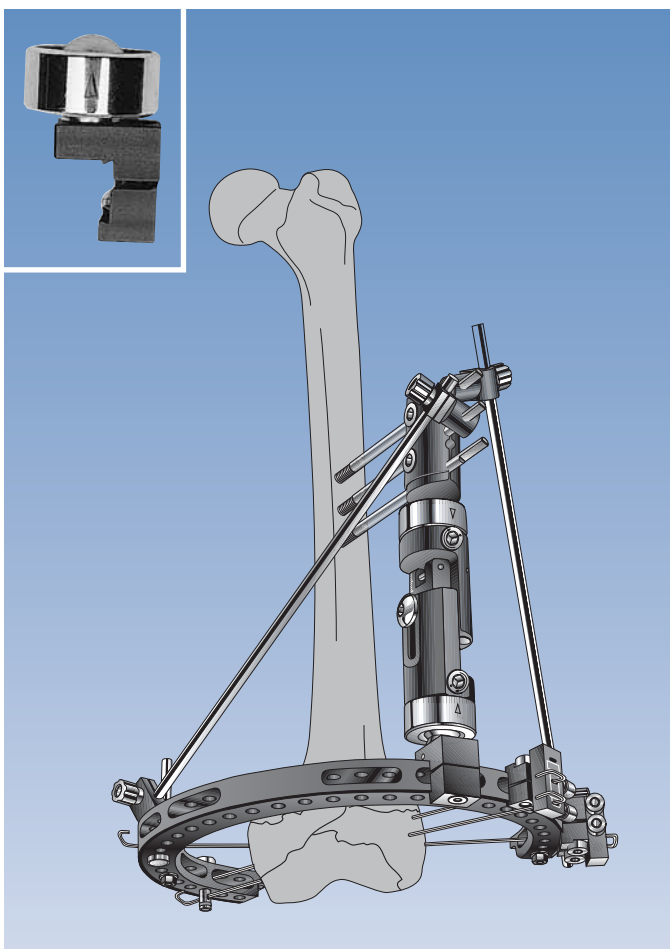
Uses: For the treatment of distal tibial and pilon fractures (see Manual 7 “Distal Tibial and Pilon Fractures”).



Angled Clamp

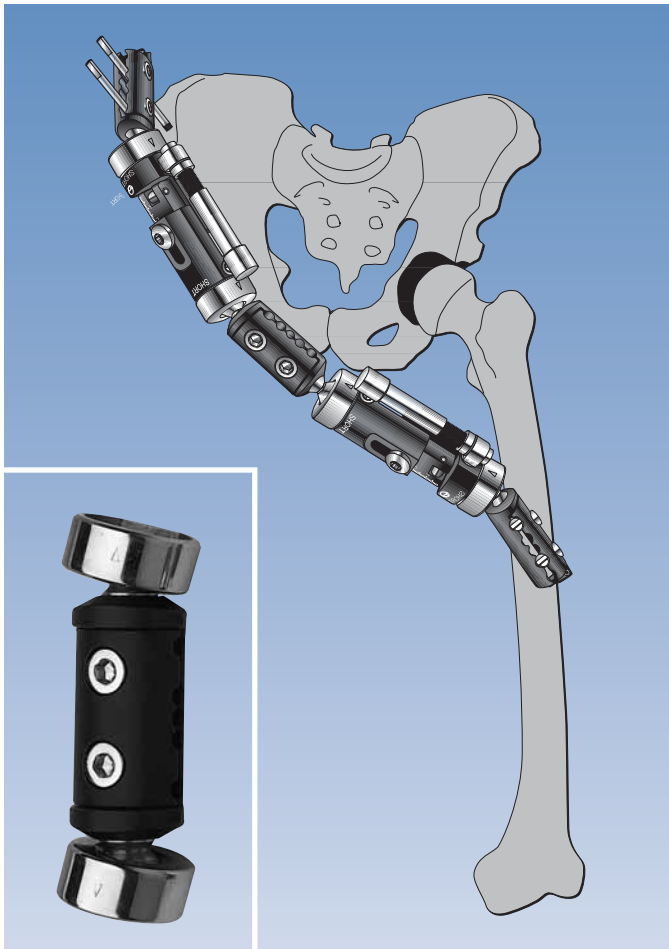
This clamp has screw seats at an angle of 35° to the transverse axis of the clamp. This enables screws to be inserted along the femoral neck while the fixator body remains parallel to the long axis of the femur.

Uses: For the treatment of trochanteric, subtrochanteric or extensive diaphyseal fractures of the femur



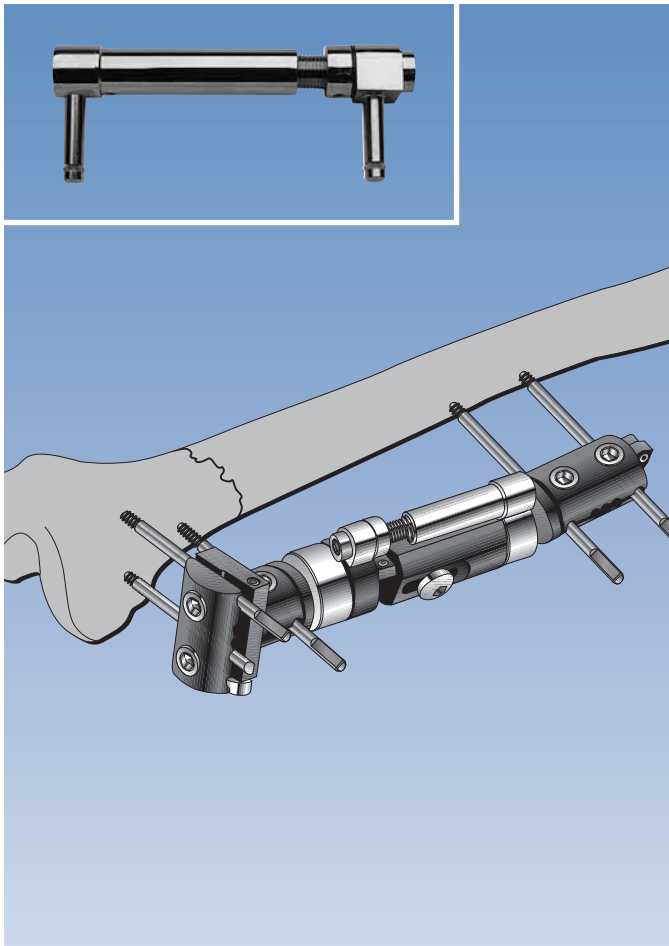
The Hybrid Coupling

Connects the ProCallus to a ring to form the Orthofix Hybrid Fixator (see below under "Ring Fixators" and Manual 12A).



The Double-Coupling Clamp

This clamp enables two ProCallus bodies to be connected together. It is used primarily to treat central dislocation of the hip, as shown here.

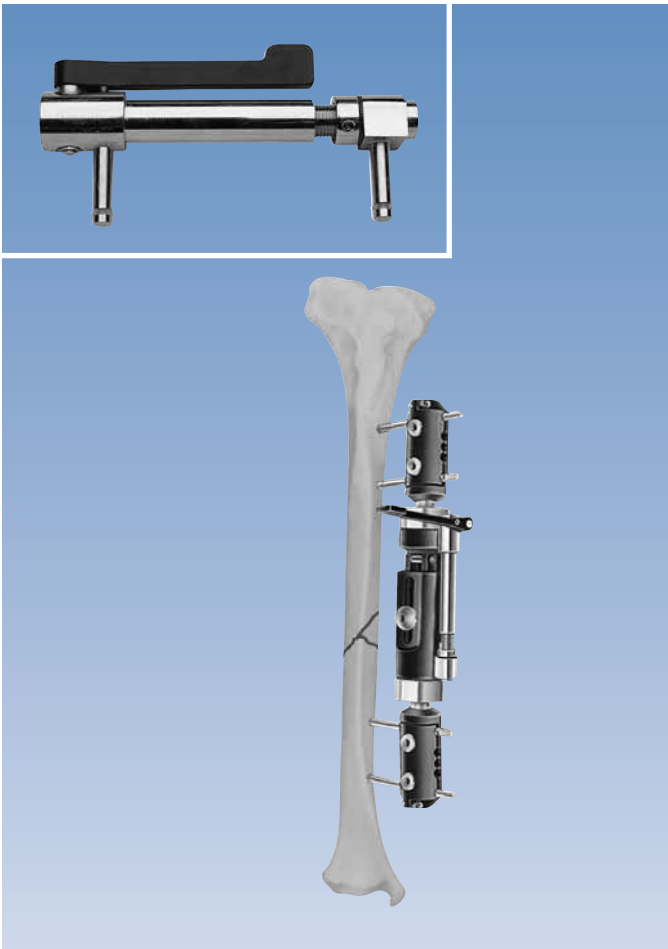


Non Ball-Jointed Attachments

The Compression-Distraction Unit

The standard Compression-Distraction Unit may be attached in place of the Actuator where compression or distraction of the fracture site is required. The device consists of a threaded bar within a cylinder. Turning an integral screw at one end will either extend or shorten the device, depending on the direction in which it is turned. If the screw is turned through 360° the device will be extended (or shortened) by 1mm. With the feet of the device inserted into the cams of the ProCallus and the Central Body Locking Nut of the fixator loosened, turning the screw of the Compression-Distraction Unit with an Allen key will open or close the body of the fixator and thus distract (or compress) the fracture site as desired. This unit comes in three sizes, standard, short and long.

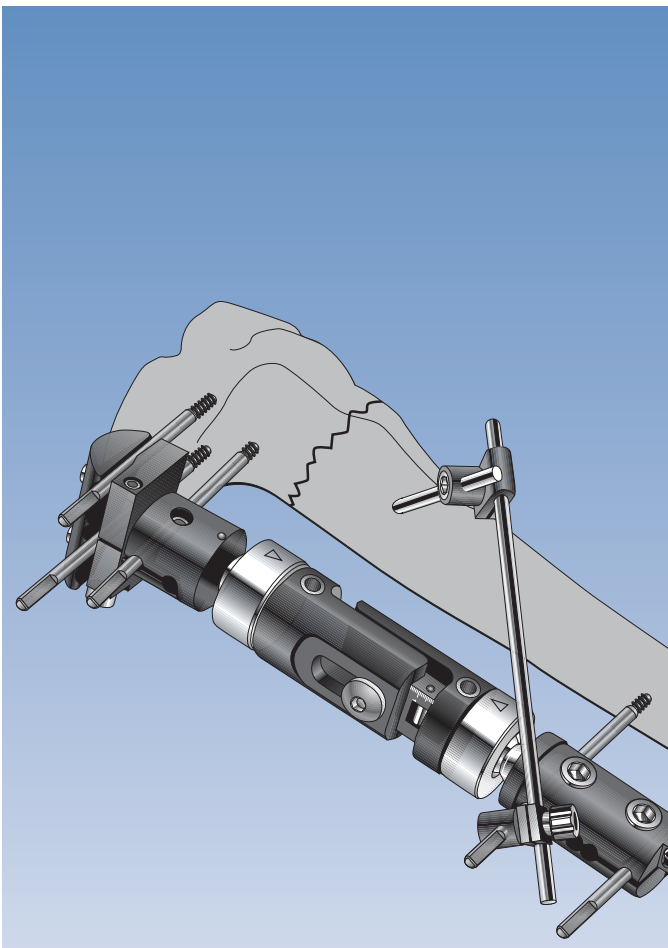
Uses: To compress a non-union site or to disimpact a fracture. For the gradual correction of deformity when used with the self-aligning articulated body (see below). N.B. these units are also used in conjunction with the Limb Reconstruction System for lengthening and bone transport purposes (see Manual 11) and with the elbow fixator where major extension is required. (See Quick Reference Guide PG13B "The Elbow Fixator - Part B: Post-Traumatic Stiffness").



The ProCallus Actuator

This attachment looks rather like a compression-distraction unit with a black lever arm. Like the compression-distraction unit it has feet which fit into the holes of the cams in the body of the fixator. When in place on the fixator, and with the micromovement locking nut loosened, moving the lever arm manually through 180° in both directions will open and close the micromovement facility, providing 2mm of cyclic micromovement at the fixator.

Uses: To apply passive cyclic micromovement to the fracture site in the period immediately following application of the fixator, and before the patient is able to partially weightbear.

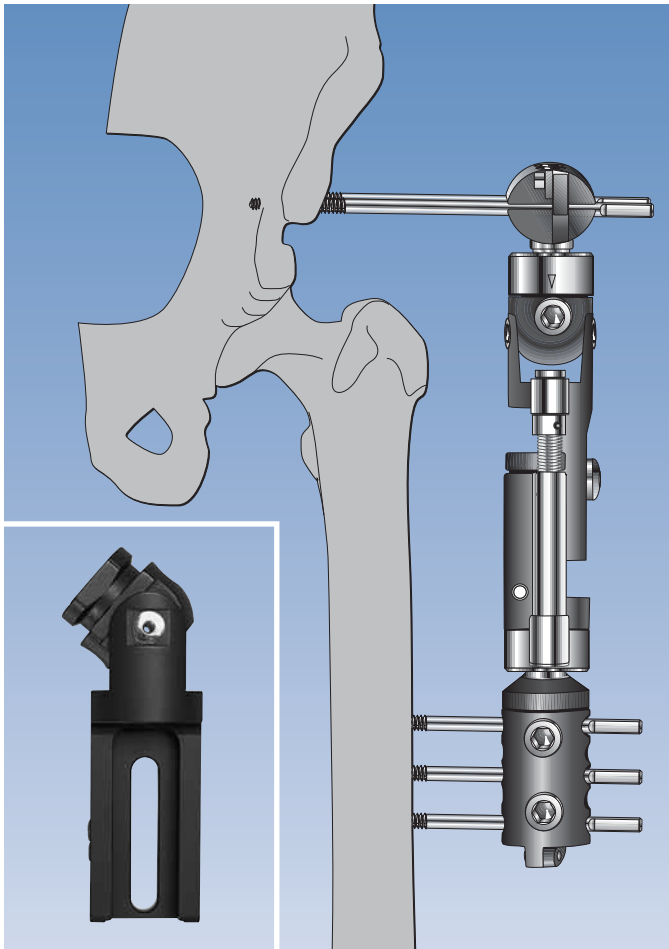


The Supplementary Screw Holder

In this module an independent bone screw clamp is attached to a bar which in turn may be attached either to the end of one of the screws in the proximal or distal cluster, or to the fixator body itself.

Uses: This module is used to clamp an additional screw inserted into an unstable third fragment in diaphyseal fractures of the long bones or to provide a similar working length on either side of the fracture to achieve optimal stability.

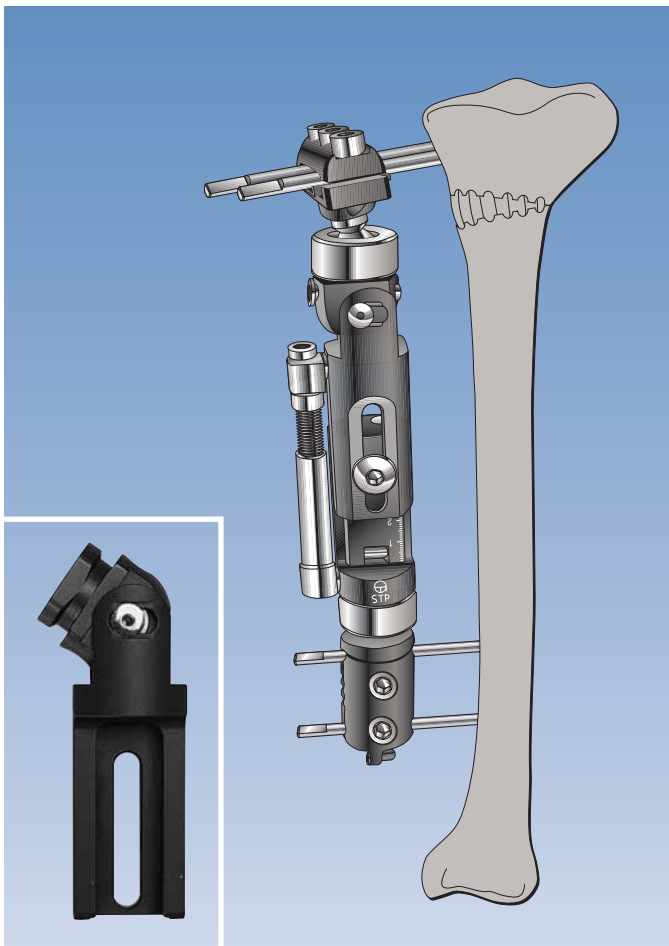
To achieve ideal stability, bone screws should be applied fairly close to the fracture, and the distances between the nearest screws and the fracture margins on both sides should be similar. A minimum distance of 2 cm between the fracture site and the nearest screws is recommended.



The Articulated Body for the Hip

This hinged module is substituted for the female component of the ProCallus Central Body. The hinged section has a ball-joint attachment point to which a standard ProCallus T-clamp will normally be connected.

Uses: For articulated distraction (Arthrodiastasis) of the hip. (See Manual 4 “Arthrodiastasis - Articulated Joint Distraction”).



The Self-Aligning Articulated Body

This module is also substituted for the female component of the ProCallus Central Body. It has a hinged section, and this hinge can alter its position in relation to the bone by sliding along a groove as the body of the fixator to which it is attached, is extended. This avoids translation during deformity correction. This module also has a ball-joint attachment point to which a standard ProCallus T-clamp or a Torbay Garches clamp will normally be connected.

(See Manual 3 “Limb Lengthening and Correction of Deformities by Callus Distraction”).

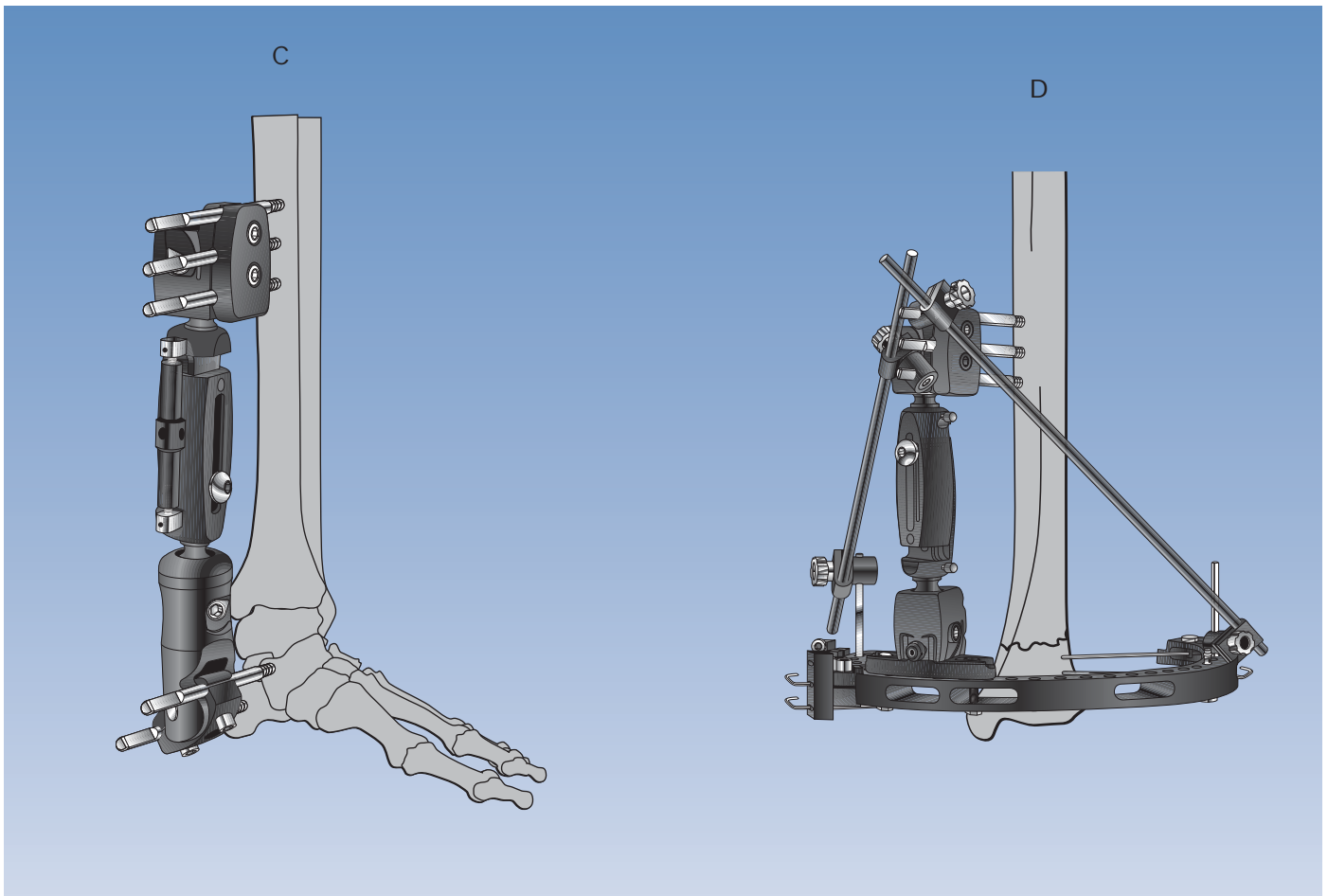
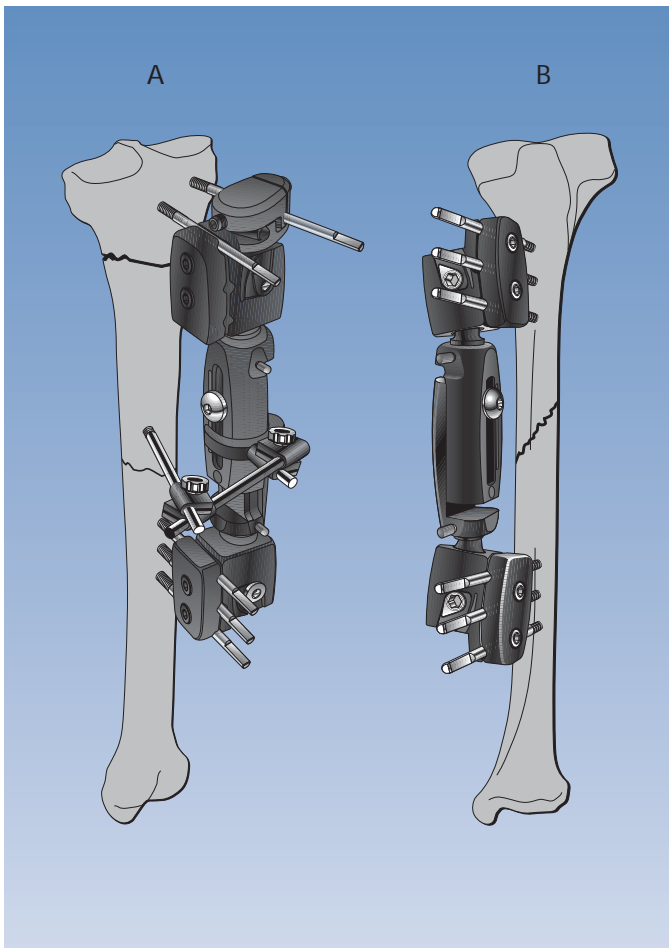
Uses: For the correction of deformity in the distal femur, proximal tibia and distal tibia, using the hemicallotasis technique. (See Manual 3 “Limb Lengthening and Correction of Deformities by Callus Distraction”).

