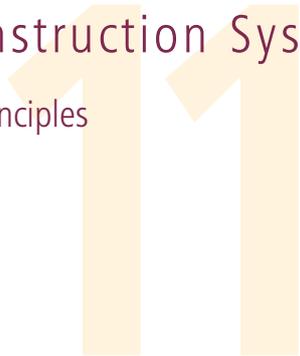


Limb Reconstruction System

Part A: General Principles



LIMB RECONSTRUCTION SYSTEM

Part A: General Principles

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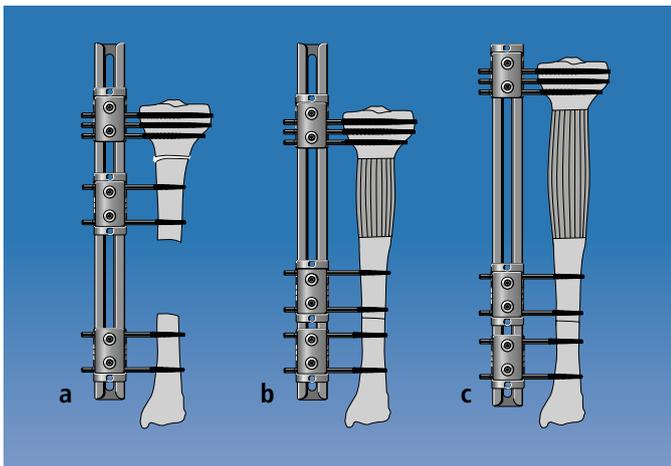
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REFERENCES 45

Please kindly refer to the product IFU PQREC, to the Orthofix implantable devices and related instrument IFU PQSCR, and to the reusable medical devices IFU PQRMD that contain instructions for use of the product.

Operative Technique Contributing Surgeons:

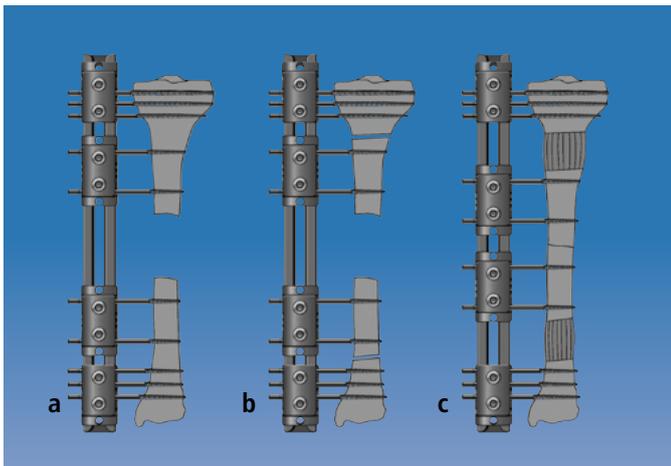
- Prof. M. SALEH
- Prof. R. ALDEGHERI
- Dr. L. RENZI-BRIVIO, MD
- Dr. F. LAVINI, MD
- Dr. S. AGOSTINI, MD
- Dr. R.W. BRIGHT, MD
- Prof. J.C. POULIQUEN



BONE LOSS

Intermediate Size Defect: Bone Transport

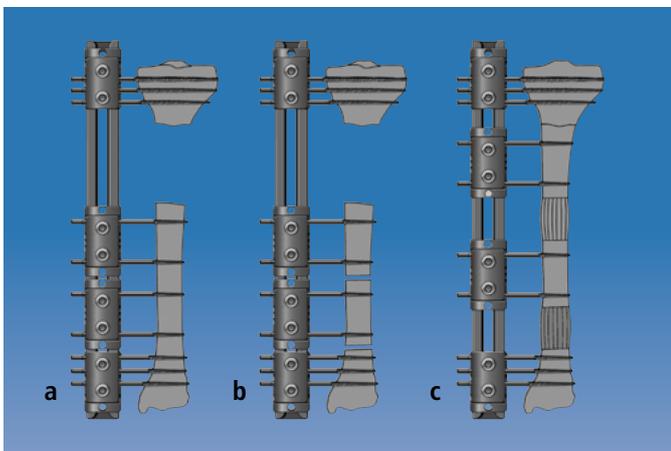
- a) Intermediate Size Distal Defect with Shortening. LRS with 3 clamps applied.
- b) Proximal metaphyseal osteotomy between clamp 1 and 2, followed by transport with clamp 1 and 3 locked to the rail and clamp 2 moved distally.
- c) Lengthening to restore the original limb length. Clamp 2 and 3 locked to rail and clamp 1 moved proximally.



Large Defect: Bifocal Transport

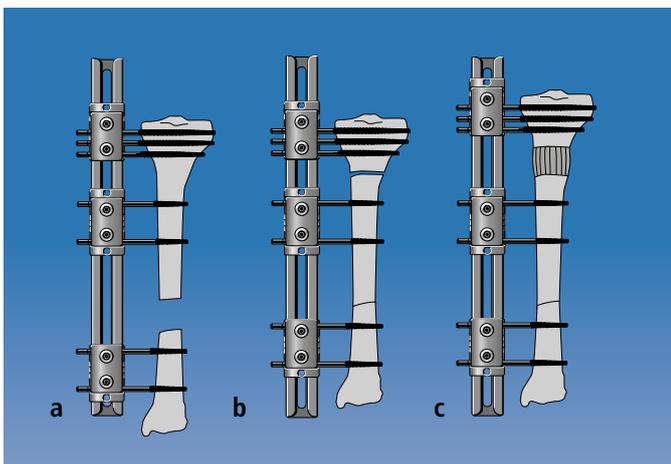
Central Defect

- a) Large central bony defect and Limb Reconstruction System in place.
- b) Proximal and distal metaphyseal osteomies performed.
- c) Simultaneous proximal and distal transport with clamps 1 and 4 locked to rail and clamp 2 moved distally and clamp 3 proximally until segments meet.



Peripheral Defect

- a) Large peripheral bony defect and Limb Reconstruction System in place.
- b) Two osteomies performed in longer bone fragment.
- c) Simultaneous proximal transport with clamps 1 and 4 locked to rail and clamps 2 and 3 moved proximally until segments meet.



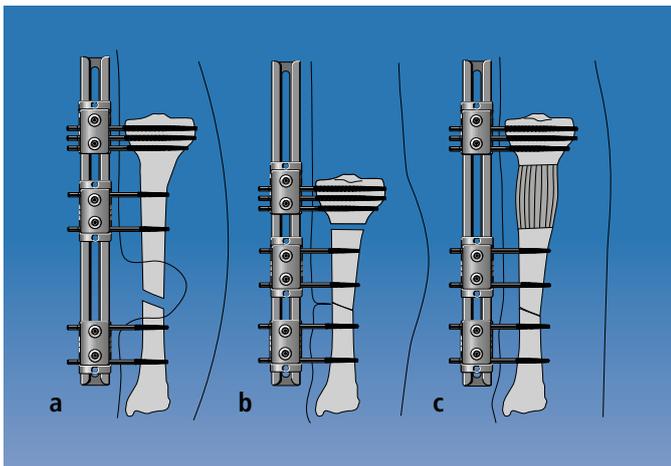
Small Defect: Compression-Distraction

- a) Small distal bone defect and Limb Reconstruction System in place.
- b) Immediate compression between clamps 2 and 3 to close defect. Proximal osteotomy performed between clamps 1 and 2.
- c) With clamps 2 and 3 locked to rail to maintain compression, clamp 1 is moved proximally to restore original limb length by Callotasis.

FRACTURES ASSOCIATED WITH MAJOR SOFT TISSUE DEFECTS

Compression-Distraction

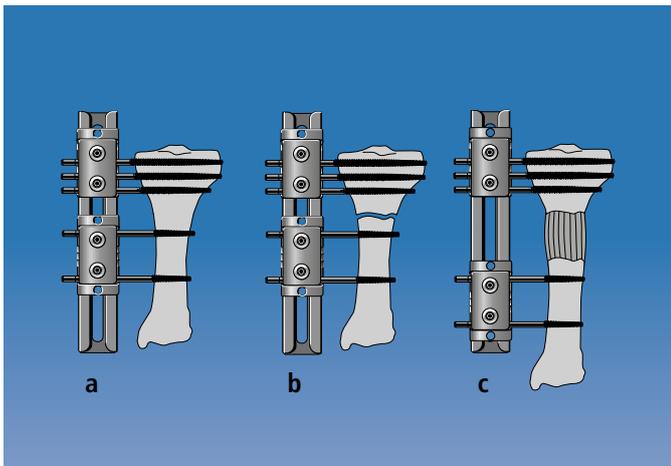
- a) Fracture with major soft tissue defect and exposed bone.
- b) Debridement and resection of sufficient bone to allow soft tissue closure; distal stabilization; proximal osteotomy.
- c) Proximal distraction (lengthening) to restore original bone length.



LENGTHENING

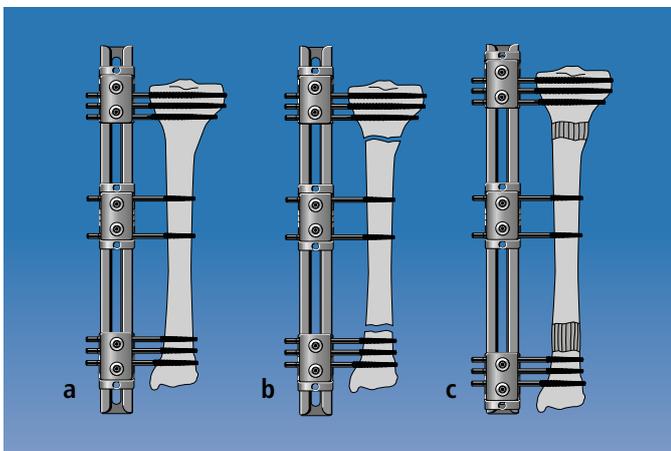
Monofocal Lengthening

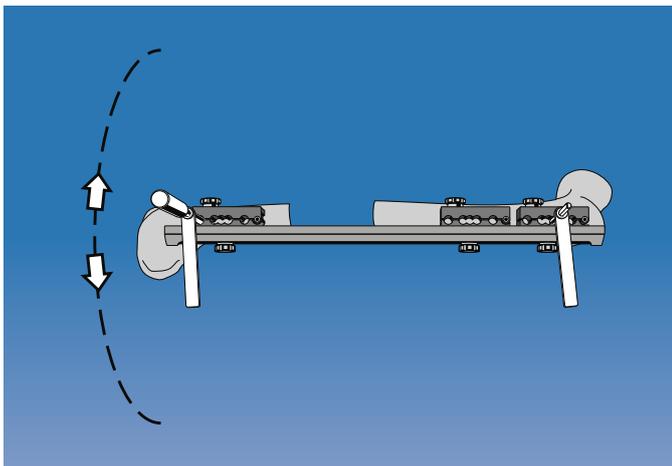
- a) Shortening and Limb Reconstruction System in place.
- b) Proximal metaphyseal osteotomy.
- c) Distraction (lengthening) with clamp 1 locked to rail and clamp 2 free to move.



Bifocal Lengthening

- a) Extreme shortening in the limb, with the Limb Reconstruction System in place.
- b) Proximal metaphyseal osteotomy between clamps 1 and 2 and distal metaphyseal osteotomy between clamps 2 and 3.
- c) Simultaneous lengthening at each osteotomy site, with clamp 2 locked to the rail and clamps 1 and 3 free to move, restoring original limb length.





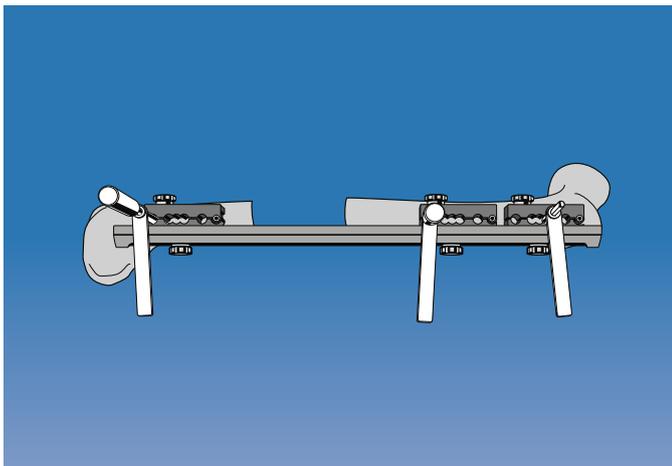
GENERAL TECHNIQUE

Screw Insertion

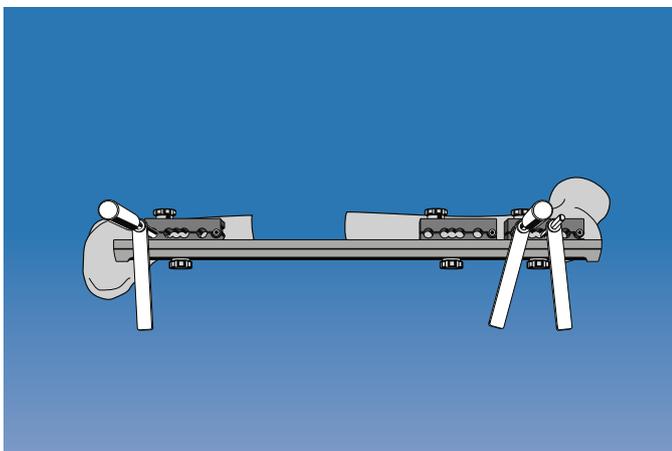
Assemble clamp templates on rail. Insert first screw in usual manner. Second screw to be inserted will be most distal one.

Identify center of bone at most distal seat of distal clamp, using trocar inserted in screw guide.

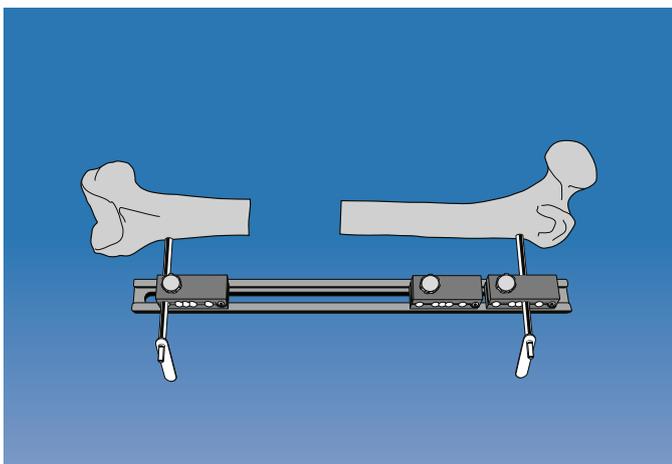
HA-Coated Osteotite™ (Osteotite hereinafter) Bone Screws are strongly recommended for all limb reconstruction procedures.



Use second trocar and screw guide to check that screws sited in outer seats of middle clamp will penetrate center of bone.

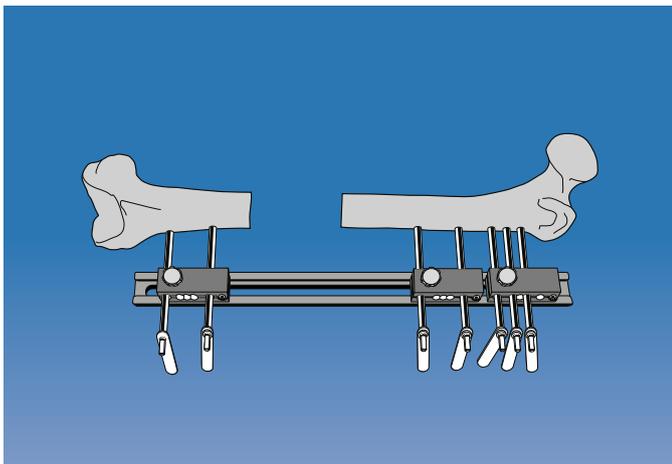


Check that satisfactory screw insertions can be achieved at chosen sites in proximal and distal clamps.

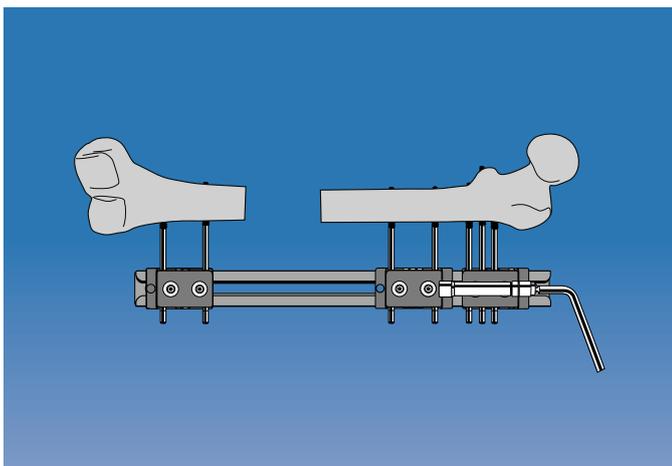


Insert most distal screw using standard technique.

QUICK REFERENCE GUIDE

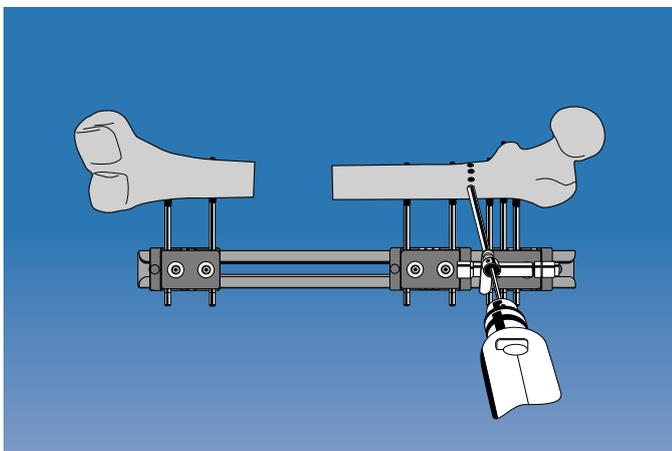


Insert remaining screws.
Use screw seats 1, 2 and 4 (starting from proposed osteotomy site) in proximal clamp. Use screw seats 1 and 5 in middle and distal clamp.

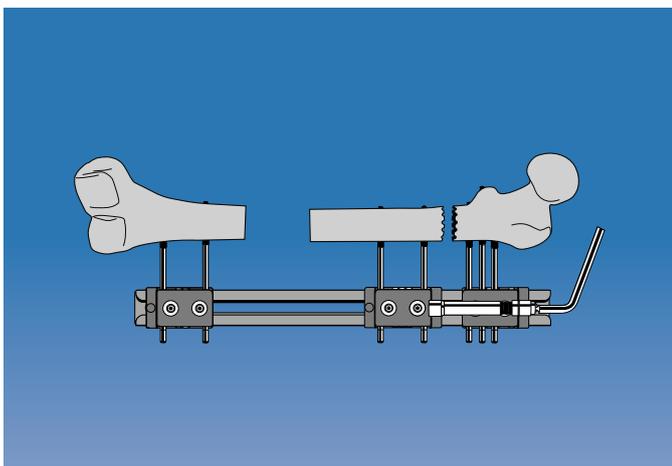


Tension Osteotomy

Remove rail with template clamps and screw guides; apply rail with definitive clamps. Lock clamps into position on rail. Place compression-distraction unit between proximal and middle clamps. With middle clamp loosened, apply distraction.



Perform osteotomy using drill bit in corresponding drill guide. Connect holes with osteotome.



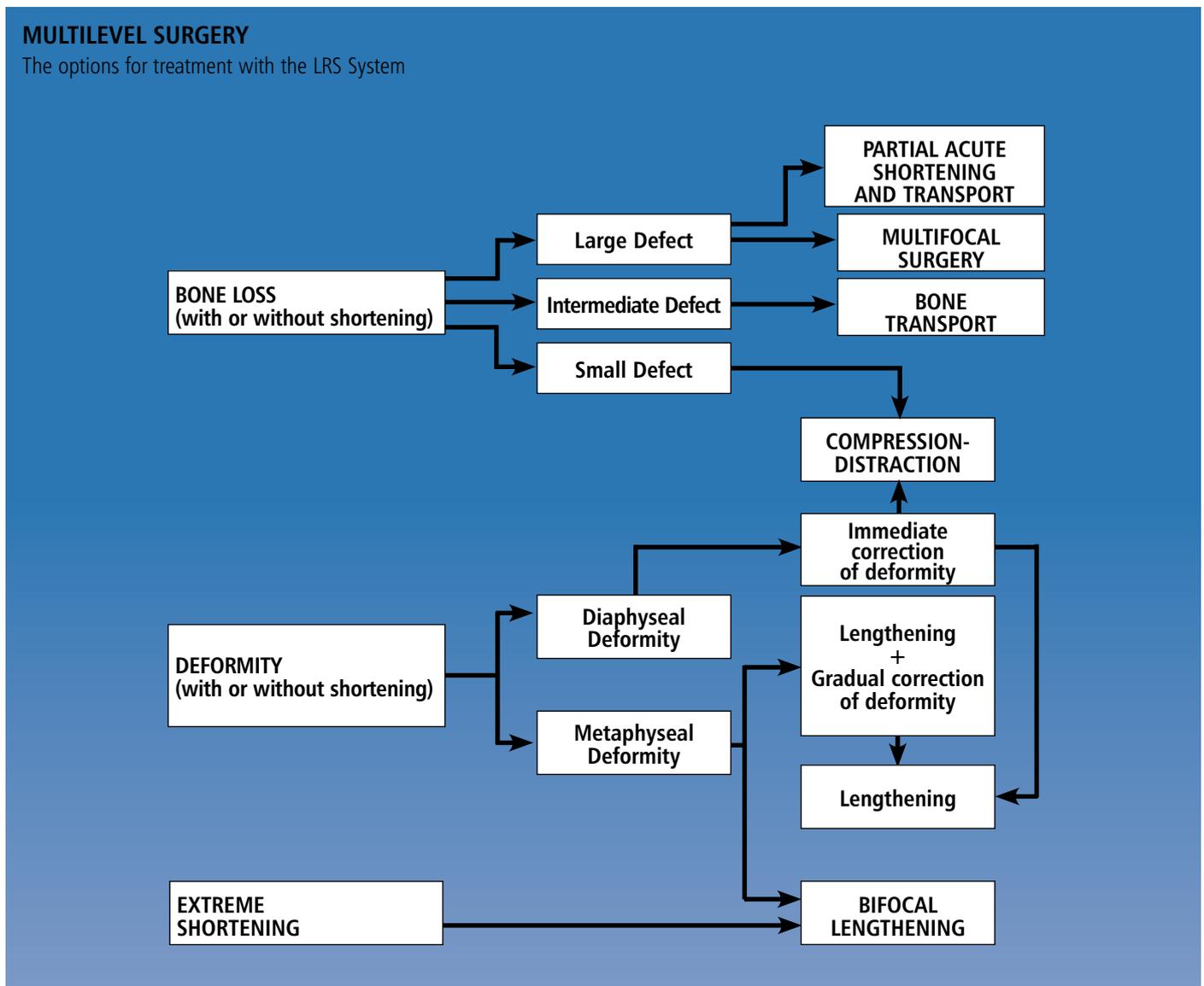
Distraction osteotomy to confirm complete. Bring both segments together and lock middle clamp. Replace periosteum, suture if possible, and close incision with single suction drain.

INTRODUCTION

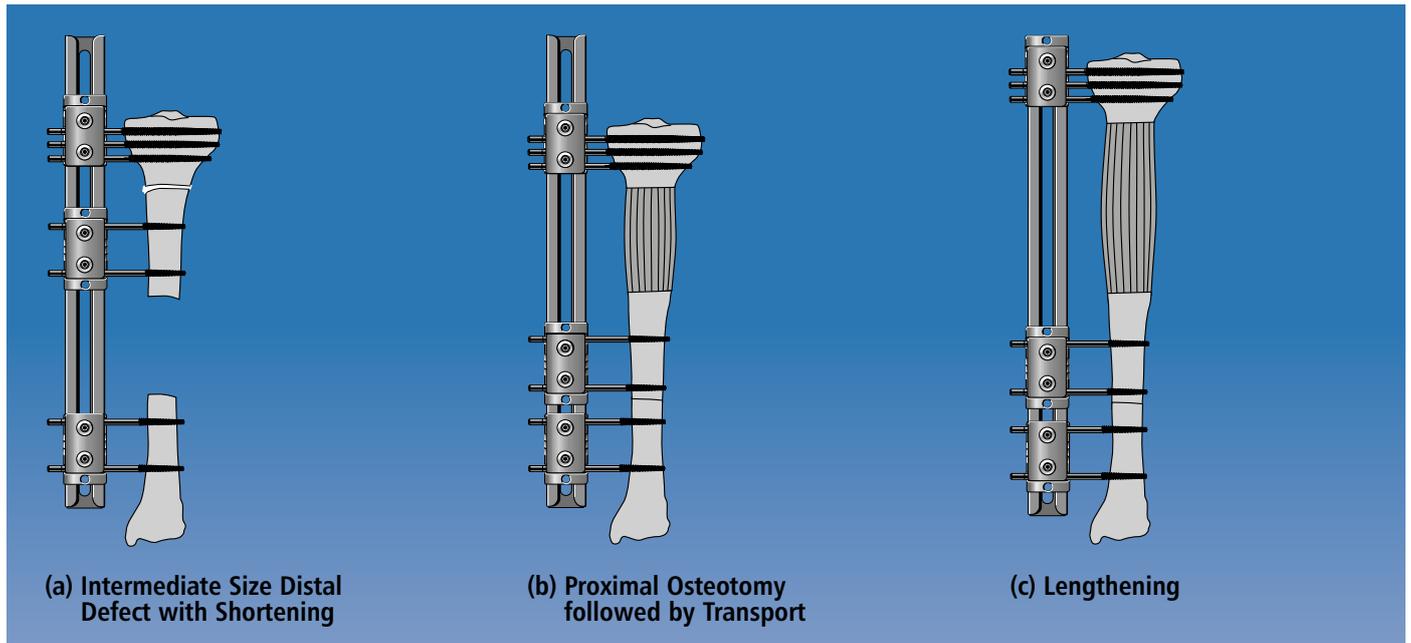
The Orthofix Limb Reconstruction System consists of an assembly of clamps (usually two or three) that can slide on a rigid rail and can be connected by compression-distraction units. It may be used for lengthening and correction of deformities acutely (using an acute correction template) or progressively (using progressive correction clamps). In comminuted fractures with bone loss, and in situations of non-union or malunion with or without some degree of osteoporosis, the Limb Reconstruction System may be used to obtain maximum stability, since the construction of the device enables the bone screw clamp positions to be varied over the whole length of the bone, depending upon the length of rail used.

Multilevel Surgery

The Limb Reconstruction System was designed primarily, for segmental (multilevel) surgery. Here, the three main indications for its use are: bone loss, with or without shortening; deformity, with or without shortening, and extreme shortening. The system provides for correction in these situations through the techniques of bone transport, compression-distraction, partial acute shortening and transport, multifocal surgery and bifocal lengthening, as shown in the summary chart below.