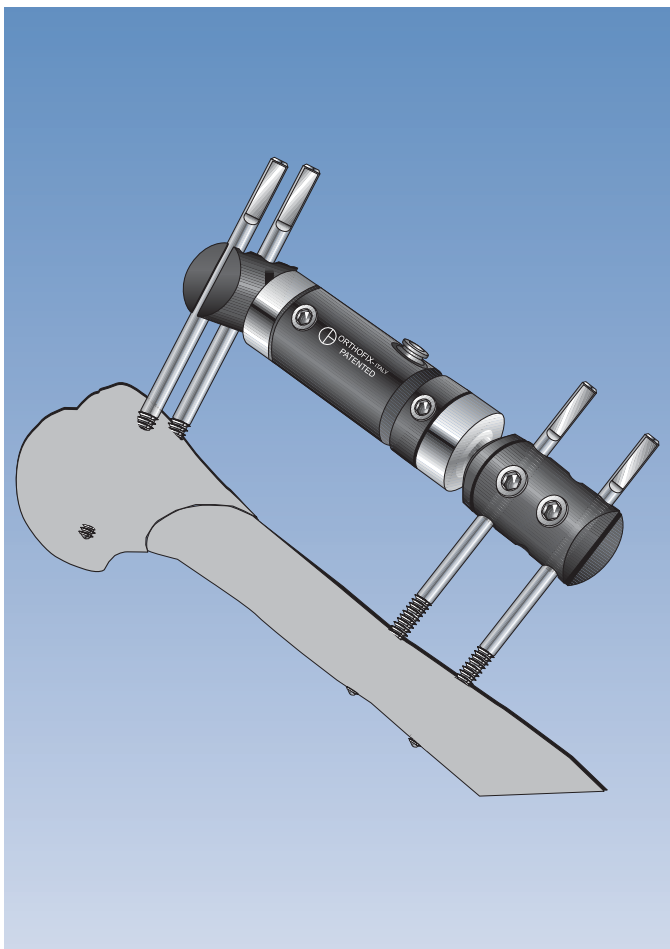
2. The XCaliber Fixator

Key Features:

- Single-use, disposable fixator
- Radiolucent
- Body length covers short and standard ProCallus lengths
- Telescopic body with Central Body Locking Nut
- Two ball-joints which permit 44° of movement in all planes, which can be tightened from either side and which do not require the use of a torque wrench
- Static or dynamic compression-distraction unit available
- Three separate configurations:
 - Meta/diaphyseal model (A), (B)
 - Articulated ankle model (C)
 - Hybrid model (D)

Uses: Diaphyseal, periarticular and articular fractures of the femur and tibia.



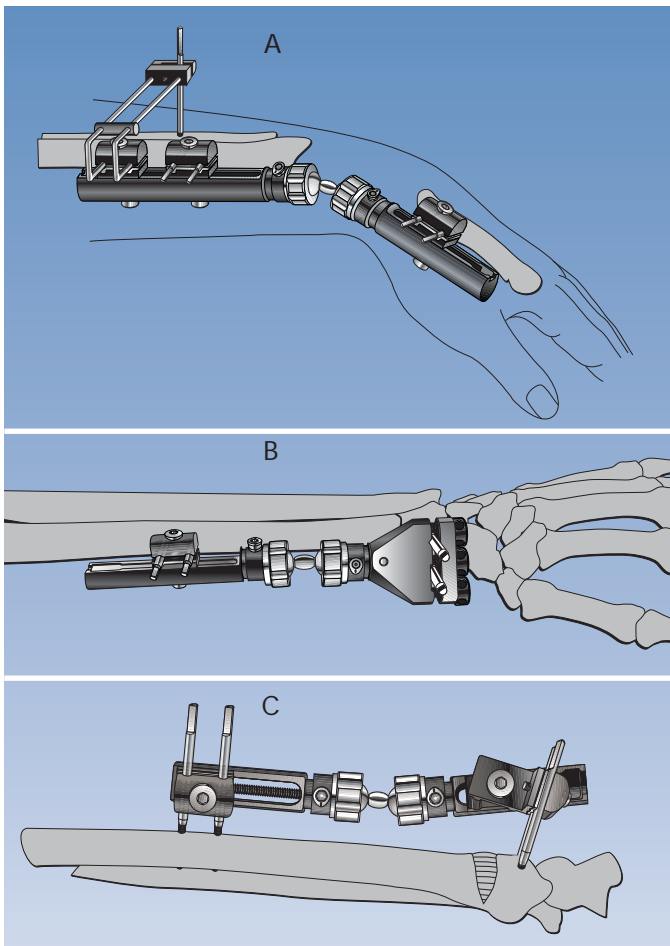


3. The Small Blue D.A.F.

Key Features:

- Small version based on original DAF design
- For paediatric (less than 40Kg body weight) or non-weightbearing adult applications
- Applied with a template
- Double telescopic body with two Body Locking Nuts, to confer extra-length when needed
- Clamps with three screw seats connect to body by ball-joints
- Final tightening of ball-joints with a torque wrench
- Dedicated attachments include: a self-aligning articulated body, and a supplementary screw holder

Uses: Trauma applications include fractures of the humerus, radius and ulna in adults; fractures of the femur and tibia in children. Note that when used for lower limb applications, maximum patient weight should not exceed 40kg (100lbs). Orthopaedic applications include correction of deformity in the distal femur and proximal and distal tibia in children.

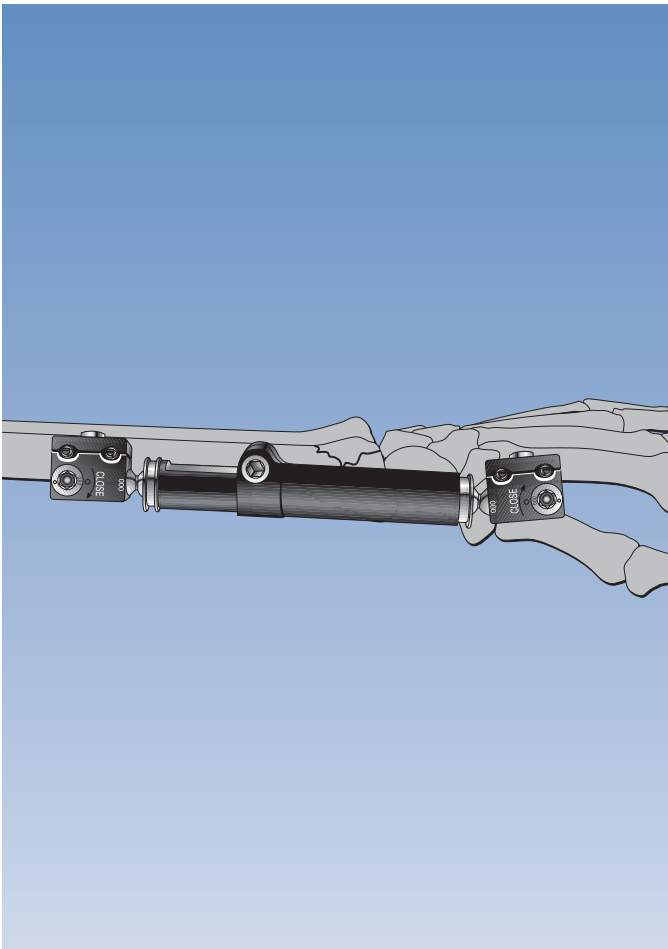


4. The Pennig Dynamic Wrist Fixator

Key Features:

- Lightweight, low-profile fixator
- Double ball-joint allows final reduction after fixator application
- Ball-joints tightened with an Allen key only
- Extra-articular or transarticular (A) configuration
- Radiolucent clamp for extra-articular applications in trauma (B)
- Extra-articular configuration with T-clamp for trauma or corrective osteotomy (C)
- Distal ball-joint can be loosened to permit mobilization of wrist joint if and when required in transarticular applications
- Dedicated, tapered bone screws (3.3/3.0mm thread diameter)
- Ulna outrigger attachment to stabilize distal radio-ulna joint (blocks pronation and supination).

Uses: Trauma Applications: Periarticular and articular fractures of the distal radius. Orthopaedic Applications: Correction of deformity of the distal radius; treatment of the stiff wrist. (See Manual 10 “The Pennig Dynamic Wrist Fixator”).

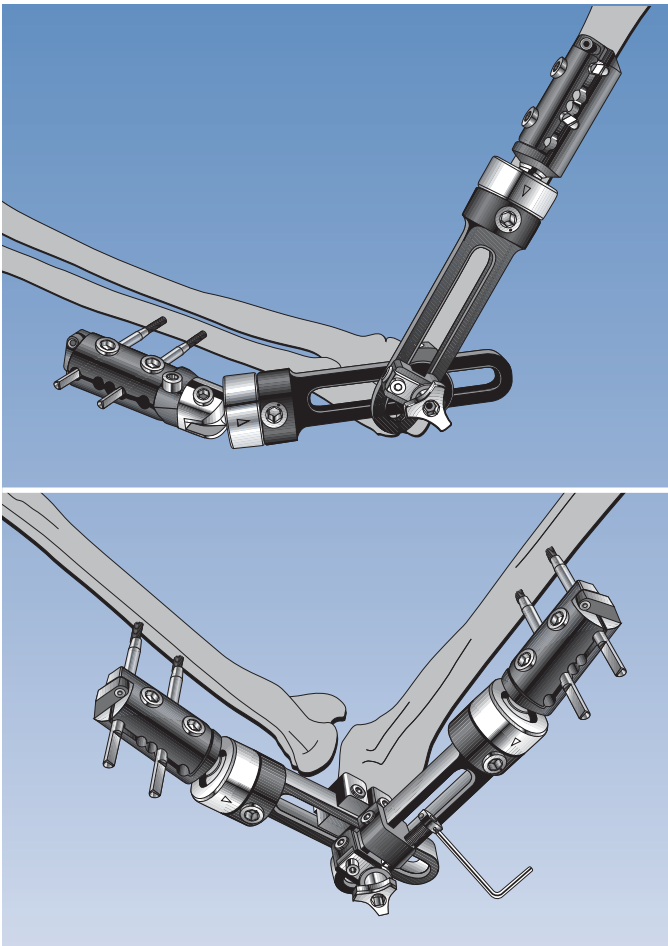


5. The RadioLucent Wrist Fixator

Key Features:

- Very lightweight, low-profile fixator
- Supplied with instrumentation as a “stand-alone”, sterile, disposable kit, for single use only
- Radiolucent body and clamps
- Ball-joint closure with an Allen wrench only
- Transarticular configuration only

Uses: Articular and periarticular fractures of the distal radius.
Not used for orthopaedic applications.
(See Manual PM RLW “The RadioLucent Wrist Fixator”).



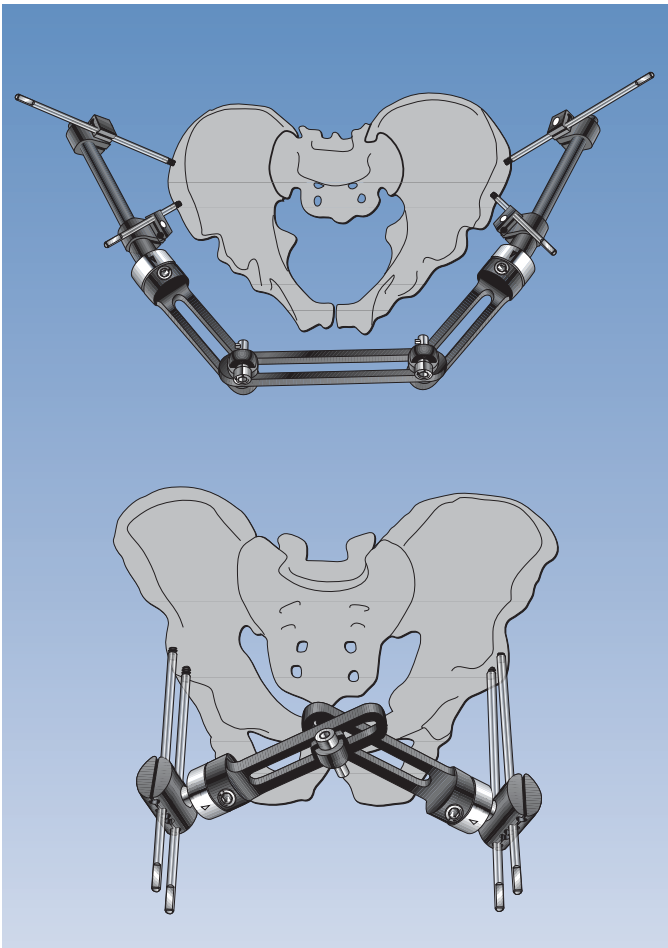
6. The Elbow Fixator

Key Features:

- Comprises two sliding links attached to straight clamps with ProCallus-type ball-joints
- Central connecting unit between the links for length adjustment and locking
- 4.5/3.5mm diameter tapered screws for use in the ulna; 6/5mm diameter tapered screws for use in the humerus
- Small distractors attaching to the links for intra-operative distraction of the injured elbow joint
- A ball-jointed extended range clamp available for more versatile ulnar screw placement

Uses: Trauma applications: unstable dislocation or fracture-dislocation of the elbow. Orthopaedic application: the treatment of the stiff elbow.

(See Quick Reference Guide PG 13 “The Elbow Fixator ” - Part A: Acute Trauma and Part B: Post-Traumatic Stiffness).



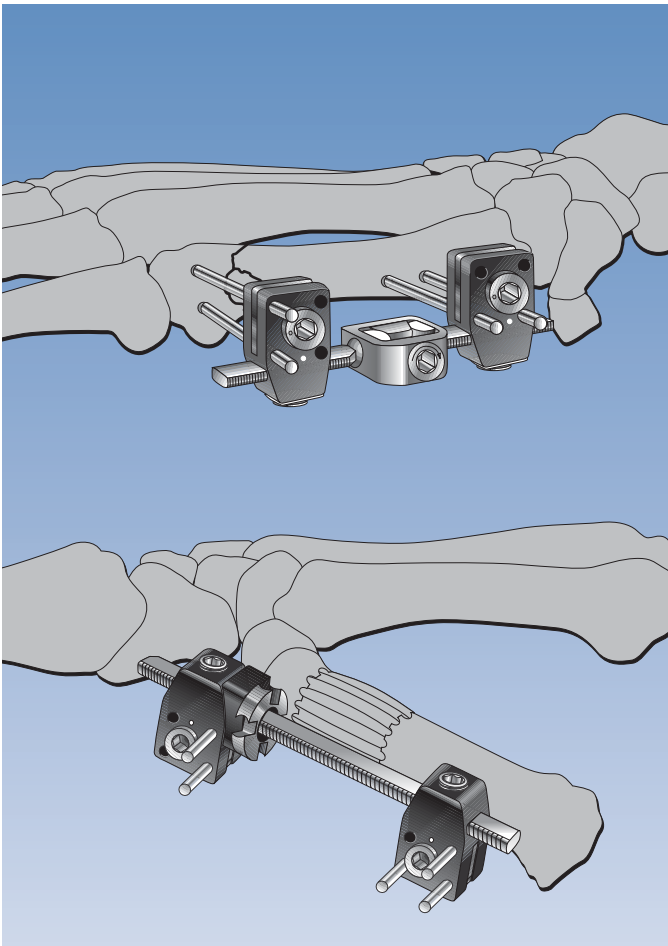
7. The Pelvic Fixator

Key Features:

- Comprises two or three sliding links with lockable connecting units for length adjustment
- End-links accept the ProCallus ball-jointed straight clamps or T-clamps
- Additional ball-jointed attachments available for independent positioning of screws
- For rapid anterior, or iliac crest application to the pelvis
- Final reduction following application of the fixator
- Provided in a “stand-alone” kit which includes self-drilling bone screws

Uses: All unstable pelvic ring fractures where anterior stabilization is indicated.

(See Manual 8 “Pelvic Applications”).



8. The Pennig Minifixator

Key Features:

- Available in three lengths: long, standard and short
- Central integral double ball-joint
- Straight or L-shaped clamps for securing threaded wires which are inserted percutaneously
- Clamps designed to allow either parallel or convergent wire placement depending on space available
- Bridging of joints avoided in many cases
- Lengthening bars (without ball-joints) available in three sizes
- Compression or distraction possible

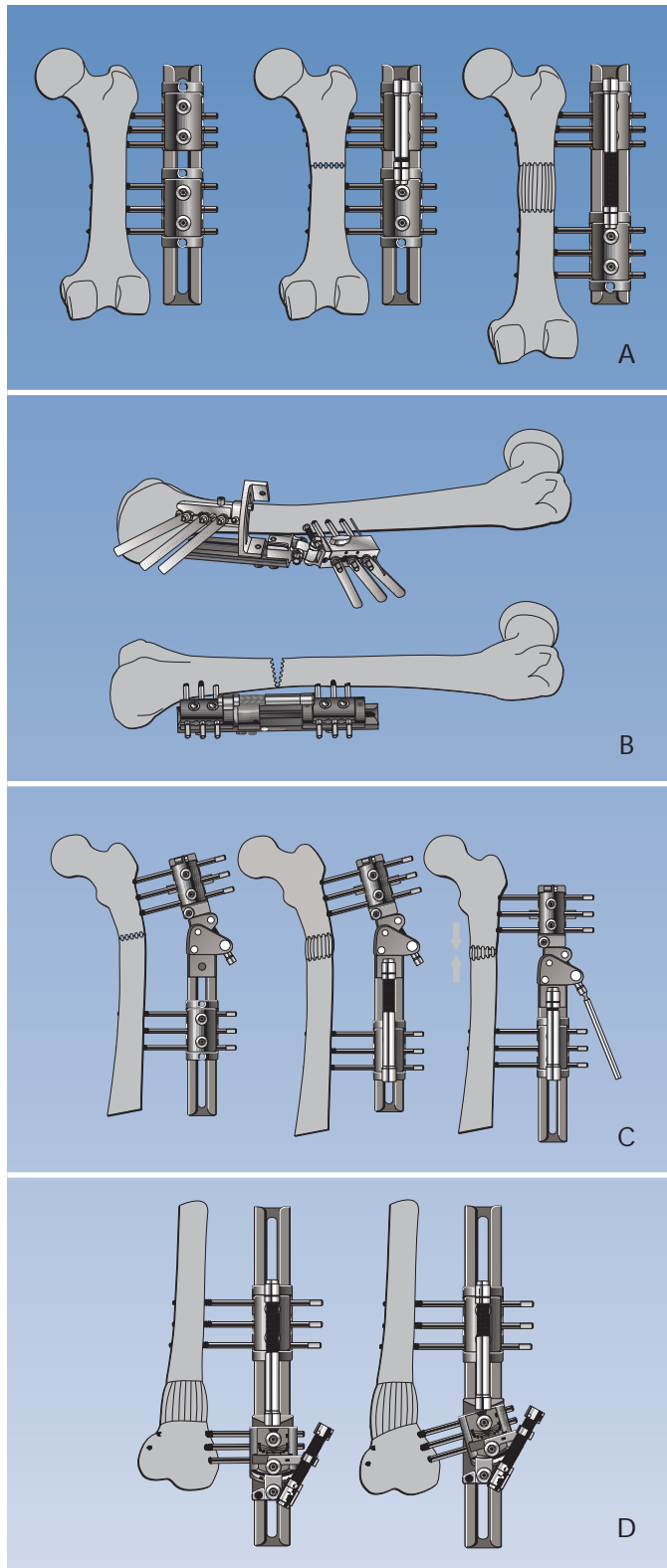
Uses: In trauma, for the treatment of shaft, articular and periarticular fractures of the small bones of the hand and foot. In orthopaedics, for reconstructive procedures in the hand and foot including the treatment of non-union; correction of deformity; lengthening and bone transport procedures, and soft tissue contractures.

(See Manual 9 “Treatment of fractures and deformities in small bones”).

Fixators without Ball-Joints

These fixators may have their major applications in orthopaedics, in trauma, or in both arenas. The devices included in this section are:

1. **The Limb Reconstruction System (LRS)**
2. **The MiniRail System**
3. **The Petrochanteric Fixator**



1. The Limb Reconstruction System (LRS)

Key Features:

- Single rail system for the attachment of two to four clamps (A)
- Screws inserted via template clamps which are temporarily attached to the rail
- Adult and paediatric systems available
- Acute Correction Templates permit precise acute correction of angular or rotational (B) deformity prior to application of the definitive device
- Special clamps (multiplanar clamp (C) and micrometric swivelling clamp (D) available for correction of specific deformities

Uses: Primarily in orthopaedics, for lengthening, bone transport, the correction of deformity and the treatment of non-union in the long bones of the lower limb. Used also for the treatment of complex trauma, due to its high stability.
 (See Manual 11 “The Limb Reconstruction System - Part A: General Principles and Part B: Correction of Deformities”

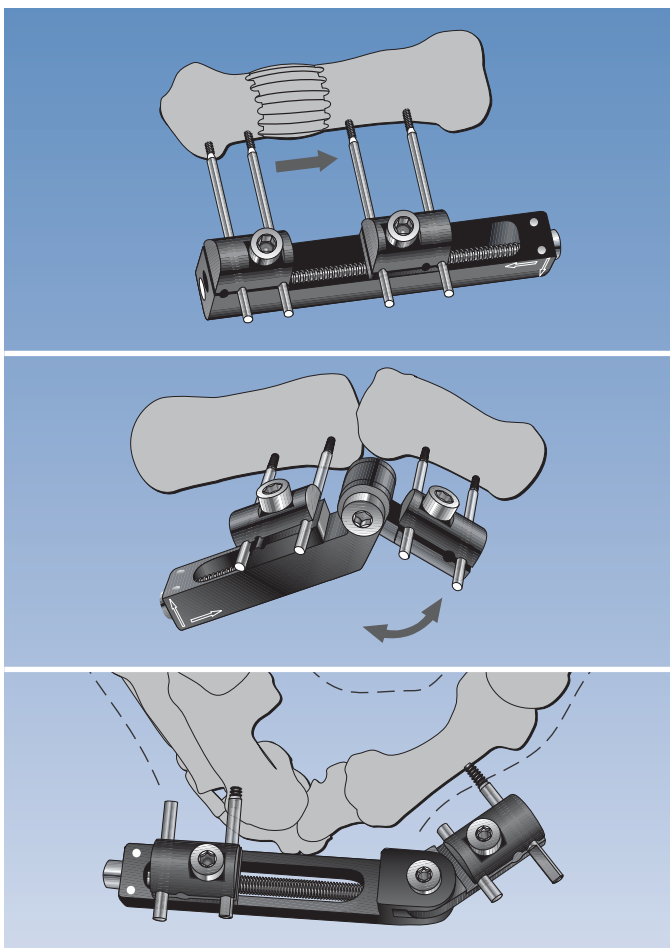
2. The MiniRail System

Key Features:

- Models with three lengths of straight rail available
- Articulated models with a vertical or horizontal hinge
- Can be used with either threaded wires or with self-drilling bone screws

Uses: In acute trauma, or for lengthening or articulated distraction in the hand, and especially in the foot.

(See Quick Reference Guide PG 14 “The MiniRail System” - Part A: Hand Applications” and Part B: Foot Applications).