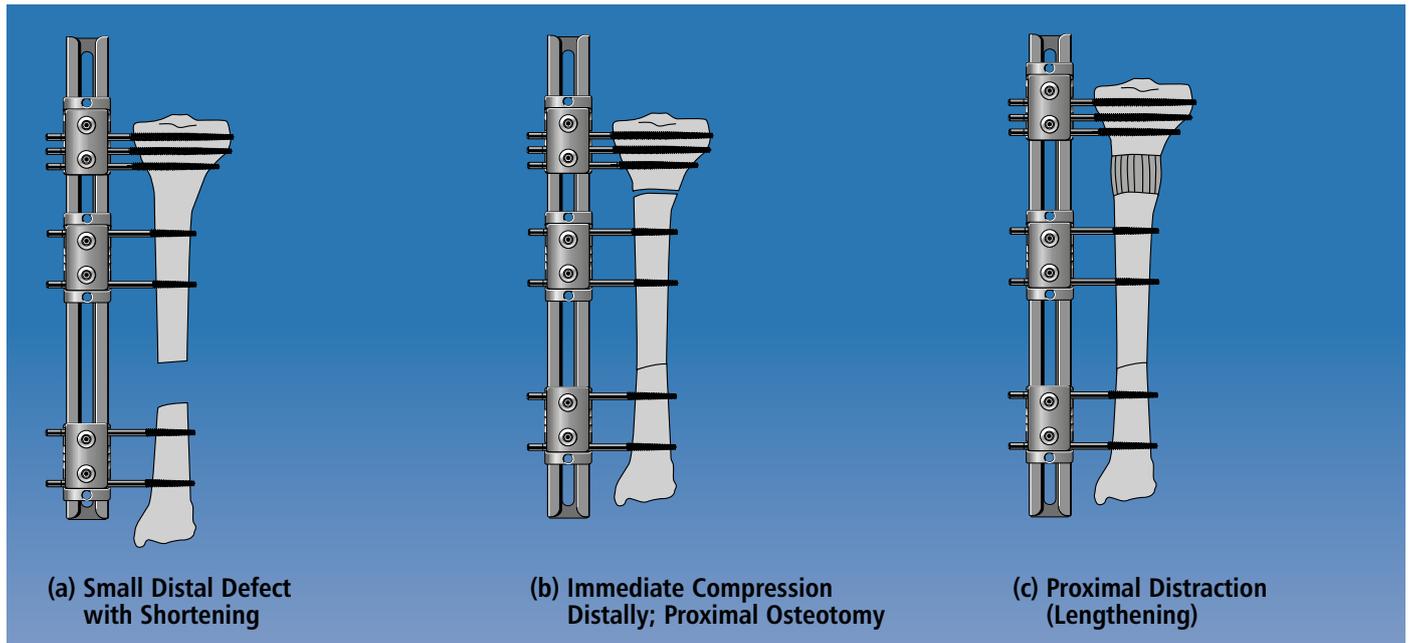


Bone Transport

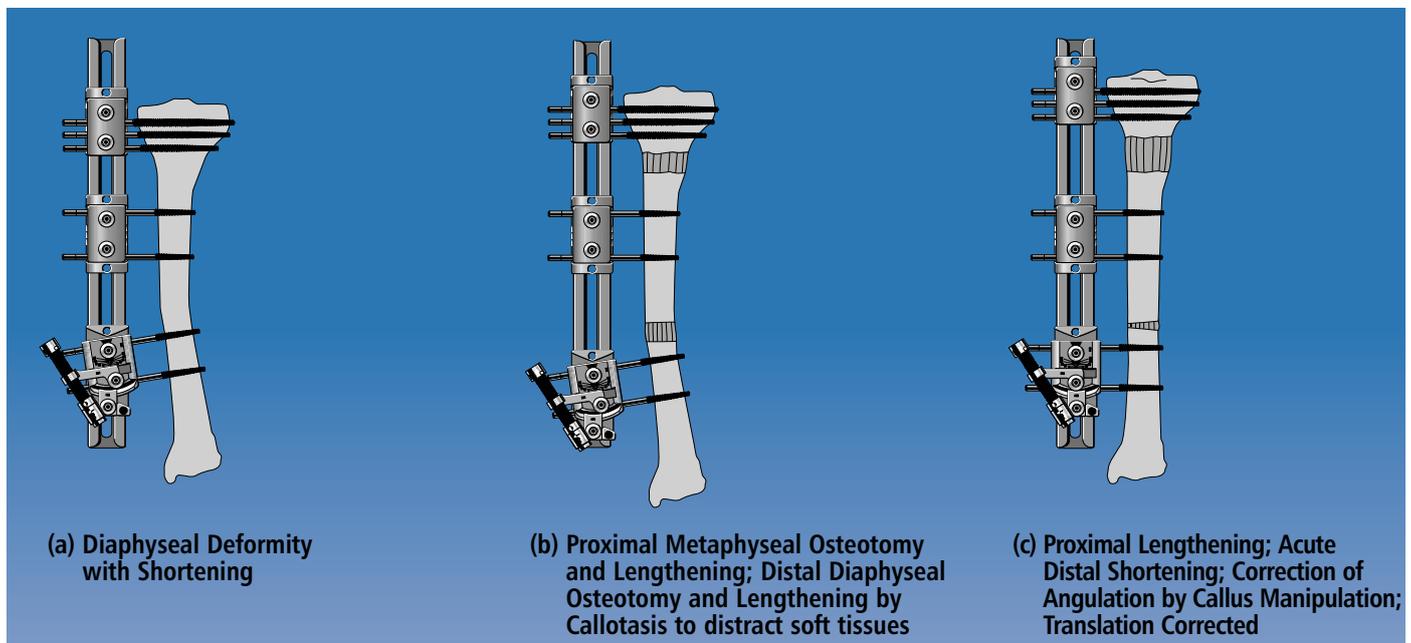


Bone transport differs from lengthening since . Instead of the bone and soft tissues maintaining a relatively fixed relationship to one another, the bone slides in the soft tissue envelope like a lift or elevator in a shaft. Bone transport is indicated in situations associated with bone loss (acute fractures, aseptic or infected non-unions, and other pathologies, e.g. tumor, osteomyelitis), where the defect is more than 3cm in the tibia or 5cm in the femur (intermediate or large defect). The method consists in stabilizing the bone segments with screws that are held in the two outer clamps. A third, intermediate clamp is used to secure a part of the proximal (or distal) segment, which is then separated from the rest of the segment by means of a standard osteotomy ((Saleh and Rees, 1995; Biermann J.S. et al., 1991). Application of the Callotasis Technique (Aldegheri R. et al., 1989; De Bastiani et al., 1987), which is symmetrical distraction of the forming callus through slow, controlled movement of the middle clamp along the rail, will now transport it towards the opposite segment with new bone forming behind it during its passage. Once transport has brought the two segments into contact, union may be achieved either by compression alone, or by a variety of other techniques (resection of the bone ends and compression, bone grafting, decortication, etc.), depending upon circumstances. If shortening is present when the two segments meet, the middle clamp can be locked to the rail and lengthening continued between the middle and proximal clamp (or middle and distal clamp, depending upon the location of the bony defect) to restore limb length.

Compression-Distraction

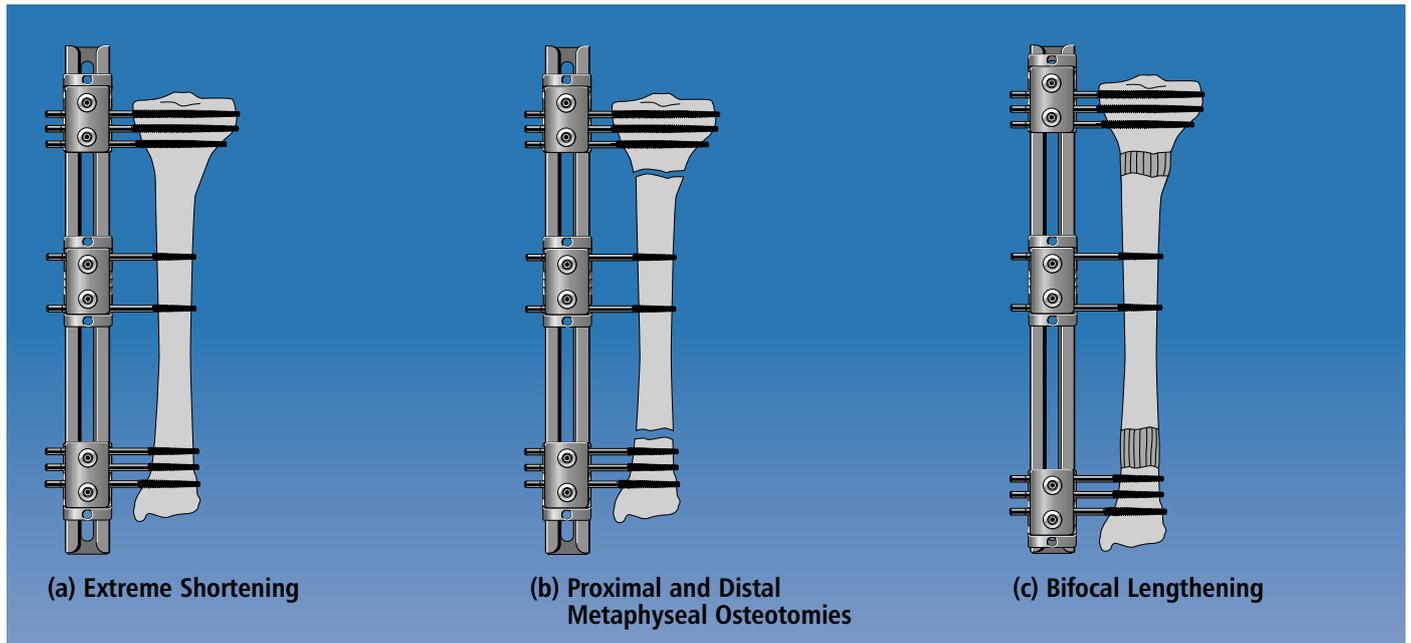


This technique is used where shortening of the limb is associated with bone loss of less than 3cm in the tibia or 5cm in the femur (small defect) (Saleh and Rees, 1995). An exception to this is the case where an intact fibula is essential for stability. Under these circumstances, even a short defect should be closed by transport. Where a larger defect is present but early shared stability between the bone and fixator is desirable, acute partial closure of the defect may be performed followed by simultaneous slow closure of the residual defect and bone transport. This effectively closes the defect by 2mm per day.

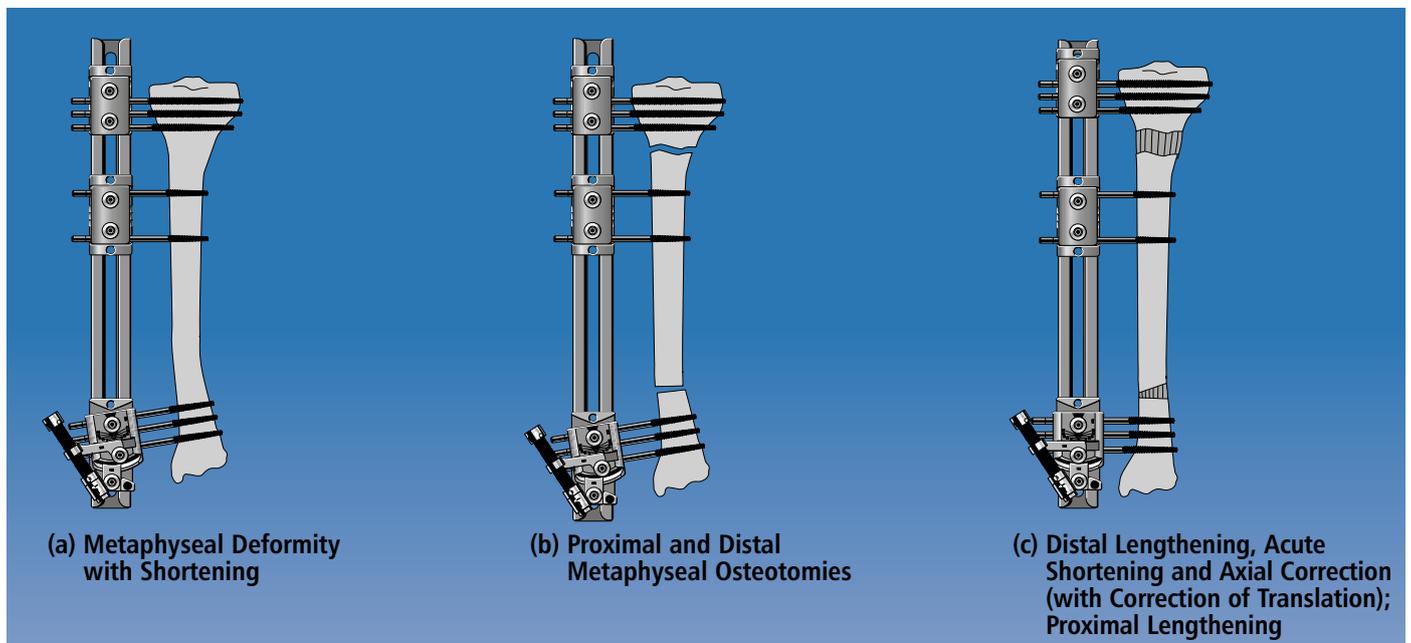


Compression-Distraction may also be used for shortening associated with a diaphyseal deformity (malunion or angulated non-union).

Bifocal Lengthening

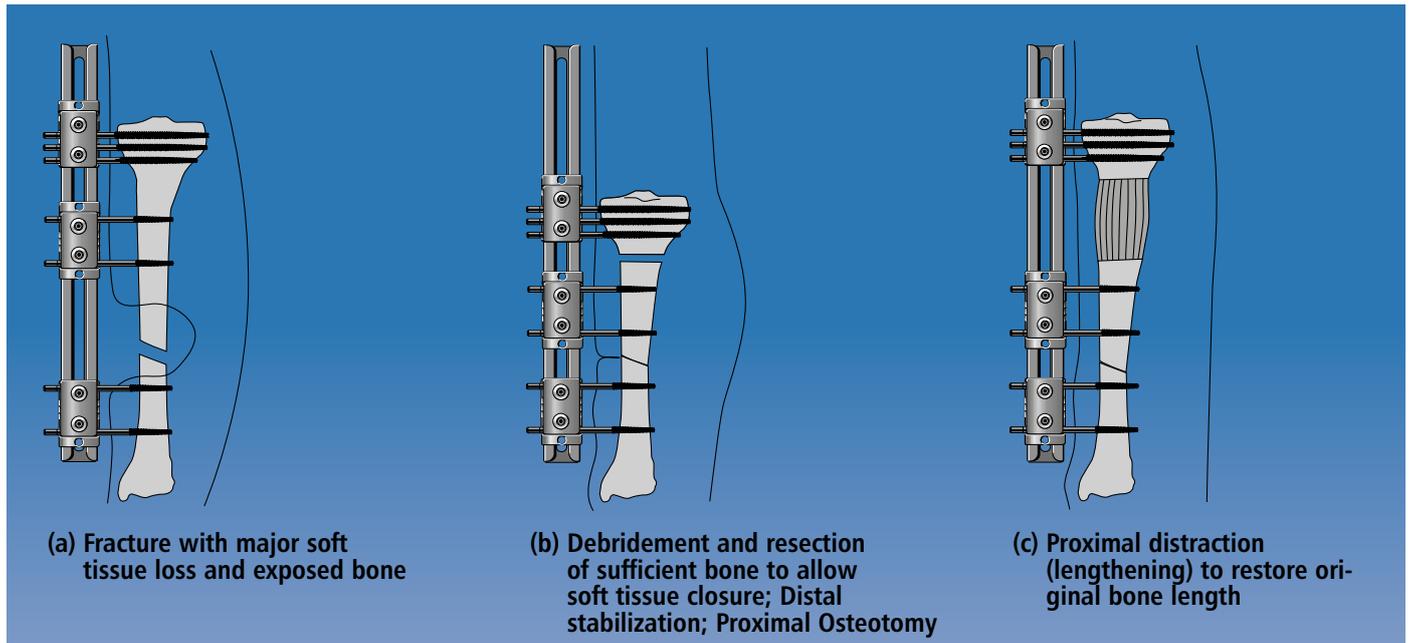


Lengthening at two sites simultaneously (Saleh M. and Burton M., 1991; Saleh and Hamer 1993) may be indicated for extreme shortening,



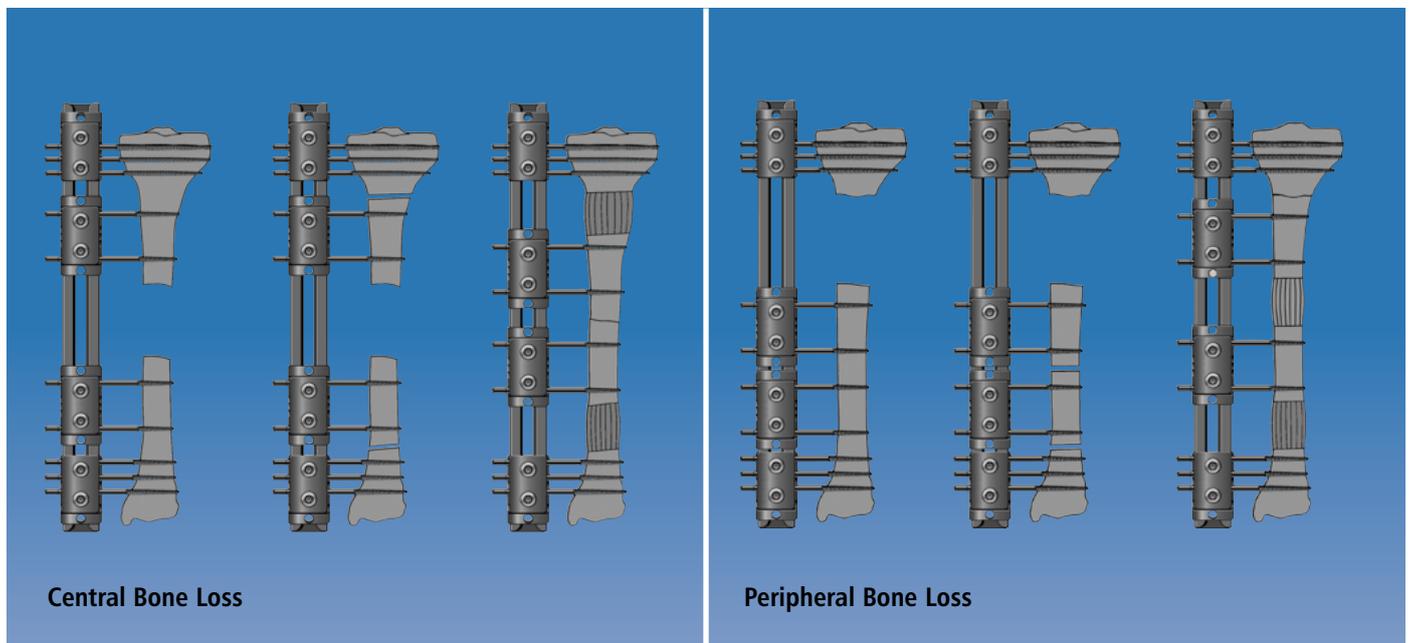
or for lengthening and correction at the site of a metaphyseal deformity, coupled with lengthening at the healthy metaphysis. Segmental procedures have been shown to increase more than twofold the blood supply to the bone (Sveshnikov A.A. et al., 1984); it has further been demonstrated that working at two sites in a given bone is not associated with an increase in complication rate as compared with monofocal surgery (Saleh M. et al., 1991; Saleh and Hamer 1993).

The Management of Fractures Associated with Major Soft Tissue Defects



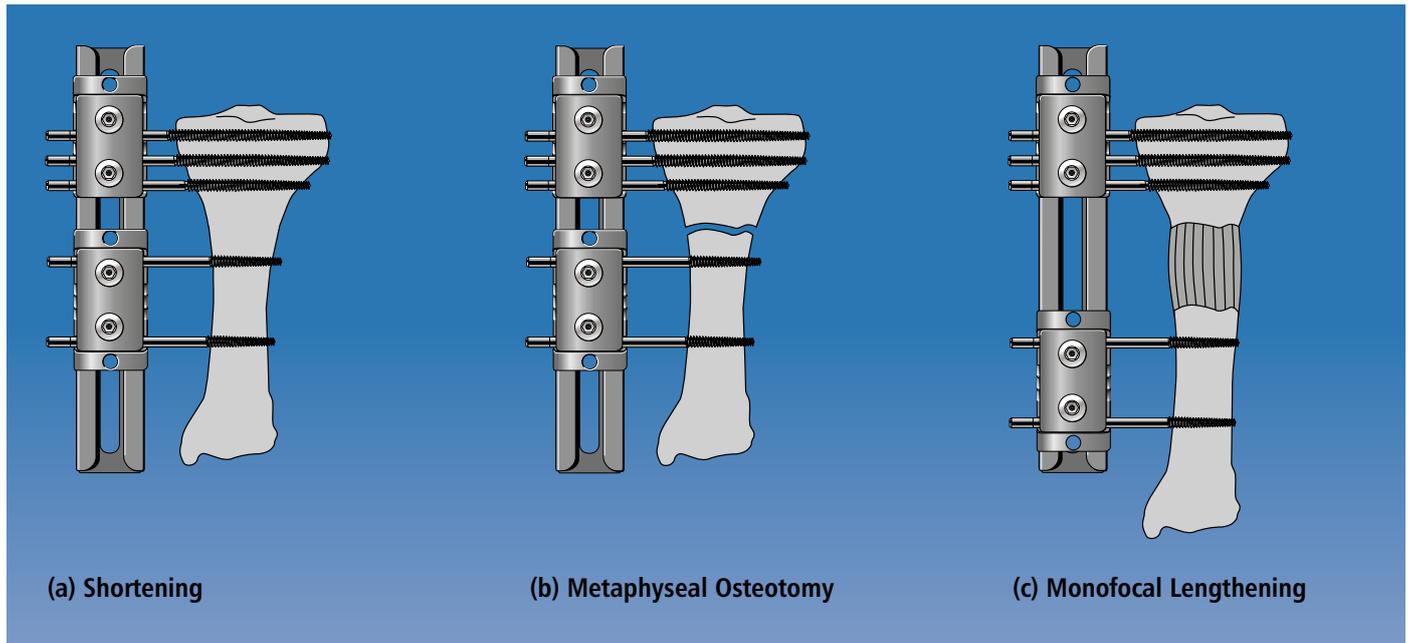
These may be treated by the Shortening - Lengthening Technique described by Giebel (Giebel G., 1991, 1992). Soft tissue defects associated with extensive bone loss may also be treated by transport combined with plastic reconstructive procedures (see under "D. The Management of Fractures Associated with Major Soft Tissue Defects", page 37 for details).

Multifocal Procedures



Where a large bone defect exists, the defect may be closed more rapidly if two osteotomies are performed. The position of the osteotomies relative to one another will depend upon whether the defect is central or peripheral (see under "Bifocal Transport", page 32 for details).

Monofocal Procedures

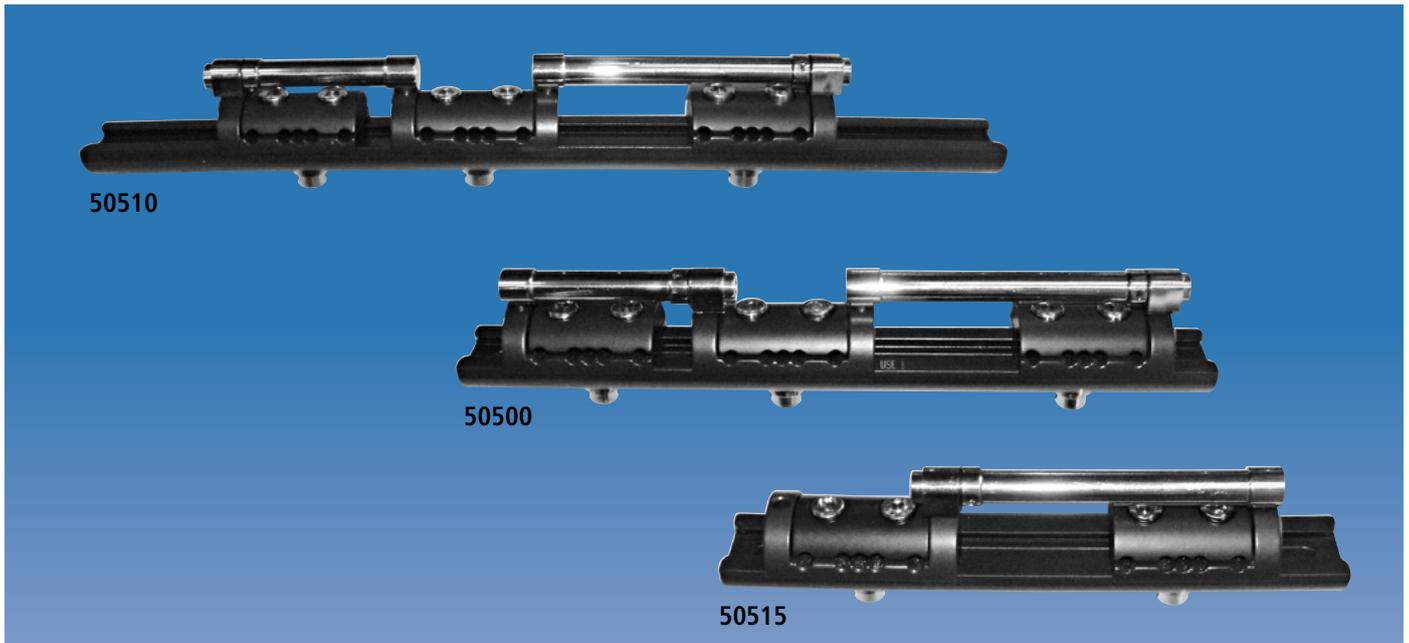


The Limb Reconstruction System can be used with two clamps for lengthening at a single osteotomy site (monofocal lengthening) (figure above), and for deformity correction with or without lengthening, using an acute correction template or progressive correction clamps. It may also be used to treat problems at a single focus when additional stability is required, e.g. for fractures and non unions in osteoporotic bone. In these circumstances, the absence of ball-joints, the closer proximity of the screws to the fracture focus and the positioning of the clamps at strategic points along the whole length of the segment confer increased stability (see under "E. Monofocal Procedures", page 38 for details). The system is especially useful for hypertrophic non unions with shortening, which may be treated by distraction (Saleh and Royston, 1996). All of the techniques described above are possible using the Orthofix Limb Reconstruction System with its facility for conversion from a static to a dynamic mode at the appropriate time, in accordance with the Orthofix philosophy.

EQUIPMENT REQUIRED

1. LIMB RECONSTRUCTION SYSTEM

Adult Models



50510 Long Model

Length 400mm

with 3 clamps and 2 compression-distraction units.

50500 Standard Model

Length 300mm

with 3 clamps and 2 compression-distraction units.

50515 Short Model

Length 230mm

with 2 clamps and 1 compression-distraction unit. Since this model has only two clamps, it cannot be used for multilevel surgery.

An Extra-Short Rail (50544, 12cm long) is also available.

Note that the outer clamps are identical, but that the central clamp is longer, with compression-distraction unit mountings at both ends. The clamps for the bone screws have the same screw-seat configuration as the clamps of the Orthofix telescopic fixators and lengtheners and allow for some interchangeability between the systems. The screws below the rail lock the individual clamps to the rail (clamp locking screws). For adults, the 40cm rail is normally chosen. In children over the age of 10 and in small females, the 30cm rail may be more appropriate.

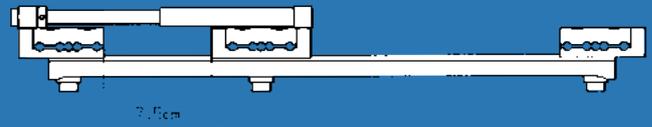
The amounts of distraction that can be achieved using the adult models in conjunction with compression-distraction units 10008 and 10009 for bone transport or bifocal lengthening (long and standard models) and monofocal lengthening (short model) are illustrated on the following pages.

EQUIPMENT REQUIRED

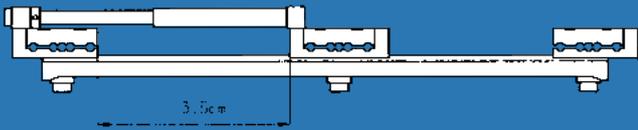
50510 Long Model Bone Transport



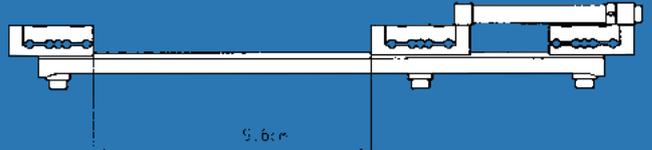
(a) The two outer clamps positioned at the extremities of the rail and the middle clamp in contact with one outer clamp.



(b) With the compression-distraction unit (10009) positioned as shown, the maximum distraction possible is 7.5cm.



(c) The amount of distraction may be increased to 13.5cm by changing the position of the compression-distraction unit from that shown in (b) to the above position and applying distraction.

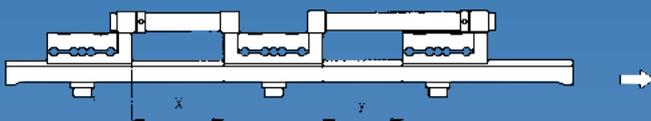


(d) Distraction may then be extended to 19.6cm by changing the position of the compression-distraction unit from that shown in (c) to the above position and applying compression.