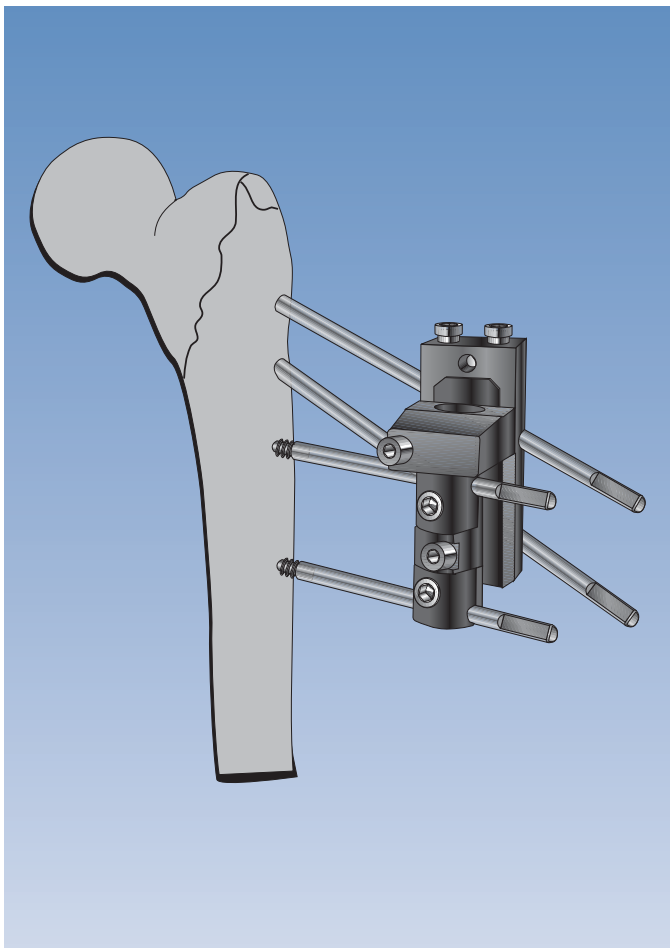


3. The Pertrochanteric Fixator

Key Features:

- Low-profile, lightweight, minimally invasive device
- Self-drilling, converging screws inserted along femoral neck
- Adjustable hinged/rotating component enables versatile placement of the distal screws in the upper femur
- Can be applied under local anaesthetic if necessary
- Early mobilization possible

Uses: For the rapid stabilization of trochanteric fractures in high risk cases.



RING SYSTEMS

Wire-bearing rings provide good fixation in short segments of bone, i.e. those less than 2cm in length, or where bone quality is poor. The Orthofix rings (which are available in 5 diameters), are made up from 2/3 and 1/3 components which can be bolted together. 2/3 or complete rings can support up to 4 tensioned wires. The devices included in this series are:

1. The Orthofix Hybrid Fixator

2. The Sheffield Ring Fixator

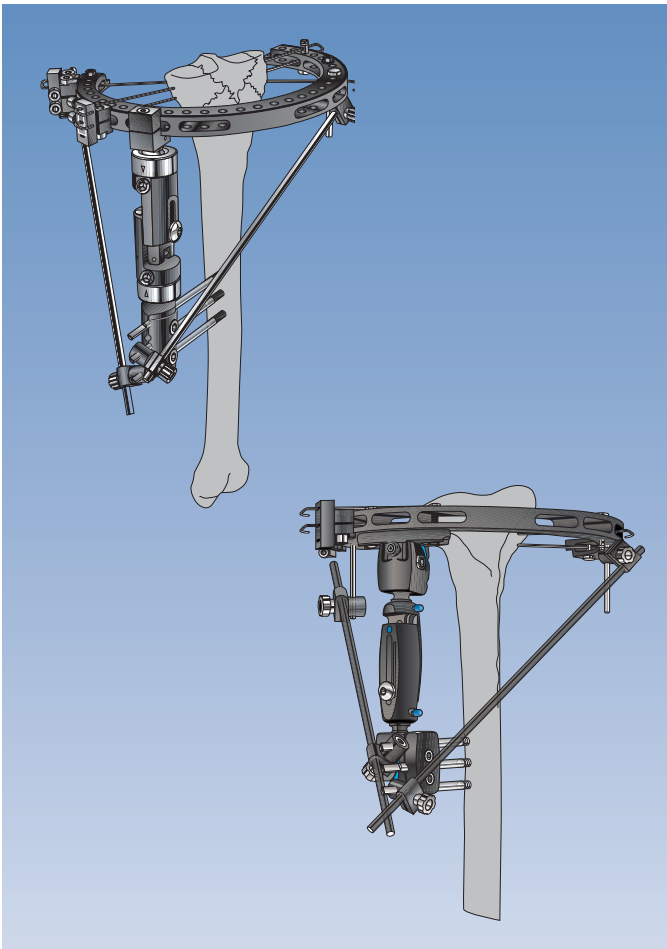
1. The Orthofix Hybrid Fixator

Key Features:

- One or two wire-bearing rings attached to one end of either the ProCallus fixator or the XCaliber fixator
- Diaphyseal screws inserted via a straight clamp at the opposite end of the fixator
- Diaphyseal screws with long shafts used to ensure fixator body is parallel to long axis of bone
- Detachable reinforcement bars increase stability of the system
- Post-operative correction of fracture position is not possible with this configuration
- Conversion to a two-ring system with full potential for correction is possible without additional anaesthetic

Uses: In Trauma, for the stabilization of articular and periarticular fractures of the distal femur and the proximal and distal tibia.

(See Manual 12A “The Hybrid Fixator”).



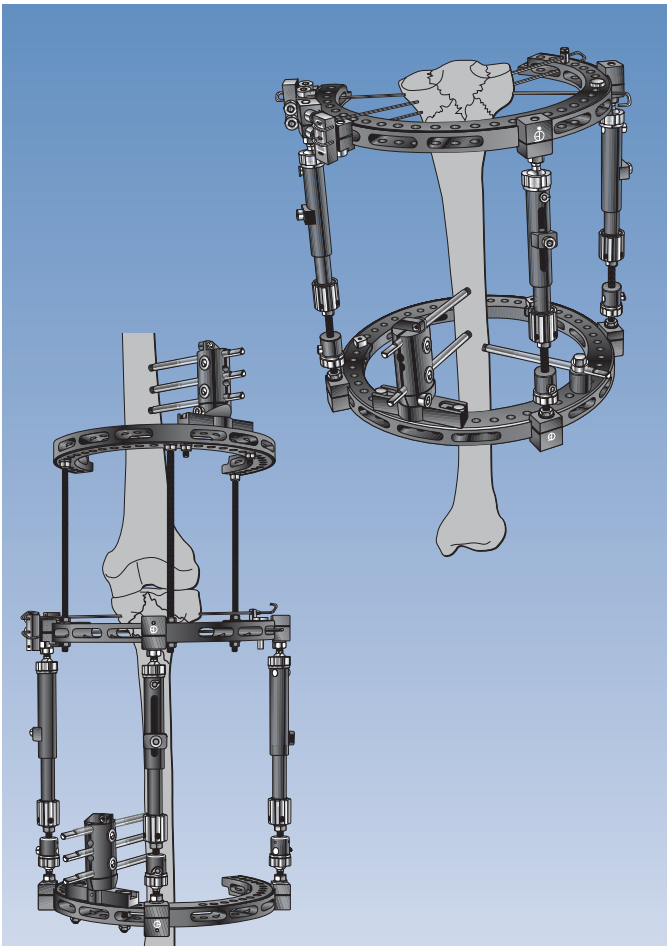
2. The Sheffield Ring Fixator

Key Features:

- Multiple ring system, with one ring per bone segment
- Each ring supported by 3 or 4 tensioned wires, or by a Sheffield Clamp with bone screws
- Normally, tensioned wires in cancellous bone and bone screws in cortical bone
- Rings connected by threaded bars or ball-jointed reduction units
- Pre-assembly of frame possible in many cases
- Any type of deformity corrected by inclusion of simple hinges, translation-rotation hinges and extension plates

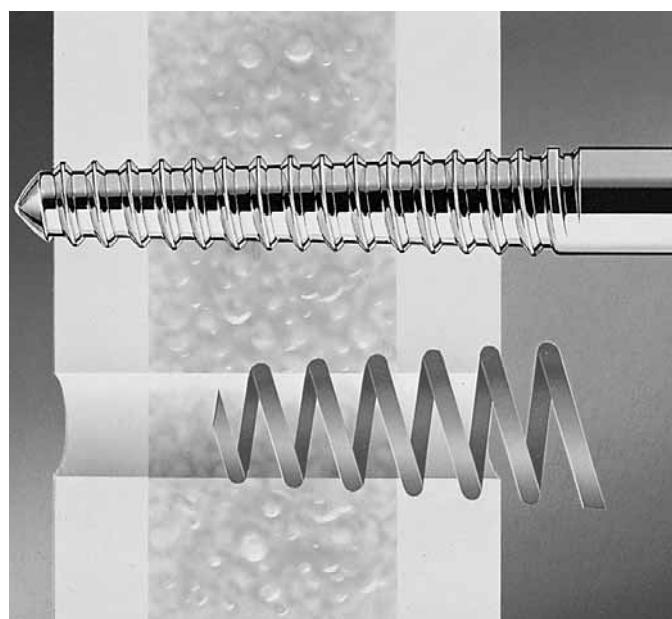
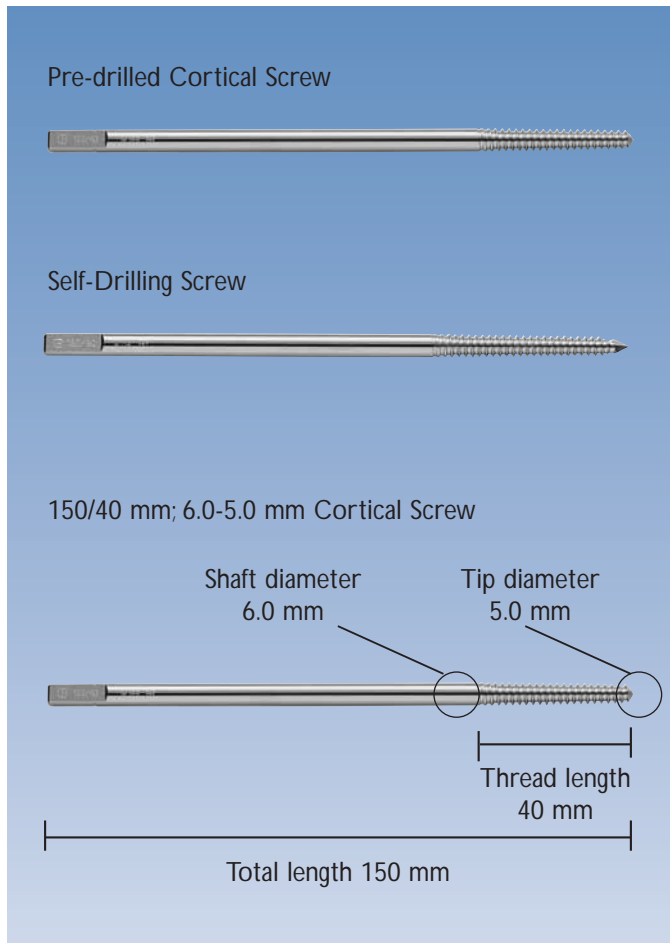
Uses: For complex trauma and reconstructive procedures in the lower limb.

(See Manual 12B “The Sheffield Ring Fixator - Standard Trauma Applications” and 12C “The Sheffield Ring Fixator - Limb Reconstruction and Complex Trauma”).



The problems classically associated with external fixation relate primarily to the pin-bone interface. Pin track infection and loosening are frequently reported in the literature and can compromise the success of a procedure. This has deterred some surgeons from using these devices. It should be emphasized, however, that while screw design plays a major part in reducing these problems, of equal importance is the selection of appropriate screws for a given site and the technique of screw insertion. Screws of inappropriate thread length, or which are not inserted parallel to one another and at right angles to the long axis of the bone may produce unequal stresses at the pin-bone interface, and osteolysis can result. The technique of screw insertion is covered in detail on page 50.

STANDARD ORTHOFIX SCREWS



The Orthofix screws have been designed specifically to produce optimal bone grip with minimal damage to the bone substance. The standard bone screws are tapered, self-tapping half-pins which provide monolateral fixation in the bone. They can be used in either cortical or cancellous bone. Some screws are designed to be self-drilling e.g. in the pelvis and in association with the pertrochanteric clamp; others are introduced into a pre-drilled track. As a general rule, screws for placement in cortical bone should always be pre-drilled.

Screws are provided in different diameters and with different thread and shank lengths. Individual screws are described as overall length/thread length in millimeters; thus a 110/40 screw implies a screw with an overall length of 110 mm and a thread length of 40mm.

The tapered design of the screw thread means that during insertion, each thread cuts a new, slightly larger path in the bone. In addition, this design exerts radial pre-load on the first (near) cortex, and facilitates removal of the screw as an office procedure. The diameter is defined by two numbers, one over the other; thus a 6/5mm screw implies a screw whose thread diameter tapers from 6mm at its thickest point immediately adjacent to the smooth shank, to 5mm at its tip.

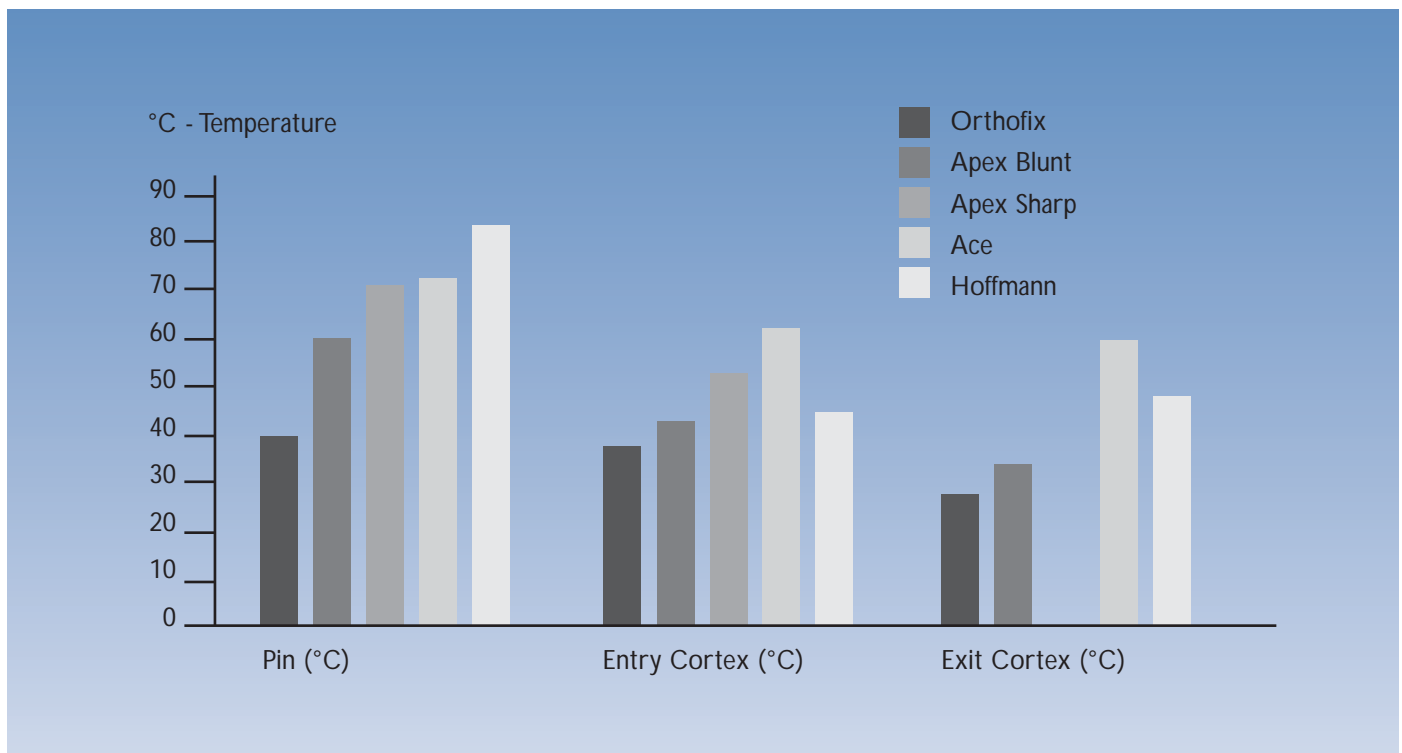
Selection of the correct shank diameter (= maximal thread diameter) and correct thread length for a given bone diameter will ensure that minimal flexion of the screw will occur at the cortex closest to the fixator under normal loads. Deformation of the screws in response to a given load will also depend both on the bone-fixator distance and on the number of screws used in each clamp. In situations where the fixator is sited at a distance of more than 4cm from the bone, the use of 3 screws per clamp is advisable to minimize screw flexion. This will routinely be the case in the lower limb, while 2 screws per clamp is adequate for all upper limb applications.

When selecting a screw for a given site, the following points should be borne in mind:

- The greatest diameter of the thread should be less than 30% of the overall diameter of the bone. Thus 6/5 mm screws should be used for bones with a diameter greater than 20 mm. Care should be taken, however, not to use a thread of too small a diameter in situations where there is high load.
- Thread length chosen is dictated by the thickness of the bone and should be 2-7mm greater than the bone diameter. This will allow about 5mm of thread to remain outside the entry cortex and about 2mm to project beyond the second cortex. Selection of the correct thread length in each case guarantees an optimal degree of contact between screw thread and bone at both cortices.
- The length of smooth shank (overall length minus thread length) in a given site will depend both on the thickness of the soft tissues overlying the bone, and the possible need to attach more than one clamp to a particular screw. It should also be noted that the fixator should be positioned at least 1cm clear of the skin surface. As an example, where the ProCallus is used in the tibia or femur, 5-7 cm of smooth shank should normally protrude from the skin to satisfy these requirements.
- An Orthofix transparent X-ray overlay is available and should be used to assist in selection of the correct thread length. There are two types of overlay, to take account of either an 8% or a 15% magnification produced by the X-ray.

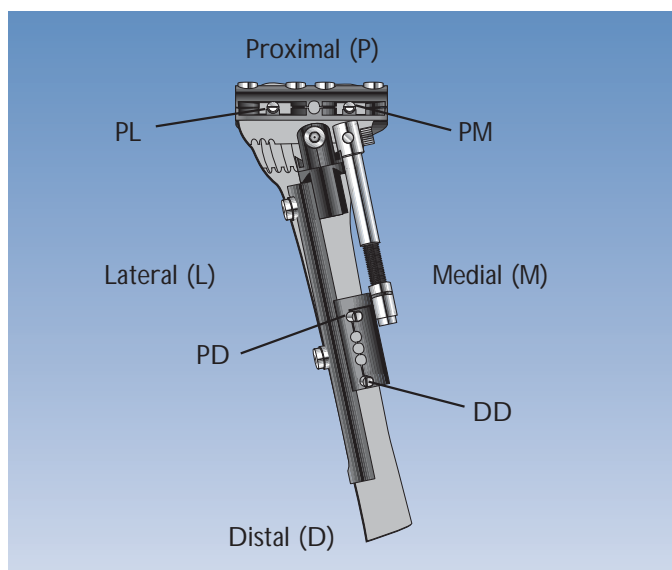
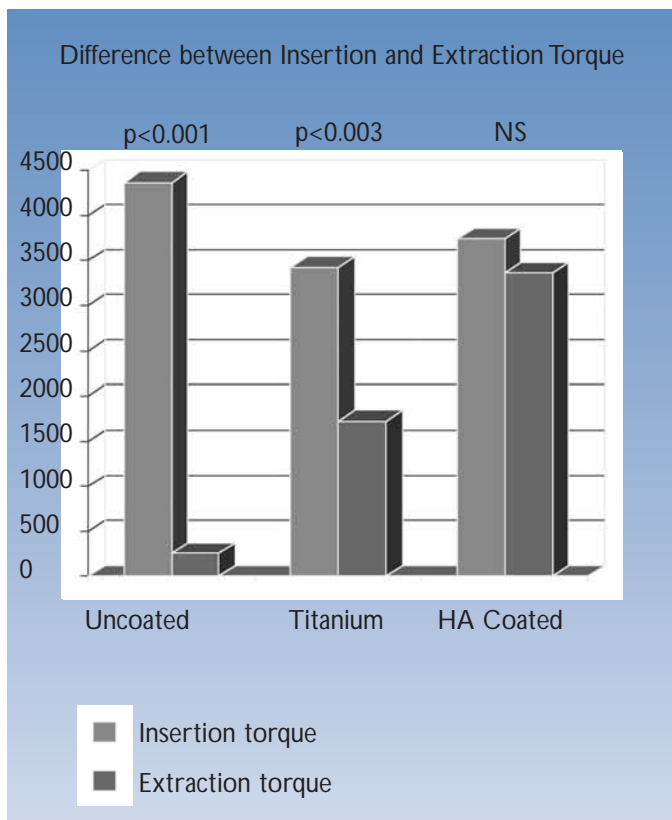
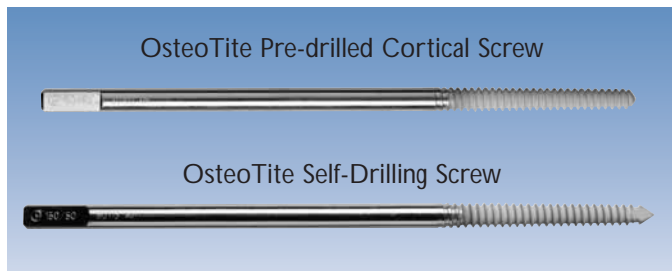
Screw design, together with the inherent rigidity of the fixator are responsible for the excellent stability of the system. Since screw flexion is very limited, this prevents the compressibility factor of bone [average 15,0 Kg/mm² (33 lbs/mm²)] from being exceeded at contact points between screw and bone. The likelihood of osteolysis/osteitis occurring is thus minimized. In addition, the technique of dynamization stimulates bone formation at the pin sites further discouraging osteolysis, and also allows a significant proportion of the axial load to be carried by the bone (rather than by the pin-bone interface).

Thermonecrosis is regarded by some authors as a major cause of pin loosening and it has been shown that at temperatures in excess of 50-55°C (122-131°F), the biological and mechanical properties of bone are irreversibly altered (Matthews et al 1984; Bonfield and Li 1968; Rouiller and Majno 1953). A study conducted on both fresh frozen sheep tibiae and RF-100 foam solid rods, demonstrated that the Orthofix pre-drilled cortical screw was associated with the lowest insertion temperatures when compared with four other commonly used bone screws (Wilkenheiser et al 1995). Temperature generated at the Orthofix screw thread in both models was below 45°C (113°F), whereas all of the other screws studied demonstrated thread temperatures of 60°C (140°F) or above.



ORTHOFIX OSTEOTITE (HYDROXYAPATITE-COATED) SCREWS

These were developed to increase the holding power of the Orthofix screw in cancellous and osteoporotic bone, and in situations where screws were likely to remain in situ for prolonged periods of time, e.g. in lengthening and other reconstructive procedures. It was considered that by reducing the likelihood of pin loosening, the incidence of pin-track infection should be substantially reduced.

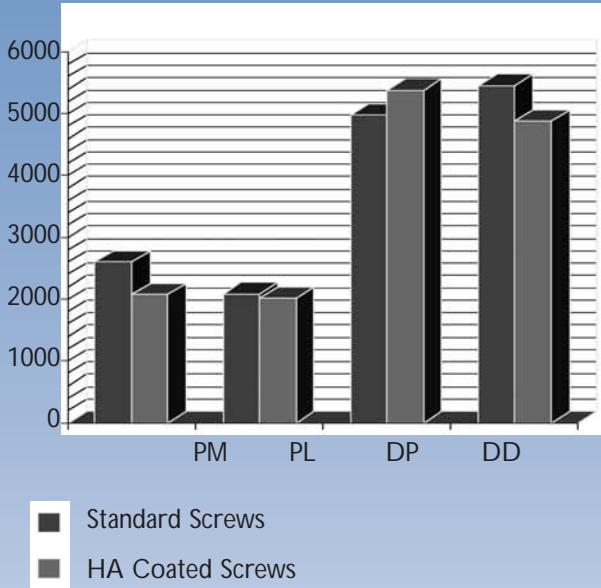


Hydroxyapatite (HA) was chosen as a coating material since it is the natural mineral substance of bone, has a proven track record of use for coating the shafts of prostheses, and should thus be more biologically friendly to the surrounding bone than metal. It was also felt that it might encourage the formation of a bond between itself and the bone to improve screw fixation. These screws are available in pre-drilled or self-drilling versions. As with Standard Orthofix Screws, when inserting into cortical bone, pre-drilling should always be performed.

All the studies reported in this section were carried out using the OsteoTite version of the current Standard Cortical Screws. Initial studies in sheep tibia (Moroni et al 1998) compared the performance of HA-coated screws with that of standard uncoated Orthofix screws and with titanium-coated screws over a six week period. This showed no significant difference in the torque (rotational force) needed to insert any of the three types of screw. Extraction torque, however, was significantly higher with the HA-coated screws than with either the uncoated Orthofix screws ($p=0.002$) or the titanium-coated screws ($p=0.03$), indicating that the HA-coated screws were more securely fixed in the bone. Furthermore, extraction torque was significantly lower than insertion torque in the case of both the uncoated Orthofix screws ($p < 0.001$) and the titanium-coated screws ($p=0.003$), indicating that these screws were looser at the time of extraction than when inserted. There was no significant difference, however, between insertion and extraction torque in the case of the HA-coated screws. Thus the HA-coated screws were as secure on removal as they were on insertion. There was also visible osteolysis associated with more than 80% of the uncoated or titanium-coated screws, but with only 41.7% of the HA-coated screws. At x 10,000 magnification, the histology showed direct contact only between the bone and the HA coating and not between the bone and either the titanium coating or the stainless steel. Microscopic bone fragments were also seen adhering to the HA coating on screw removal. This provided further evidence of bonding between the HA coating and the surrounding bone.

Clinical studies have confirmed the better fixation provided by the HA-coated screws. Nineteen patients underwent upper tibial osteotomy and hemicallotasis for medial compartment osteoarthritis of the knee (Magyar et al 1997). In this procedure, the two proximal screws (PM, PL) are inserted into the cancellous bone of the metaphysis where secure fixation is always a problem; the distal screws (DP, DD) are inserted into the cortical bone of the diaphysis, where better fixation can be expected. Half of the 76 screws used in this study were standard, uncoated Orthofix screws and half were HA-coated screws.

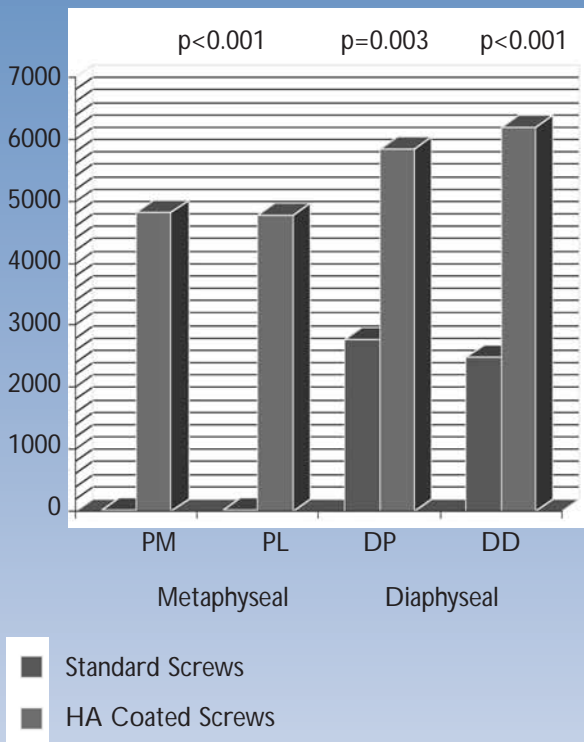
Average Insertion Torque Standard and HA Coated Screws



PM = Proximal Medial PL = Proximal Lateral
 DP = Distal Proximal DD = Distal Distal

As can be seen, there was no significant difference in average insertion torque for standard uncoated, or HA-coated screws at either site.

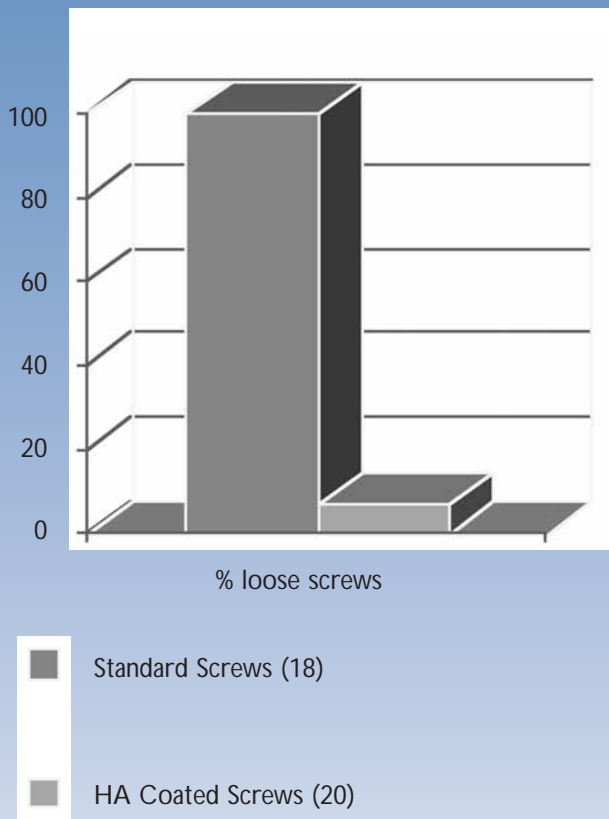
Average Extraction Torque Standard and HA Coated Screws



Mean fixation time: 101 days

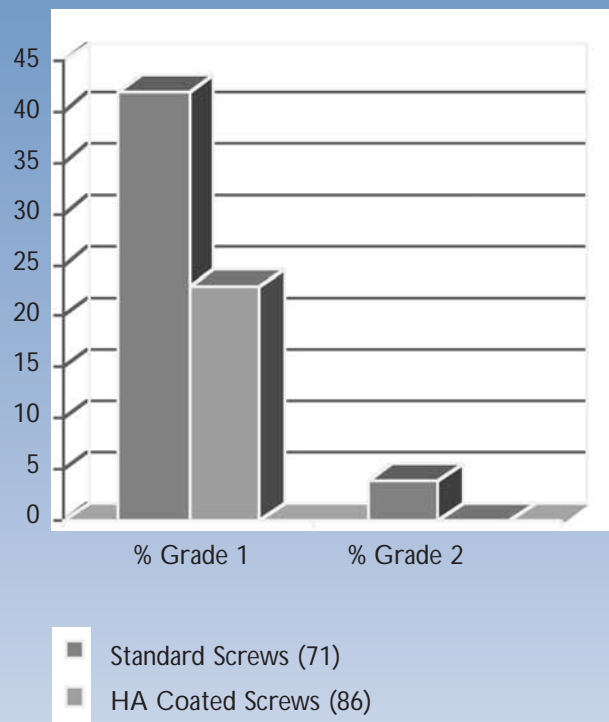
After a mean period of 101 days, however, average extraction torque showed major differences. There was a huge improvement in the security of fixation in metaphyseal bone (high extraction torque) with the HA-coated screws compared to the standard uncoated screws. There was also a significant, but less marked increase in extraction torque with the HA-coated screws in cortical bone. Despite the much improved fixation, screws could still be removed without undue discomfort.

Metaphyseal Screw Loosening



Of the 38 screws located in metaphyseal bone, 18 were uncoated and 20 HA-coated. On removal, 100% of the uncoated screws were loose, compared to less than 10% of the HA-coated screws.

Incidence of Pin Site Infection



A lower incidence of pin track infection has now been demonstrated in association with HA-coated screws as compared to uncoated screws. In a multicenter study, after mean treatment times of 166 days (uncoated screws) and 178 days (HA-coated screws) respectively, the incidence of both Grade I and Grade II infections was markedly higher in the 71 uncoated screws than in the 86 HA-coated screws (Moroni et al 1999).

With the uncoated screws, infected screws were significantly looser than non-infected ones ($p < 0.0001$), whereas with the HA-coated screws, there was no difference. Furthermore, the higher strength of fixation of the HA-coated screws ($p < 0.001$) corresponded to a lower pin-track infection rate ($p < 0.05$).

As a direct result of these findings, Orthofix OsteoTite (Hydroxyapatite-Coated) Screws are now routinely recommended for use in situations where there is an increased risk of screw loosening over time, e.g. in cancellous or osteoporotic bone, or in any application where the external fixation is expected to remain in place for a long period of time, e.g.:

- High energy trauma (slow union)
- Bone transport for bone loss
- Lengthening procedures
- Other limb reconstruction procedures

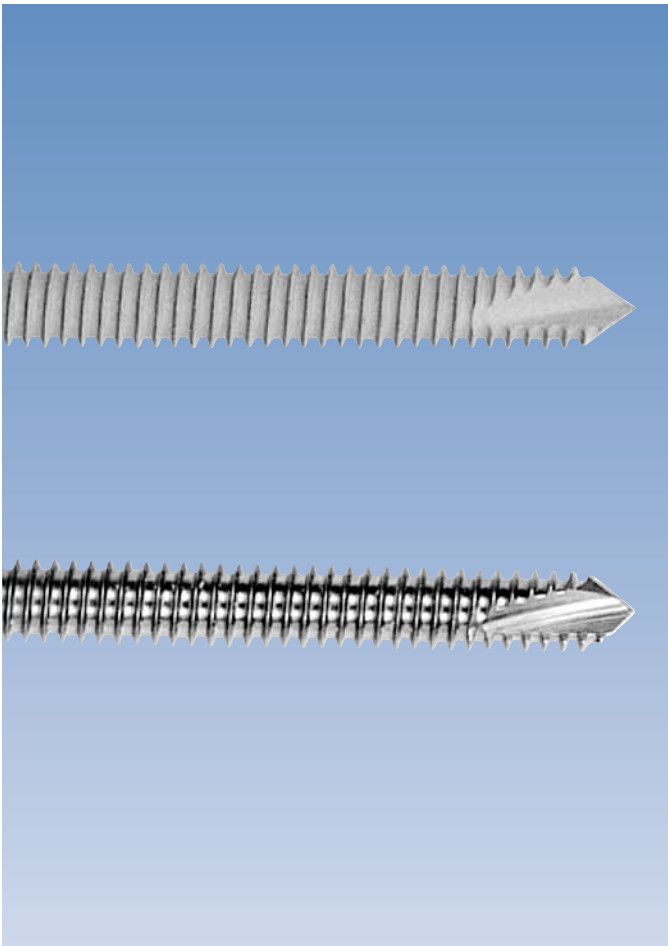
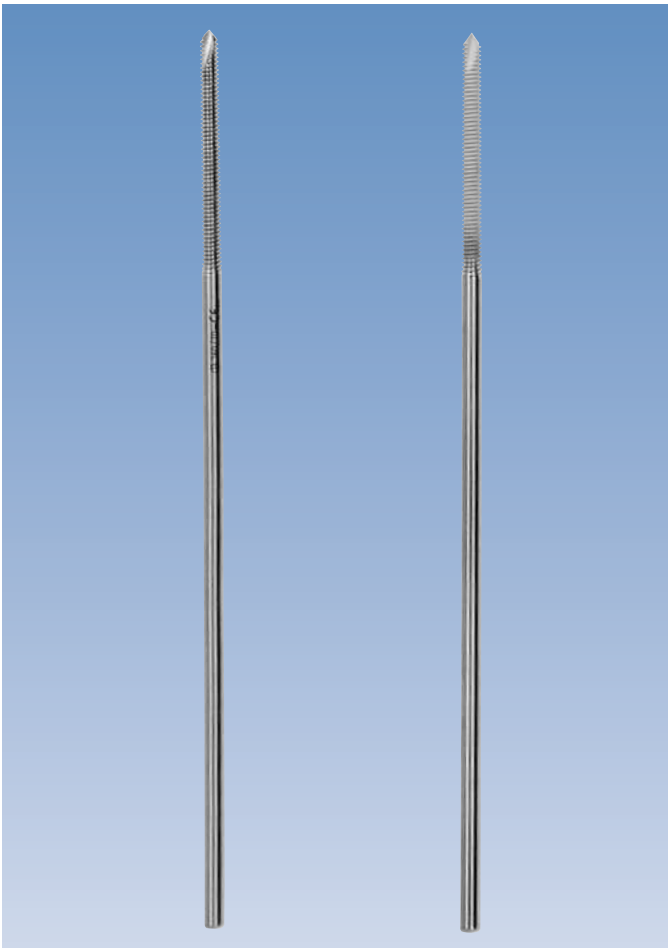
These screws are available in a range of sizes and are supplied sterile.

Note: Neither Standard nor Hydroxyapatite-Coated (OsteoTite) screws should ever be reused.

ORTHOFIX XCALIBER BONE SCREWS

Following extensive research, a new, and even better bone screw has been designed and produced by Orthofix engineers. Among the main objectives of the development program was to find a way to reduce the overall inventory of screws required and to further improve fixation in cancellous bone. The key features of these screws are:

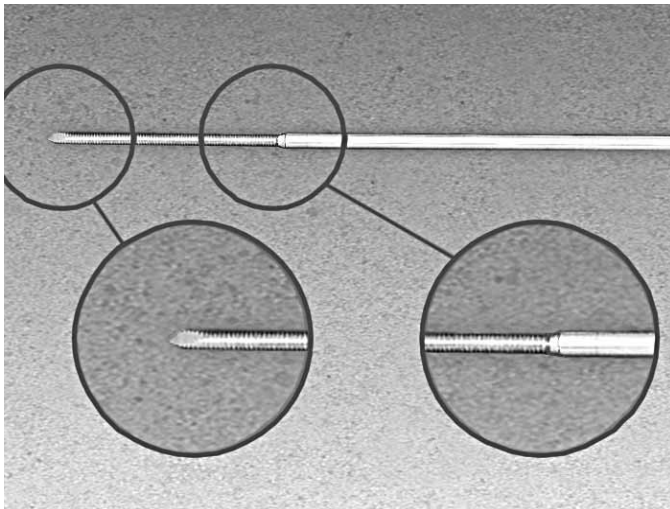
- **A single thread design for all types of bone:**
An increased number of threads per unit length in the XCaliber screw increases the contact area between screw and bone for improved stability. This is coupled with a modified thread profile, which provides a safe and effective level of contact pressure at the pin/bone interface, contributing to the security of fixation without provoking bone resorption.
- **Increased stiffness:**
The core diameter has been increased in the XCaliber screw. This has resulted in an increase in stiffness, and an increase in fatigue resistance of 20% compared to the other Orthofix screw ranges.
- **A lesser degree of taper:**
The characteristic Orthofix taper is still present, but to a lesser degree. Thus the thread diameter of the XCaliber screw tapers from 6.0 mm at the shank/thread junction, to 5.6 mm at the screw tip. This means that if absolutely necessary (and this should not be considered normal practice), backing out a screw by two full turns has minimal effect on reinsertion torque (bone grip), which is still very much higher than that of the Apex (Stryker Howmedica) and Selfdrill (Synthes) bone screws (data on file).
- **Self-Drilling:**
The XCaliber screw has a short cutting flute, and a distinctive tip design which has several benefits. The surgeon can “feel” the second cortex more easily, which allows for more accurate screw placement. The threads reach almost to the tip which ensures good anchorage in the second cortex with only minimal penetration. The surgeon can insert this screw with or without pre-drilling, although pre-drilling is always recommended in cortical bone.
Work carried out at the Independent Breda Laboratory in Milan has shown that without pre-drilling, the XCaliber screw produces a lower temperature in the bone on insertion, with less temperature difference between the screw tip and the bone at the end of drilling than the Apex self-drilling screw.
- **Only two lengths of screw:**
XCaliber screws either 150mm or 260mm in length are each available in seven different thread lengths. The shank can be cut to the desired length either before, or after insertion, with dedicated screw cutters. This has reduced the screw inventory from 52 sizes to 14.
- Available in uncoated or HA-coated (OsteoTite) versions.



1. THE FRAGMENT FIXATION SYSTEM (FFS)

This system was developed as a major improvement over other available methods of securing small fragments during the management of intra-articular and periarticular fractures. The FFS implants combine the dimensions and simplicity of use of K-wires, with the security of fixation afforded by larger and less versatile screws.

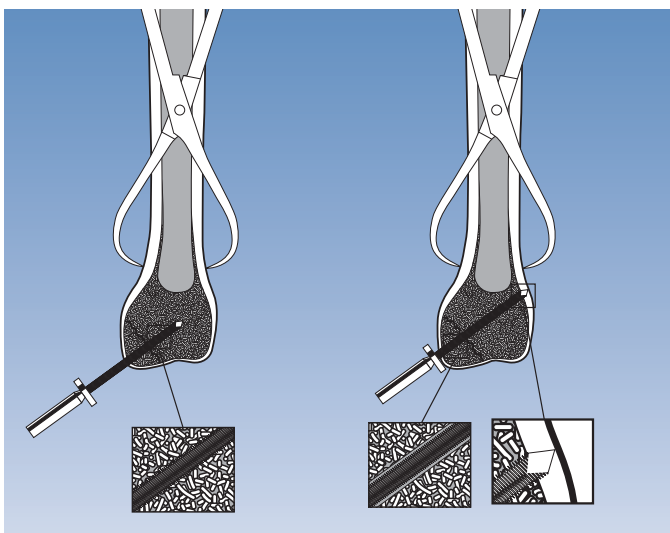
Note that while the FFS is described here as an ancillary system for use in conjunction with external fixation techniques, it can also be used in many instances as a stand alone system for fracture fixation.



Each implant has a three-edged tip similar to that of a K-wire, and a fine machined thread of uniform diameter, followed by a polished shaft of slightly greater diameter. The shoulder, or chamfer at the junction between shaft and thread is similar to that of a screw head. Where indicated, e.g. in osteoporotic bone, the size of the shoulder can be increased by the use of a washer.

Three Thread Diameter/Shaft Diameter Combinations are Available:			
Small	1.2 mm	1.5 mm	Very small fragments in hand surgery
Medium	1.6 mm	2.0 mm	Typical implant for fractures in hand/foot
Large	2.2 mm	3.0 mm	Intra-articular or periarticular fractures of the long bones

Each of these is available in a variety of thread lengths, but the total length of each implant is 120mm. The implants are fitted into a standard drill and drilled directly into the fragment to be secured, using either an open or a percutaneous approach. The holding power of the FFS implants in terms of pull-out strength has been demonstrated to be equivalent to that of larger diameter conventional pre-drilled cortical or cancellous interfragmentary screws (Gausepohl and Pennig 2000). This is considered to be due to the presence of impacted drill flour, which in the case of conventional pre-drilled screws, is removed by the drill.

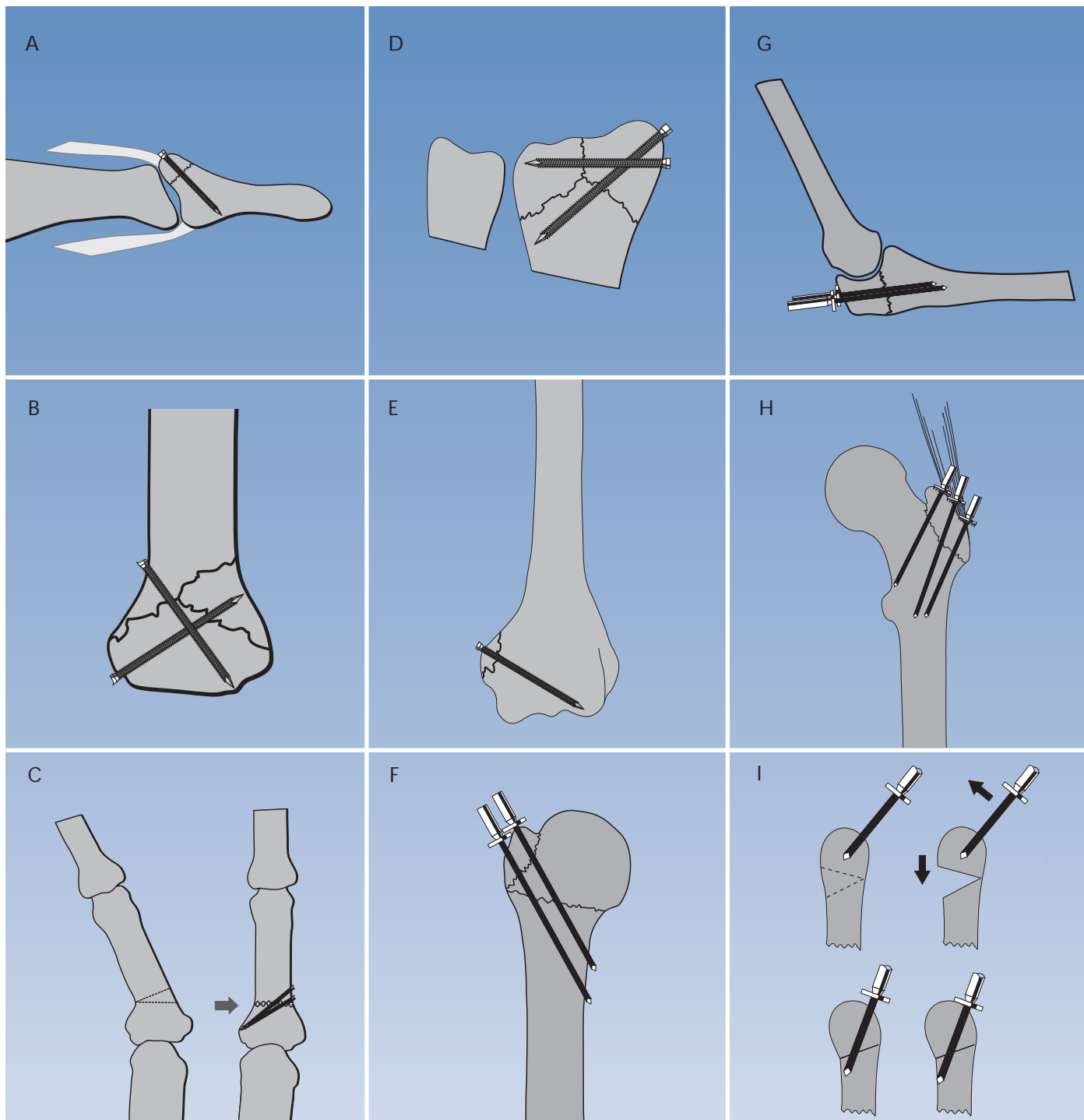


An important property of the FFS implants is the ability to exert a compressive effect on insertion. This can be explained as follows:

To reattach the detached fragment in the figure opposite, the implant is drilled obliquely through its cancellous bone, and across the fracture line. When the tip of the implant reaches the opposite hard cortex drilling speed is reduced. As the implant meets the resistance of the hard cortical bone, the drill initially revolves without advancing the implant. This has the effect of stripping the thread proximally to form a gliding hole, while leaving a threaded hole distally. Now when the chamfer with the washer reach the bone the two fragments will be compressed together.

Once inserted, implants are cut just above the chamfer, and it is usually possible for them to be covered by skin. Implants are left in place until healing has occurred, when they can be removed using a dedicated extractor.