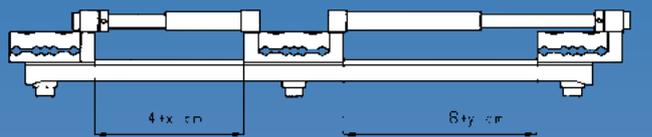


(e) The maximum distraction may be obtained by changing the position of the compression-distraction unit from that shown in (d) to the above position and compressing further.

Bifocal Lengthening



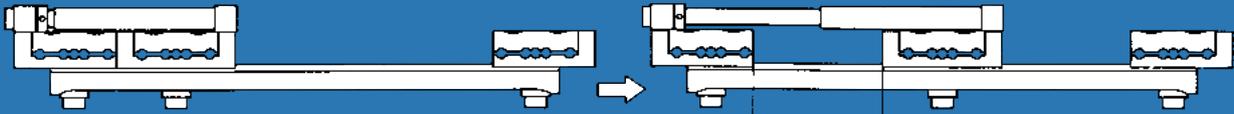
(a) With the compression-distraction units (10008) and (10009) positioned as shown, there are gaps x and y between the clamps.



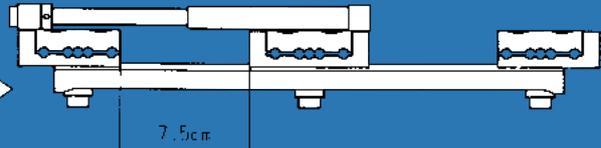
(b) A maximum of 4cm of distraction can be achieved with compression-distraction unit 10008, and 8cm with compression-distraction unit 10009.

EQUIPMENT REQUIRED

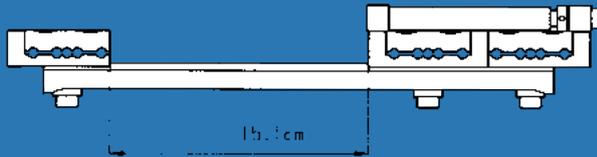
50500 Standard Model Bone Transport



(a) The two outer clamps positioned at the extremities of the rail and middle clamp in contact with one outer clamp.

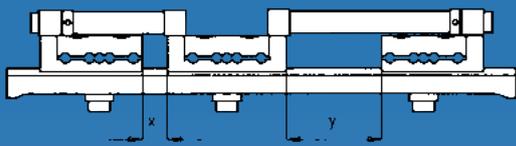


(b) With the compression-distraction unit (10009) positioned as shown, the maximum distraction possible is 7.5cm.

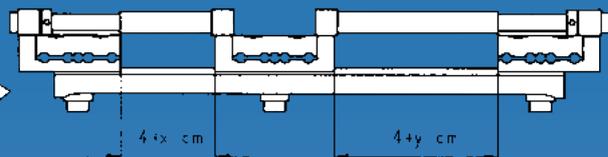


(c) The distraction may be increased to 15.1cm by changing the position of the compression-distraction unit from that shown in (b) to the above position and applying compression.

Bifocal Lengthening

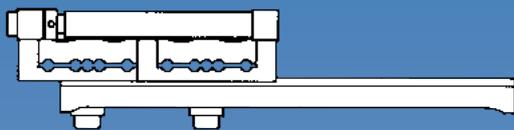


(a) With the compression-distraction units (10008) and (10009) positioned as shown, there are gaps x and y between the clamps.

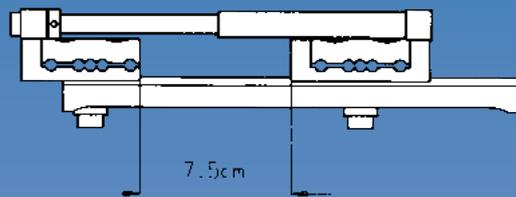


(b) A maximum of 4cm of distraction can be achieved with each compression-distraction unit.

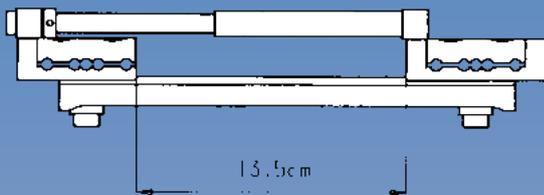
50515 Short Model



(a) One clamp at the extremity of the rail and the other clamp in contact with it.

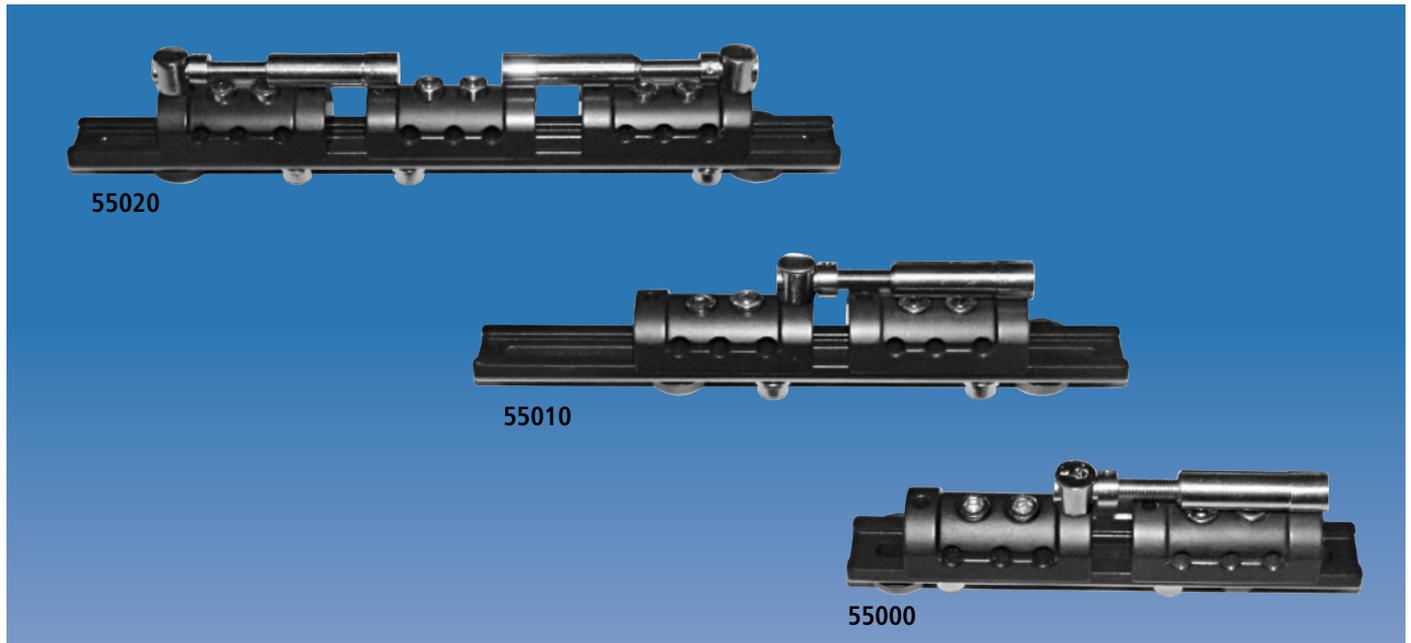


(b) With the compression-distraction unit (10009) positioned as shown, the maximum distraction possible is 7.5cm.



(c) The amount of distraction may be increased to 13.5cm by changing the position of the compression-distraction unit from that shown in (b) to the above position and applying further distraction.

Pediatric Models



55020 Long Model

Length 250mm
with 3 clamps and 2 compression-distraction units.

55010 Standard Model

Length 200mm
with 2 clamps and 1 compression-distraction unit.
Since this model has only two clamps, it cannot be used for multilevel surgery.

55000 Short Model

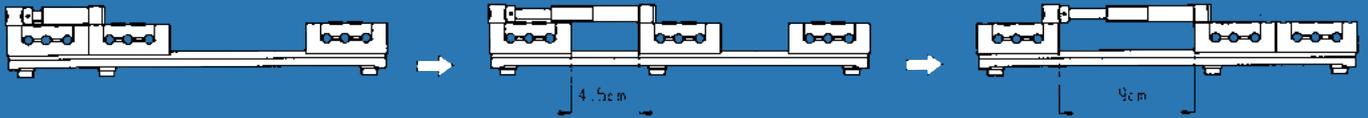
Length 150mm
with 2 clamps and 1 compression-distraction unit.
Since this model has only two clamps, it cannot be used for multilevel surgery.

These models were designed for use in children under the age of 10, but may also be appropriate for forearm applications in adults.

An Extra-Short Rail (55055, 10cm long) is also available. The amounts of distraction that can be achieved using the pediatric models in conjunction with compression-distraction unit 30008, for bone transport or bifocal lengthening (long model) and monofocal lengthening (standard and short models) are illustrated above.

An additional pediatric compression-distraction unit (55008), which extends to 6.2cm, is also available. When used with the long pediatric model with two clamps for monofocal lengthening procedures it permits lengthening of up to 14.4cm.

**55020 Long Model
Bone Transport**



(a) The two outer clamps positioned at the extremities of the rail and middle clamp in contact with one outer clamp.

(b) With the compression-distraction unit (30008) positioned as shown, the maximum distraction possible is 4.5cm.

(c) The amount of distraction may be extended to 9.0cm by changing the position of the compression-distraction unit from that shown in (b) to the above position and applying further distraction.

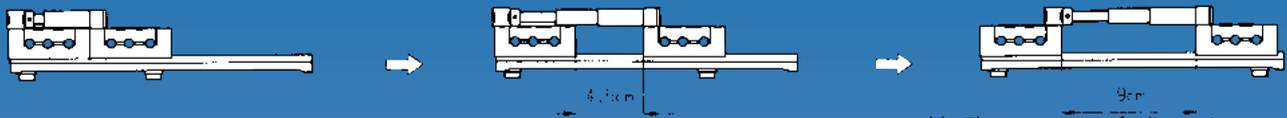
Bifocal Lengthening



(a) All three clamps in contact with one another.

(b) A maximum of 4.5cm of distraction can be achieved with each compression-distraction unit.

55010 Standard Model



(a) One clamp at the extremity of the rail and the other clamp in contact with it.

(b) With the compression-distraction unit (30008) positioned as shown, the maximum distraction possible is 4.5cm.

(c) The amount of distraction may be extended to 9.0cm by changing the position of the compression-distraction unit from that shown in (b) to the above position and applying further distraction.

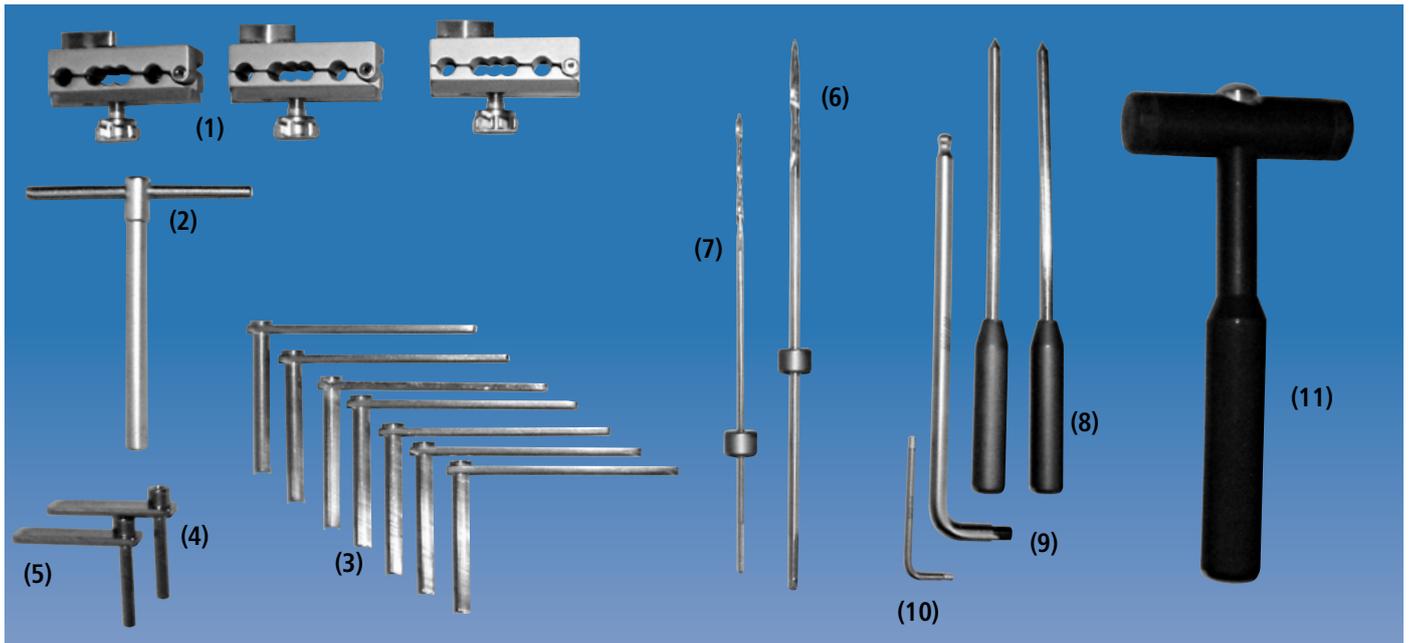
55000 Short Model



(a) One clamp at the extremity of the rail and the other clamp in contact with it.

(b) With the compression-distraction unit (30008) positioned as shown, the maximum distraction possible is 4.5cm.

2. INSTRUMENTATION



(1) Straight Clamp Templates (14107): These replace the straight clamps during screw insertion and are used together with the definitive rail. Three clamp templates are required for bone transport, compression-distraction and bifocal lengthening; two are needed for monofocal lengthening and four for bifocal transport. The seats in the clamp template have a greater diameter than those of the screw seats in the clamp to allow for positioning of the screw guides.

(2) T-Wrench: This is used either for inserting or removing the bone screws.

(3) Screw Guides: These ensure correct positioning of the screws, which must be inserted at right angles to the long axis of the bone. The screw guides are available in different lengths. The length chosen will depend upon the dimensions of the patient's soft tissues. In most cases, medium screw guides will be used in the tibia and long screw guides in the femur.

(4) 4.8mm Drill Guide: This is used in association with the 4.8mm drill bit. The length chosen will depend upon the length of screw guide used.

(5) 3.2mm Drill Guide: This is used in association with the 3.2mm drill bit. The length chosen will depend upon the length of screw guide used.

(6) 4.8mm Drill Bit: This is used when 6/5mm thread diameter cortical screws are to be inserted. Different lengths of drill bit are available. The correct length must be chosen according to the dimensions of the soft tissues it must pass through and the length of the screw guide selected. A mechanical stop on the drill bit is used to prevent excessive penetration into the soft tissues when drilling the second cortex.

(7) 3.2mm Drill Bit: This is used when 4.5/3.5mm thread diameter cortical screws are inserted. It may also be used prior to insertion of cortical screws (standard or HA-coated) into cancellous bone. For choice of correct length see (6) above.

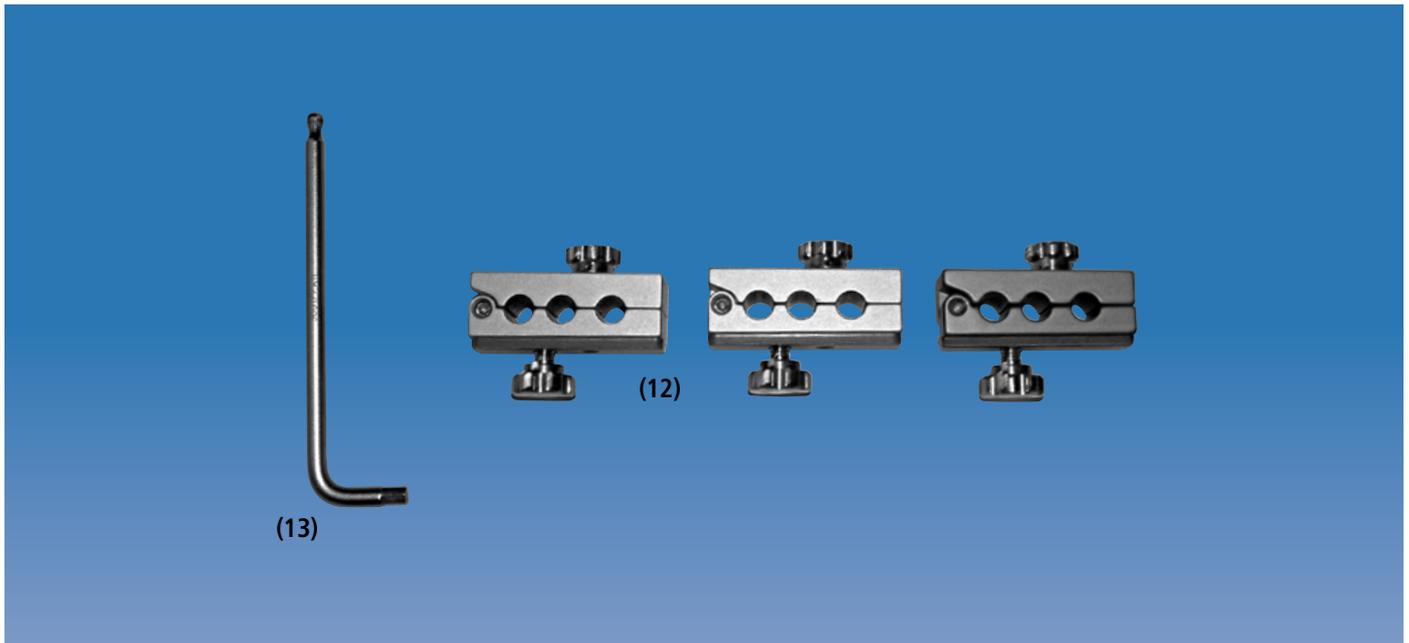
(8) Trocar: This is used within a screw guide to locate an appropriate position on the cortex.

(9) 6mm Polyhedral Allen Wrench: This is used to lock and unlock the clamp screws and the clamp locking screws.

(10) 3mm Allen Wrench: This is used to lock the drill stop unit onto the drill bit.

(11) Hammer.

EQUIPMENT REQUIRED



With the Pediatric Models the following Instrumentation is used instead of items (1) and (9) above:

(12) Pediatric Straight Clamp Templates (15500): Note that these have three seats as compared to five in the adult models.

(13) 5mm Polyhedral Allen Wrench: This is used to lock and unlock the clamp cover screws and the clamp locking screws.

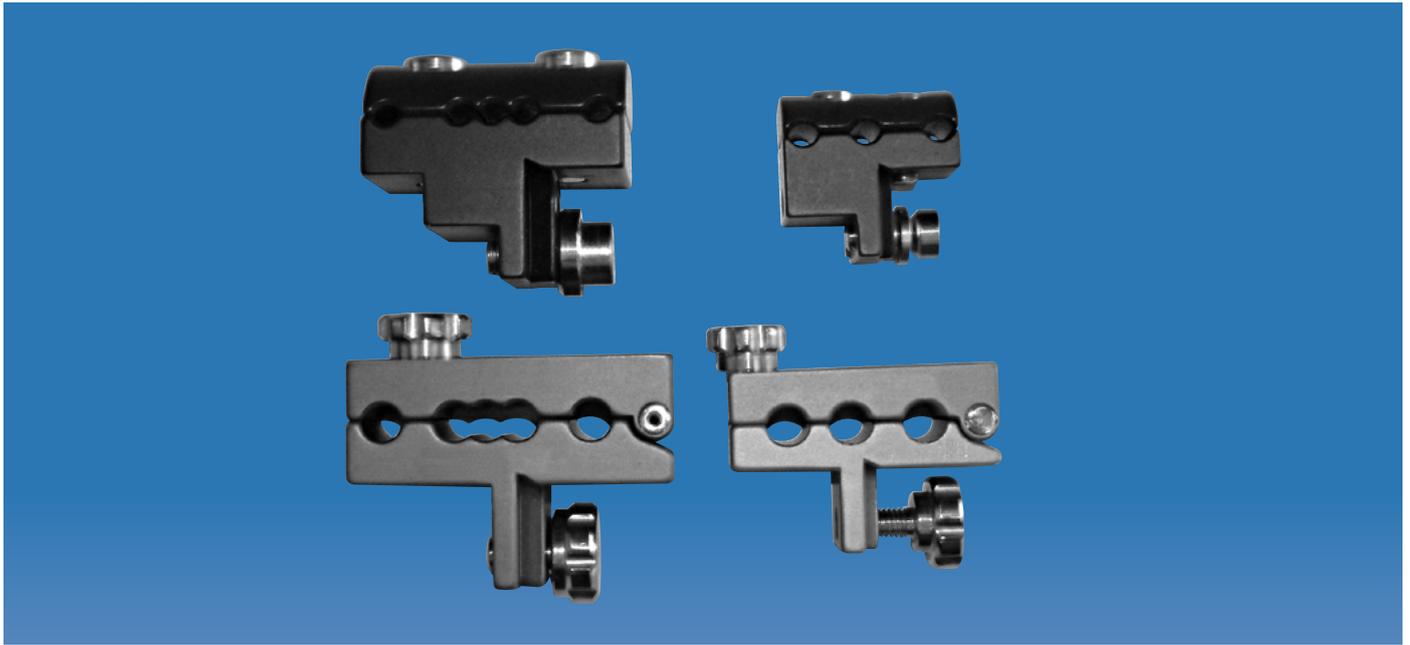
3. SCREWS

Two or three 6/5mm screws are used in each clamp where the diameter of the bone is greater than 20mm. For smaller bones, 4.5/3.5mm screws are used. Screw length and thread length should be estimated from the patient's X-rays, using the Orthofix transparent X-ray overlay. Thread length should be such that about 5mm of thread will remain outside the entry cortex and about 2mm will project beyond the second cortex.

Orthofix OsteoTite Bone Screws with Hydroxyapatite Coating can be used in both metaphyseal and diaphyseal sites for enhanced fixation and improved stability at the pin-bone interface (Magyar G. et al., 1997).

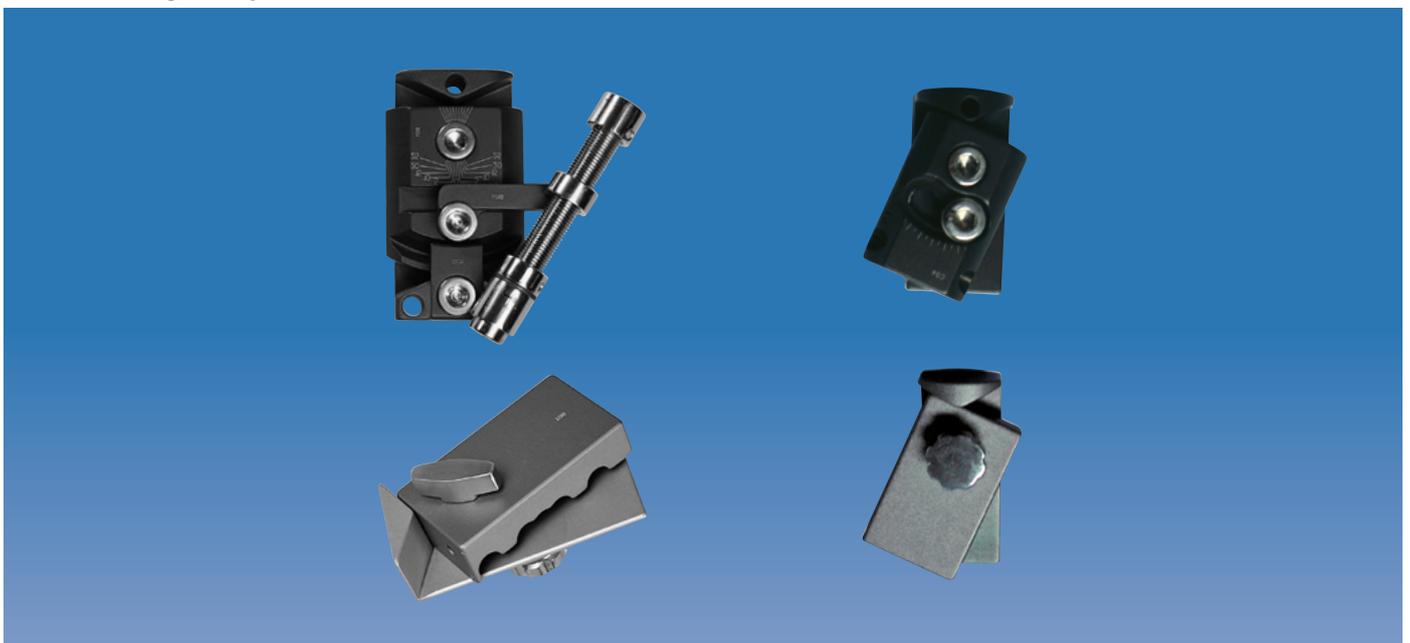
4. ACCESSORY MODULES

The T-Clamp



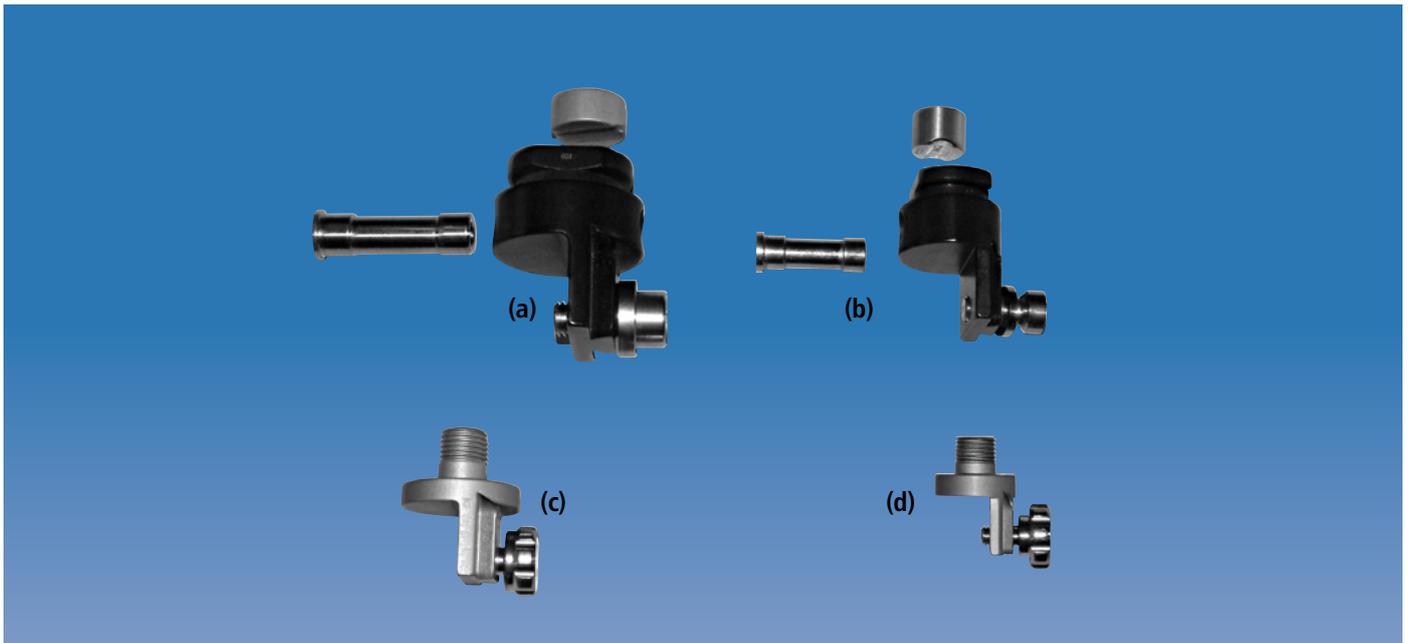
This module (adult 50520; pediatric 55030) may be attached to either end of the rail, but it is not free to slide along it. It has its own template (adult 14108; pediatric 15510). For a description of the use of this module, see page 40.