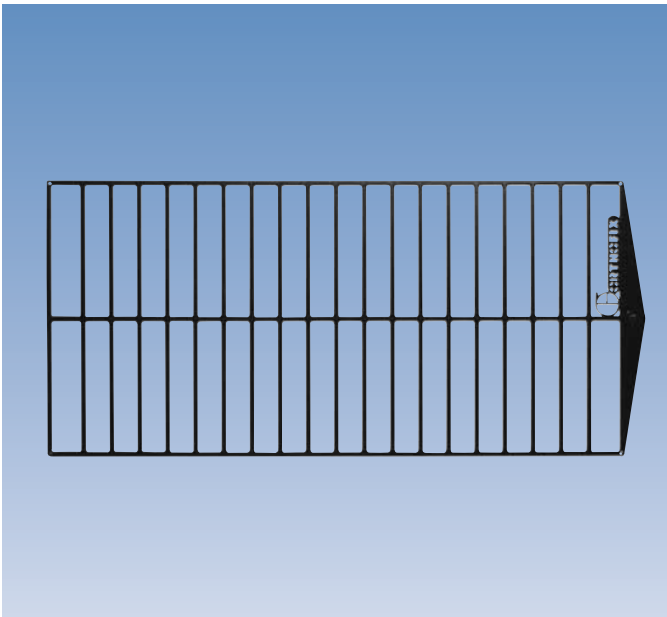
The following are examples of the use of the FFS in a variety of trauma and orthopaedic settings:



- A: Re-attachment of an avulsed tendon in mallet finger
- B: Fracture at the base of a phalanx
- C: Correction of deformity in a digit
- D: The use of medium implants to stabilize fragments in a distal radius fracture
- E: Distal humeral fractures
- F: Proximal humeral fractures
- G: Olecranon fractures
- H: The use of large implants to reattach the greater trochanter
- I: Corrective osteotomies

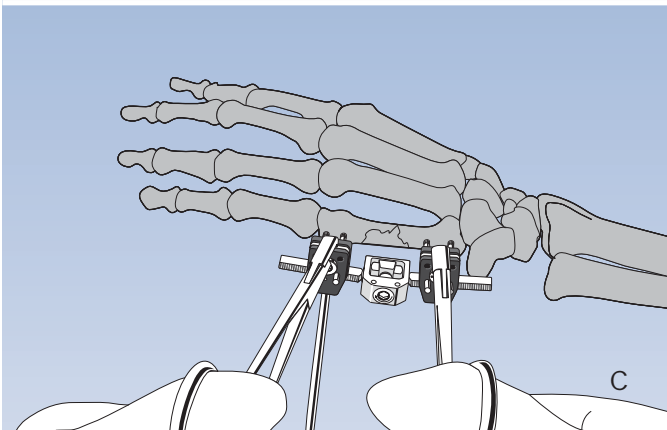
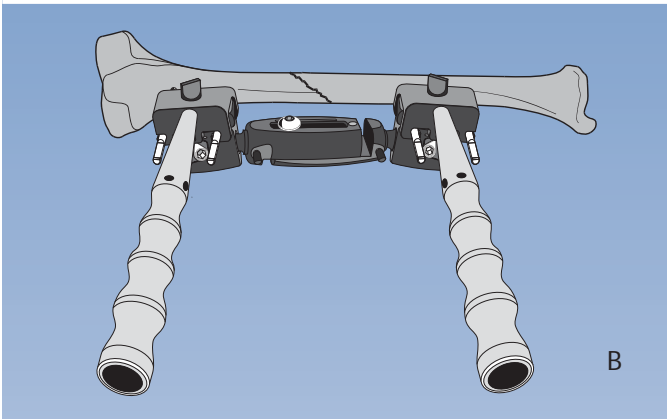
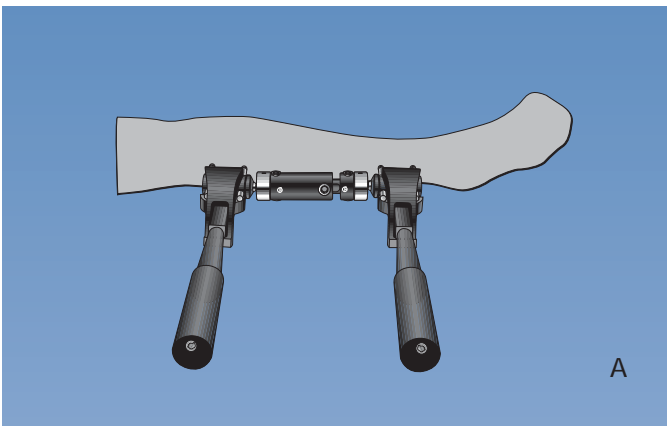
2. ALIGNMENT GRID

This alignment grid has been designed to be used in conjunction with a mobile Image Intensifier before fixator application, to enable the surgeon to identify and correct angulation and to detect any translation of the joint above and below the deformity.



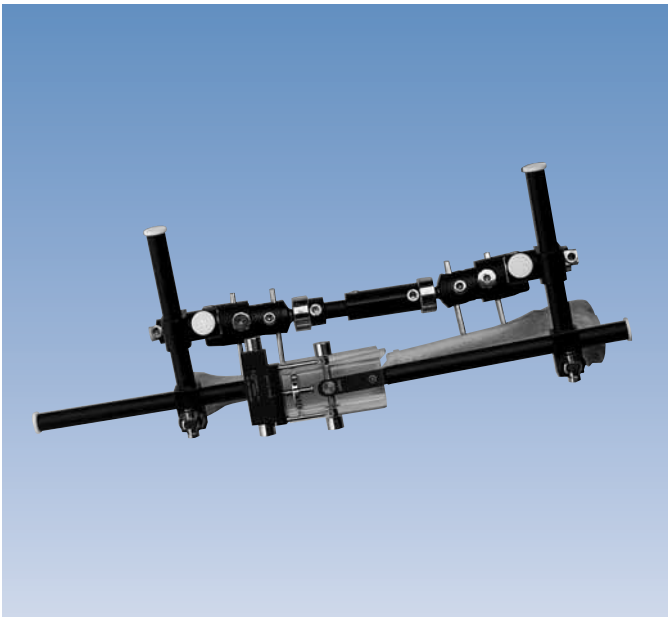
3. MANIPULATION FORCEPS

These can be attached to the fixator clamps and used, where necessary, to achieve final reduction, while keeping the surgeon's hands clear of the x-ray beam. There are specific manipulation forceps for use with the ProCallus Fixator (A), the XCaliber Fixator (B) and the MiniFixator (C).



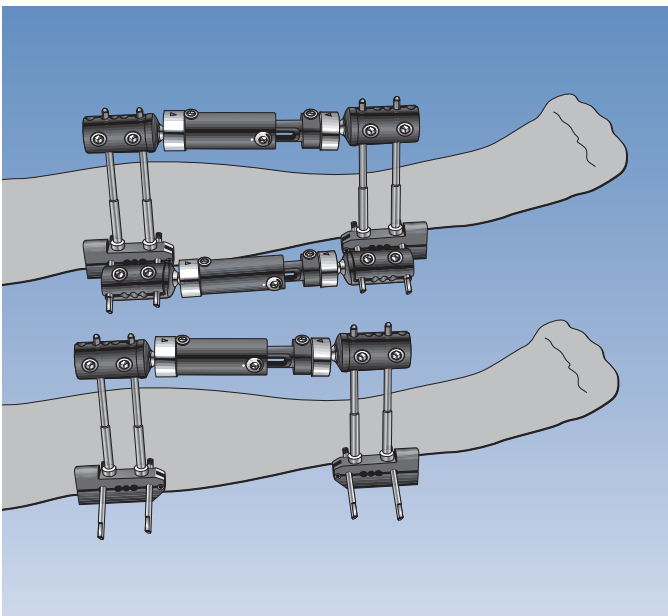
4. MICROMETRIC CORRECTION DEVICE

This attaches to the fixator clamps and allows fine-tuning of reduction to be carried out post-operatively, while the callus is still plastic, without the need for an anaesthetic. Axial, angular and translational correction can be made in any given plane at the fracture site itself.



5. EXCHANGE UNIT

A device which can help to maintain reduction if the fixator is temporarily removed to allow easier access to soft tissues or the fracture site, to enable plastic surgery or bone grafting procedures to be carried out.



6. SCREW CUTTERS

These are designed to cut bone screws to any desired length following insertion.



The precise nature of any pre-operative planning will depend upon the procedure to be undertaken. This will vary in complexity from the straightforward - where a mid-shaft diaphyseal fracture of a long bone is to be treated, to the extremely complex planning required prior to, for example, the application of a Sheffield Ring Fixator to correct varus angulation and procurvatum in a short femur. It is not proposed in this section to deal with specific situations. These are covered in the various Operative Technique Manuals. There are, however, a number of general principles which are integral to the successful accomplishment of any Orthofix Technique, and these are outlined here.

Ensure that you have all the equipment required for the procedure to be undertaken:

this task has been made considerably easier by the publication of an Orthofix reference book - "Applications by Anatomical Site". The initial section of this book provides illustrations of virtually all the possible uses of all of the Orthofix range of external fixation devices. It is now a simple matter to identify the application to be performed and then, to look in the second section, which details exactly the equipment required. This effectively removes any doubts as to which size of fixator to use, which sizes of screw to use, and so on.

Check the correct functioning of critical components:

this means checking that the cams and bushes are not worn (see p. 27 above), that ball joint collars are correctly tightened or screwed down, that compression-distraction units function effectively to open or close the body of the fixator when the integral screw is turned clockwise or anticlockwise, etc.

Ensure that you have all the instrumentation needed:

this is detailed in the manual describing the use of the chosen device.

Read the appropriate manual carefully, or review the same on the CD-ROM now available, prior to commencing the procedure:

it is recommended that the procedure should be reviewed in this way for the first few times it is carried out, and especially if some time has elapsed since the last occasion on which it was performed.

Assemble the fixator before sterilization where possible:

this will usually be possible where the monolateral fixators are used, and will sometimes be possible with the ring fixators where these can be pre-constructed. Fixators can be sterilized in the assembled state as long as ball-joints, locking nuts and locking screws are left untightened.

Fixator application in long bone fractures:

before screw insertion, the fracture should be approximately reduced and any rotational displacement corrected as accurately as possible. When fixator application is complete and the fracture finally reduced, the body of the fixator should be sufficiently open to permit later dynamization (10 mm is recommended). To ensure this, it is important that the bone screws are inserted with the fixator body open by about 20 mm. This is because during final reduction the fixator body may close a little if the fixator is on the convex side of any angulation. At the end of the procedure the body of the fixator should be parallel to the long axis of the bone to allow maximal efficiency of dynamization.

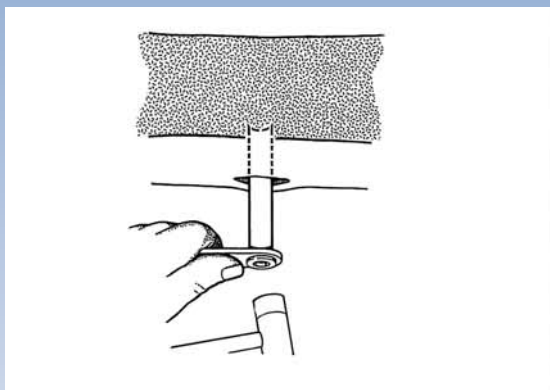
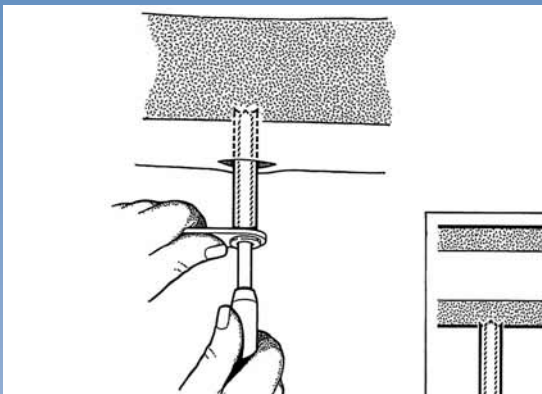
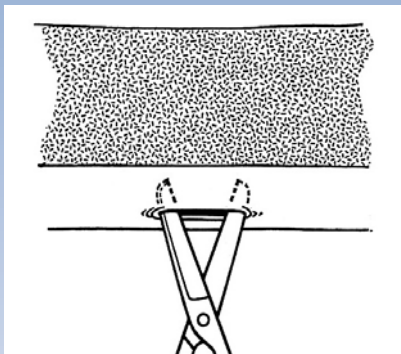
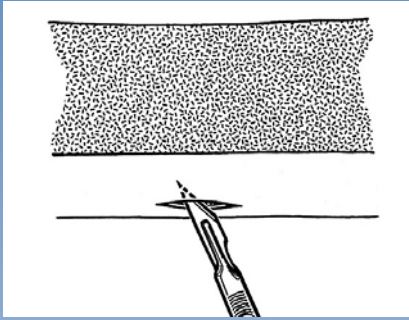
Working Length:

this is the distance between the fracture or osteotomy site and the nearest screw or wire fixation point. As a general principle, it is preferable to have a similar working length on either side of the fracture or osteotomy to achieve optimal stability. Supplementary screws or wires may be used for this purpose.

THE TECHNIQUE OF SCREW INSERTION

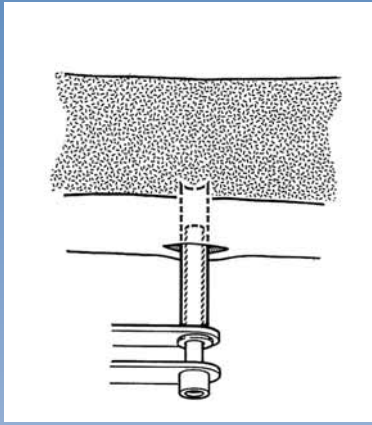
This is described in association with the application of the ProCallus Fixator to a tibial fracture; the procedure is identical, however for the diaphyses of all long bones. The fracture should always be approximately reduced before the fixator is applied. Use of the Image Intensifier is advisable.

- Screws are inserted into the shortest or most difficult segment first. A long incision in the skin is required for each screw so that the skin around the screw is not too taut. This shows the incision being made for the first screw.
- The underlying fascia also requires broad dissection to ensure that it is not taut around the screws, since this would cause discomfort to the patient and limit muscle function.



- A screw guide of suitable length (appropriate to the dimensions of the soft tissues through which the screws must pass) is selected. Usually, short screw guides (lengths: 32 mm, 45 mm) are used for the forearm, metacarpal bones and for the distal screws in the humerus; medium screw guides (lengths: 60 mm) for the tibia and the proximal screws in the humerus and long screw guides (lengths: 80 mm, 100 mm, 160 mm) for the femur. Insert the chosen screw guide into the incision using a trocar to enable the mid-line of the cortex to be located. It is important to ensure that the screw guide is perpendicular to the longitudinal axis of the bone.

- Using gentle pressure to keep the screw guide in contact with the cortex, withdraw the trocar and using a hammer, tap the screw guide lightly to engage its distal end in the cortex.



- The correct drill guide, chosen according to the drill bit diameter to be used and the screw guide length) is now inserted into the screw guide.

The following drill guides are available:

Drill Guides Ø 4.8 mm

Lengths: 40 mm, 60 mm, 80 mm, 140 mm

Drill Guides Ø 3.2 mm

Lengths: 20 mm, 40 mm, 80 mm

Drill Guide Ø 2.9 mm

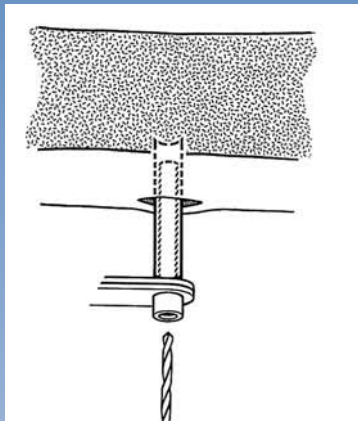
Length: 20 mm

Drill Guide Ø 2.7 mm

Length: 20 mm

Drill Guide Ø 2.0 mm

Length: 20 mm



Insert the correct drill bit, fitted with a drill stop, into the drill guide. It is important to ensure that the drill bit is not worn. Matching grooves on screws and drill bits help the surgeon to select the correct diameter drill bit.

Drill Bits Ø 4.8 mm

Lengths: 180 mm, 240 mm, 280 mm

Used where 6.0/5.0 mm thread diameter screws are to be inserted into cortical bone

Drill Bits Ø 3.2 mm

Lengths: 140 mm, 200 mm

Used where 6.0/5.0mm screws are inserted into cancellous bone, and where 4.5/3.5 mm thread diameter screws are inserted into cortical bone

Drill Bit Ø 2.9 mm

Length: 140 mm

Used where 3.5/3.2 mm thread diameter screws are inserted

Drill Bit Ø 2.7 mm

Length: 127mm

Used where 3.3/3.0mm thread diameter screws are inserted

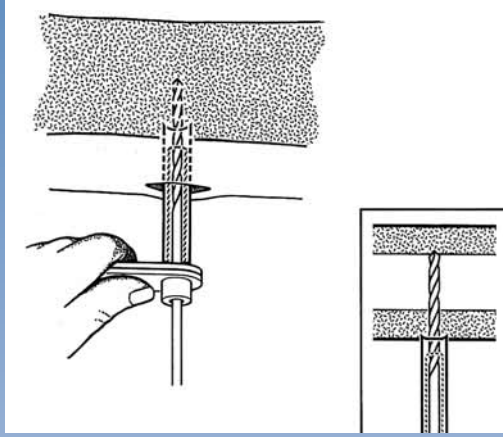
Drill Bit Ø 2.0 mm

Length: 127mm

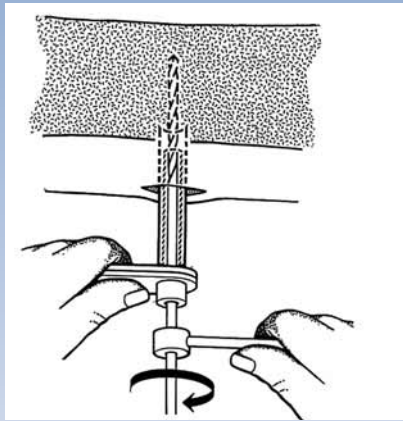
Used where 3.0/2.5mm thread diameter screws are inserted



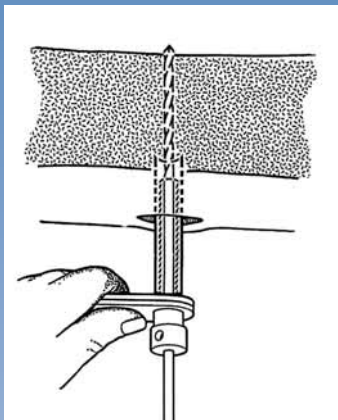
The correct length of drill bit must be chosen according to the dimensions of the soft tissues it must pass through, and the length of the screw guide selected.



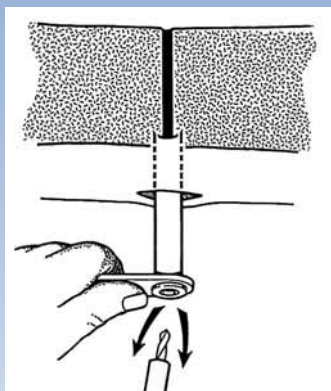
- When the point of the drill bit is placed on the bone, check that it is at 90° to the long axis of the bone before drilling the first cortex. Drill through the first cortex up to the second cortex. A power drill may be used at speeds not exceeding 500-600 r.p.m.. Excessive drill speeds should not be used, to avoid overheating the bone, since this may result in local necrosis and an increased risk of osteolysis. In addition to screw design, drilling time and drilling force are important factors to consider if thermal damage to bone is to be avoided. It has been shown that temperatures generated within the bone are inversely proportional to drilling force and directly proportional to drill-bone contact time (Data on file). The force applied to the drill must be firm and the time during which the drill is in contact with the bone the shortest possible.



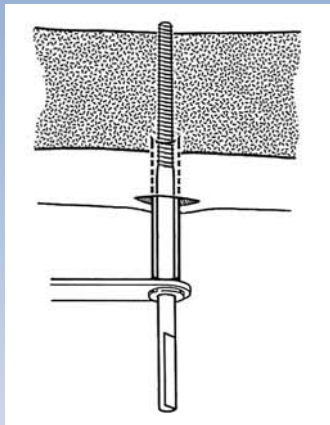
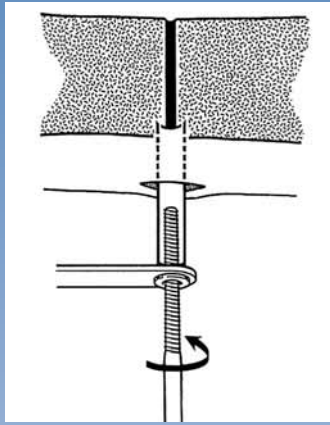
- An adjustable mechanical stop on the drill bit should always be used, since this prevents excessive penetration into the soft tissues. It should be moved into a position 10 mm from the top of the drill guide before drilling the second cortex.



- Ensure that the drill bit completely penetrates the second cortex.

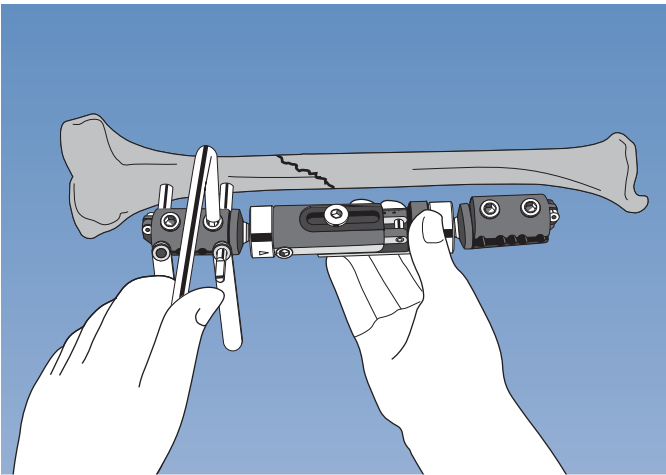


- Remove the drill bit and drill guide keeping pressure on the screw guide handle.

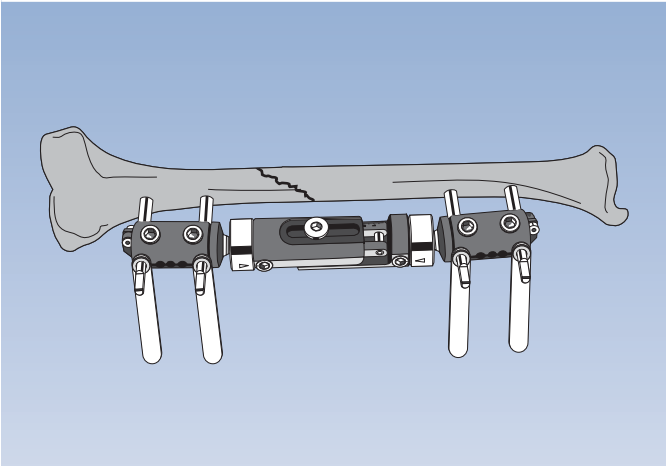


- Insert the selected screw into the screw guide and turn the self-tapping screw with the T-wrench. Minimum force is required at first and when the first cortex is engaged, the screw can be tightened with little effort. If excessive resistance is encountered at any stage, it is possible that the screw is not following exactly its predrilled path, or the bone may be unusually hard or thick. Under such circumstances the screw should be withdrawn using the T-wrench, irrigated with saline and reinserted along the correct path. An increase in resistance is felt as the screw penetrates the second cortex in normal cortical bone. When inserting screws into cancellous bone or poor quality bone, this change in resistance is not felt and an Image Intensifier should be used in these circumstances to verify that the second cortex has been penetrated.

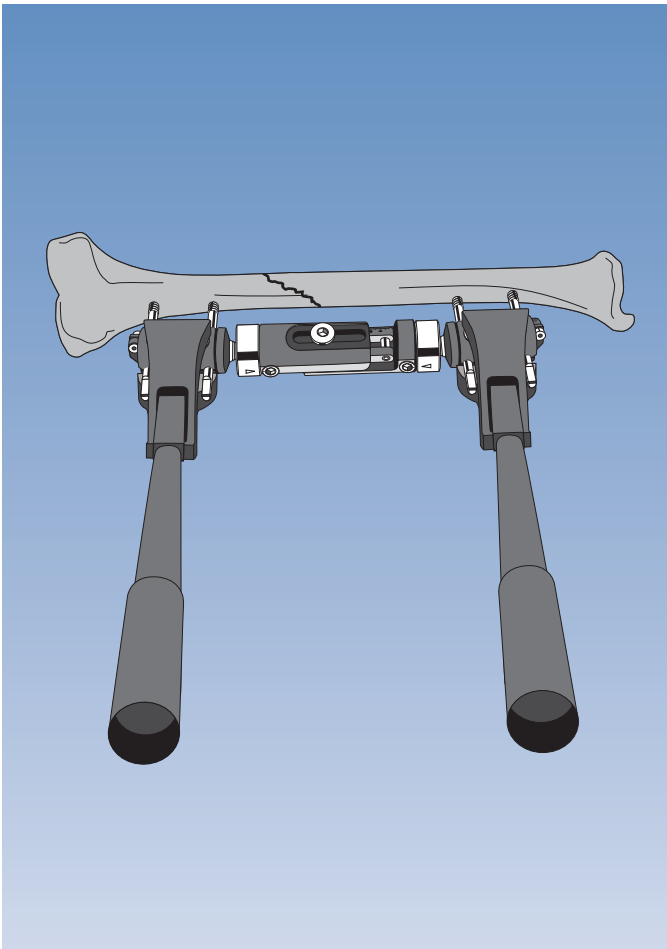
- A further 5 or 6 half turns are then normally required to ensure that about 2 mm of the screw protrudes beyond the second cortex. As the thread is tapered, re-positioning the screw by turning counterclockwise IS NOT POSSIBLE since this will loosen it. If there is doubt as to whether the second cortex has been reached, this should be checked by X-ray.



- Leave the screw guide in position and apply one clamp of the ProCallus fixator to it. There is no need to use a template. This is because the clamps for the bone screws can be tightened on either the screw guides or the bone screws, depending upon the position of the hinge in the slot. Note: To accommodate the screw guides, the clamp must be opened fully, to allow the hinge to move to its furthest extent. Using the screw seats of the clamp as a reference, make the incision for the second screw. At least two screws per clamp are used, positioned in the outermost seats of the clamp for maximum stability. Repeat the screw insertion procedure, taking care that now, both screw guides are securely located within the clamp, to ensure that the screws will be exactly parallel to one another. In the upper limb only two screws per clamp are required. However, in the lower limb, in poor quality bone, in overweight patients, in particularly unstable fractures, and/or if the fixator is sited at a distance of more than 4 cm from the bone, three screws per clamp are recommended.



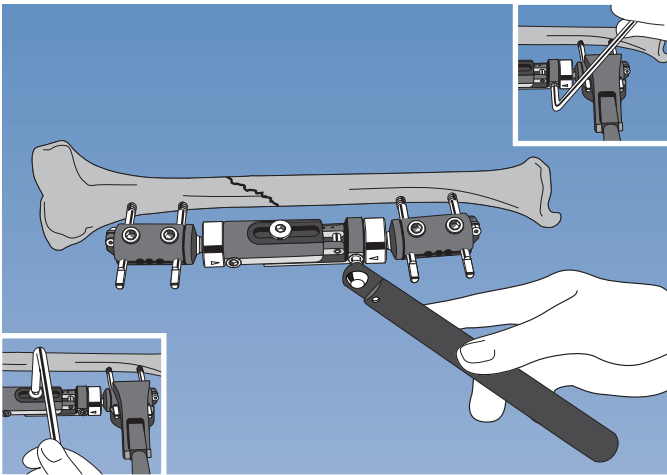
- Before placement of the screws in the second bone fragment, the body of the ProCallus must be adjusted to the correct length. Make sure it is neither completely closed nor fully open. This will allow for final reduction, for subsequent Progressive Loading and, where indicated, for dynamic axial compression. Attempt to maintain the initial reduction while applying the remaining screws, once again ensuring that the screw guides are locked into the clamp as shown.



- Once all the screws have been inserted, the screw guides are removed and the clamps tightened on the shafts of the bone screws. At this stage the Central Body Locking Nut and the cams are all loosened; the micromovement facility locking nut is tightened.

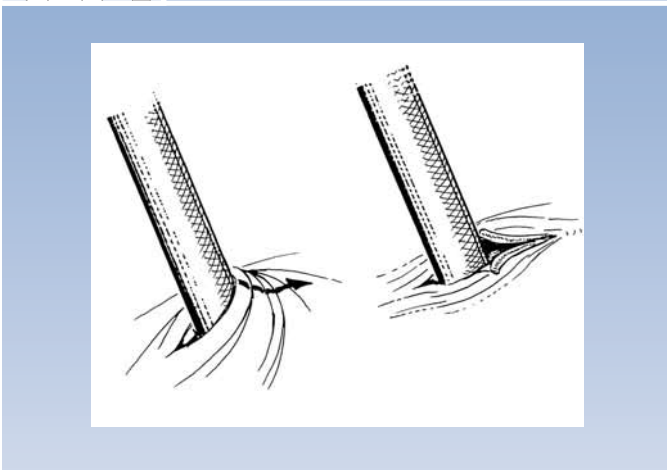
The surgeon should ensure that both cams, the central body locking nut and the micromovement locking nut are accessible.

- Position the fixator at least 2cm from the skin to allow for post-operative swelling and for cleaning pin sites. It is essential to fit the body parallel to the major axis of the segment being treated, so that the forces which occur during dynamization are equally distributed over the entire circumference of the bone segment. Tighten the clamp screws first using the Allen wrench. Each clamp screw should be tightened a little at a time until it is well seated, and finally firmly locked. If one of the two outer seats of the clamp has not been used, it is good practice to place a dummy screw in the vacant outer seat. This prevents abnormal stresses when locking the clamp screws.
- Final fracture reduction is achieved using manipulation forceps, attached to the two clamps. In this way, manipulation force and control are facilitated while keeping the surgeon's hands clear of the X-ray beam during the reduction procedure.



- Once acceptable reduction has been achieved, this is maintained by the surgeon while an assistant tightens the cams with Allen Wrench.
- Final locking of the cams is performed with the torque wrench.
- The central body locking nut is now tightened, again using the Allen wrench.

- If skin tension around the screws is observed, this should be released by extending the skin incision.

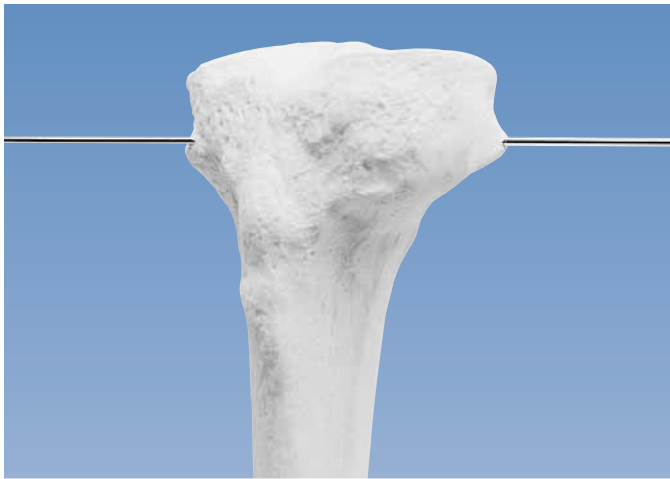


THE TECHNIQUE OF WIRE INSERTION

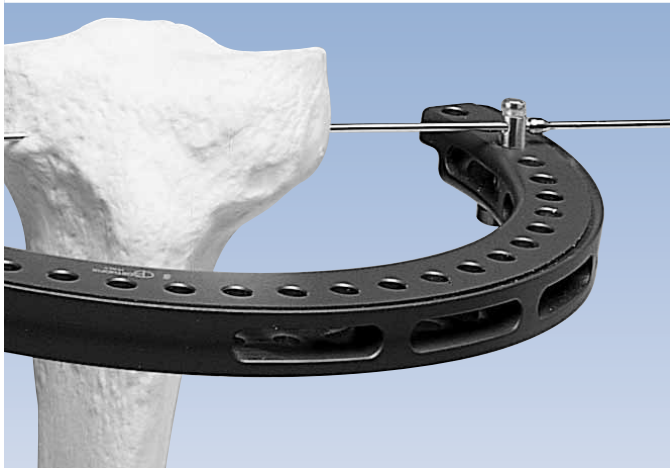
The Orthofix External Fixation System includes hybrid constructs where, in some instances rings may be linked directly to a monolateral fixator, while in others, wire-bearing rings are combined with rings bearing specially designed clamps for bone screws in a modular system (The Sheffield Ring Fixator). For this reason, a working knowledge of the correct technique of wire insertion is integral to the correct application of these forms of external fixation.

General Principles

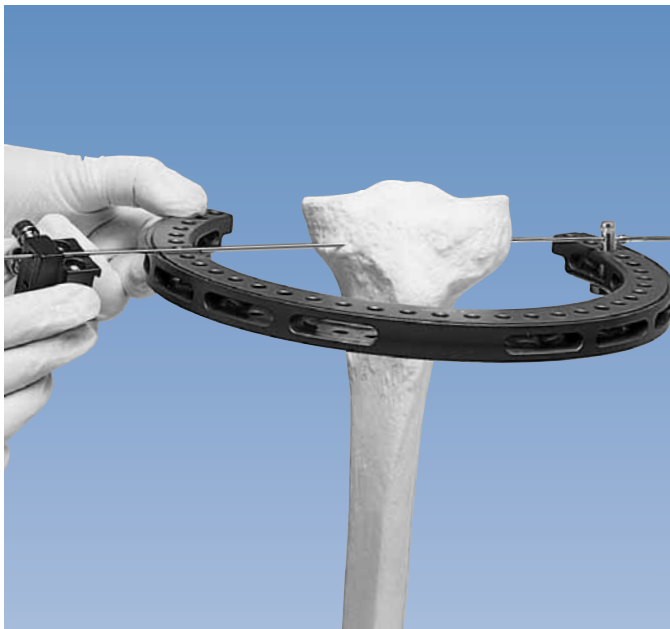
- When using Kirschner wires, it is important to ensure that the path they will take will avoid tendons or neurovascular elements. In the region of important neurovascular structures, an incision should be made, dissecting the tissues down to the bone and inserting the wire under direct vision.
- To ensure a stable construct we recommend four fully tensioned wires for a proximal tibial or distal femoral ring, and three for a distal tibial ring.
- The correct number of wires should be inserted such that at least two of them have a crossing angle of 60° or more, for ideal stability in all planes. This will be achieved if there are at least eight holes on the ring between the crossing wires and the first wires inserted.
- Whenever possible, in order to avoid drilling in unprotected soft tissues, the wires should be inserted through the skin on the side of maximum soft tissue coverage, and pushed gently, stretching muscle groups before transfixion while advancing it to the bone surface, before commencing drilling. The use of a cannulated driver will greatly facilitate accurate positioning of the wire. Note that no attempt should be made to insert a wire more than once, since the tip will have become blunt, and as this is the only cutting surface, undesirable heating of the bone may occur.
- Once the wire has exited from the far cortex the adjacent muscles are stretched, and the wire tapped through the muscles and overlying skin with a small mallet. Note that some deflection of the wire may be produced during its passage through the limb and care should be taken to avoid this as it may cause abnormal stresses at the wire-bone interface.
- Wire-bearing rings in the lower limb will normally be applied to the proximal or distal tibial metaphysis, or to the distal femoral metaphysis, and the safe corridors for Kirschner wire insertion in each of these regions is discussed in detail in Manual 12.



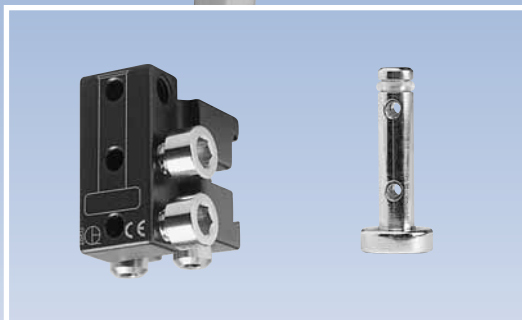
- The first wire to be inserted is always the wire nearest the joint, avoiding penetration of the joint capsule. In the proximal tibia the minimal distance from the joint line is 15mm, and in the distal tibia it is 5 mm.

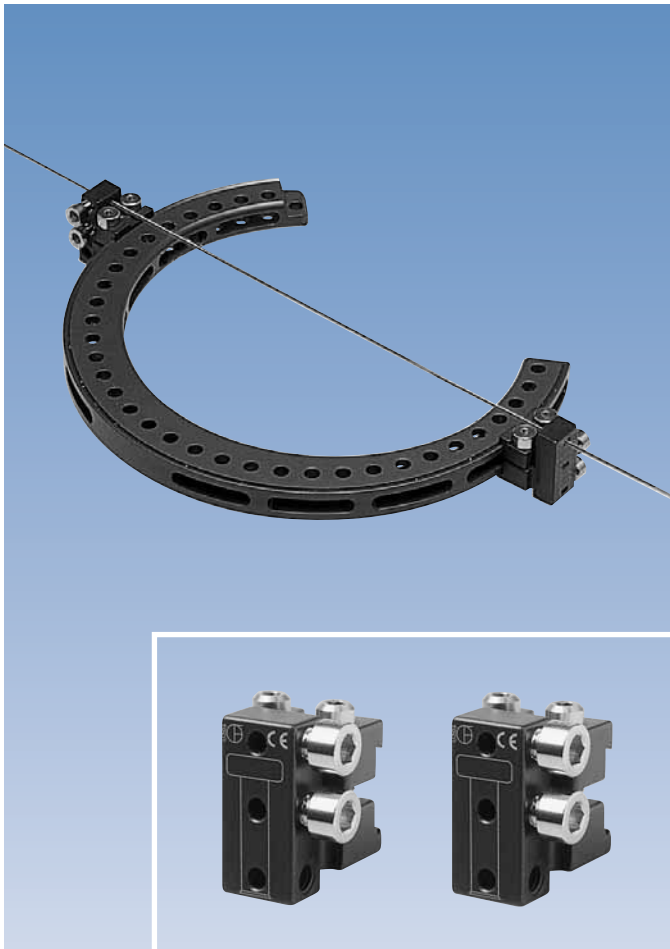


- This wire is always inserted either above (proximal tibia) or below (distal tibia) the ring through the tip of a wire securing pin inserted through the ring.

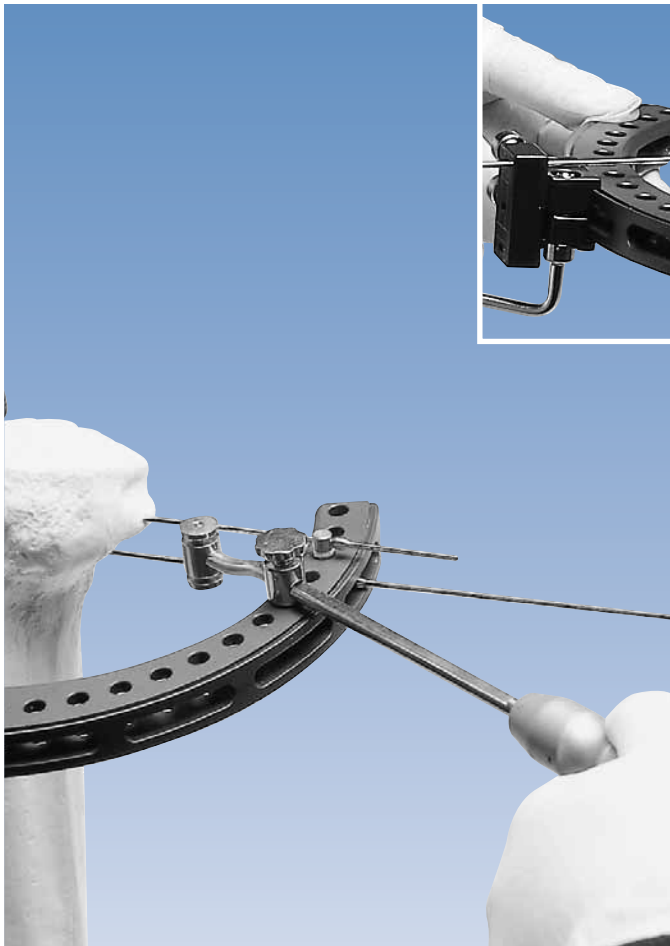


- A three-hole wire clamp slider unit, with all screws loosened, is now oriented so that the etched outline of the securing pin on the clamp matches the position of the securing pin at the other end of the wire. The wire is inserted through the hole nearest to the joint, and the slider unit slid down to the ring.

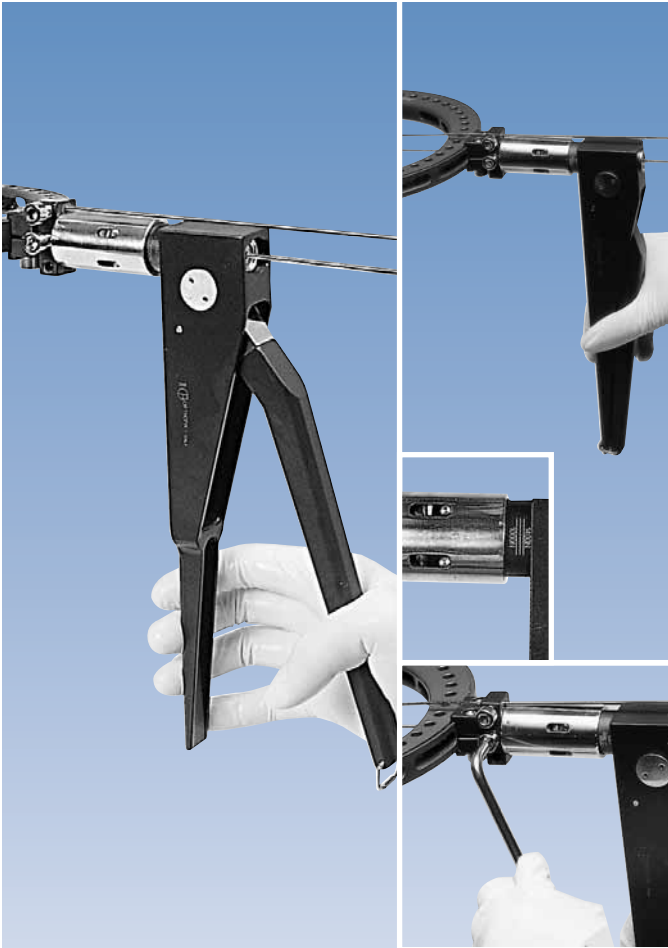




- If the first wire is inserted freehand, a three-hole wire clamp slider unit is mounted on each end of the wire through the hole which will be nearest to the joint. Both slider units should be oriented the same way when they are attached to the ring.

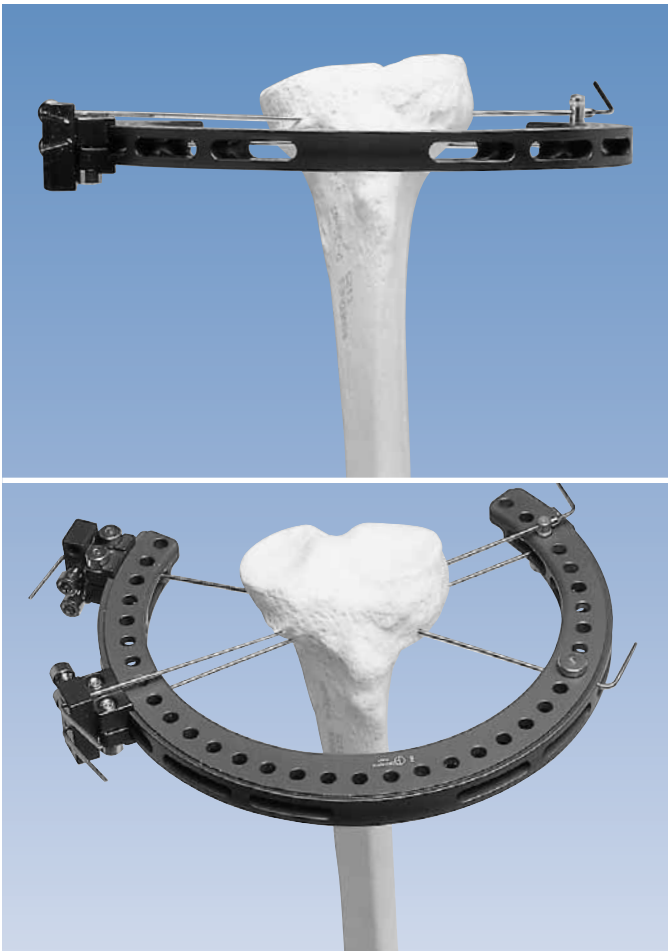


- The parallel wire is inserted next. The wire guide (**18002**) may be used to assist in this procedure. With its knob loosened, the sliding support unit of the wire guide is inserted into one of the holes in the ring and its position on the bar adjusted so that one groove in the head of the wire guide is in contact with the wire already in place. The second wire is then kept in contact with the remaining groove in the head of the wire guide during its insertion. The slider unit may be temporarily disconnected from the ring, and then inserted over both wires using the appropriate two holes. The slider unit is then firmly secured to the ring by tightening the appropriate screws evenly with a 3 mm Allen wrench.



- The ring must now be adjusted so that the limb lies at its center, since such adjustments cannot be made subsequently. Both wires are now tensioned, starting with the wire in the center hole. The wire tensioning device is opened fully and advanced over the wire until it touches the wire clamp slider unit. The handle is now closed and clipped, and the tension read off on the graduated scale. If it is less than 1200N, the wire clamp screw is temporarily tightened using the 5mm Allen wrench and the procedure repeated. Once the correct tension is achieved (i.e. 1200N), the wire clamp screw is fully tightened.

N.B. While tightening the wire clamp screw, it is important not to lever the wire tensioning device to avoid breakage of the Kirschner wire.



- The Kirschner wires are now cut 4cm from the slider unit and bent at both ends. The cut end should be turned in towards the ring to avoid sharp edges being exposed, and a wire cover (80200) may be applied. Note that if the first wire of a pair is tensioned before the second is inserted, some difficulty may be experienced in guiding the second wire into the appropriate hole in the wire slider unit.

- The position and direction of the crossing wires should allow a 50°-70° wire separation angle. Ring stability is optimal if the wire crossing angle is as large as possible and the wires cross in the center of the tibia. The crossing wires are now inserted, using the technique described above, taking care that the Kirschner wire securing pin is inserted from the OPPOSITE surface of the ring from that of the first pair of wires. This will ensure that the crossing wires are not in contact at the bone interface. These wires are now tensioned. Once tensioned, the ring may be considered to be securely attached to the metaphyseal segment. In order to avoid undue stress on a ring no more than two pairs of wires should be used on one ring.