The Swivelling Clamp



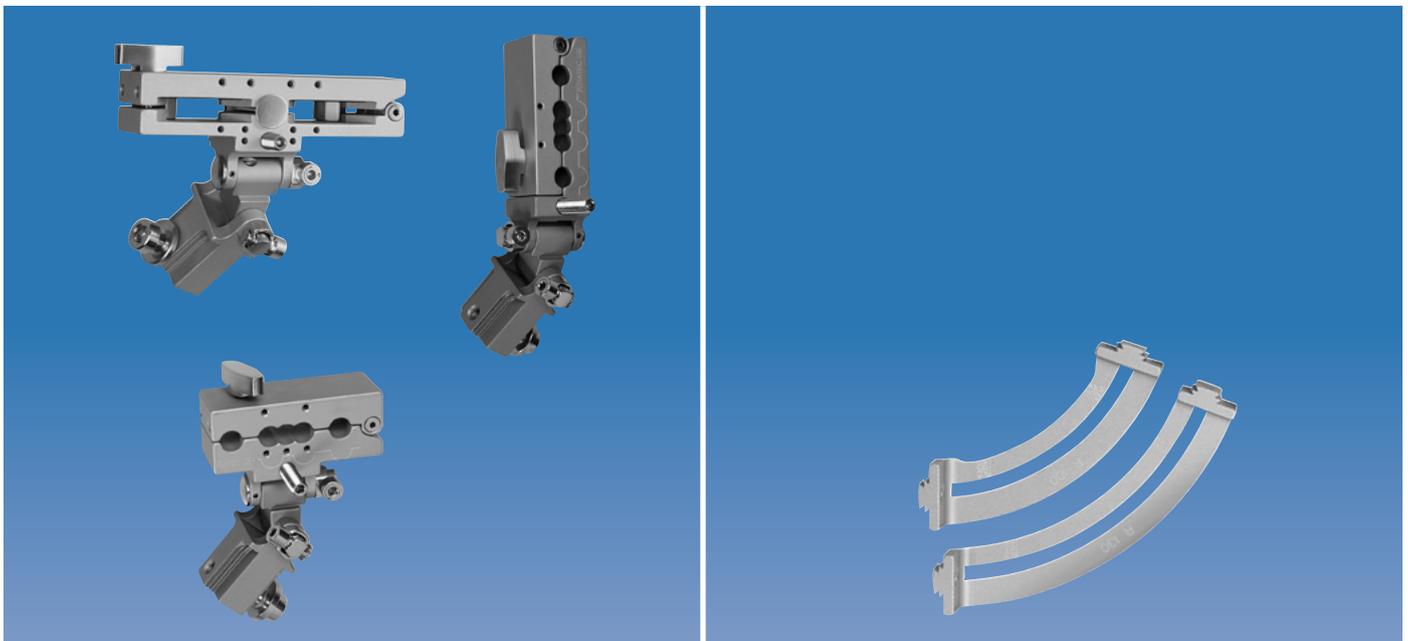
This module (adult 50111; pediatric 55100) allows for correction (up to 50°) of any pre-existing valgus or varus deformity or of a valgus or varus deformity that may have occurred during lengthening or transport. It has its own template (adult 14116; pediatric 15520). For a description of the use of this module, see Manual 11, Part B: Correction of Deformities. The adult model permits gradual correction to be made with the use of a distractor unit (50112).

The Ball-Joint Coupling



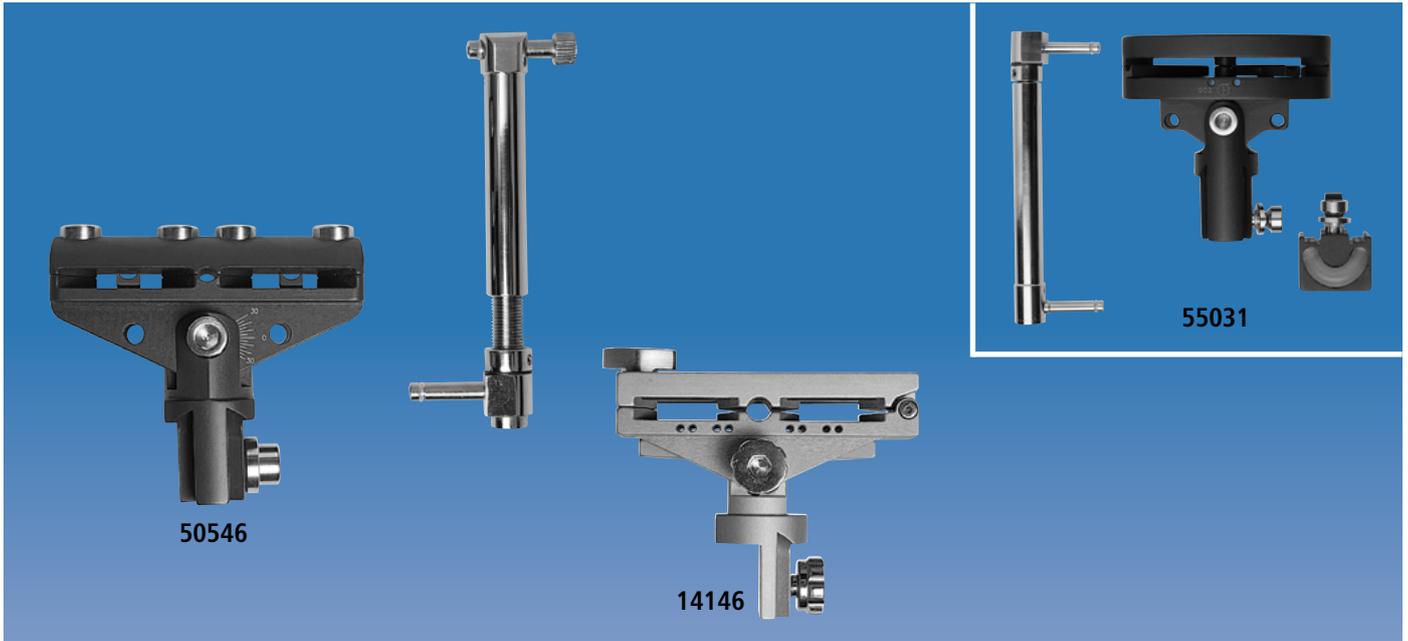
This module (adult 50541 **(a)**; pediatric 55041 **(b)**) may be attached to either end of the rail, but it is not free to slide along it. When used with any Orthofix ball-jointed module, it enables precise, immediate corrections to be made at an osteotomy or deformity site. In its unlocked state, the ball-joint allows free rotation and up to 36° of angulation of the clamp in all planes. Once the desired correction has been achieved, the ball-joint is locked using the torque wrench (see Manual 1 "Orthofix External Fixation: Basic Considerations"). The ball-joint coupling has its own template (adult 14130 **(c)**; pediatric 15530 **(d)**), which is used in association with the clamp template of the selected ball-jointed module.

The Acute Correction Templates



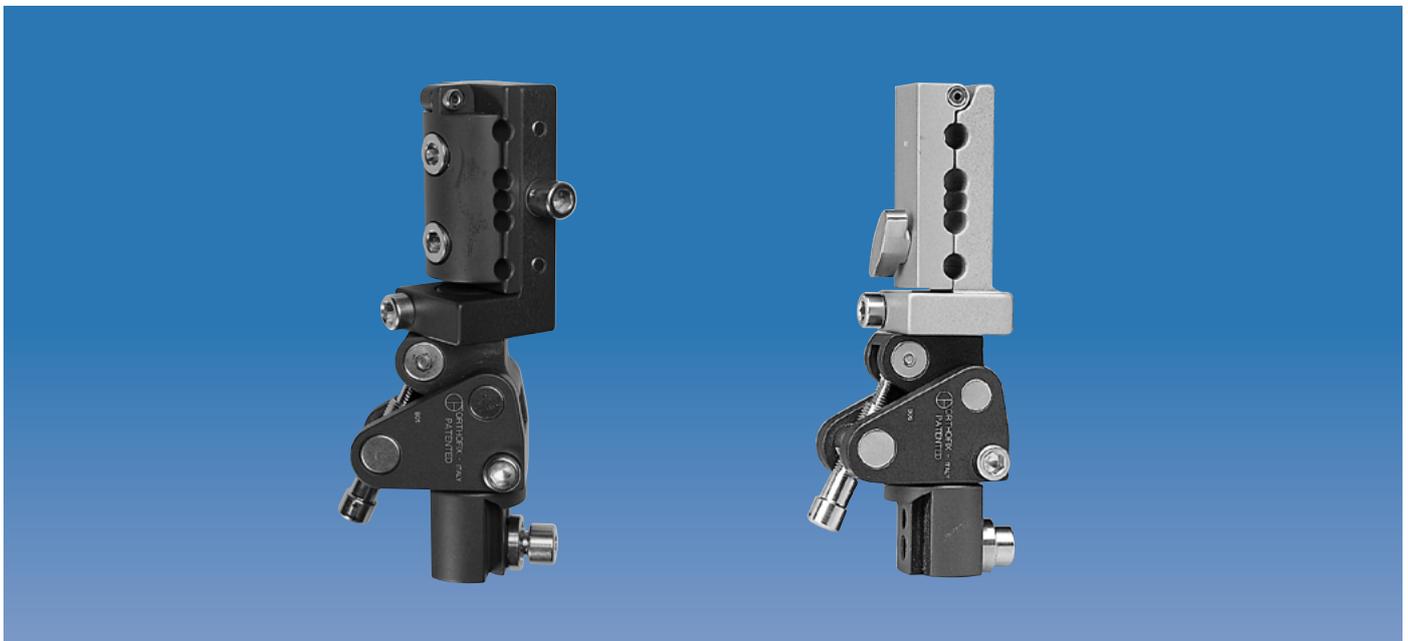
These templates for angular and rotational correction may be attached to the rail in order to insert screws to reflect the deformity. The angular correction templates are mounted on the end of the rail but the rotational correction templates are free to slide along the length of the rail. They may be used to correct angulation in any plane or rotational deformities. For a description of the use of these templates, see Manual 11, Part B: Correction of Deformities.

The OF-Garches T-Clamp



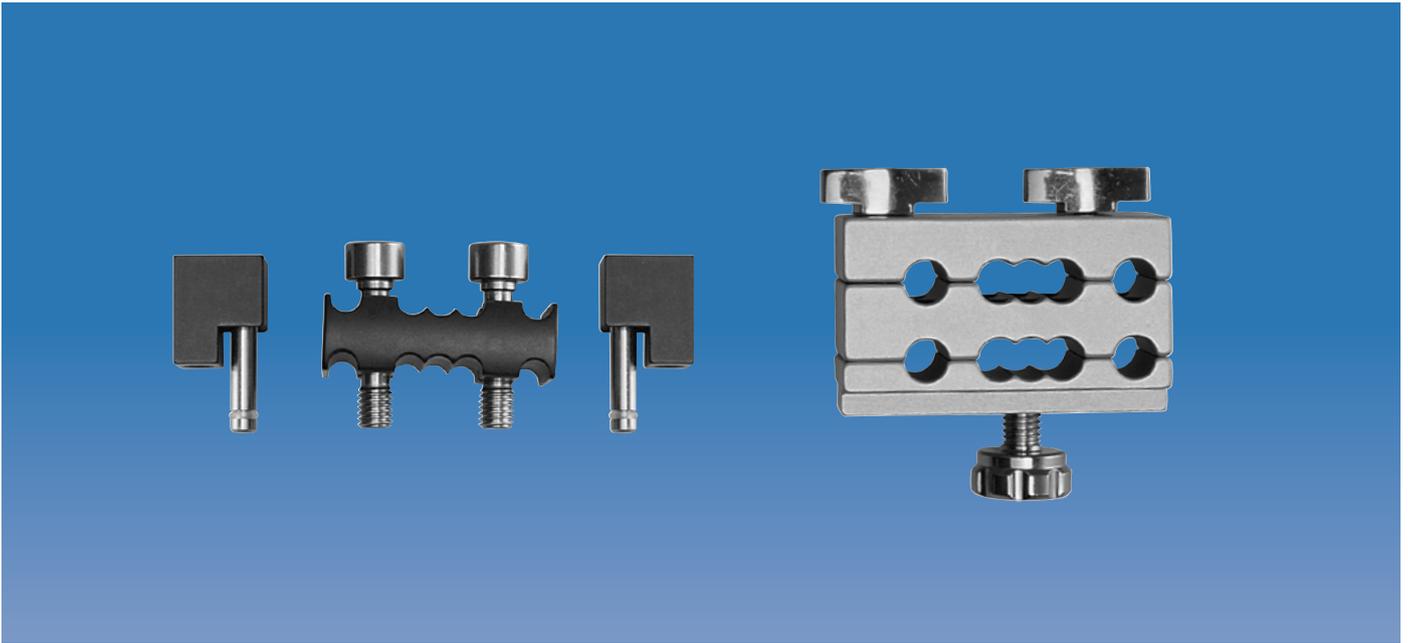
This module (50546) may be attached to one end of the rail. It permits tibial lengthening in the upper metaphyseal region, allowing better control of valgus or varus deviation. It can be used in cases of tibia vara or tibia valga for gradual or immediate angular correction. It has its own template (14146). The OF-Garches T-Clamp can move in one plane only, and has swivelling screw seats that allow convergent siting of the outer screws. The compression-distraction unit (20005 long, 20004 standard) may be attached in one of two ways, depending upon whether lengthening or angular correction is desired. A Pediatric OF-Garches T-Clamp Kit is also available (55031). For a description of the use of this module, see pp. 40-43 of this manual, and also in Manual 11, Part B, Correction of Deformities.

The Multiplanar Clamp



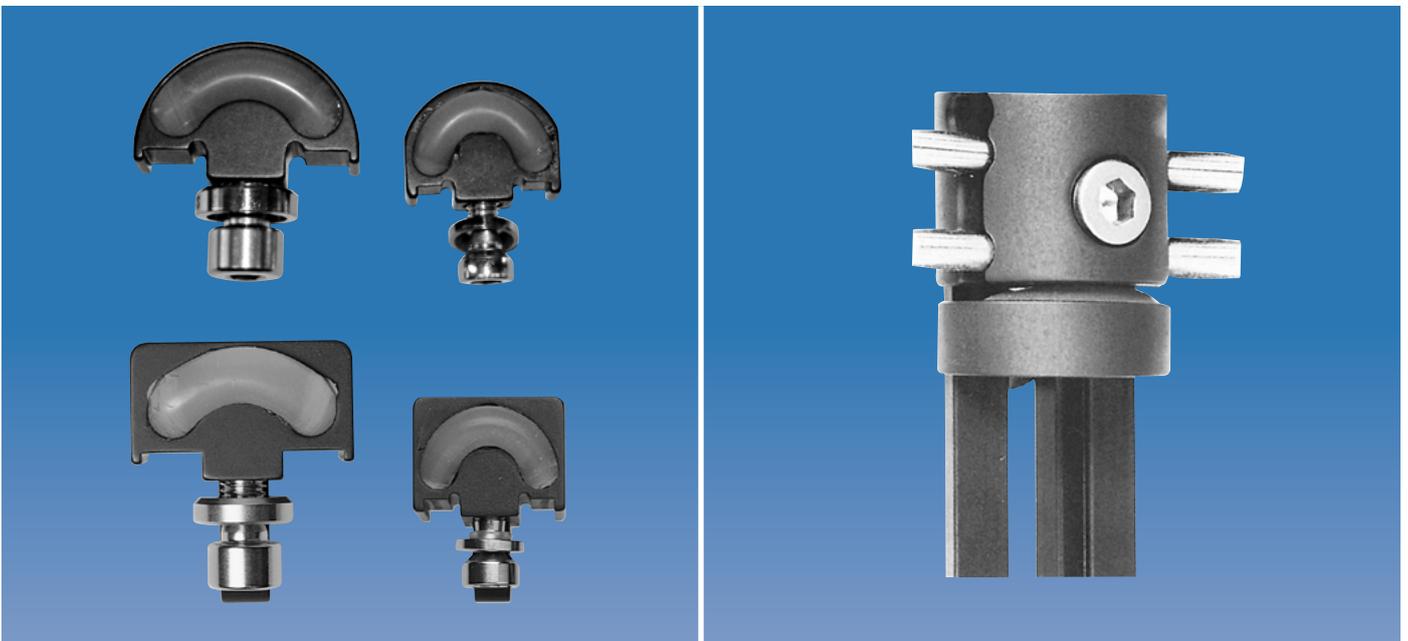
This clamp (50580) can be attached to either end of the rail, but it is not free to slide along it. It may be used for the gradual correction of angular deformity up to 70° (including translation up to a maximum of 12mm) in any plane. It has its own template (14109), which replaces the clamp element and is attached to the angular correction element. For a description of the use of this module, see Manual 11, Part B: Correction of Deformities.

The Sandwich Clamp



The Sandwich Clamp (50547) allows the surgeon to raise the plane of the screws above the rail or to place them in two planes, as described on page 23. It has its own template clamp (14147).

The Dyna-Ring



This module (adult 50535; pediatric 55035) is locked to the rail with its silicone cushion facing the clamp that has been unlocked for dynamization, and just in contact with it. When attached in this way, it permits only limited dynamization of the segment concerned and acts as a safeguard against collapse. The Dyna-Ring allows earlier conversion from a rigid to a dynamic mode and a corresponding reduction in the neutralization period. A guide to its use is as follows (Pouliquen J.C., 1992): when, after a variable period in neutralization, the callus shows evidence of early corticalization, the Dyna-Ring is attached to the rail as described above. At follow up, if the Dyna-Ring cushion appears compressed, the clamp is again locked to the rail and the Dyna-Ring offset from the clamp until it has regained its shape and is once again just in contact with the clamp. When, on subsequent review the Dyna-Ring no longer appears compressed, it may be left in this position until full corticalization is evident. A model with compression-distraction unit attachment is also available (adult 50536; pediatric 55036).

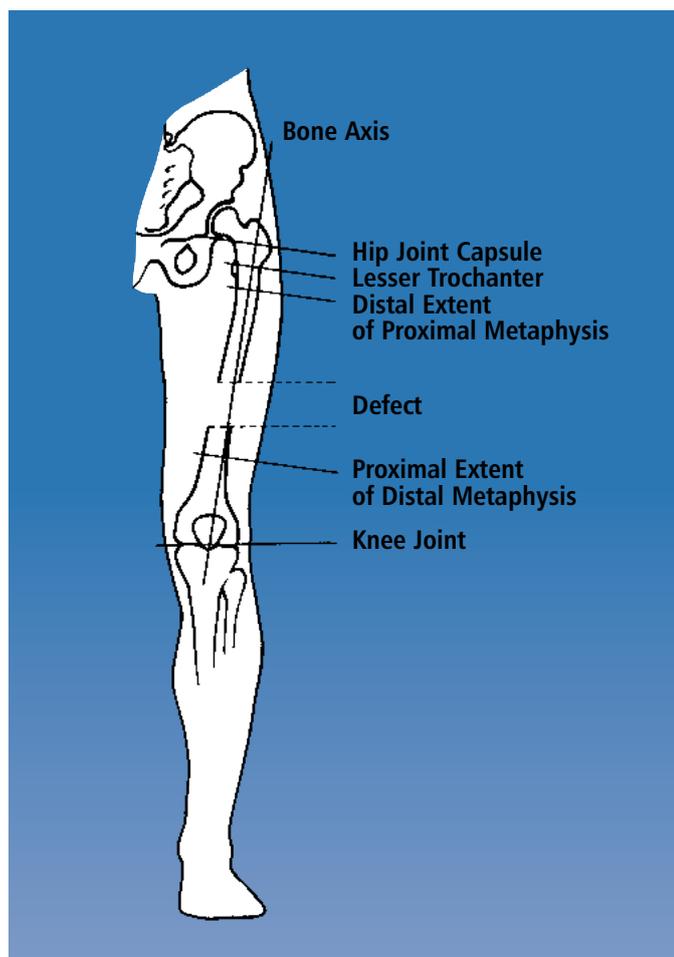
A. BONE TRANSPORT

A) DISTAL BONE LOSS IN THE FEMUR

The technique of bone transport is described in detail for the femur, but the principle is the same for any long bone application. Since major use of the system will be in lower limb surgery, specific differences between its application in the femur and the tibia will be considered.

Pre-Operative Planning

AP and lateral radiographs of the whole affected femur are taken. A radio-opaque scale incorporated in a comparative X-ray may be helpful in determining both bone loss and shortening. This enables selection of the correct length rail and allows for planning of screw positions. A weightbearing X-ray from hip to ankle may be required if correction of a deformity is involved. Other investigations will depend on the pathology.



Operative Technique

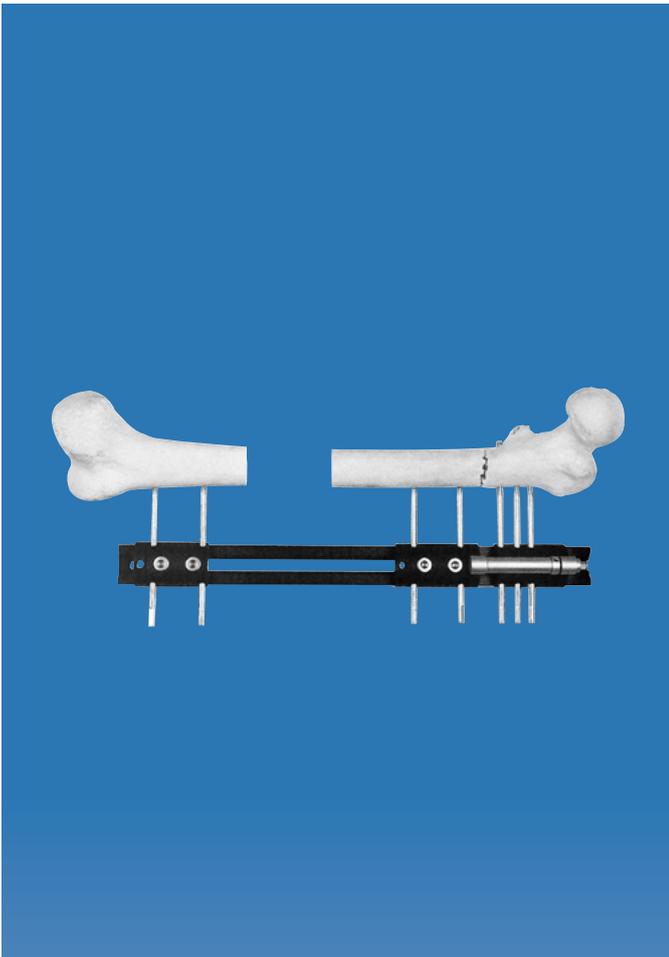
A radiolucent table is used and the Image Intensifier placed at right angles to the table on the opposite side of the patient to the surgeon. A sandbag is placed under the lower back and buttock to bring the leg from its normal externally rotated position to neutral, making sure that the image of the hip will not be obscured. Where there is an unstable segment, care must be taken when handling the limb. The skin of the whole limb should now be prepared, from the toes to the lower abdomen. A disposable U-drape should be used to isolate the perineum. The U-drape should be applied in such a way that the leg can be moved freely. The Image Intensifier should be used to identify important bony landmarks, namely, the lesser trochanter, the end of the proximal metaphysis, the beginning of the distal metaphysis and both joints. A marking pen is used to indicate these landmarks on the skin. Each mark is made perpendicular to the axis of the bone so that a line drawn at right angles defines the axis of the bone and will be parallel to the final position of the fixator. The position of the defect should also be marked together with any other landmarks to be avoided, e.g. the position of previous screw sites or implants.



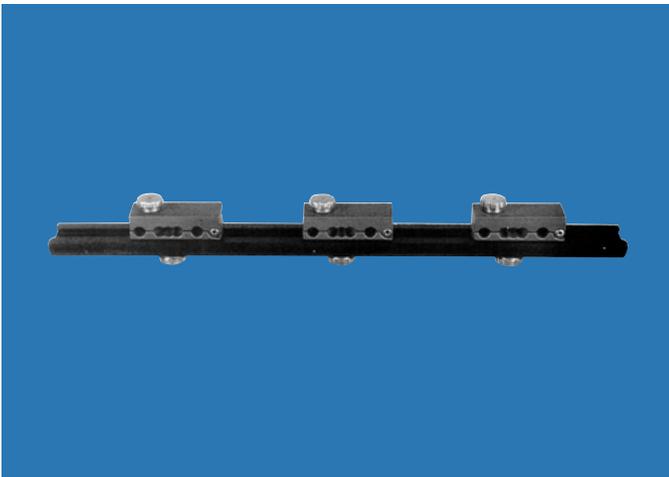
PRECAUTION: During and after insertion of the implants, ensure their correct positioning under image intensification.

A. BONE TRANSPORT

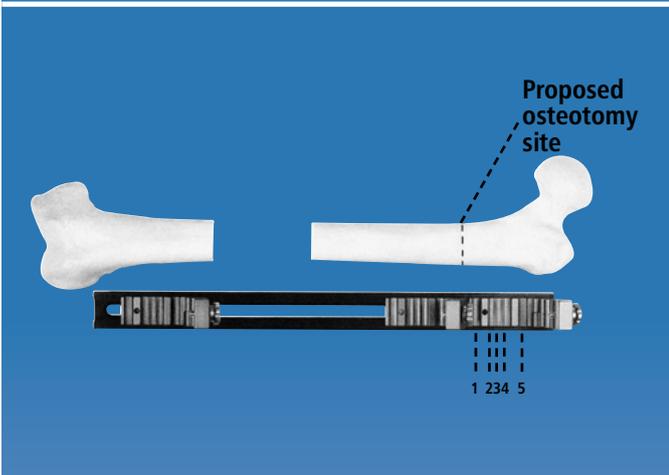
With the defect in the distal femur, proximal osteotomy and proximal to distal transport are indicated.



The clamp templates are first assembled on the rail with their locking screws loosened to allow free movement.



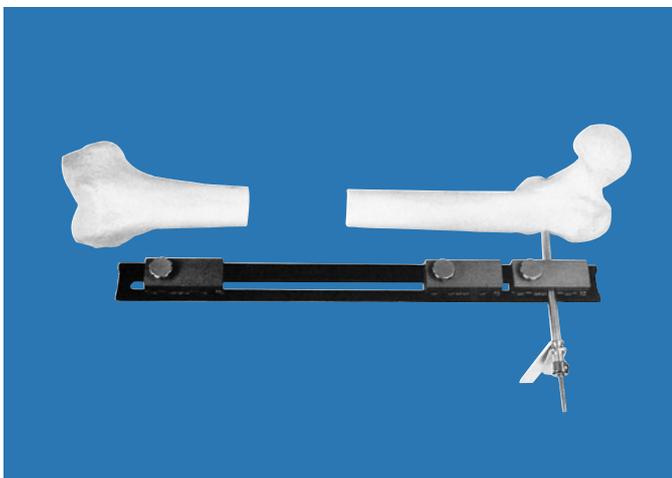
The precise positions of the clamps and screws should now be planned. Use of the 1 and 5 positions in the clamps will provide the greatest stability, but in the proximal clamp, with a high osteotomy 1.5cm below the most distal screw, screw seats 1 and 4 or 1, 2 and 4 (numbering from the proposed osteotomy site) should be used. Hydroxyapatite coated (OsteoTite) bone screws are strongly recommended for limb reconstruction procedures. A 3.2mm drill bit is generally recommended for cancellous bone applications whether standard or HA-coated screws are used. Occasionally, especially in younger patients, the first cortex only may require drilling with a 4.8mm drill bit prior to screw insertion.