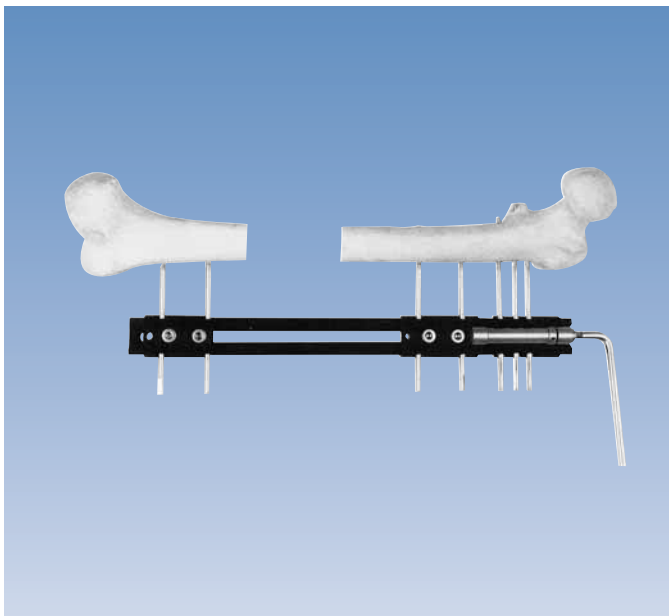
- Wires with a central olive may be used in conjunction with a washer (**W2200**) where large translational forces are anticipated along the line of the wire, e.g. in any situation where narrow crossing angles may occur. The skin must be incised to permit passage of the olive through the soft tissue. As the olive cannot pass through a securing pin, the wire is inserted freehand, at approximately the height of the top hole of the wire clamp slider unit. Once the wire has been inserted, the slider units are attached and used to secure the wire to the ring. Wire tensioning is performed from the side distant to the olive, and tension should be reduced to between 800 and 1000N to avoid excessive pressure on the cortex of the bone.

PERFORMING AN OSTEOTOMY

A carefully performed osteotomy at a suitable site is a prerequisite for good callus formation and the successful accomplishment of a wide range of reconstructive procedures, including lengthening, the correction of deformity and bone transport. The methods described below have each been used in association with Orthofix devices, and the final choice of method is a matter of surgeon preference. The original technique described by De Bastiani (De Bastiani et al. 1987) was a corticotomy rather than an osteotomy, since it was originally thought important to preserve the medullary blood supply. It is difficult to achieve a true corticotomy, however, and since there is now considerable evidence of the rapid recovery of the medullary blood supply following a complete osteotomy, the latter is normally performed today.

It is important, however, to preserve the periosteum, since this layer has been demonstrated to be a most important site of osteogenesis (Kojimoto et al 1988).

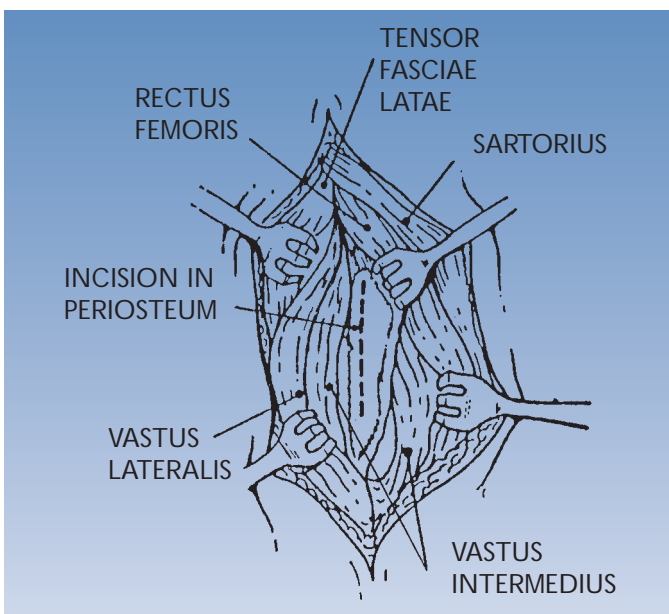
The site chosen for the osteotomy should ideally, be metaphyseal or immediately submetaphyseal, since this is a wider and more vascular region and has been shown to have better osteogenic potential than the diaphysis (Aldegheri et al 1985).



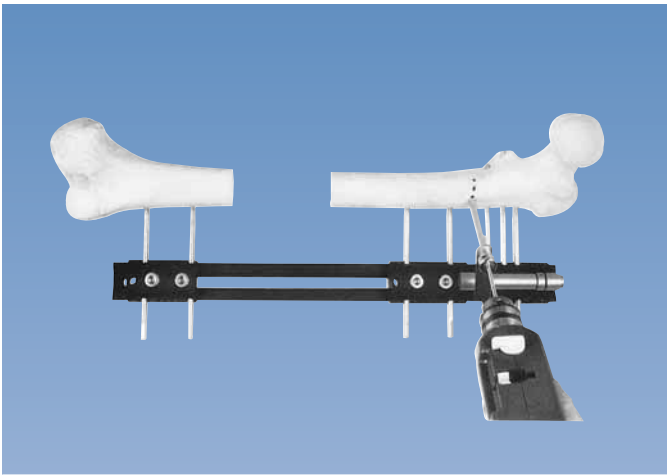
The Multiple Drill Hole Tension Osteotomy

This method (Aldegheri et al 1989; Saleh and Burton 1991; Saleh 1992), which is a variation of the original De Bastiani technique, is widely used. The steps involved are described below:

Tension is applied to the region of the bone in which the osteotomy is to be performed. In the example shown, a Compression-Distraction Unit has been connected between the upper (locked) and middle (free to move) clamps on a Limb Reconstruction System rail, and 2-3 mm of distraction applied.



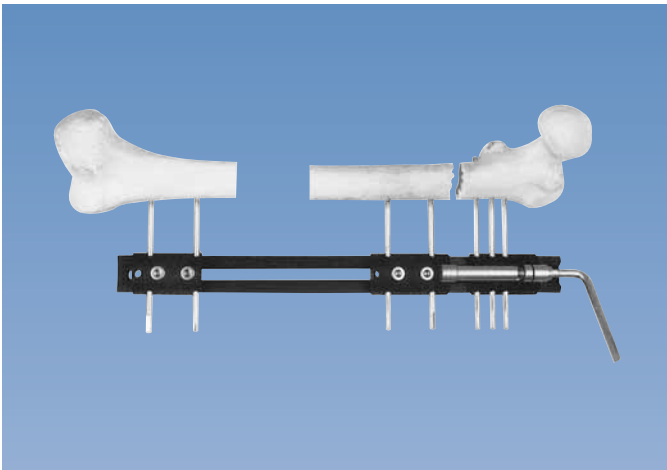
In the case of the femur, shown here, the bone is exposed via an anterior incision and the periosteum incised longitudinally and carefully detached from the cortex. Bone levers are now passed on either side of the bone to protect muscle and periosteum. (Some surgeons prefer using a minimally invasive approach up to this point; this involves blunt dissection of the soft tissues down to the bone through a 15-20mm incision. A screw guide is inserted through this incision. The periosteum is not incised longitudinally, but drilled through, as described for the bone, below. The periosteum appears to heal very well following this procedure).



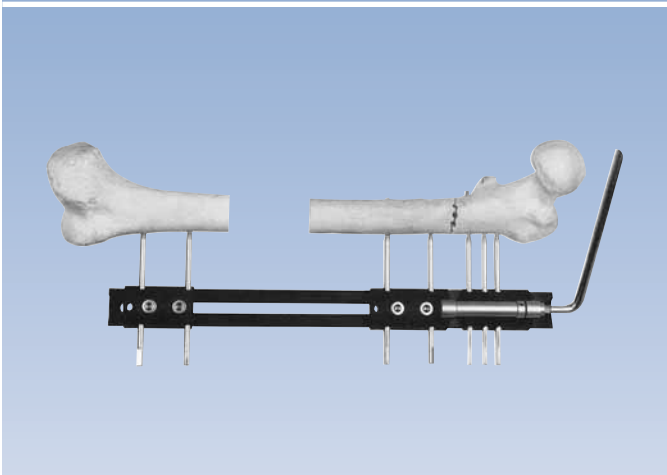
- A screw guide with drill guide is now placed on the bone and a series of controlled drill holes made across the bone, penetrating the far cortex each time. A drill stop is used to prevent damage to the soft tissues.



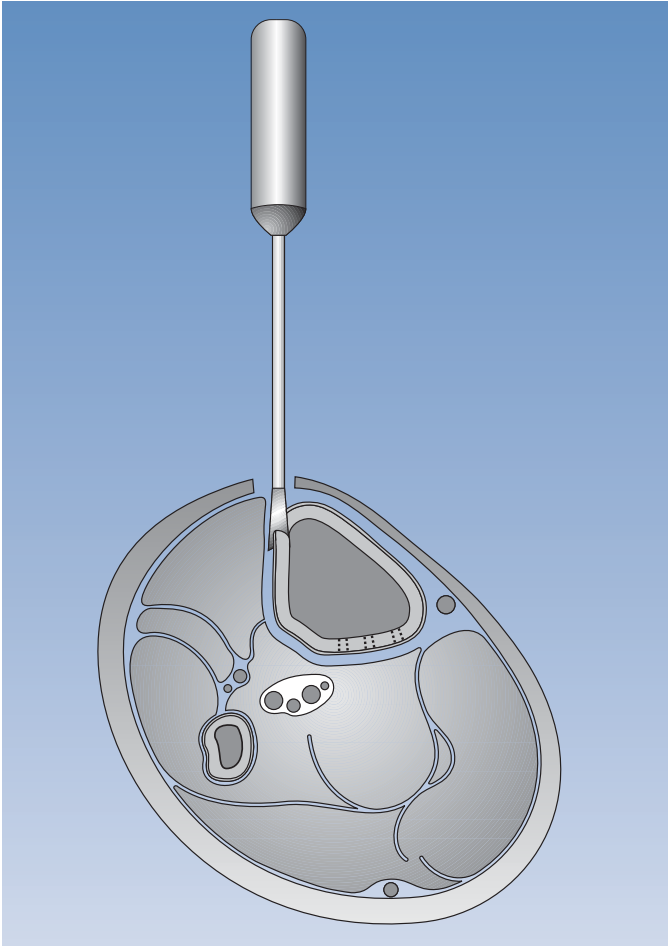
- The holes are now connected with an osteotome and since the bone has been pre-tensioned the bone ends will gently drift apart once the osteotomy has been completed.



- Completeness of the osteotomy is confirmed by exploration of the gap using a probe, assessment of the ease of distraction and the appearance under image intensification.



- The osteotomy is then gently compressed, the periosteum reconstituted in cases where it has been incised, and the wound closed without a drain.



The Osteotome Corticotomy

This method is used by some surgeons who still advocate preservation of the medullary blood supply (Giebel, 1992).

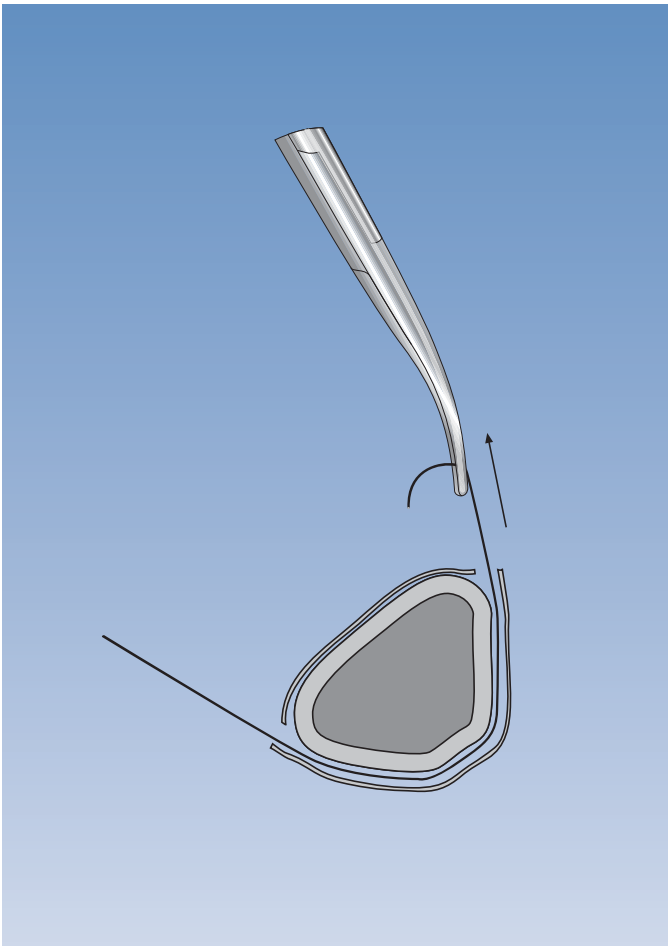
A Small incision, 1.5 cm in length is made directly over the site of the intended corticotomy, with blunt dissection down to the bone.

A sharp very flat osteotome with a blade about 6mm wide, and bounded by a projecting metal prong ("flag chisel", cement splitting chisel) is now used to divide the medial and lateral cortices, using small taps of the hammer. The medullary contents are preserved.

During this procedure the projecting prong is maintained in contact with the bone to prevent damage to soft tissues or nerves. As an alternative to the use of the flag chisel, an elevator can be used to lift the periosteum from the surface of the bone, and the cortex divided anteriorly, medially and laterally using a standard osteotome under the protection of the elevator.

In many cases the dorsal cortex will now break spontaneously. If it does not, three boreholes, each 2.0mm in diameter are drilled through the dorsal cortex from the anterior aspect of the bone. The dorsal cortex is now broken by manual osteoclasis.

In some instances the fracture line may not be completely transverse when this technique is used, and may result in additional fracture lines which can extend to adjacent pin holes. For this reason the "tension" osteotomy described above, is preferable.

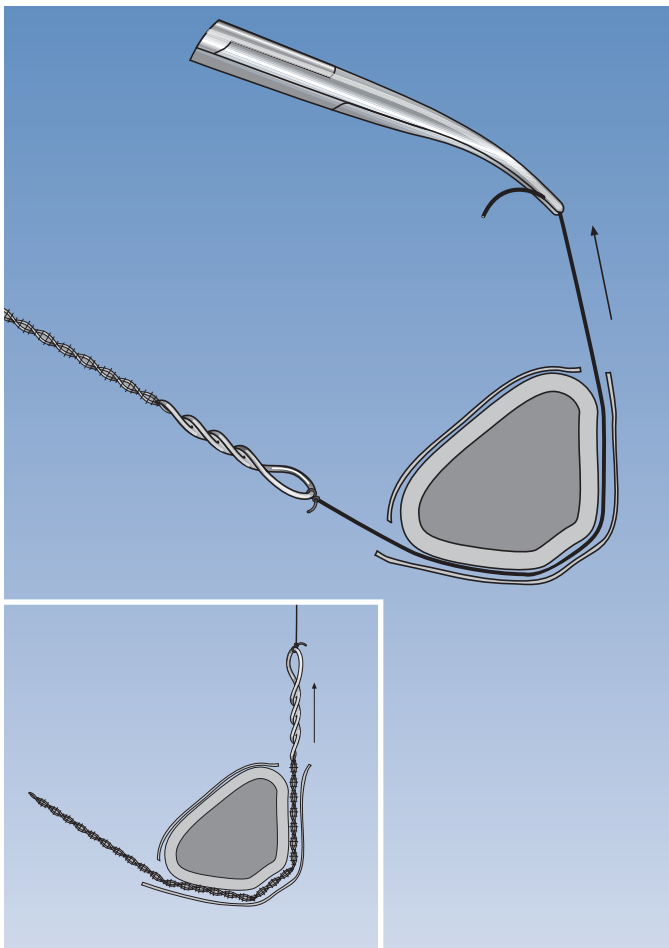


The Percutaneous Gigli Saw Osteotomy

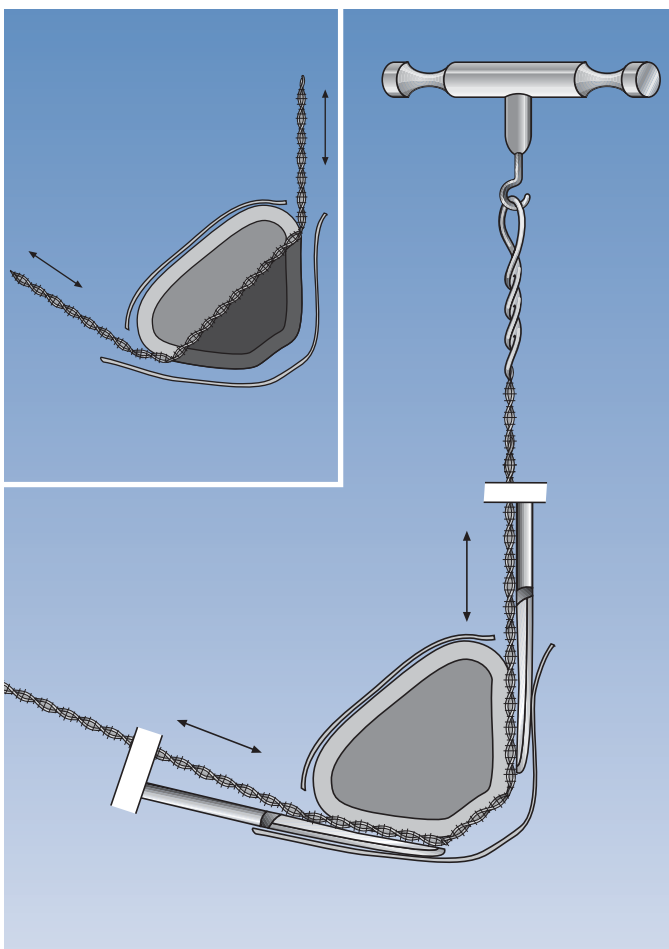
This method is used by some surgeons for dividing the proximal tibia, the distal tibia (unless there is thick diaphyseal cortical bone) and in the supramalleolar region of the tibia. It is less often used where complete osteotomy of the femur is planned, since the multiple hole tension osteotomy is easier, quicker and less traumatic in these sites.

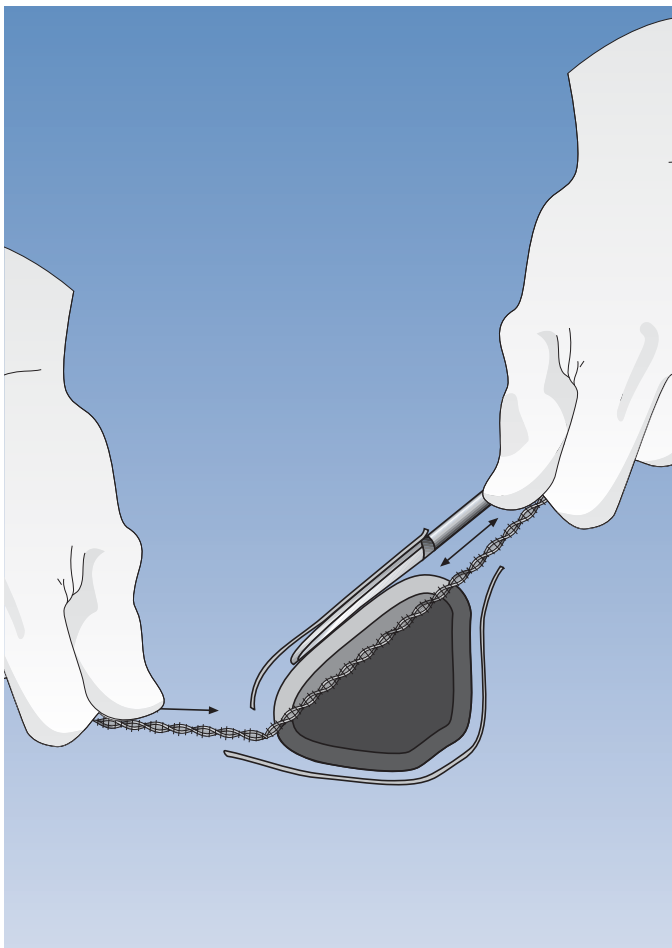
In the proximal tibia, two transverse incisions are made, and a suture is passed subperiosteally from posteromedial to anterolateral.

A Gigli saw is then tied to the suture and pulled through to surround the posterior aspect of the bone.

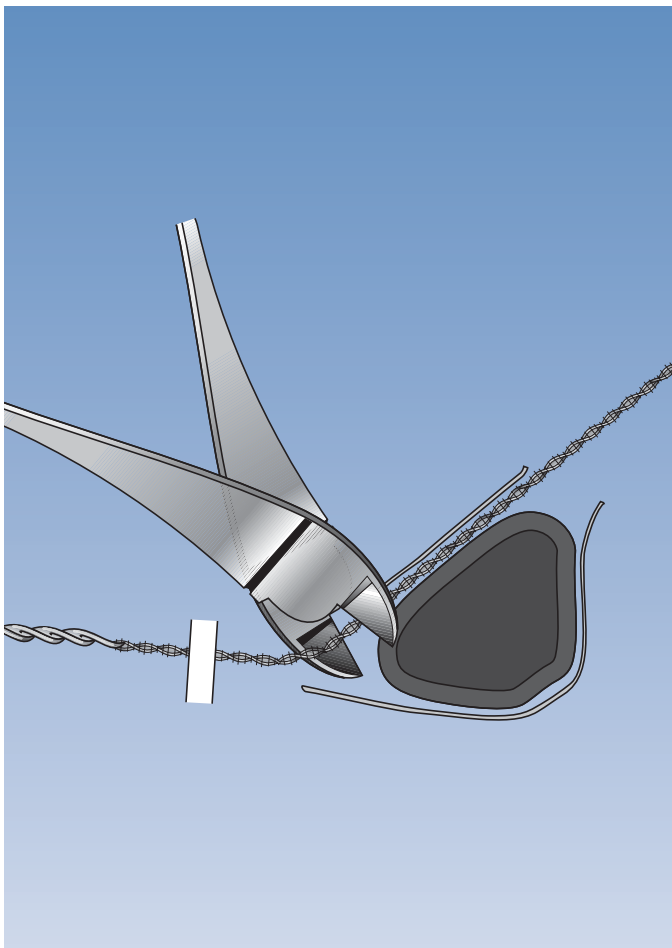


The posterior and lateral cortices of the bone, and the medullary canal are now cut by advancing the saw anteriorly using elevators to protect the periosteum and soft tissues.





The periosteum overlying the medial cortex is now elevated and the medial cortex cut by flattening the saw as it is pulled forwards.



The saw is then cut and removed.

PIN SITE CARE

The Principles of Pine Site Care

The maintenance of healthy pin sites is integral to successful external fixation, and surgeon, nursing staff and patient all have a part to play in ensuring this. Much will depend upon an excellent technique for screw insertion and this is detailed on p.50 above. Traditional Orthofix advice on the post-operative care of pin sites has been based on the excellent work by Mr. R. Checketts and Sister M. Otterburn at Sunderland Royal Hospital, UK (Checketts et al 1993; Checketts et al 2000). This involves regular cleaning of the screw shanks and surrounding skin with sterile water, using new cotton buds for each screw; keeping the skin mobile around the screw, and the avoidance of skin tethering by means of skin releases as required. These workers emphasised the importance of patient education both prior to surgery where possible, and in the post-operative period. This excellent system has withstood the test of time. It is appreciated, however, that other surgeons have developed their own techniques for pin site care, all of which seem to produce similar results. Some surgeons dress the pin sites in the operating theatre and leave them undisturbed for two weeks, after which they dress them weekly, while others favour more frequent intervention.