A. BONE TRANSPORT

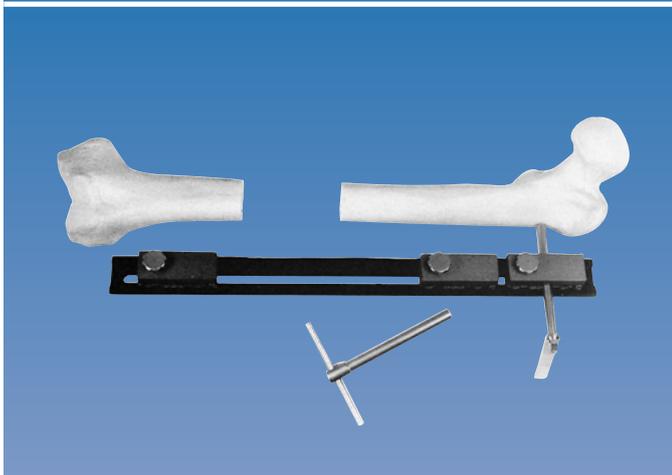


The first screw to be inserted is the most proximal one. It will engage the thick calcar bone at a point just above the lesser trochanter, avoiding the capsule of the hip joint. (Where there is a varus deformity of the femoral neck, the first screw is placed anterior to, but at the level of, the lesser trochanter). When the surgeon has become an expert in the technique, it is possible to insert this screw freehand. Initially, however, this screw should be inserted with the aid of the template to ensure that the rail will be parallel to the long axis of the bone. A longitudinal skin incision is made and the soft tissues separated down to the bone by blunt dissection. The vastus ridge concavity is scraped gently with an elevator to provide good purchase for the screw guide. The appropriate length screw guide is now selected and inserted into the incision using the trocar to locate the mid-point of the bone. It is then locked into the fourth seat of the proximal clamp (counting from the site of the proposed osteotomy), with the locking screws of the template clamps loosened so that they can all move freely on the rail. With an assistant holding the rail in the correct position, parallel to the long axis of the bone, the surgeon ensures that the screw guide is in a plane 15° anterior to the coronal plane. Since the natural position of the leg in bed is in slight external rotation, positioning of the screws antero-laterally will avoid undue pressure being exerted upon them. At this point the proximal clamp template is locked to the rail. Orthofix OsteoTite Bone Screws: The use of hydroxyapatite coated screws in this type of procedure is strongly recommended, because fixation time is likely to be prolonged. In any case, three evenly spaced screws in each clamp are strongly recommended for all but the lightest adults and children.



The proximal clamp cover is now tightened. Using gentle pressure to keep the screw guide in contact with the cortex, the trocar is withdrawn, and the screw guide tapped lightly with a hammer to engage its teeth in the cortex. The correct length 4.8mm drill guide is now inserted into the screw guide and, using a 4.8mm drill bit, the first and second cortices are drilled. It is advisable to use a drill stop offset by 5mm once the second cortex is reached to prevent damage to the soft tissues beyond it.

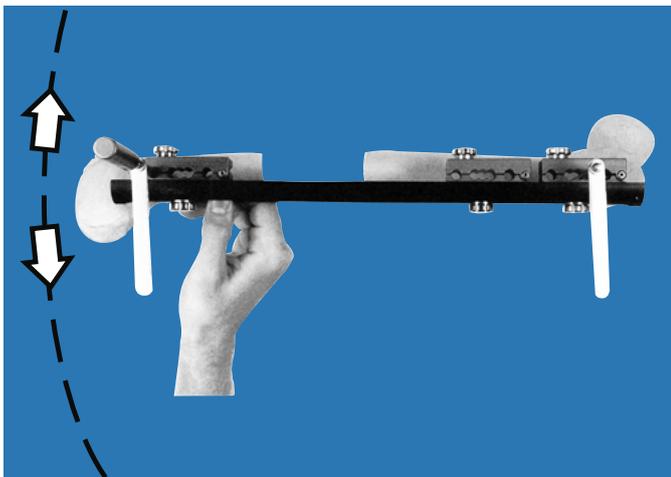
 **WARNING:** Do not excessively penetrate the second cortex with any type of screws to avoid soft tissue damage.



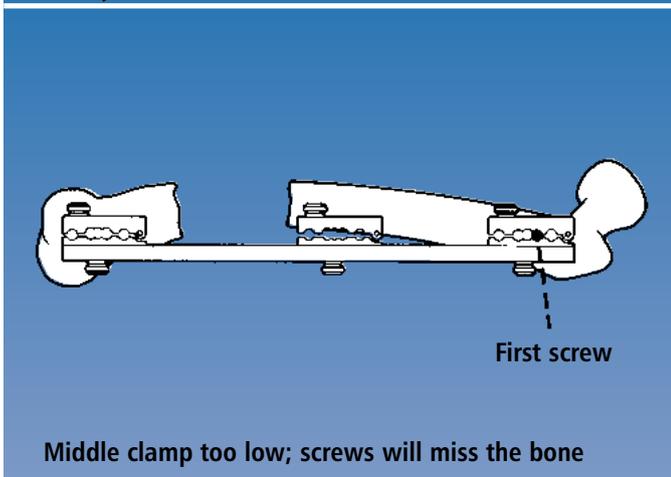
The drill bit and drill guide are now removed while maintaining pressure on the screw guide handle, and a cortical screw of appropriate dimensions inserted using a T-wrench. A slight increase in resistance is normally felt as the screw penetrates the second cortex. At this point, a further 5 or 6 half turns are required to ensure that about 2mm of the screw thread will project beyond the second cortex. This should be verified using the Image Intensifier.

 **PRECAUTION:** During and after insertion of the implants, ensure their correct positioning under image intensification.

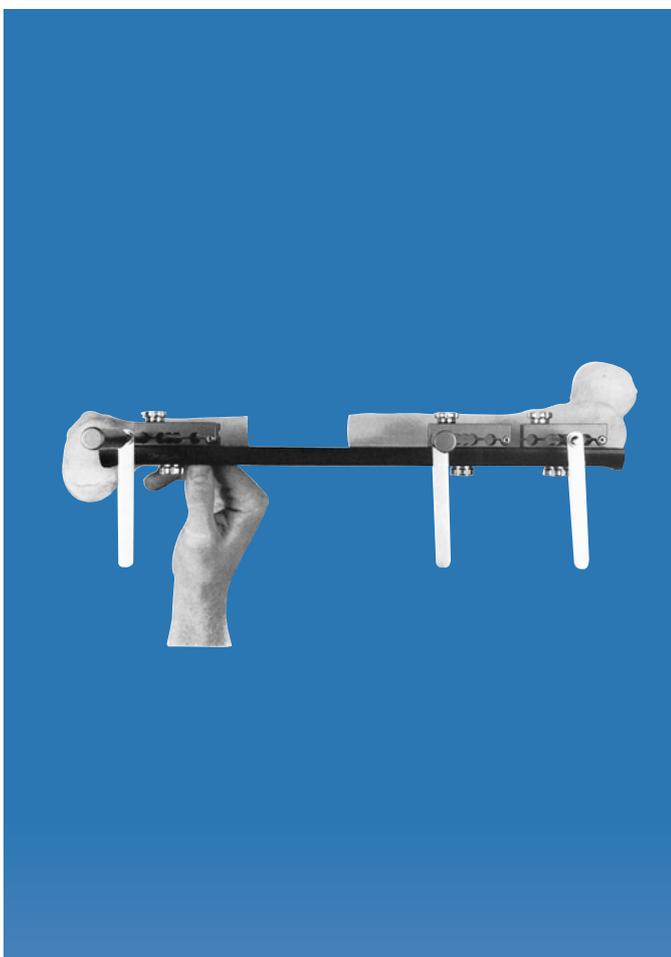
A. BONE TRANSPORT



The next screw to be placed will be the most distal one. The skin incision is made and the soft tissues separated down to the bone. An assistant now places the screw guide and trocar in the most distal seat of the distal clamp, introduces them into the incision and with the rail pivoting on the first screw, identifies the center of the bone at this point.



The position of this distal screw is critical since, if it is incorrectly sited, the screws in the middle clamp (which will be used to transport the bone segment) may miss the bone.

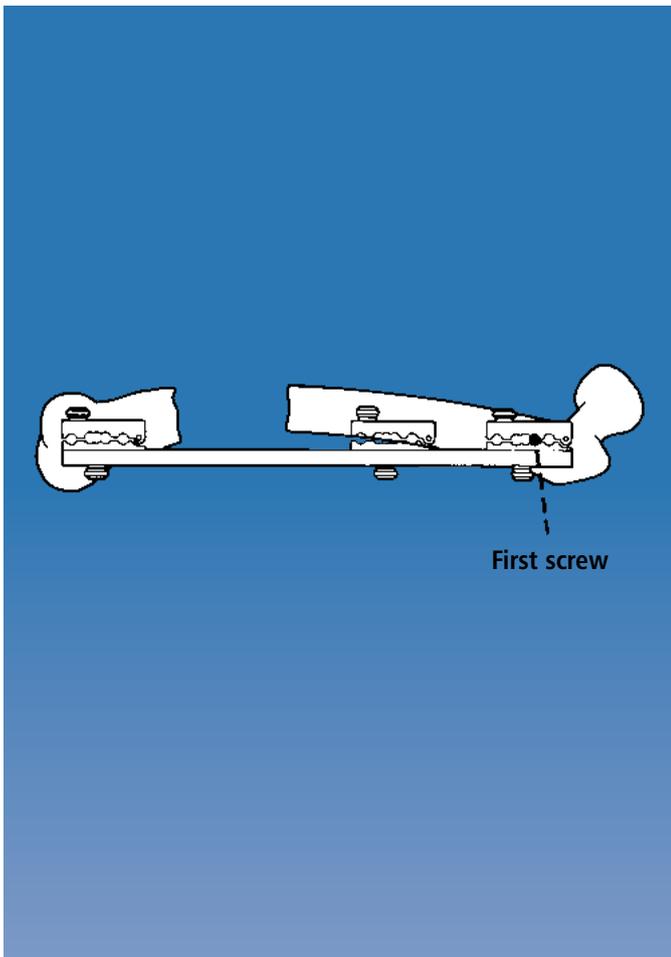


The surgeon now chooses a position for the middle clamp. It is important to ensure that the middle clamp is not placed so close to the advancing end of the middle segment that it would abut against the distal clamp before the bone ends have docked. Skin incisions are made and a second trocar and a screw guide used to check that screws sited in the outer seats of the middle clamp will penetrate the center of the bone.

 **PRECAUTION:** Diaphyseal bone screws and wires should always be inserted perpendicular to and in the center of the bone axis to avoid weakening it.

If the middle clamp is too low or too high on this test, its position can normally be corrected by asking the assistant to move the distal end of the rail either anteriorly or posteriorly until a more satisfactory position is identified. If, however, after exploring all possible positions for the most distal screw, one or both of the screws in the middle clamp would fail to engage the bone, a number of measures may be attempted.

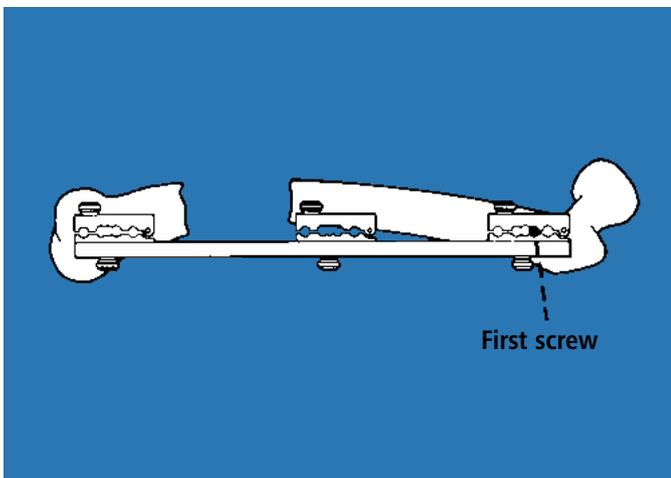
A. BONE TRANSPORT



Only one of the middle clamp screws would engage the middle segment.

In these circumstances, there are four possible solutions:

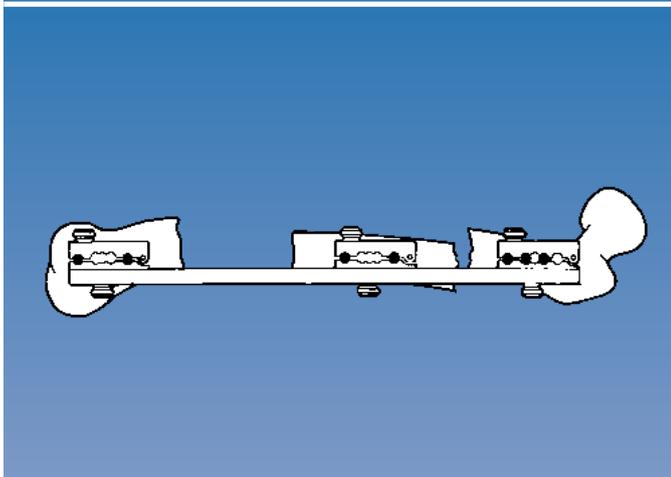
1. The middle clamp may be moved either more proximally or more distally.
2. It may be possible to use another available screw seat.
3. The proximal bone segment may be moved either anteriorly or posteriorly, through an angle of not more than 5-10°.
4. The Sandwich Clamp may be used for the middle segment (see page 23).



Both of the middle clamp screws failed to engage the middle segment.

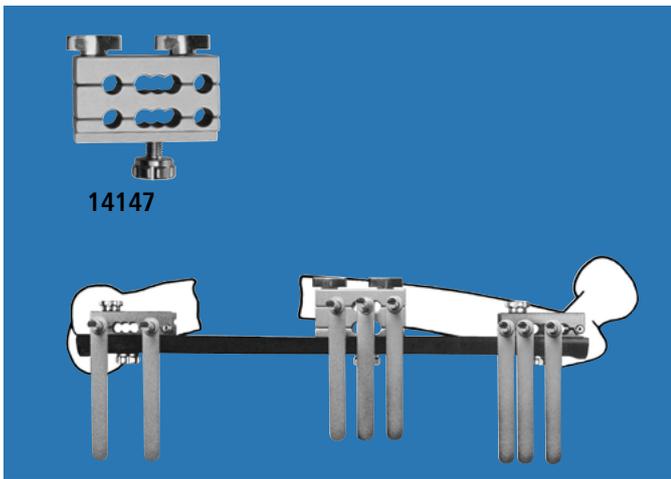
In these circumstances, there are five possible solutions:

1. An attempt should be made to locate the middle clamp in a more favorable position by moving it either more proximally or more distally within the middle segment.
2. The proximal bone segment may be moved either anteriorly or posteriorly, through an angle of not more than 5-10°.
3. The first screw may be resited.

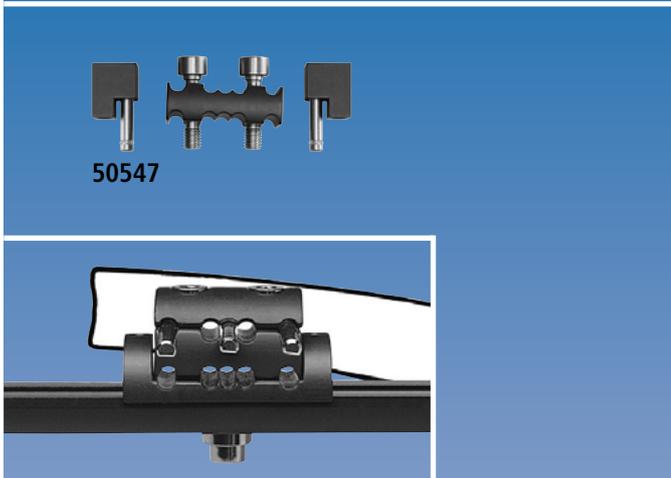


4. The osteotomy may be performed and the middle segment displaced either anteriorly or posteriorly.

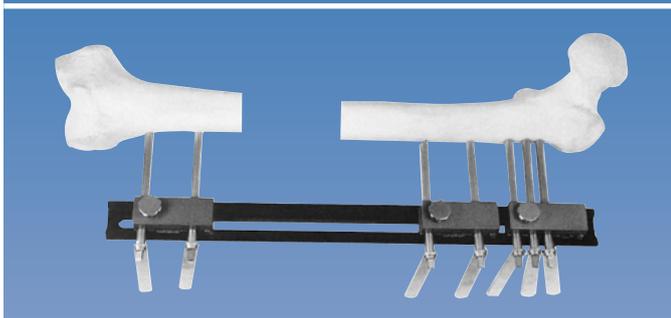
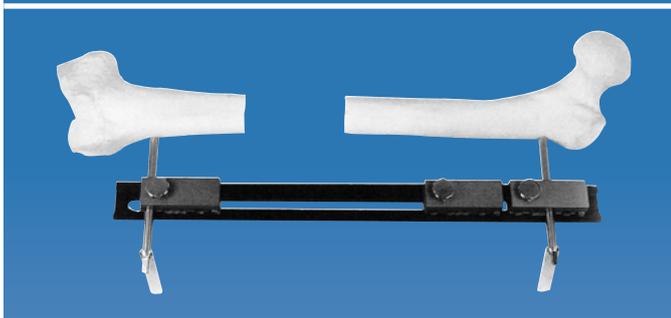
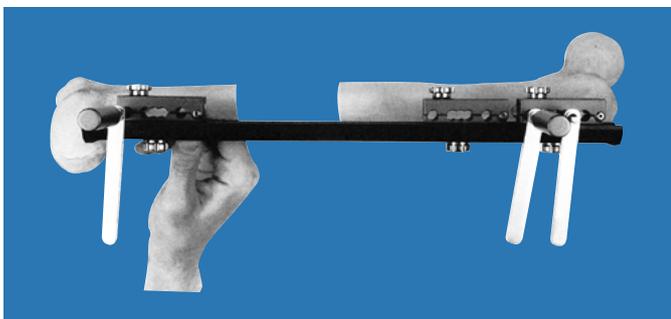
A. BONE TRANSPORT



14147



50547

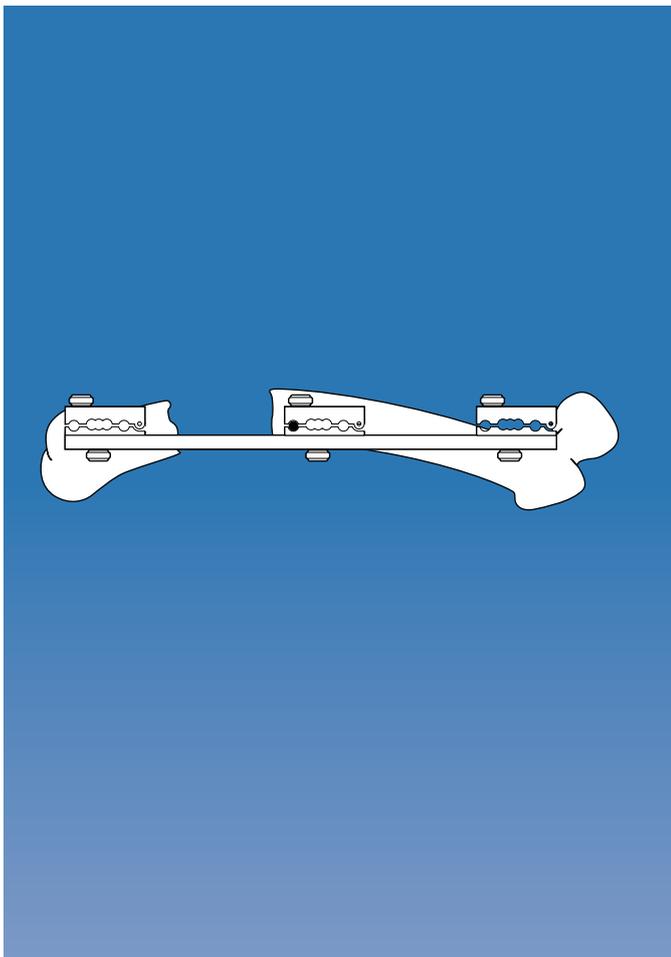


5. A Sandwich Clamp (50547) may be used to raise the position of screw insertion above the rail. It is useful when the femur is curved, as above, to allow placement of screws in the middle clamp in the center of the bone. It may also be used for metaphyseal screw insertion to allow screws to be inserted at two levels for better fixation. There is an accompanying template clamp (14147). Both are used with longer clamp locking screws to allow fixation to the rail. Extension pieces (compression-distraction unit attachments) for the seating of the compression-distraction modules are provided.

With the assistant holding the distal clamp firmly in place, the surgeon checks in a similar fashion that satisfactory screw insertions can be achieved at chosen sites in the proximal and distal clamps. In every case, a guide to correct positioning will be provided both by the bony resistance encountered by the trocar and the audible sound as it strikes the bone.

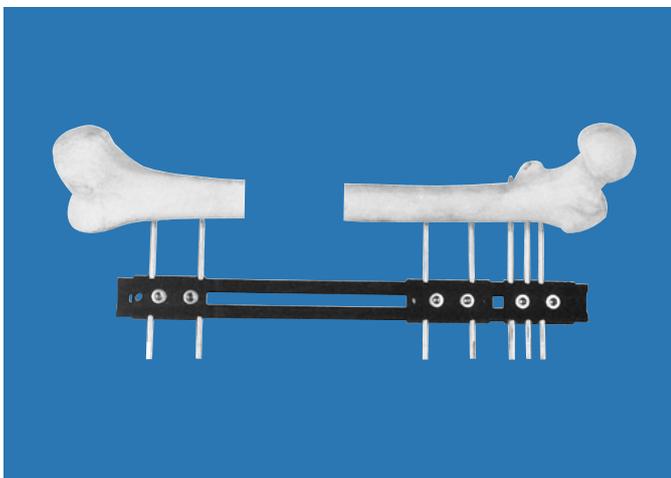
Once this has been achieved, the clamp templates are locked to the rail, which is held in position while the most distal screw is inserted using the standard technique.

The remaining screws are now inserted in the normal way, using the screw seats indicated (see page 19).



Alternative Method for Ensuring Correct Screw Placement

The method described above, where the first screw is inserted proximally, is generally recommended. Where the bone is excessively curved or diaphyseal deformity exists, however, an alternative method may be tried. One of the two screws in the middle (diaphyseal) clamp is inserted first. The two trocars are inserted through each of the outer clamps onto the bone. If one is not centrally placed, the rail is pivoted around the middle clamp screw until satisfactory positioning of both outer clamps is achieved. A Sandwich Clamp may also be very useful in this situation.

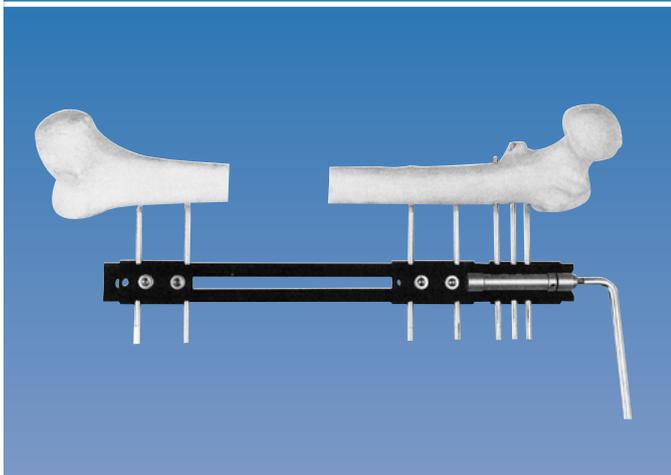


The definitive Limb Reconstruction System is now applied.

The assistant steadies the leg while the clamp template screws are loosened, so that the rail and clamp templates can be removed together with the screw guides. The protruding screw shanks should now be cleaned. The clamp templates are exchanged for three straight clamps. The assembly is now reapplied with the clamp locking screws and the clamp cover screws loosened. When applying it, adequate distance (about 2cm) should be left between the skin and the rail.



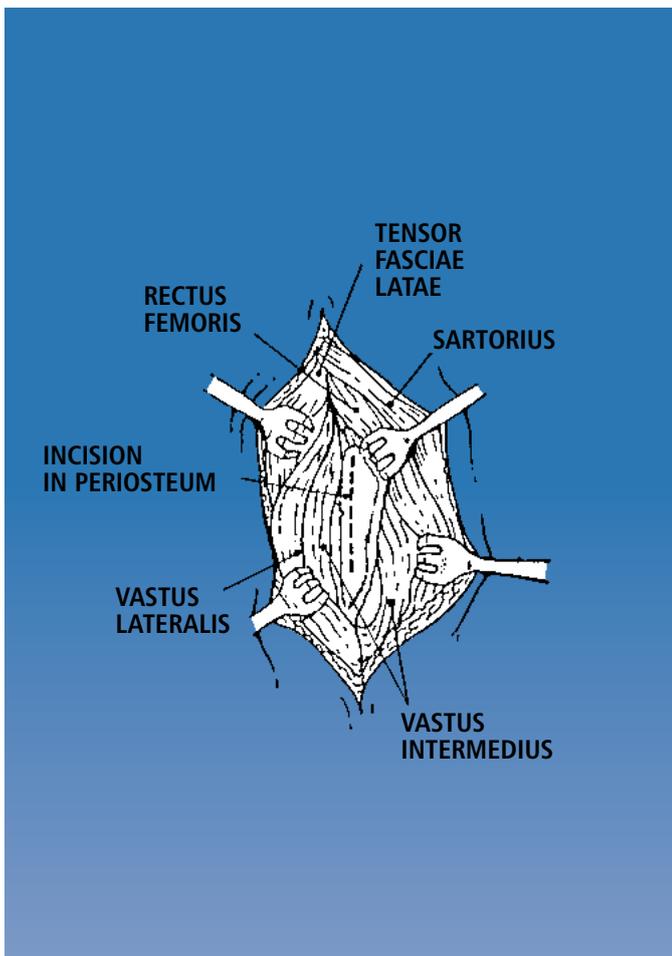
WARNING: The fixator should be applied at a sufficient distance from the skin to allow for post-operative swelling and for cleaning, remembering that the stability of the system depends upon the bone-fixator distance. If the fixator is sited at a distance of more than 4cm from the bone, the use of 3 screws per clamp is advisable.



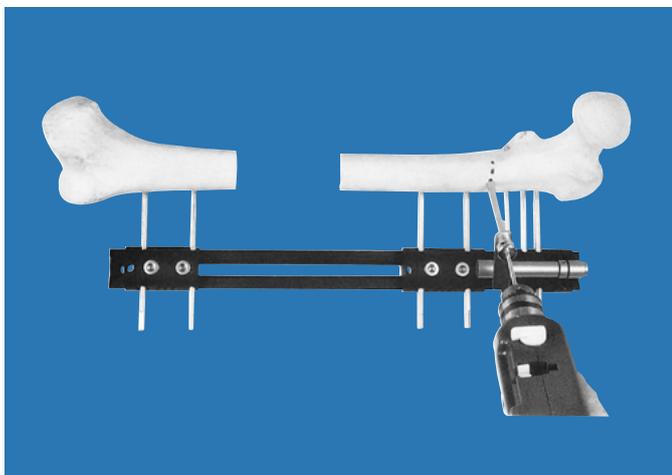
Tension Osteotomy

With the clamps locked into position on the rail, the compression-distraction unit is placed between the upper and middle clamps. The middle clamp locking screw is now loosened and 3 to 4mm of distraction applied. The end point is reached when firm resistance is met on turning the Allen Wrench. This represents the first stage of the tension osteotomy.

A. BONE TRANSPORT

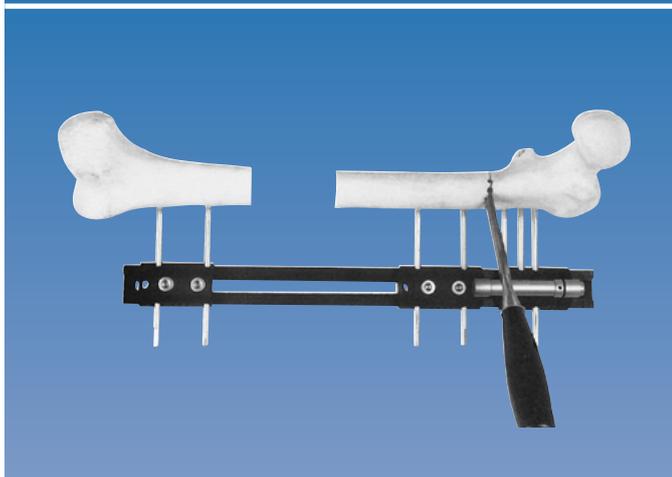


The site of the osteotomy is approximately 1.5cm below the distal screw of the proximal clamp. The bone is exposed via an anterior incision dividing the deep fascia and proceeding between the rectus femoris medially and the vastus lateralis laterally, separating the fibers of vastus intermedius to expose the periosteum covering the femur. The periosteum must be incised longitudinally and carefully detached from the cortex. Bone levers are placed on either side of the bone to hold the muscle and periosteum away from the bone surface. Some surgeons with experience in this field are now performing osteotomies by a minimally invasive technique. A 15-20mm incision is made, the soft tissues cleared down to the bone and a screw guide inserted, exactly as in the standard technique for screw insertion. Care is taken to ensure that it is in contact with the bone throughout the drilling procedure. A drill guide is inserted, and the steps outlined below are carried out. The periosteum cannot be sutured in this technique.