The are, nevertheless, certain universal principles which should be routinely followed to ensure healthy pin sites, and these are shown in the box below:

Key Points for Healthy Pin Sites

- Blunt dissection down to the bone, splitting the soft tissues to allow the screw guide to sit on the bone, avoiding tethering of the screw by the deep structures. Distal femur: split the tensor fascia lata longitudinally to allow screw movement.
- Ensure that the screw clamp is tightened around the screw guides so that screws are inserted exactly parallel to one another.
- ALWAYS use sharp drill bits; remove and destroy blunt ones to prevent recycling. Blunt drills cause thermal damage and may produce ring sequestrae around bone screws.
- ALWAYS irrigate screw sites with saline after screw insertion. Any bone fragments which remain are a potent cause of inflammation post-operatively.
- ALWAYS check for skin or fascial tethering at the end of surgery, by moving adjacent joints through their full range. Perform skin or fascial releases as necessary.
- Clean screw shanks, fixator and surrounding skin. If using an antiseptic ensure that none comes into contact with the black parts of the aluminium fixators.
- Wind dressings around the screws between fixator and skin to exert gentle skin pressure. This helps to prevent haematoma formation.
- ALWAYS ensure that there is a standard hospital protocol for post-operative pin site management. The patient should be carefully instructed in this, and it should be known to everyone who might be involved with the patient.

Dealing with Pin Site Problems

The patient should be provided with an information sheet which should explain how pins sites are to be looked after; when help should be sought, and how to do this. It should also be addressed to medical or nursing staff outside the hospital. **IT IS VERY IMPORTANT THAT THE MEDICAL AND NURSING STAFF IN AN INSTITUTION HAVE A SINGLE PROTOCOL FOR LOOKING AFTER PIN SITES.** In the absence of a specific hospital protocol, Orthofix provide pin site care booklets and a video which describe the Checketts / Otterburn technique. There may be some loss of serous fluid especially in overweight patients and with femoral screws. This should not be mistaken for infection and is not a true complication. It may be the result of excessive patient mobility and subsequent irritation of the tissues around the screws. Good pin site hygiene is all that is required, and this should be carried out according to the standard hospital protocol.

Where inflammation is seen and the exudate is purulent with the skin around the screw red and warm, a bacteriological swab should be taken before initiating treatment with antibiotics, and treatment adjusted as necessary after the results are known. In the lower limb, weightbearing should be restricted until resolution has occurred. Should local conditions not improve, the patient should return to hospital for more aggressive therapy, including possible removal of the screw or screws involved. If X-rays taken in the pre-dynamization phase show signs of osteolysis around a screw and there is clinical evidence of screw loosening, it is advisable to reposition the screw, if simple removal would compromise the stability of the assembly. Special care should be taken when repositioning a screw since osteolysis usually implies that the procedure for screw insertion has not been strictly adhered to.

If osteolysis occurs in the EARLY dynamization phase, it may be necessary to remove frame and screws and apply a functional brace. If osteolysis occurs in the LATE dynamization phase, it is usually possible to leave the entire assembly in place until final healing is achieved, provided the situation is regularly reviewed. If three screws have been placed in the clamp and osteolysis occurs at one screw site, that screw may be removed, as two screws per clamp are sufficient to secure the bone during the late dynamization phase.

WEIGHTBEARING AND DYNAMIZATION

Reference to weightbearing is applicable only to situations where a fixator has been applied to a lower limb.

The duration of the neutralization period (i.e. the time following fixator application during which the central body locking nut remains tightened) and the amount of weightbearing allowed, will depend upon a number of variables e.g.: the type of fracture, the type of Orthofix frame used, bone-fixator distance, total weight of the patient, the extent of fracture repair, the physical condition of the patient, the presence or absence of multiple trauma in the same, or other limbs, the pain threshold, and the emotional state of the patient.

Where the ProCallus or the XCaliber are used, passive cyclic micromovement can be applied before any weightbearing has commenced. When progressive loading is desired, the central body locking nut is loosened.

The actual time points at which progressive loading and weightbearing will occur will depend upon whether the fracture is stable or unstable. As a general rule, however, it can be stated that in stable fractures, progressive loading should commence 2-4 weeks post-operatively, and in unstable fractures, 5-8 weeks post-operatively.

(i) Stable Fractures

With stable fractures, 30% weightbearing should start from day one and increase to 75% by two to three weeks after operation, at which point progressive loading is started. Weightbearing is gradually increased to 100% over the next three weeks.

(ii) Unstable Fractures

In unstable fractures, 15% weightbearing should start from day one and increase to 75% within 40 to 60 days after the operation, at which time there should be radiological evidence of callus formation. Progressive loading is started at this point and weightbearing is gradually increased to 100% over the next four weeks.

OUTPATIENT FOLLOW-UP

X-rays should be taken on the day the patient is discharged from hospital after the operation, at which time fixator ball-joints should also be checked with a torque wrench. Outpatient visits should then be scheduled every 20-30 days. On each occasion, X-rays should be taken, the condition of the skin around the screws should be reviewed, clamp locking nuts retightened, and ball-joints checked.

It is not generally recommended that patients bathe fully while the fixator is in place, but some surgeons allow it, provided disinfectants are used in the water. Some surgeons allow their patients to take a shower.

FIXATOR REMOVAL

Once there is clinical and radiological evidence of fracture healing, the fixator is removed as an outpatient procedure. First, the central body locking nut is tightened to maintain the exact length of the fixator prior to removal, in case the fracture should require a further period of fixation. The fracture can be manipulated after removal of the fixator to ensure that clinical healing has been achieved.

If there is any doubt regarding clinical and radiological healing and provided the screws are well-tolerated, the fixator can remain in situ for a further period of two weeks. If, on the other hand, there is clinical evidence of complete healing, but prudence suggests a final clinical test, the screws can be left in situ for a further week and full weightbearing allowed. If any problem arises in relation to the fracture, the patient can return to the surgeon for the device to be refitted without the need for an operation. If no further problems have been encountered at the end of this one week period, the screws can be removed without performing an X-ray.

If the surgeon is confident that clinical and radiological healing has been achieved, the fixator and screws can be removed immediately as a simple outpatient procedure. The screw entry holes are then usually dressed every two days until they close spontaneously, which normally takes place after 7-10 days.

To ensure full follow-up documentation of the case, an X-ray should be taken at one or two months from final healing and removal of the fixator.

The present section is a general overview of the way in which Orthofix devices should be treated following their removal from a patient, or where not supplied sterile, prior to initial use. Detailed instructions, however, accompany all Orthofix devices, and these should be meticulously followed.

Reusable devices and instrumentation should be reprocessed as soon as is reasonably practicable following use. Used fixators should be disassembled completely, using the instrumentation designated for the purpose in the relevant Operative Technique Manual. Bone screws should be discarded immediately, as they are not reusable. It is also recommended that cams and bushes should not be reused. All components should be inspected, since damage to the surface of metal components can reduce the strength and fatigue resistance, and may lead to corrosion. Wherever possible, all parts of disassembled devices should be kept together in one container.

General

- Unless supplied sterile, all Orthofix medical devices must be sterilized prior to surgical use.
- A new product means any device taken out of its original Orthofix packaging.

Recommended decontamination process

The following sequence of processes is recommended for rendering the Orthofix Fixation System devices which are supplied non-sterile safe for their **first clinical use**:

1. CLEANING
2. STERILIZATION

Preparation for cleaning of new products

- When applicable, the device should be disassembled completely.
- Wherever possible, all parts of disassembled devices should be kept together in one container.
- For disassembly/reassembly the specific instrumentation should be used as described in detail in the Operative Manuals.

STEP 1: Cleaning of new products

- REMOVE products from their original packaging. All equipment should be carefully examined prior to use to assure proper working condition.
- CLEAN with a woven-non woven tissue soaked using a solution of 70% medical grade alcohol and 30% distilled water or with compatible detergent. **Detergents with fluoride, chloride, bromide, iodide or hydroxyl ions MUST NOT be used.**
- RINSE with sterile distilled water.

STEP 2: Drying

- HAND-DRY carefully, using absorbent, non-shedding cloth or industrial hot hair dryer, or place into drying cabinet.

STEP 3: Sterilization of new products

- Prior to surgical use, new products should be cleaned as described at Step 1.
- PACKAGING: Where products are to be packaged to maintain their sterility after sterilization and to prevent damage of the instrument prior to use, an appropriate medical grade packaging material should be used. Ensure that the pack is large enough to contain the instruments without stressing the seals.
- STERILIZATION CONTAINERS: Instruments may be loaded into a dedicated instrument tray, or general-purpose sterilization tray. Ensure that cutting edges are protected and do not exceed the recommended content or maximum weight indicated by manufacturer.
- PRECAUTIONS: Fixators can be sterilized in the assembled state as long as ball-joints, central body locking nut and clamp locking screws are left untightened. If any joints are tightened, they may sustain damage from thermal expansion during the sterilization process.
- STERILIZATION: Sterilize by steam autoclaving, utilizing a pre-vacuum cycle. *Orthofix recommends the following cycle: Steam autoclave 132-135°C (270-275°F), minimum holding time 10 minutes.*
- Any other **validated** pre-vacuum autoclave cycle may be used in alternative.

Instructions for Reprocessing of Reusable Devices for Subsequent Re-Use

General

- Unless supplied sterile, all Orthofix devices must be sterilized prior to surgical use.
- PRODUCTS LABELED FOR SINGLE-USE MUST NOT BE REUSED.
- Repeated reprocessing has minimal effect on reusable instruments. End of life is normally determined by wear and damage due to use.

Recommended decontamination process

The following sequence of decontamination processes is recommended for **reprocessing re-usable Orthofix Fixation System medical devices** and rendering them safe for subsequent clinical use.

1. CLEANING
2. DISINFECTION
3. STERILIZATION

Preparation at the point of use of used devices

- All **used** surgical instruments should be regarded as **contaminated**. Their handling, collection and transportation should be strictly controlled to minimise any possible risks to patients, personnel and any area of the healthcare facility.
- It is recommended that instruments are reprocessed as soon as is reasonably practicable following use.
- Ensure that items are securely and safely packaged during transport to the decontamination area.

Preparation for cleaning of used devices

- Used fixators should be disassembled completely, and all cams and bushes discarded since they are not re-usable.
- All components should be inspected, since damage to the surface of metal components can reduce the strength and fatigue resistance and may lead to corrosion.
- Wherever possible, all parts of disassembled devices should be kept together in one container.
- For disassembly/reassembly, the specific instrumentation should be used as described in detail in the Operative Manuals.

STEP 1: Cleaning of used products

- Cleaning is an essential pre-requisite to ensure effective disinfection or sterilization.
- The preferred method of decontamination of used devices is mechanical cleaning followed by disinfection.
- Where an automated washer-disinfector is not available, manual cleaning may be used, followed by disinfection.

Manual Cleaning (by immersion)

Equipment required:

- a sink (not hand wash basin) or receptacle which will hold enough detergent so that the item of equipment to be cleaned can be fully immersed;
- a detergent solution. **Orthofix recommends use of a 0,3% enzymatic detergent solution, immersion for 30 minutes at 40°C (104°F). Detergents with fluoride, chloride, bromide, iodide, or hydroxyl ions [free halogen ions or sodium hydroxide] MUST NOT be used;**
- a receptacle to contain rinse water;
- a drainage surface;
- a clean, disposable, absorbent, non-shedding cloth or mechanical drying facility (drying cabinet or industrial hot air dryer);
- a brush and jet washer.

Procedure:

- I. Ensure that the cleaning receptacle is clean and dry.
- II. Wearing protective equipment, fill the receptacle with sufficient water/detergent solution.
- III. Carefully immerse all components in the solution in order to displace trapped air; it is important to ensure that the cleaning solution reached all surfaces, including those of devices that have holes or recesses or are cannulated.
- IV. Brush, wipe, agitate, irrigate, jetwash or hand spray the item to dislodge and remove all visible dirt, ensuring that the action is performed beneath the surface of the solution.
- V. Remove the items from the solution and drain.
- VI. Remove any residue with a brush in running water.
- VII. Soak in sterile distilled water to remove traces of hard water.
- VIII. Remove item from rinse water and drain.
- IX. Carefully hand-dry using absorbent, non-shedding cloth or an industrial hot air dryer, or place in a drying cabinet.
- X. Complete the necessary documentation.
- XI. Proceed with disinfection.

Mechanical Cleaning (using an automated washer)

- Mechanical cleaning followed by disinfection is the preferred method of decontamination of used devices.
- If a washer-disinfector is used, it must have a validated cycle.
- Ensure that the washer-disinfector and all services are operational.
- Select and start a cycle according to the recommendations of the washer manufacturer
- **Detergents with fluoride, chloride, bromide, iodide, or hydroxyl ions [free halogen ions or sodium hydroxide] MUST NOT be used.**
- Proceed with disinfection.

STEP 2: Disinfection

Disinfection Procedure (manual)

Equipment required:

- a sink (not hand wash basin) or receptacle which will hold enough disinfectant so that the item of equipment to be cleaned can be fully immersed;
- a compatible water/disinfectant solution at dilution and temperature recommended by its producer. **Disinfectants with fluoride, chloride, bromide, iodide, or hydroxyl ions [free halogen ions or sodium hydroxide] MUST NOT be used; Orthofix recommends use of 3% hydrogen peroxide, with immersion, for 3 hours at room temperature;**
- a receptacle to contain rinse water;
- a drainage surface;
- a clean, disposable, absorbent, non-shedding cloth or mechanical drying facility (drying cabinet or industrial hot air dryer);
- a brush and jet washer.

Procedure:

- I. Wearing protective equipment, fill the receptacle with sufficient disinfectant solution to ensure complete immersion of the item.
- II. Carefully immerse all components in the solution in order to displace trapped air; it is important to ensure that the cleaning solution reached all surfaces, including those of cannulated devices.
- III. Leave the items for the time required (3 hours with 3% Hydrogen Peroxide).
- IV. Remove the items from the solution and drain.
- V. Remove any residue with a brush in running water.
- VI. Soak in sterile distilled water to remove traces of hard water.
- VII. Remove item from rinse water and drain.
- VIII. Carefully hand-dry using absorbent, non-shedding cloth or industrial hot hair dryer, or place in a drying cabinet.
- IX. Complete the necessary documentation.
- X. Proceed with sterilization.

Disinfection Procedure (automatic)

Equipment required:

- I. A thermal washer-disinfector, cabinet or continuous process type.
- II. A sufficient number of racks for stacking items to be processed.
- III. A compatible disinfectant and rinse aid. **Disinfectants with fluoride, chloride, bromide, iodide, or hydroxyl ions [free halogen ions or sodium hydroxide] must not be used; Orthofix recommends use of 0,5% phenolic disinfectant solution at 80°C (176°F). The validated cycle time is 80 minutes.**
- IV. A drainage surface.
- V. A clean, disposable, absorbent, non-shedding cloth or mechanical drying facility.

Procedure:

- I. Ensure the washer-disinfector and all services are operational.
- II. Wear protective equipment, load the rack/machine ensuring that the loading configuration does not impede the cleansing process.
- III. Select and start a cycle according to the recommendation of the washer manufacturer. On completion on the cycle, ensure that all stages and parameters have been achieved; remove the load and visually check and inspect the cleanliness of the item, drain off excessive water and dry if necessary.
- IV. Complete the documentation.
- V. Proceed with sterilization.

Disinfection Procedure (ultrasound)

Equipment required:

- I. An ultrasonic washer with lid which will hold enough liquid so that the items of equipment to be cleaned can be fully immersed.
- II. A sufficient number of supporting racks or trays for stacking items to be processed.
- III. A timing device.
- IV. A compatible water-detergent solution at dilution and temperature, recommended by manufacturer.
- V. A clean, disposable, absorbent, non-shedding cloth or mechanical drying facility.

Procedure:

- I. Ensure the ultrasonic washer is clean and dry prior to use.
- II. Wear protective equipment, fill the fluid reservoir with sufficient water/disinfectant to ensure complete immersion of items. **Disinfectants with fluoride, chloride, bromide, iodide, or hydroxyl ions [free halogen ions or sodium hydroxide] must not be used; Orthofix recommends use of 0,5% phenolic disinfectant solution immersion at 50°C (122°F) for 15 minutes (ultrasound frequency 50/60 Hz).**
- III. Switch on and leave for required time to degas the water.
- IV. Remove lid and carefully immerse the item in the fluid ensuring that any air contained within the item is displaced. Irrigate cannulated devices.
- V. Re-place the lid and leave for the time recommended (15 minutes).
- VI. Switch off, lift the lid, remove the item and drain before transferring to a clean-rinse receptacle.
- VII. Rinse thoroughly with clean water, ensuring irrigation of lumen devices, and drain.
- VIII. Carefully hand-dry using absorbent, non-shedding cloth, industrial hot air dryer or place in a drying cabinet.
- IX. Complete the documentation.
- X. Proceed with sterilization.

STEP 3: Drying

Carefully hand-dry using absorbent, non-shedding cloth or industrial hot air dryer, or place in a drying cabinet.

STEP 4: Inspection, maintenance and testing

- All instruments and product components should be visually inspected for cleanness and any signs of deterioration that may cause failure in use (such as cracks or damage to surfaces) and functions tested before being sterilized (see detailed Operative Technique Manuals and Instructions for use). Particular attention should be given to:
 - Cannulated devices (NB: cannulated drill-bits are single-patient use only)
 - Cutting edges: Discard blunt or damaged instruments
 - Hinged instruments: check for smooth movement of hinges without excessive "play".
 - Locking mechanisms should be checked for action.
- If a component or instrument is believed to be faulty, damaged or suspect, it should NOT BE USED.
- When instruments form part of an assembly, check assembly with matching components.
- Lubricate all parts, except for cam, bush and ball coupling with Orthofix silicone oil whenever required (see detailed Operative Technique Manuals).
- Final locking of the ball-joints of the 10000, 30000/31000 or 90000 range of fixators is performed with a torque wrench, which must be turned in a clockwise direction only. A click indicates that the correct torque has been applied. Any attempt to unlock the cam or any screw using the torque wrench will damage its gearing. The torque wrench is pre-set at a specific value, which is 15 Nm±0.5 for the 30000/31000 Range (30025) and 27 Nm±1 for the 10000 and 90000 Ranges (10025). This value should be checked at least every two years or any time the instrument becomes damaged, by returning it to the local authorized representative. The cams and bushes in the ball joints of the 10000, 30000, 31000 and 90000 range of fixators must be replaced after every use.

Note: If on tightening the cams and bushes with the torque wrench, the mark on the cam moves more than 170° from the fully unlocked

position, all cams and bushes must be replaced. If the problem persists, the whole fixator should be replaced. The use of a torque wrench is not required for final locking of the ball joints in the XCaliber External Fixator. Final locking is achieved with the Allen Wrench. The cams can be locked from either side of the clamp. They should be turned towards the thicker section of the coloured insert until tightly closed, and the cam is at least 50% of the way across the recess.

STEP 5: Sterilization

- **PACKAGING:** Where products are to be packaged to maintain their sterility after sterilization and to prevent damage of the instrument prior to use, an appropriate medical grade packaging material should be used. The pack should be large enough to contain the instruments without stressing the seals.
- **STERILIZATION CONTAINERS:** Instruments may be loaded into a dedicated (Orthofix) instrument tray, or general-purpose sterilization tray. Cutting edges should be protected and the recommended content or maximum weight not exceeded as indicated by manufacturer.
- **PRECAUTIONS:** Fixators can be sterilized in the assembled state as long as ball-joints, central body locking nut and clamp locking screws are left untightened. If any joints are tightened, they may sustain damage from thermal expansion during the sterilization process.
- **STERILIZATION:** Sterilize by steam autoclaving, utilizing a pre-vacuum cycle. *Orthofix recommends the following cycle: Steam autoclave 132-135°C (270-275°F), minimum holding time 10 minutes.*
- Any other **validated** pre-vacuum autoclave cycle may be used in alternative.
- Processed items should be stored in clean and secure stores to avoid damage or tampering.

Disclaimer: “The instructions provided above have been validated by Orthofix as being a true description of the preparation of a device for first clinical use or for re-use of multiple use devices. It remains the responsibility of the reprocessor to ensure that the reprocessing, as actually performed using equipment, materials and personnel in the reprocessing facility, achieves the desired result. This normally requires validation and routine monitoring of the process. The cleaning, disinfection and sterilization processes should be adequately recorded. Likewise any deviation by the reprocessor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences and should also be appropriately recorded”.

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MANUALS

- PM 010 ORTHOFIX EXTERNAL FIXATION:
BASIC CONSIDERATIONS
- PM 020 GROWTH PLATE DISTRACTION
 - Chondrodiatasis
 - Hemichondrodiatasis
- PM 030 LIMB LENGTHENING AND CORRECTION OF
DEFORMITIES BY CALLUS DISTRACTION
 - Callotasis
 - Hemicallotasis
 - Tibial lengthening and angular correction with
the OF-Garches limb lengthener
- PM 040 ARTHRODIATASIS (Articulated Joint Distraction)
 - Hip
 - Ankle
- PM 050 ARTHRODESIS (Joint Fusion)
 - Shoulder
 - Hip
 - Knee
 - Ankle
- PM 060 DIAPHYSEAL FRACTURES
 - Humerus
 - Forearm
 - Femur
 - Tibia
- PM 070 DISTAL TIBIAL AND PILON FRACTURES
- PM 080 PELVIC APPLICATIONS
- PM 090 TREATMENT OF FRACTURES AND
DEFORMITIES IN SMALL BONES
- PM 100 THE PENNIG DYNAMIC WRIST FIXATOR
- PM 110 THE LIMB RECONSTRUCTION SYSTEM
 - Part A: General Principles
 - Part B: Correction of Deformities
- PM 120 THE RING FIXATION SYSTEM
 - Part A: The Hybrid Fixator
 - Part B: The Sheffield Ring Fixator -
Standard Trauma Applications
 - Part C: The Sheffield Ring Fixator -
Limb Reconstruction and Complex Trauma

QUICK REFERENCE GUIDES

- PG 040 Arthrodiatasis (Articulated Joint Distraction)
- PG 050 Arthrodesis - Joint Fusion
- PG 06A Diaphyseal and Metaphyseal Fractures - The D.A.F.
(10000 Series)
- PG 06B Diaphyseal and Metaphyseal Fractures - TheProCallus
Fixator (9000 Series)
- PG 070 Distal Tibial and Pilon Fractures with the RadioLucent
Ankle Clamp
- PG 080 Pelvic Applications - Fractures and Disruptions of the
Pelvic Ring
- PG 090 Treatment of Fractures and Defomities in Small Bones -
The Pennig Minifixator
- PG 10A The Pennig Dynamic Wrist Fixator - Trans-articular
Application
- PG 10B The Pennig Dynamic Wrist Fixator - Extra-articular
Application with the RadioLucent Wrist Clamp
- PG LRS Limb Reconstruction System - Part A: General Principles
and Part B: Correction of Deformities
- PG HFS The Orthofix Hybrid Fixation System
- PG 13A The Elbow Fixator - Part A: Acute Trauma
- PG 13B The Elbow Fixator - Part B: Post-Traumatic Stiffness
- PG 14A The MiniRail System - Part A: Hand Applications
- PG 14B The MiniRail System - Part B: Foot Applications
- PG 150 The RadioLucent Wrist Fixator
- PG 160 One-Step Fracture Fixation - The Fragment Fixation
System
- PG 170 The XCaliber Meta-Diaphyseal Fixator
- PG 180 The XCaliber Articulated Ankle Fixator
- PG 190 The XCaliber Hybrid Fixator
- PG 200 The XCaliber Bone Screws
- PG 210 The PreFix Fixator (92000 Series)

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