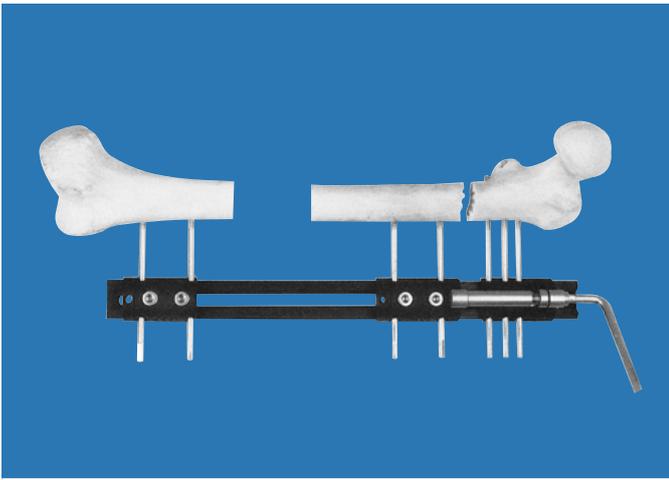
Now, using a drill bit in its corresponding drill guide, holes are drilled from the anterior face of the bone and from the medial and lateral surfaces as far back as possible, penetrating the far cortex each time. The drill stop is used to prevent excessive travel into the soft tissues beyond the second cortex.

WARNING: Do not excessively penetrate the second cortex with any type of screws to avoid soft tissue damage.

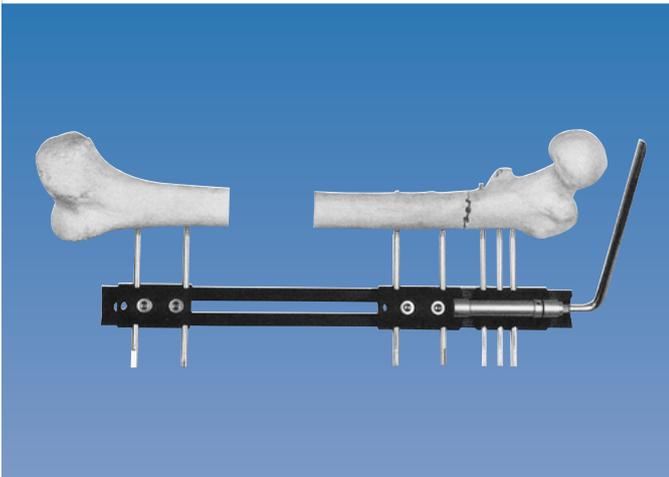


The holes are now connected with an osteotome, taking particular care to divide the postero-medial and postero-lateral columns. When enough of the cortex has been divided in this way, the osteotomy will glide apart under the tension previously applied.

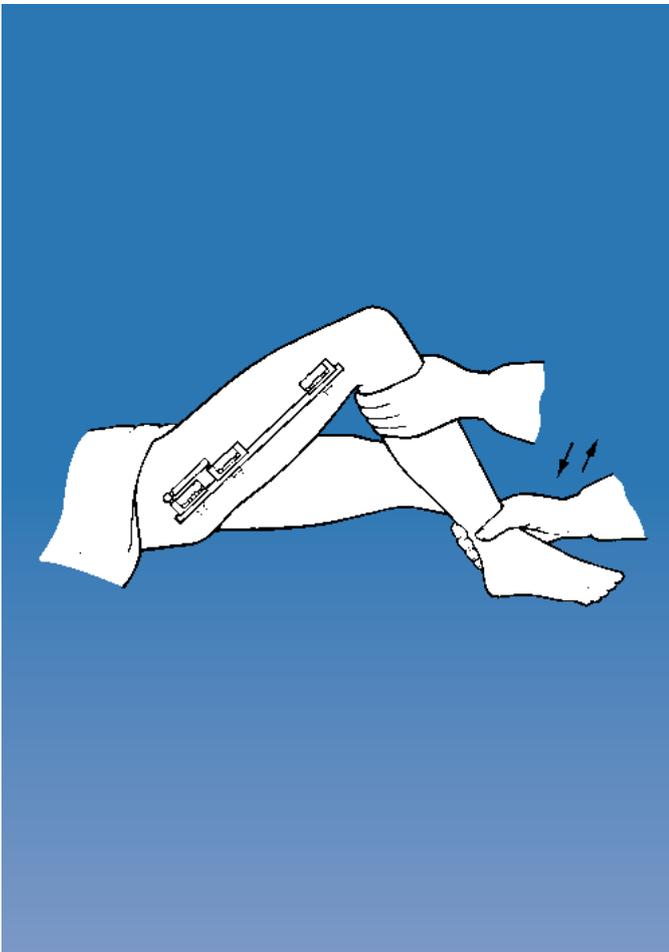
A. BONE TRANSPORT



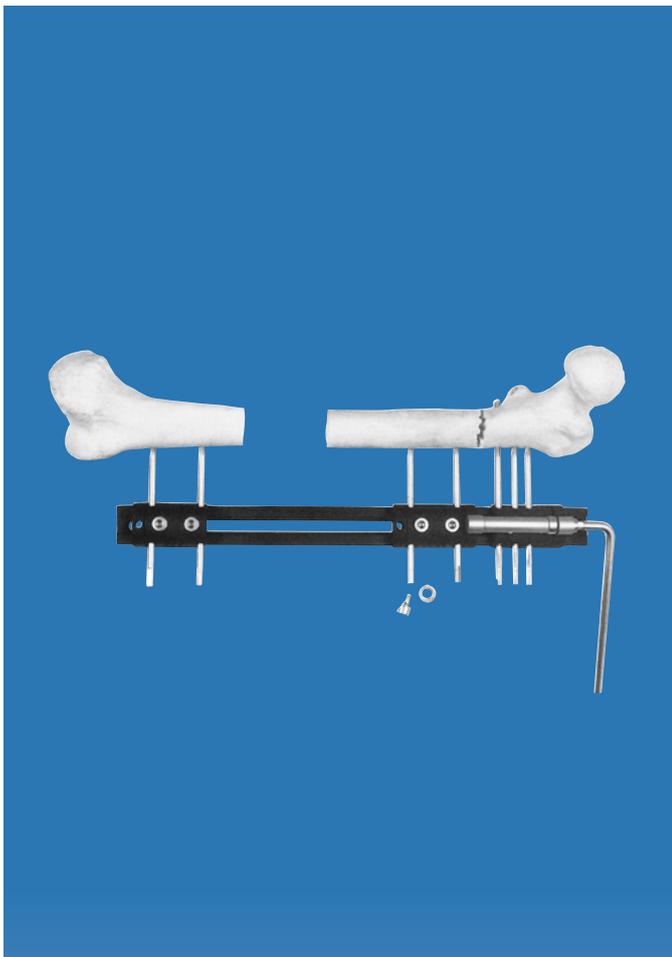
Completeness of the osteotomy should be confirmed by the demonstration of a gap using the Image Intensifier and the obvious lack of resistance when the segments are distracted by turning the compression-distraction unit screw counterclockwise. If the osteotomy does not open as expected, this indicates that a bony bridge still exists, most probably in the posterior cortex. In these circumstances the osteotome or drill should be used to complete the osteotomy.



The two segments are now brought together again under slight compression and the middle clamp is now locked. The periosteum is laid back, sutured if possible, and the incision closed with a single suction drain.

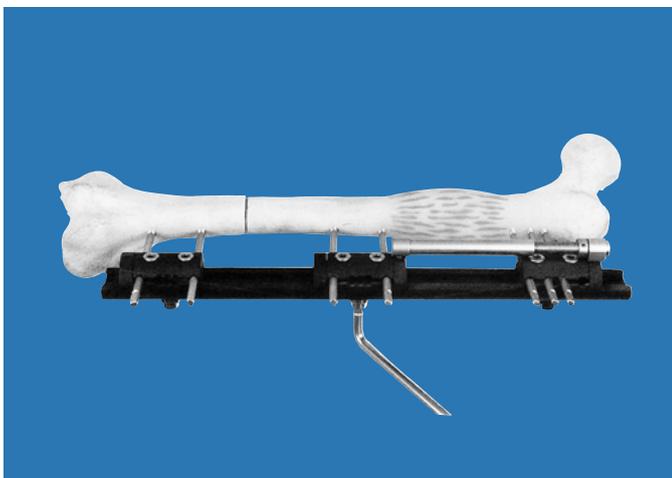


The osteotomy completed, the hip is flexed to 70° and the knee to 90° to check for skin and/or soft tissue tethering around the screws, which will need to be released. Special attention should be paid to the fascia lata, which should be divided longitudinally in association with each of the screws in the middle and distal clamps. Assuming good pre-operative function, the knee should flex passively to 90° without tethering at the conclusion of this procedure. Bulky dressings are now placed around each screw to prevent shuttling of the soft tissues around the screws. The suction drain is left clamped and removed at 48 hours. It should only be released within this period if a hematoma develops.



Segmental Transport

Transport should commence after 7-10 days at a rate of 0.25mm four times a day. Any slack in the system should first be taken up by turning the compression-distraction unit counterclockwise, with the middle and proximal clamps locked to the rail. The middle clamp locking screw and its washer should now be removed and distraction carried out by turning the compression-distraction unit screw counterclockwise, 90° every six hours. In practice, after opening an initial gap, the rate of transport may be adjusted to 0.75mm or 1.25mm a day, according to the quality of the new bone as judged by its appearance on X-ray or ultrasound. As transport proceeds, it is not uncommon to encounter some skin tension at the leading edge of the screws in the middle and to a lesser extent, in the proximal clamp. Additional skin and soft tissue release may therefore be indicated at various **times time-points**. This is readily performed as a limited procedure under local anesthesia. Towards the end of transport, X-ray evaluation may demonstrate less than ideal alignment between the advancing segment and the docking site. In the case of medial or lateral translation, correction may be achieved by unscrewing the middle clamp cover screws and moving the screw shanks further out of or further into the clamp under general anesthesia where indicated.



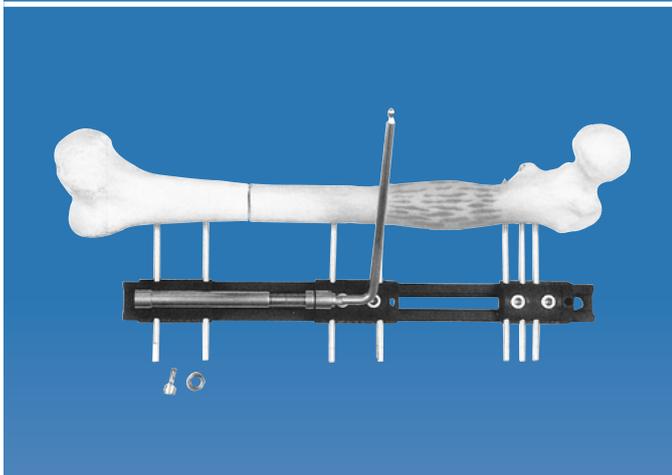
The Docking Procedure

At the conclusion of transport, the defect will close with varying degrees of contact between the bone ends. The middle clamp should now be locked on to the rail.

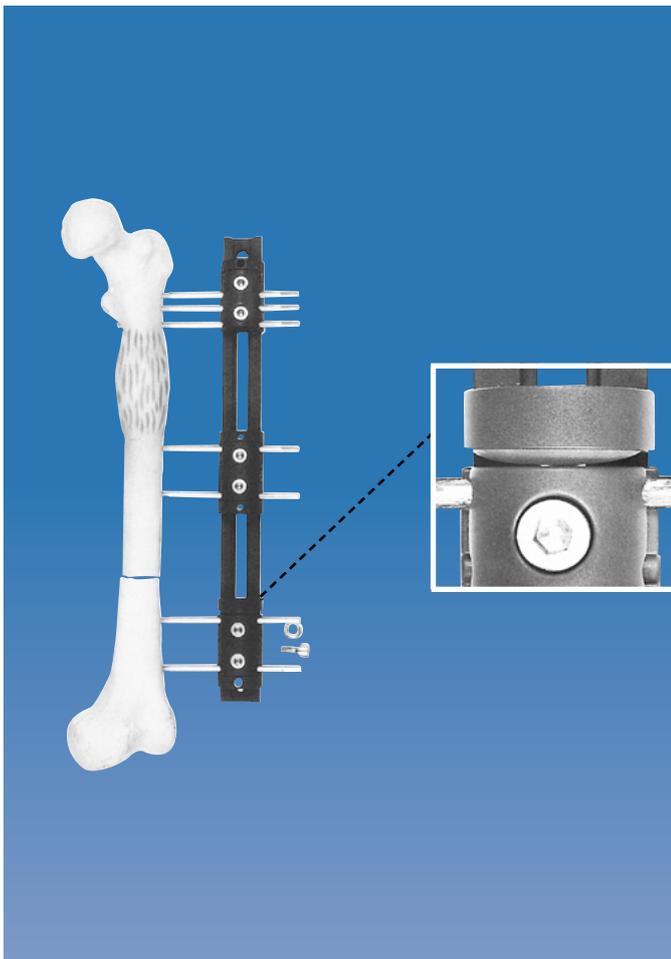
If compression is required, a compression-distraction unit is attached between the middle and distal clamps with the distal clamp locking screw and washer removed. Gentle compression is now applied by turning the compression-distraction unit screw clockwise, after which the distal clamp is once again locked on to the rail. Depending upon the quality of the bone and the extent of contact achieved, various measures may be required to stimulate union. These will vary from the limited compression described above, to resection of the bone ends and compression, bone grafting for small defects, or extensive decortication of the entire fracture area coupled with bone grafting for more serious defects (see under "F. Non-Union", page 41 39 for details). Consolidation of the docking site is monitored by means of serial AP radiographs.



PRECAUTION: In patients undergoing callus distraction, the regenerated bone must be checked regularly and monitored radiologically.



Surgeons with experience in this field suggest that if transport has been carried out over a distance of 3 centimeters or more, the docking site should be treated as a non-union as soon as docking has occurred because, in difficult cases of bone loss, the docking site usually achieves final union after the new bone formed by lengthening has consolidated.



Dynamization of the Docking Site

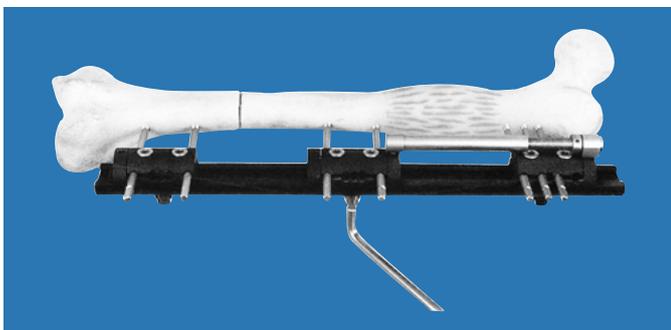
Since the Limb Reconstruction System will permit independent dynamization of the docking site and the distracted callus, this may be instituted at different times for each, according to circumstances. Once any additional surgery has been accomplished and a broad contact area achieved, the docking site may be dynamized by loosening the appropriate clamp (in this case the distal one). Where significant or asymmetric collapse of the fracture might be predicted, attachment of the Dyna-Ring above the loosened distal clamp is recommended. Further loading of the bone may be achieved by removing individual screws and moving the rail further away from the skin.

Distal Clamp and Screw Removal

Consolidation at the docking site should be confirmed with radiographs in two planes. The distal clamp, together with its screws, may be removed, leaving the middle and proximal clamps in situ, if indicated.



PRECAUTION: In patients undergoing callus distraction, the regenerated bone must be checked regularly and monitored radiologically.



Management of the Newly-Formed Segment

At the conclusion of transport, if there is no residual limb length discrepancy, the middle clamp is locked onto the rail, the compression-distraction unit removed, and the consolidation period commenced.

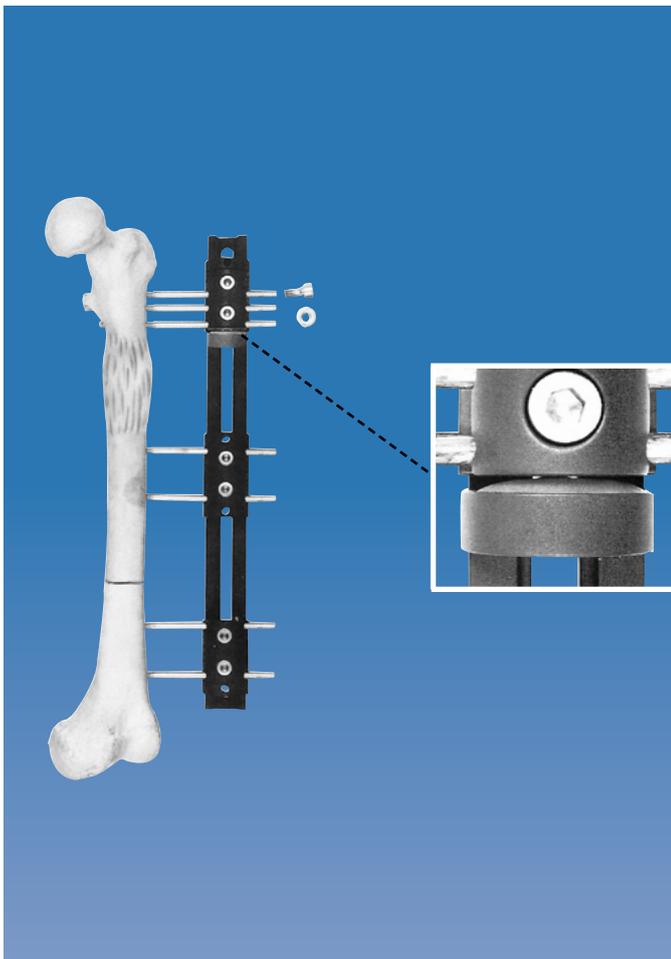
If, at the conclusion of transport, there is some residual limb length discrepancy, the middle clamp is locked on to the rail, the proximal clamp locking screw removed, and lengthening carried out. Once the desired limb length has been achieved, the proximal clamp is locked onto the rail, the compression-distraction unit removed, and the neutralization period commenced. During the neutralization period, the site should be monitored with serial AP radiographs until continuity of the medial and lateral cortices of the lengthened segment is demonstrated. At this stage, a lateral or oblique radiograph is used to demonstrate cortical continuity in another plane.



PRECAUTION: In patients undergoing callus distraction, the regenerated bone must be checked regularly and monitored radiologically.



A. BONE TRANSPORT



Dynamization of the Newly-Formed Segment

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 since, when locked to the rail beneath the proximal clamp, it will prevent the newly formed segment from collapsing (see inset). To initiate dynamization, the middle and distal clamps should be locked to the rail and the proximal clamp locking screw removed.

Clamp and Screw Removal

Once four distinct and complete cortices are evident on X-ray, the remaining clamps and screws may be removed. It is quite common for the docking site and the newly-formed segment to heal at different rates and the timing of clamp and screw removal will therefore frequently vary at the different sites.



PRECAUTION: In patients undergoing callus distraction, the regenerated bone must be checked regularly and monitored radiologically.



B) PROXIMAL BONE LOSS IN THE FEMUR

The distal screw clamp-cluster should be well within the cancellous bone of the distal metaphysis, avoiding the suprapatellar pouch. The clamp seats used in this site are similar to those used in the proximal clamp in distal transport (ie. 1 and 4 or 1, 2 and 4 numbering from the proposed osteotomy site). The surgical approach for the osteotomy is via a 3-4cm antero-lateral incision between rectus femoris and vastus lateralis. A minimally invasive method is also described on page 25.

Post-Operative Management

Segmental Transport

The proximal and distal clamps are locked to the rail and the middle clamp moved proximally to fill the defect. For full details, see "A) Distal Bone Loss in the Femur", page 27.

The Docking Procedure

When the segments meet, the middle clamp is locked to the rail. If compression is required, a compression-distraction unit is attached between the middle and proximal clamps, and the proximal clamp locking screw loosened. For full details see "A) Distal Bone Loss in the Femur", page 27.

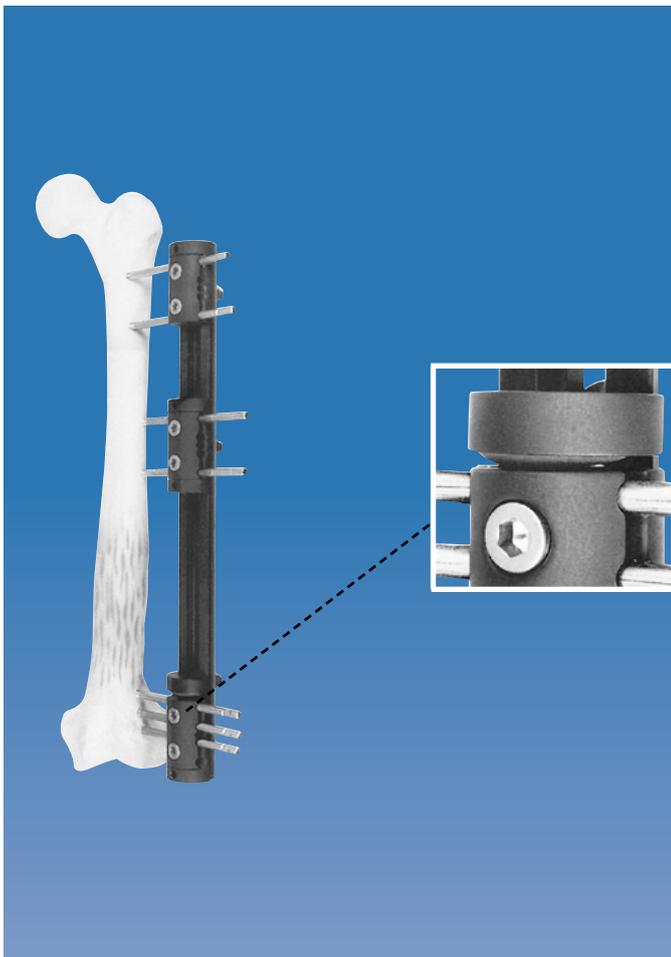
Dynamization of the Docking Site

This is performed with the proximal clamp free to move on the rail and the middle and distal clamps locked to the rail.

Proximal Clamp and Screw Removal

Once consolidation at the docking site has been confirmed on X-ray, the proximal clamp together with its screws may be removed, leaving the middle and distal clamps in situ, if indicated.

A. BONE TRANSPORT



Management of the Newly-Formed Segment

At the conclusion of transport, if there is no residual limb length discrepancy, the distal and middle clamps are locked on to the rail, the compression-distraction unit removed, and the period of neutralization commenced. If, at the conclusion of transport, there is some residual limb length discrepancy, the middle clamp is locked onto the rail, the distal clamp locking screw is loosened, and lengthening carried out. Once the desired limb length has been achieved, the distal clamp is locked onto the rail, the compression-distraction unit removed and the neutralization period commenced.

Dynamization of the Newly-Formed Segment

Three complete cortices should be evident prior to the initiation of dynamization. To initiate dynamization, the middle and proximal clamps should be locked to the rail, and the distal clamp locking screw removed. If the Dyna-Ring Attachment (50535 adult, 55035 pediatric) is used, dynamization may be commenced at an earlier time since, when locked to the rail above the distal clamp it will prevent the newly-formed segment from collapsing.

Clamp and Screw Removal

See "A) Distal Bone Loss in the Femur", page 29.

C) DISTAL BONE LOSS IN THE TIBIA

The procedure for bone transport in the tibia is similar to that in the femur with certain notable differences. The device is normally mounted antero-medially, but in exceptional cases may be mounted either medially or anteriorly. For pre-operative planning the same general principles are followed as for application in the femur (see page 18).

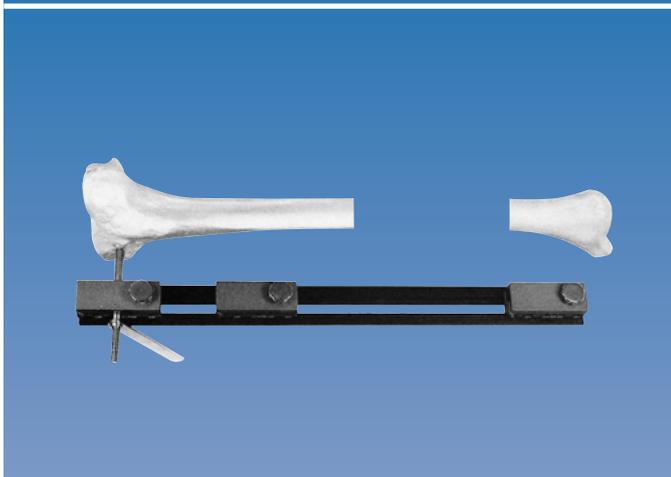
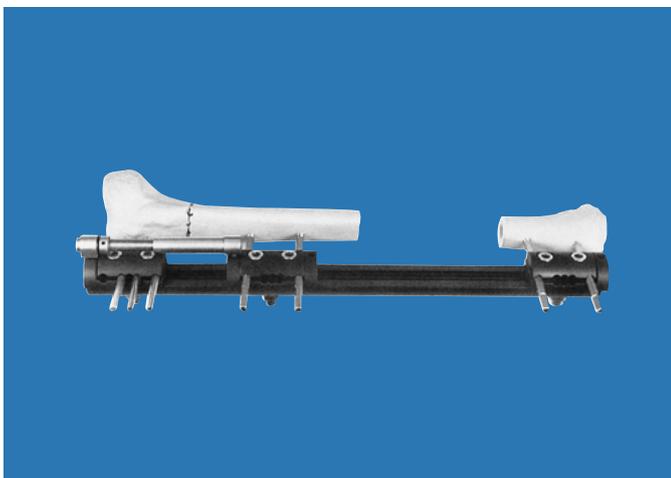
For this application, the proximal clamp screw-cluster should use the 1 and 4 or 1, 2 and 4 screw seat positions, numbering from the proposed osteotomy site. To ensure a high metaphyseal osteotomy, the first screw should be inserted into the wide metaphyseal bone just below the tibial articular surface, taking care to avoid the joint capsule.

 **WARNING:** During screw and wire insertion, do not enter the joints or the growth plates in pediatric patients to avoid joint damage or growth impairment.

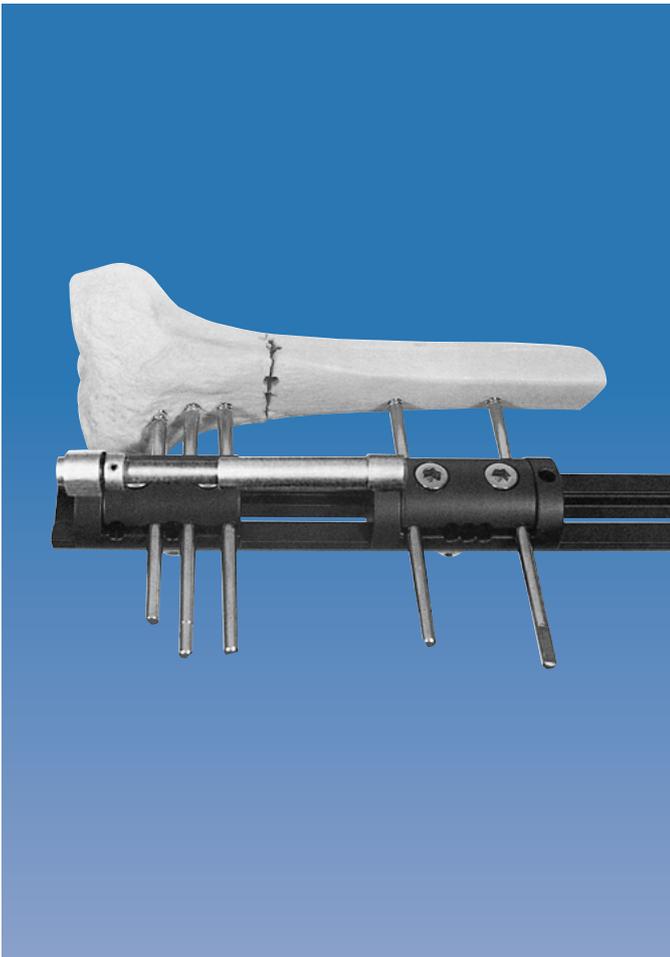
As with the proximal screw in the femur, an elevator is used to scrape the bone surface to provide good purchase for the screw guide. For the positioning of the second (most distal) screw and the technique for ensuring that all the remaining intermediate screws engage the bone, see "A) Distal Bone Loss in the Femur", pp. 21-23. Since the saphenous vein and nerve are superficial to the subcutaneous border in the lower third of the tibia, careful longitudinal skin incisions and deep dissection are required in order to avoid damage to these structures.

 **PRECAUTION:** Screws and wires must be inserted with full knowledge of the safe corridors to avoid damage to the anatomical structures.

Orthofix OsteoTite Bone Screws: The use of hydroxyapatite coated screws in this type of procedure is strongly recommended, because fixation time is likely to be prolonged. In any case, three evenly spaced screws in each clamp are strongly recommended for all but the lightest adults and children.



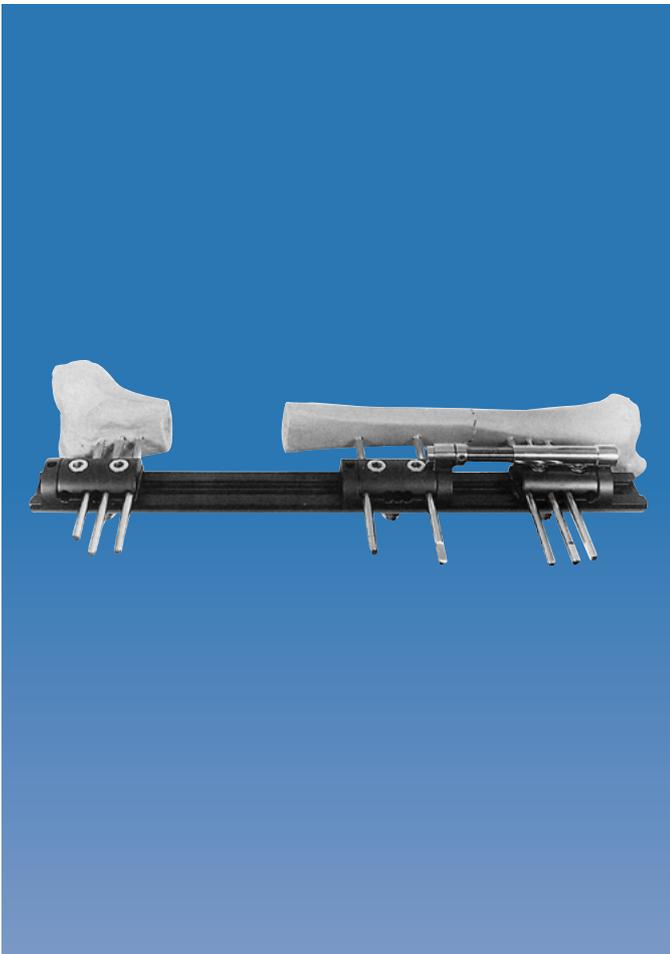
A. BONE TRANSPORT



A longitudinal 3cm incision is used for the osteotomy, just medial to the anterior crest so that the osteotomy is performed 1-1.5cm below the distal screw in the proximal clamp and below the patellar tendon attachment to the tibial tuberosity. The technique for performing the osteotomy is similar to that described "A) Distal Bone Loss in the Femur", pp. 25-26. As in the femur, a minimally invasive technique is possible, page 25.

Post-Operative Management

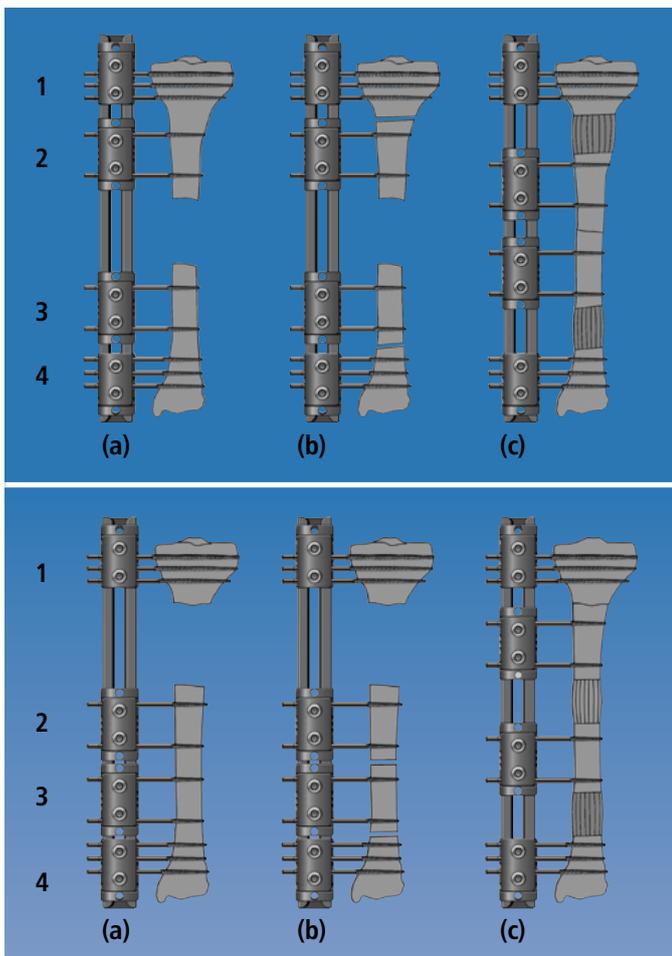
The principles of post-operative management, including segmental transport, the docking procedure and management of the newly-formed segment, are similar to those described for the femur (see pp. 27-29) to which reference should be made. In general, soft tissue problems during transport are less evident in the tibia since the bone is subcutaneous. If shortening is present when the two segments meet, the middle clamp is locked to the rail and lengthening carried out between the middle and proximal clamps. If the fibula is intact, before lengthening can be performed, a 1cm segment of its length must be resected in the distal third and the lateral malleolus secured to the tibia with a screw.



D) PROXIMAL BONE LOSS IN THE TIBIA

The distal clamp screw-cluster should use the 1 and 4 or 1, 2 and 4 screw seat positions numbering from the proposed osteotomy site. The approach for the osteotomy is just medial to the anterior crest using a 2.5-3.0cm incision. For the principles of post-operative management, see "B) Proximal Bone Loss in the Femur", pp. 29-30. If shortening is present when the two segments meet, the middle clamp is locked to the rail and lengthening carried out between the middle and distal clamps. If the fibula is intact, before lengthening can be performed a 1cm segment of its length must be resected in the distal third and the lateral malleolus secured to the tibia with a screw.

A. BONE TRANSPORT



E) BIFOCAL TRANSPORT

This is indicated for large central or peripheral bone defects. The application of four clamps with two osteotomies is required.

Central Defect

- (a) Large central bony defect and Limb Reconstruction System in place.
- (b) Proximal and distal metaphyseal osteotomies performed.
- (c) Simultaneous proximal and distal transport with clamps 1 and 4 locked to the rail and clamp 2 moved distally and clamp 3 proximally until segments meet.

Peripheral Defect

For a peripheral defect, two osteotomies are performed in the longer bone fragment. Since both segments thus produced will be moving in the same direction, the more peripheral of the two segments is advanced at normal speed, while the more central of the two is advanced at twice the normal speed. This will ensure that the rate at which the two osteotomies open will be the same.

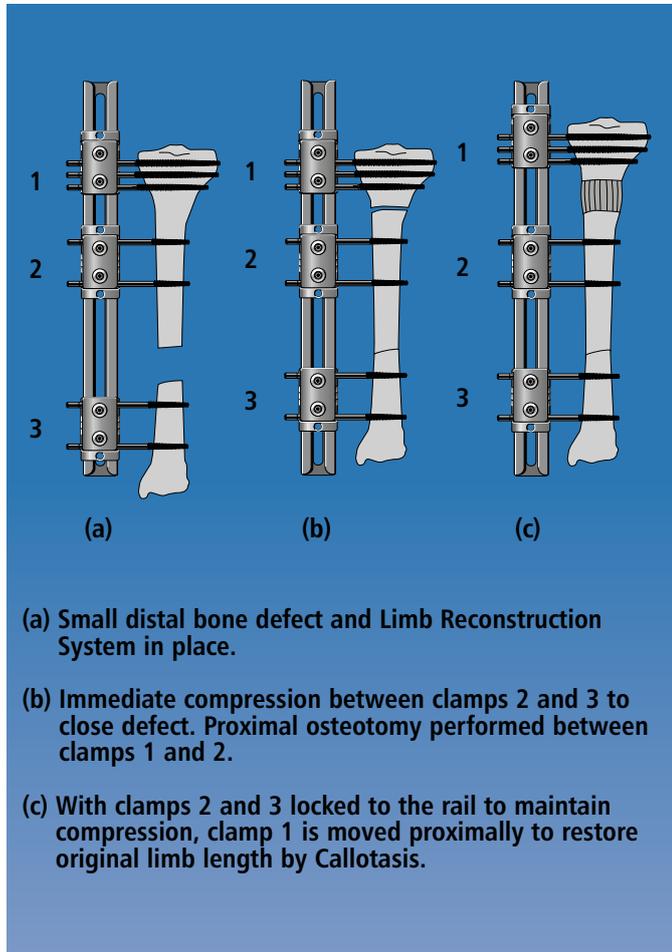
- (a) Large peripheral bony defect and Limb Reconstruction System in place.
- (b) Two osteotomies performed in the longer bone fragment.
- (c) Simultaneous proximal transport with clamps 1 and 4 locked to the rail and clamps 2 and 3 moved proximally until segments meet.

Post-Operative Management

This is similar to that described under "A) Distal Bone Loss in the Femur" (see pp. 27-29). Where this technique is used in the tibia and shortening is present when the two segments meet, the middle clamps (2 and 3) and either the proximal (in proximal transport) or the distal clamp (in distal transport) are locked to the rail. Lengthening is then carried out between that outer clamp, which remains unlocked, and the adjacent middle clamp. If the fibula is intact, before lengthening can be performed a 1cm segment of its length must be resected in the distal third and the lateral malleolus secured to the tibia with a screw.

B. COMPRESSION-DISTRACTION

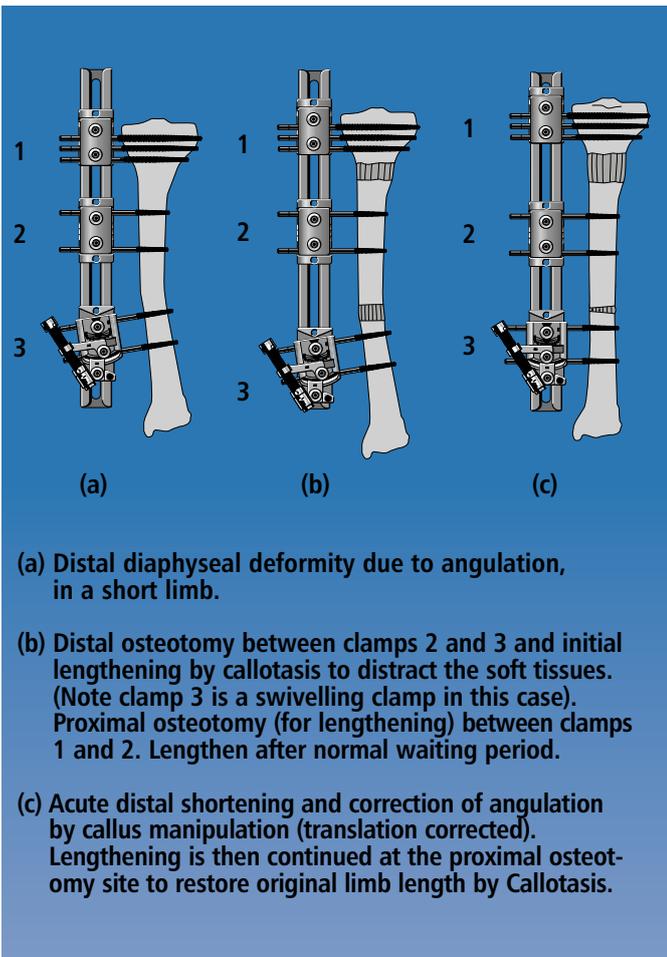
The principle of compression-distraction is discussed below, but since the application technique is similar to that of bone transport, it is not described in detail. In this procedure, one site is lengthened and another site either immediately or progressively compressed. In infected cases it may be appropriate to delay the osteotomy until the infection has been controlled. It is indicated in cases of shortening associated with small bone defects and in cases of shortening with diaphyseal deformity, since diaphyseal bone is less suitable for lengthening (see "C. Bifocal Lengthening" page 35). Shortening, whether acute or gradual, should always be accompanied by careful monitoring of the venous and arterial circulation.



A) SHORTENING WITH A SMALL DEFECT

If there is a bony defect in the tibia of 3cm or less or in the femur of 5cm or less, immediate compression to close the defect, followed by lengthening at a healthy metaphysis may have significant advantages over bone transport. These include: immediate contact between the bone ends, optimal contact of the fragments, and immediate stimulation of the site without the problems of transport through the soft tissues and docking. As a result, delayed and non-union are less common with this technique than with transport. At the site of compression there is invariably a soft tissue bulge which resolves during lengthening. In exceptional circumstances the compression may be performed gradually, post-operatively. Osteotomy, followed by lengthening using the callotasis technique is carried out at a healthy metaphyseal site as described earlier. When treating bone loss in the tibia by this technique, a segment of the fibula 1cm longer than the tibial defect should be resected in its distal third and the lateral malleolus secured to the tibia with a screw.

B. COMPRESSION-DISTRACTION



B) SHORTENING WITH DIAPHYSEAL DEFORMITY

In the case of a diaphyseal malunion or non-union, realignment by surgical osteotomy, or manual osteoclasis may be performed. As a general guide, a deformity with less than 10° of angulation may be corrected by osteotomy alone, while more than 10° of angulation will require the removal of a wedge of bone. Where this technique is used in the tibia in the presence of an intact fibula, a variable amount of the latter must be resected, (depending upon the degree of angulation in varus or valgus), to produce a fibular defect of approximately 1 cm following corrective osteotomy of the tibia. Lengthening is performed at a healthy metaphyseal site as described above. For a full description of this technique, see Manual 11, Part B: Correction of Deformities.

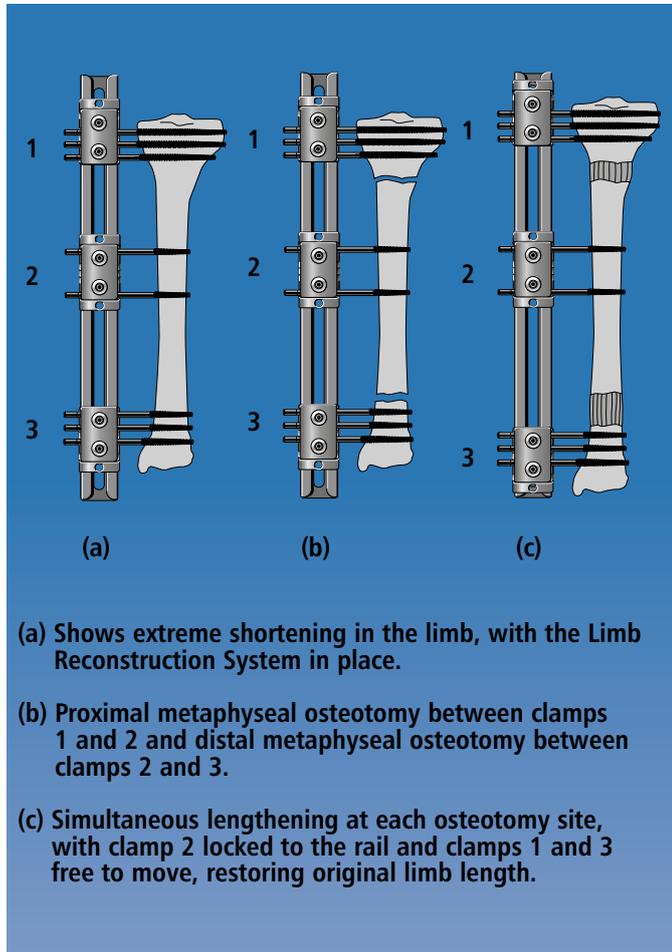
Post-Operative Management

In either case this is similar to that described under "A) Distal Bone Loss in the Femur", see pp. 27-29.

C. BIFOCAL LENGTHENING

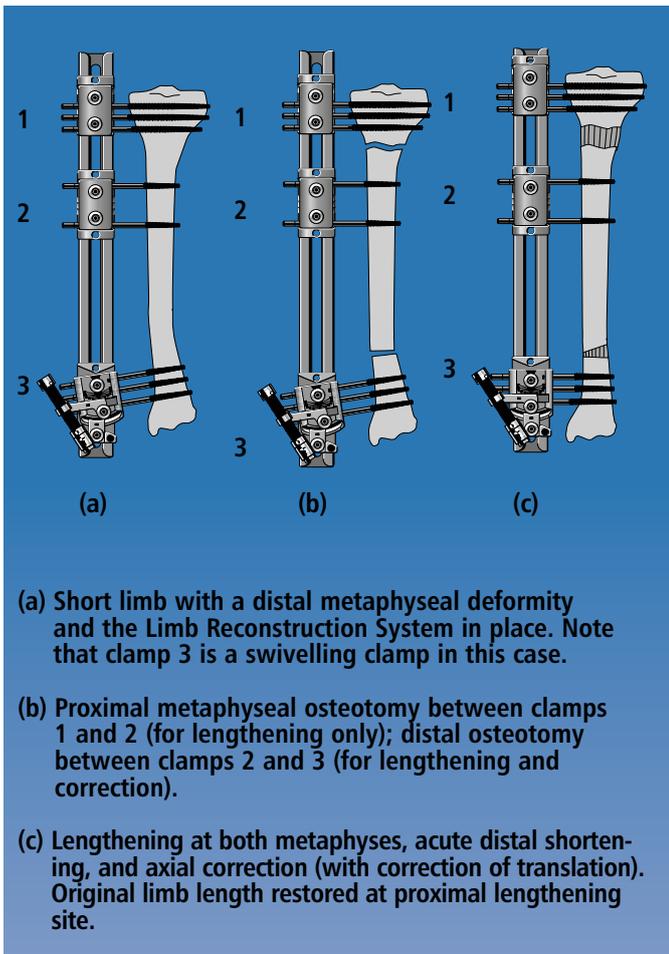
The principle of Bifocal Lengthening is discussed below. The application technique is similar to that for Bone Transport, the only difference being that in this procedure two compression-distraction units are used simultaneously. Special care, therefore, should be paid to the position of the clamps, since, as both middle clamp mountings are occupied, there is no possibility for alternative positioning of the compression-distraction units.

Bifocal Lengthening is indicated in cases of extreme shortening, or shortening combined with metaphyseal deformity (Saleh and Hamer, 1993).



A) EXTREME SHORTENING

This is the simplest application for the device, since there is no instability from the presence of a bony defect and no angular deformity requiring realignment. In contrast to the other situations described, both the proximal and distal screw-clusters must be well within the metaphyseal regions so that the osteotomies are both within metaphyseal bone. In this indication, the alignment of the rail should be along the mechanical axis of the limb (i.e. a line drawn from the center of the femoral head to the middle of the ankle joint). The clamp seats used in the proximal and distal clamps are similar to those used in the clamp adjacent to the osteotomy site in bone transport (ie. seats 1 and 4 or 1, 2, and 4). The middle clamp should be sited in the middle of the middle segment, and in this case two compression-distraction units of the same size will be used. They are connected between the middle and proximal, and middle and distal clamps, and tensioned. The approaches and the manner in which the osteotomies are performed are described under "(A) Bone Transport". Where this technique is used in the tibia in the presence of an intact fibula, before lengthening can be performed, a 1cm segment of the latter must be resected in the distal third and the lateral malleolus secured to the tibia with a screw.



B) SHORTENING ASSOCIATED WITH METAPHYSEAL DEFORMITY

Correction of deformity may be performed by surgical osteotomy or manual osteoclasis, as described under "B. Compression-Distraction". Some lengthening is necessary at this site in order to achieve gradual, controlled correction of the deformity (see Manual 11, Part B: Correction of Deformities). Further lengthening, when required, may be achieved through an osteotomy in the healthy metaphysis. Where this technique is used in the tibia in the presence of an intact fibula, a variable amount of the latter must be resected, (depending upon the degree of angulation in varus or valgus), to produce a fibular defect of approximately 1 cm following correction of the metaphyseal deformity. For a full description of this technique, see Manual 11, Part B: Correction of Deformities.

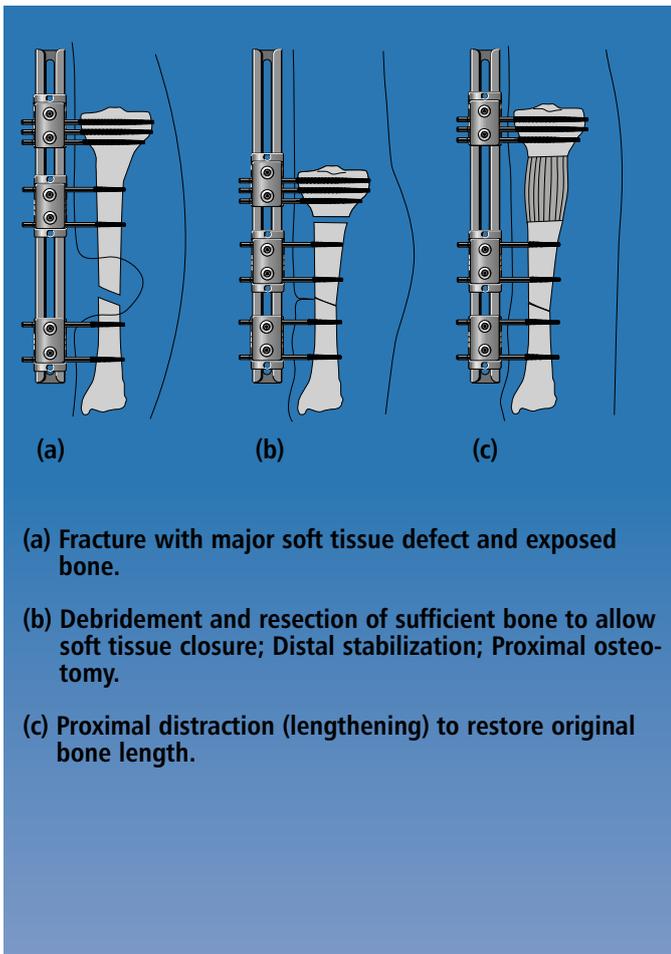
Post-Operative Management

This is similar to that described in association with the lengthened segment under "A. Bone Transport", see pp. 28-29. However, since lengthening is taking place at two sites, soft tissue tension increases more rapidly. The first 14-21 days of lengthening must proceed at a rate of 1mm/site/day. After this, the rate of lengthening should be reduced to a cumulative maximum of 1.5mm/day to avoid undue soft tissue tension. The precise rate at each site should be tailored according to the quality of the bone as judged from serial X-rays.



PRECAUTION: In patients undergoing callus distraction, the regenerated bone must be checked regularly and monitored radiologically.

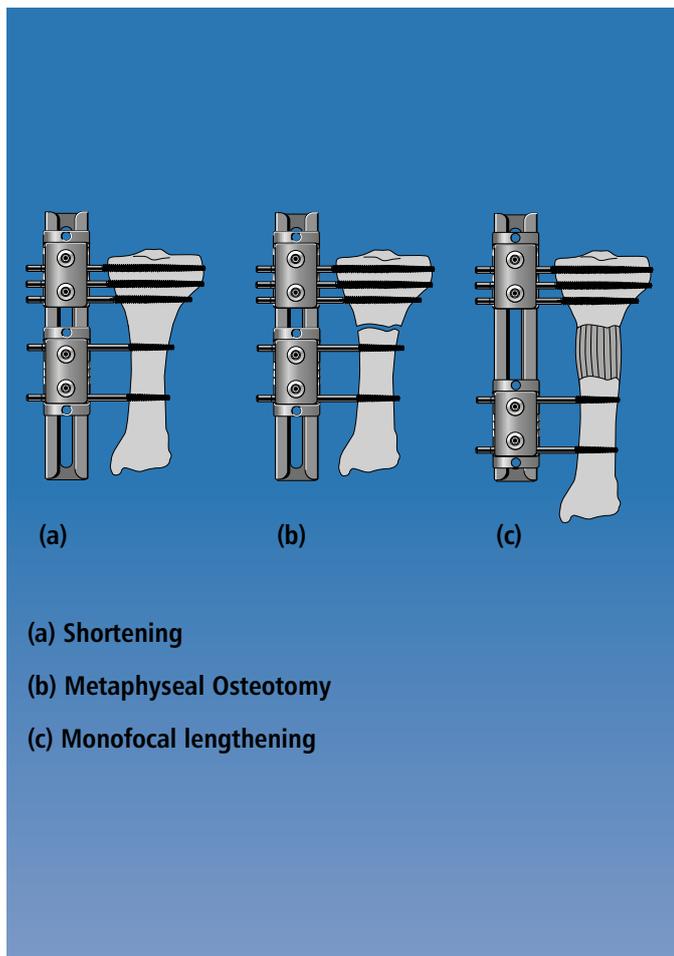
D. THE MANAGEMENT OF FRACTURES ASSOCIATED WITH MAJOR SOFT TISSUE DEFECTS



Bifocal procedures may be used to treat fractures with major soft tissue defects and exposed bone, or delayed or non-unions with osteomyelitis and soft tissue necrosis. The Shortening-Lengthening technique described by Giebel, involves primary resection of sufficient bone to allow closure of the soft tissues, followed by callotasis at a healthy metaphyseal site to restore segment length, and has been used to reduce extensive defects (4-12cm). When the procedure is carried out in the tibia, a segment of the fibula 1cm longer than the length of the tibial bone to be resected, is removed in its middle third (Giebel G., 1991, 1992).

Large bone and soft tissue defects may also be treated by transport (Saleh M., 1997). Soft tissue cover is provided either immediately, at the time of bone stabilization, by importing a skin or muscle flap, or at the end of transport, by skin grafting over granulation tissue. In the latter situations, granulation tissue follows the leading edge of the transported segment. Immediately prior to docking, exposed bone is trimmed back, allowing healthy bone covered with granulation tissue to abut at the docking site. Any residual defect may be covered with a split skin graft.

E. MONOFOCAL PROCEDURES



A) MONOFOCAL LENGTHENING

In addition to its obvious applications in multilevel surgery, the Limb Reconstruction System can also be used for monofocal lengthening procedures in association with callotasis at a single osteotomy site. When used in this way, only two clamps are needed, in contrast to the three, and occasionally, even four clamps used in multilevel surgery. The indications for use of the Limb Reconstruction System for monofocal lengthening include application to very short bone segments where the smallest possible distance between proximal and distal clamps is required. It is also recommended for lengthenings in excess of 10cm, where its extreme rigidity is of particular value, and in femoral lengthenings in children or individuals with short stature, where the distal clamp must be positioned as far as possible from the knee joint to preserve joint function. Finally, it may be used for lengthening in association with angular correction of either valgus or varus deformity using the swivelling clamp.

B) SITUATIONS WHERE INCREASED STABILITY IS REQUIRED

In established non-union with osteoporotic bone (see under "F. Non-Union", page 39), or in delayed union or malunion in the heavy patient, the Limb Reconstruction System may be used to confer extra stability, since clamps may be placed at suitable points along the whole length of the segment involved (Saleh M., 1992).

C) DEFORMITY CORRECTION WITH OR WITHOUT LENGTHENING

A deformity is conventionally described by reference to the position of the distal fragment. Bony deformity may be corrected acutely or progressively. The limits of acute corrections depend on the site, quality of the bone and the tension generated in tissues, especially nerves. Progressive deformity correction is indicated where soft tissue and nerve complications may be anticipated, where further surgery is contraindicated or refused, where the precise degree of correction cannot be predicted, or where a deformity occurs during treatment and correction may be achieved without recourse to further surgery. For a full description of these techniques, see Manual 11, Part B: Correction of Deformities.

F. NON-UNION

Non-union treatment should aim not only to regain bony continuity at the fracture site, but also to produce restoration of the mechanical axis and thereby maximize the functional result. The principles of non-union surgery are: Realignment, Stabilization and Stimulation (Saleh M., 1992, Ribbans W.J. et al., 1992). The distinction between hypertrophic (stiff) and atrophic (lax) non-union is critical to treatment.

Realignment

With marked or segmental malalignment, realignment must be achieved manually prior to the application of the fixator. Fine-tuning or the reduction of smaller deformities may be achieved after application of the fixator by appropriate use of the ball-joint or swivelling clamp. A stiff non-union may need to be broken down to facilitate reduction, using an osteotome inserted percutaneously under X-ray control.



PRECAUTION: During and after insertion of the implants, ensure their correct positioning under image intensification.

Stabilization

A pseudarthrosis after failed internal or external fixation often presents with poor quality bone. The Limb Reconstruction System confers great stability to the segment since screw clamps may be spread along the whole length of the bone. It is particularly indicated in infected cases where internal fixation is contraindicated. Fracture site surgery can often be avoided altogether, but if the bone ends are exposed and squared, a large perpendicular contact area will result, leading to a reduction in shear forces and shared loading between the bone and fixator. This is particularly useful in osteoporosis.

Stimulation

(a) Hypertrophic Non-Union

This is generally vascular and wants to heal. Healing can normally be induced by realignment and stabilization in neutralization. If the fracture has a large surface area, compression can be used to increase fracture site stability by shared loading, while simultaneously inducing osteogenesis (Charnley and Baker, 1952). If the fracture is oblique or deficient, compression may not be advisable, since it may induce angulation at the fracture site. Progressive distraction can also be used, since it combines osteogenesis with an increase in length (Saleh and Royston, 1996).

(b) Atrophic Non-Union

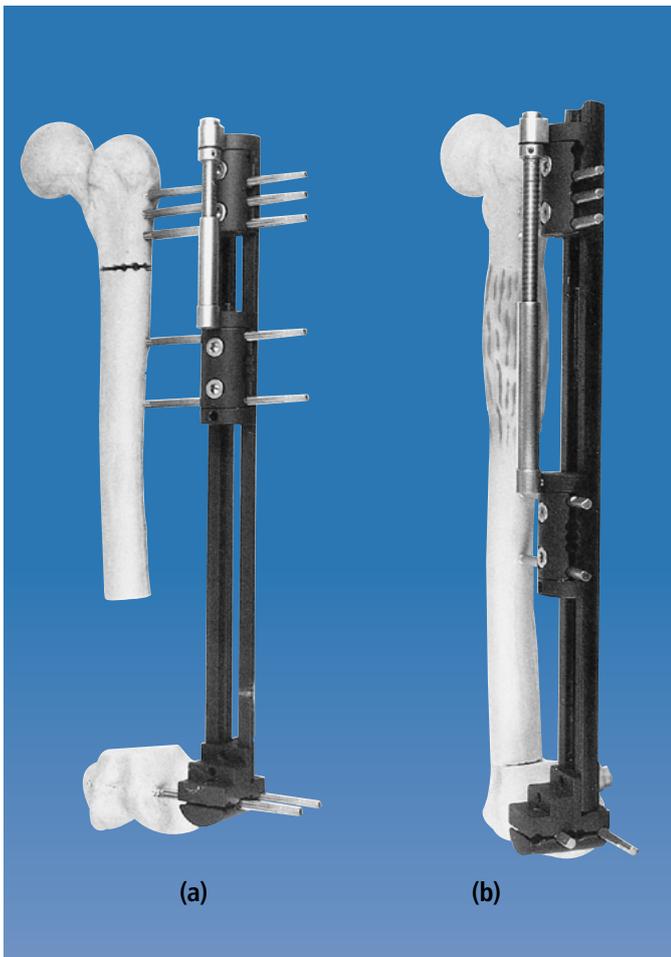
An atrophic non-union is more difficult to deal with. It is usually lax and by definition may have an impaired blood supply. Treatment should aim to promote revascularization of the fracture ends using either direct or indirect methods. Indirect methods include walking (Bohler L., 1929) and the use of the muscle pump (Trueta J., 1965), pulsed electromagnetic field therapy (PEMF's), improved fracture support and segment stability, or a further osteotomy in the same segment (Sveshnikov A.A. et al., 1984). Direct methods of improving the blood supply should also be considered. A square osteotomy or, if necessary, a short diaphysectomy with immediate closure of the defect will improve stability and protect the pin bone interface by allowing the bone to take some of the load. A good blood supply is ensured by increasing stability and resecting back to healthy vascular bone. Length may be regained using a metaphyseal osteotomy and compression-distraction. Other direct methods include the appropriate use of vascularized skin flaps where the soft tissues are poor and local revascularizing measures such as osteoperiosteal decortication (Judet R. and Patel A., 1972), osseous and soft tissue scarifications (Colchero R.F. et al., 1982) and centro-medullary perforations as advocated by Trueta. Autogenous bone grafting is the most effective local measure in bone regeneration and three main mechanisms are described: osteogenesis, osteoinduction and osteoconduction (Glowacki J. and Mulliken J.B., 1985). The management of infected cases is beyond the scope of this manual, but the principles are described elsewhere (Saleh M., 1992).

The transport docking site is effectively an atrophic non-union and the same principles of realignment and stimulation apply.

The T-Clamp

This is a fixed clamp in the T-configuration, attaching to either end of the rail (a), and applied with a dedicated template.

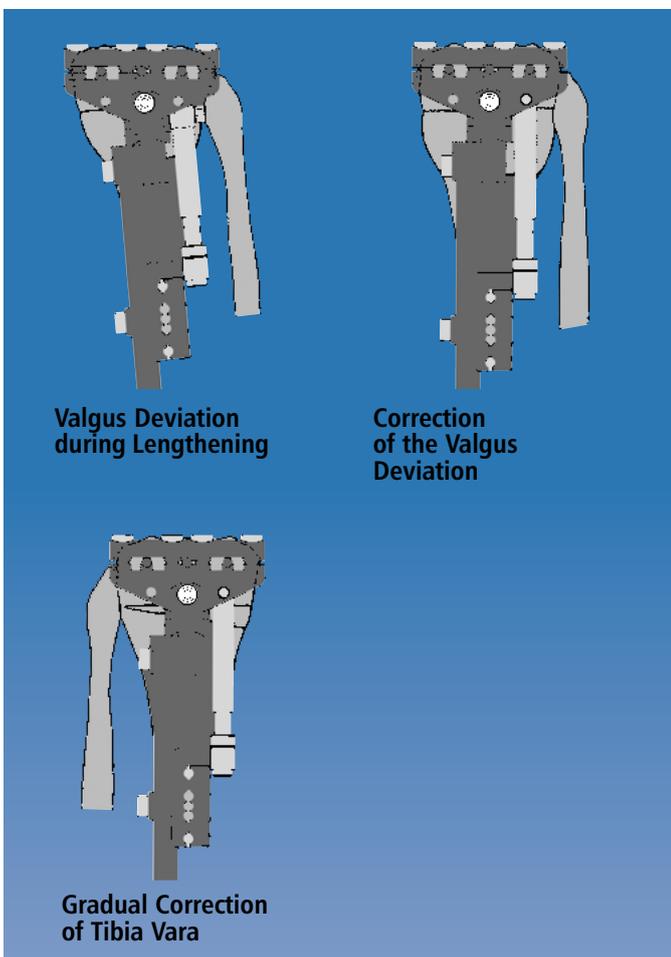
It enables purchase to be gained in smaller fragments where use of a straight clamp would not allow sufficient room for the positioning of a metaphyseal osteotomy or the control of a short bone fragment. A straight clamp should, however, be used whenever possible, since it confers greater stability. Since the T-clamp is fixed at one end of the rail, dynamization of the segment between the T-clamp and the middle clamp is only possible if the locking screws of the other two clamps are loosened and the distance between them maintained using a compression-distraction unit, (b). In the exceptional situation that two T-clamps are used, dynamization and lengthening are not possible.

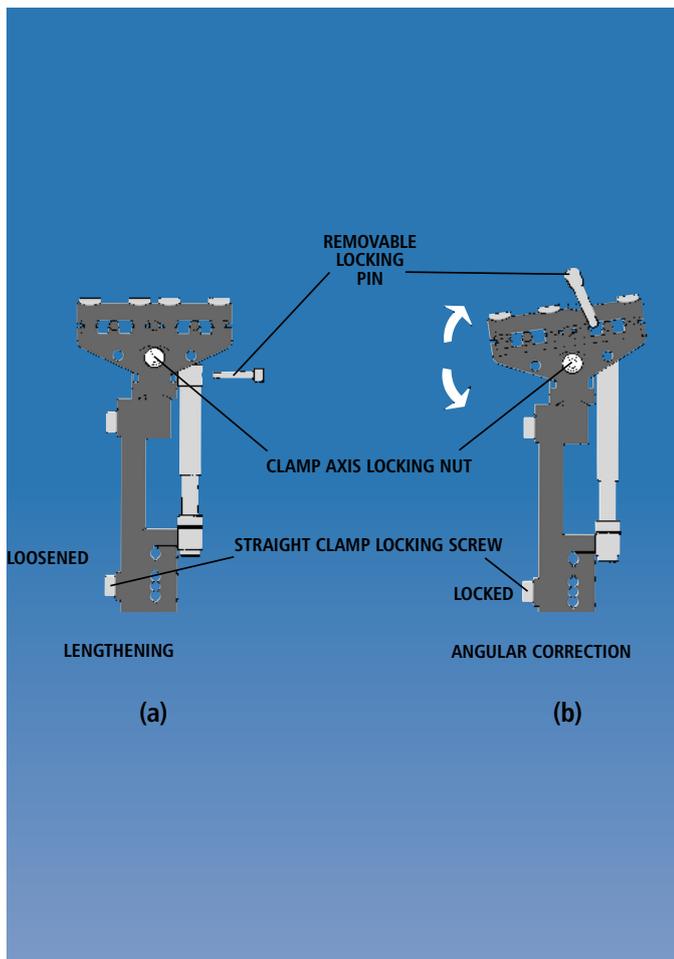


The OF-Garches T-Clamp

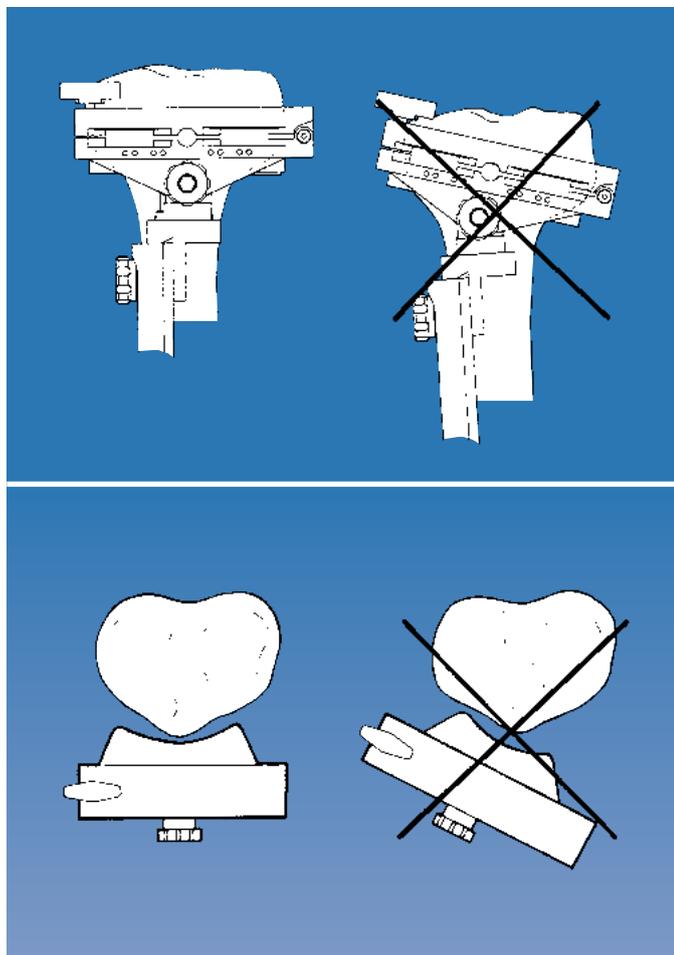
This module (50546) may be attached to one end of the rail to permit tibial lengthening in the upper metaphyseal region, with better control of valgus or varus deviation. It can also be used in cases of tibia vara or tibia valga for gradual or immediate angular correction. A Pediatric OF-Garches T-Clamp Kit is also available (55031), and is applied without a template.

The OF-Garches T-Clamp is capable of moving in one plane only, and has swivelling screw seats to allow convergent siting of the outer screws. The compression-distraction unit may be attached in one of two ways, depending upon whether lengthening or angular correction is desired.





(a) shows the position of the removable locking pin of the compression-distraction unit when lengthening along the axis of the bone is required;
 (b) shows the position of the removable locking pin of the compression-distraction unit when an angular correction is required.



Tibial Lengthening: Operative Technique

FIRST STAGE: Fixation and section of the fibula in its distal region

A screw fixing the fibula to the tibia is placed obliquely from below upwards in order to prevent any displacement of the malleolus during the lengthening procedure. About two centimeters of the fibula are then removed above the screw. The incision is closed, without drainage.

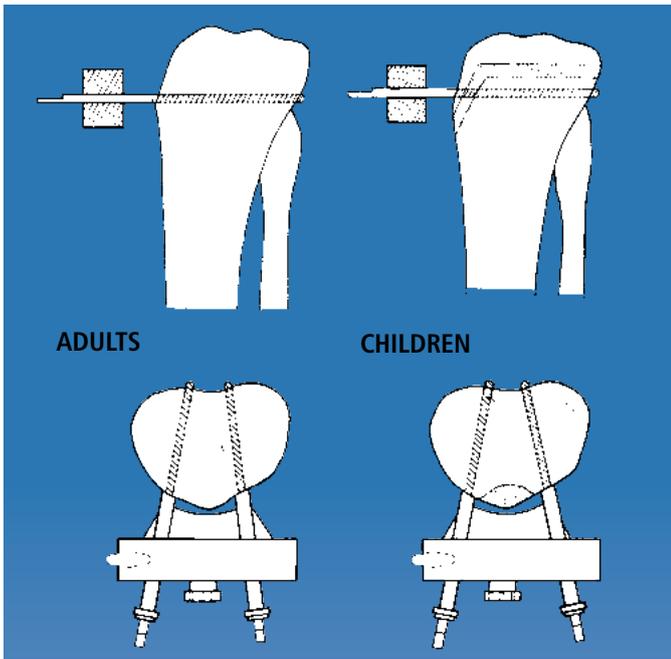
SECOND STAGE: Positioning of the template

The joint line of the knee and the anterior tuberosity of the tibia must be located by careful palpation and the use of image intensification.



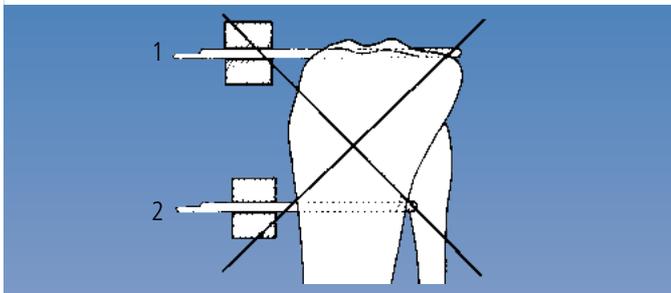
PRECAUTION: During and after insertion of the implants, ensure their correct positioning under image intensification.

The template is kept at the correct distance from the skin by means of a guard. The T-clamp must be placed parallel to the upper surface of the tibia and in the coronal plane, since, if it is not, accurate correction in the desired plane will not be possible. A Kirschner wire may be used as a reference point and inserted parallel to the tibial plateau, 5-8mm below the upper border.



ADULTS

CHILDREN



The upper limit of the T-clamp template should be positioned in such a way that the clamp axis locking nut is at the same level as the osteotomy site, i.e. just below the tibial tuberosity. When planning the upper limit of the T-clamp template in children, the surgeon should also bear in mind that the screws must be placed below the growth plate.

Particular care should be taken to avoid:

1. Placing the T-clamp too high, with the risk of screws entering the joint or damaging the growth plate in children.
2. Placing it too low, in which case the osteotomy will be in the diaphysis rather than the metaphysis.

The above steps are the most important in the technique.

WARNING: During screw and wire insertion, do not enter the joints or the growth plates in pediatric patients to avoid joint damage or growth impairment.

Once the T-clamp template has been correctly positioned, as described above, it should be anchored temporarily to the tibia by means of Kirschner wires inserted through holes in the template designed for this purpose. Correct positioning should then be confirmed by X-ray.

PRECAUTION: During and after insertion of the implants, ensure their correct positioning under image intensification.

The rail is now arranged so that it is parallel to the tibial diaphysis. It must be at the same distance from the bone as the T-clamp. The rail can then be anchored using Kirschner wires, inserted into the tibial crest through holes in the straight clamp template for this purpose. The clamp axis locking nut of the template is then tightened.

THIRD STAGE: Screw insertion

The proximal screws are inserted first. The screws should be inserted so that they converge as little as possible, to avoid future tension. Screw placement should be performed under image intensification to ensure that adequate penetration of the bone is achieved and that the screws project beyond the posterior cortex by not more than one thread.

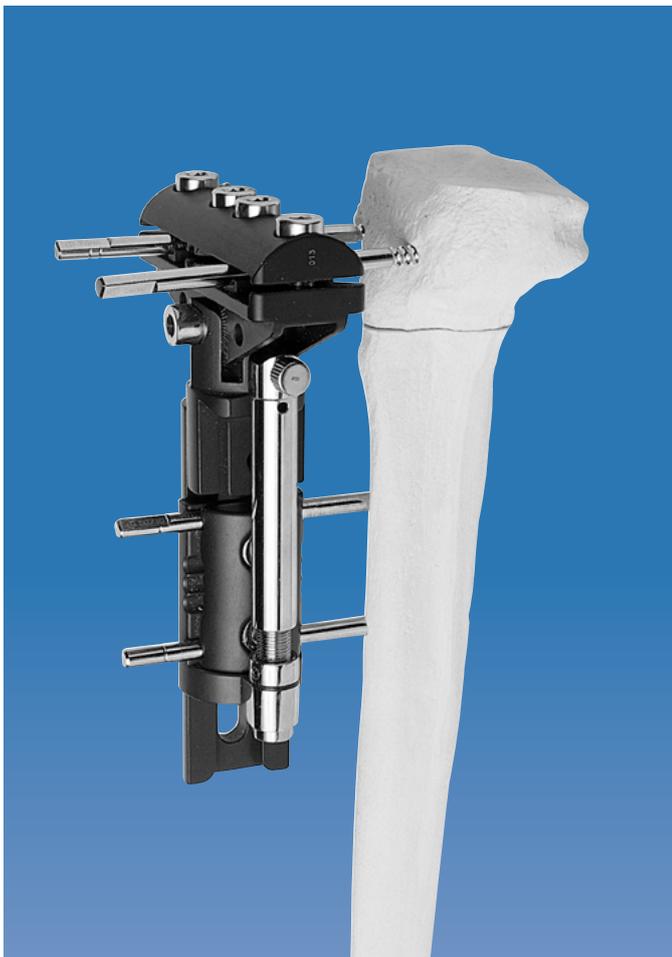
PRECAUTION: During and after insertion of the implants, ensure their correct positioning under image intensification.

WARNING: Do not excessively penetrate the second cortex with any type of screws to avoid soft tissue damage.

In children, a middle screw must not be included in the assembly, since it would damage the growth plate of the tibial tuberosity.

WARNING: During screw and wire insertion, do not enter the joints or the growth plates in pediatric patients to avoid joint damage or growth impairment.

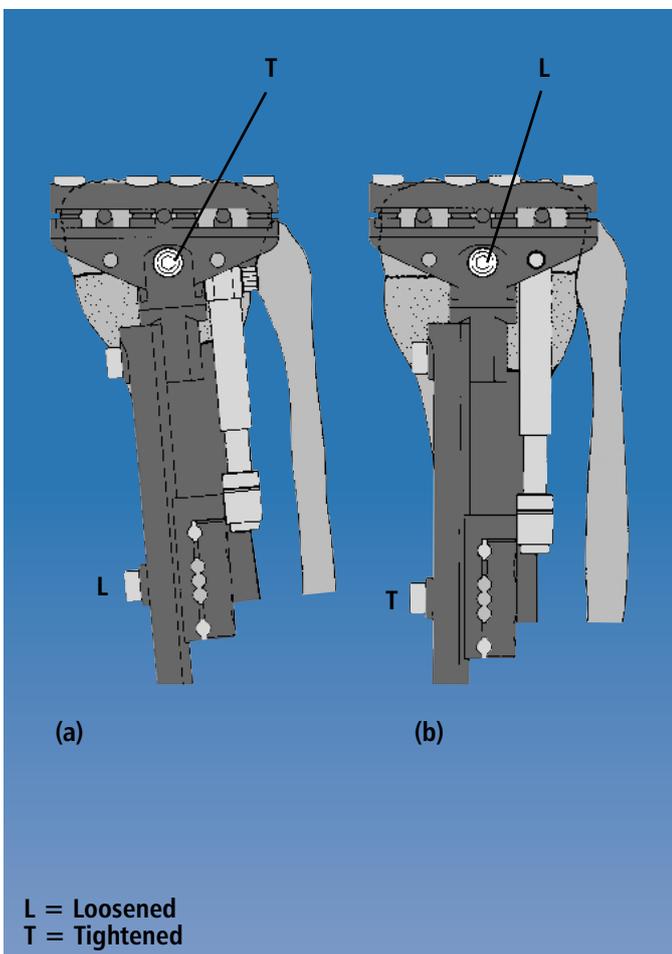
In adults, use of this middle screw is advisable. The diaphyseal screws are then inserted into the straight clamp template and, at this point, Kirschner wires, templates and screw guides are removed.



The rail with the OF-Garches T-Clamp proximally and a straight clamp distally is then positioned, without the upper clamp cover. Once the rail has been fitted, the clamp cover is screwed tightly into place. The clamp axis locking nut should now be tightened.

FOURTH STAGE: Tibial osteotomy

An antero-medial or an antero-lateral approach may be used. The periosteum is detached immediately below the tibial tuberosity and on all faces of the tibia where the osteotomy will be performed. Osteotomy is then performed at the level of the clamp axis locking nut, just below the insertion of the patellar tendon. The technique for performing the osteotomy is similar to that described under "A) Distal Bone Loss in the Femur" (see pp. 24-26). To check whether the osteotomy is complete the bone segments are distracted by two or three millimeters using the compression-distraction unit (one turn anticlockwise = 1mm distraction). The bone segments are then brought back into minimal contact (one turn clockwise = 1mm compression). For this procedure the compression-distraction unit must be positioned as shown in Fig. a) page 41. The straight clamp locking screw is then tightened. Closure is by suture of the periosteum, muscles and skin, in layers, without drainage.



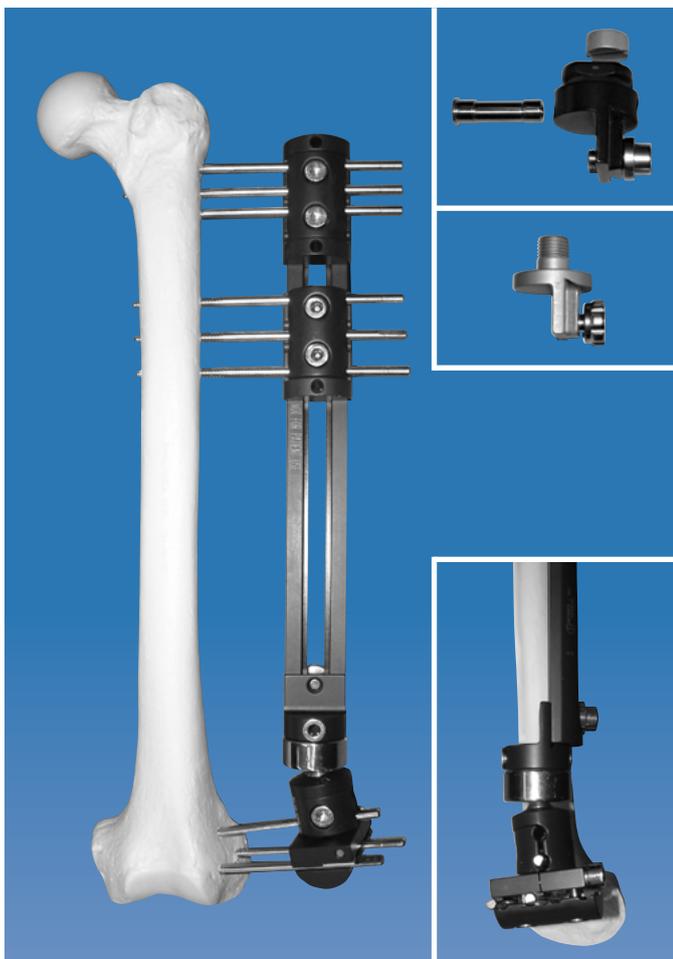
Post-Operative Management

If a varus, or more frequently, a valgus deviation appears during lengthening, its cause must first be ascertained (incomplete tightening of the clamp axis locking nut, bending of the screws, premature consolidation of the fibular osteotomy).

If angular deviation occurs (a), correction is performed with the compression-distraction unit on the same side as the deviation (b), and the position of the removable locking pin as shown in Fig. b) page 41. Distraction is then applied at a rate of 1/4 turn four times per day, with the clamp axis locking nut loosened and the straight clamp locking screw tightened. Once the deviation has been corrected, the position of the removable locking pin is changed to that shown in Fig. a) page 41, and lengthening resumed. This clamp is also particularly useful for the correction of deformities in the proximal tibia. For a full description of its use in this situation, please refer to Manual 11, Part B: Correction of Deformities. Optimal alignment is best judged by means of an AP X-ray of the entire lower limb with the patient standing. Any additional correction may be achieved where necessary by means of either distraction or compression using the compression-distraction unit. A lateral X-ray is also important in order to detect any interfragmentary gap, which may be corrected by means of axial compression.



PRECAUTION: In patients undergoing callus distraction, the regenerated bone must be checked regularly and monitored radiologically.



The Ball-Joint Coupling

This is a fixed module that can be sited at either end of the rail, but cannot slide along it. It has a bayonet fitting that will accept any Orthofix ball-jointed module. When unlocked, it allows free rotation and up to 36° of angular movement in any plane. It is applied with a dedicated template. The use of this coupling for angular correction has now been superseded by the acute correction templates and the micrometric clamps (see Manual 11, Part B: Correction of Deformities).

PEDIATRIC USE OF THE LIMB RECONSTRUCTION SYSTEM

Bone transport and allied techniques are complex and require a high degree of cooperation. In particular, it is difficult in some cases to control the degree of mobilization, since some children are very active and others find it difficult to use mobilization aids such as crutches and walking frames. The procedures are similar to those described above.

Screw Size

As a general rule, if the hole to be drilled is less than 30% of the diameter of the bone adult size bone screws should be used where possible, as the strength of the bone will not be significantly affected, provided that the screw hole is drilled in the center of the bone. The choice of screw size should be made on the size of the child and the bone to be treated, and cannot be determined by age.

REFERENCES

- ALDEGHERI R., RENZI BRIVIO L., AGOSTINI S., The Callotasis method of Limb Lengthening. *Clin. Orthop.*, (1989), 241: 137-145.
- BIERMANN J.S., MARSH J.L., NEPOLA J.V., LAVINI F., RENZI BRIVIO L., Unilateral Bone Transport System for Segmental Deficiency of Bone. Presented at the American Academy of Orthopaedic Surgeons, Anaheim, California 7-12 March 1991.
- BOHLER L., The treatment of pseudoarthrosis. In: *The treatment of fractures*. Vienna, Wilhelm Maudrich, 1929, 23-28.
- CHARNLEY G., BAKER S.L., Compression Arthrodesis of the knee. A clinical and histological study. *J. Bone Joint Surg.*, (1952), 34-B: 187-199.
- COLCHERO R.F., ORST G., VIDAL J., La scarification, son intérêt dans le traitement de l'infection ostéo-articulaire chronique fistulisée à pyogènes. *Int. Orthop.*, (1982), 6 (4): 263-271.
- DE BASTIANI G., ALDEGHERI R., RENZI BRIVIO L., TRIVELLA G., Limb Lengthening by callus distraction (Callotasis). *J. Paediatr. Orthop.*, (1987), 7 (2): 129-134.
- DONNAN L.T., SALEH M., Monolateral external fixation in paediatric limb reconstruction. *Current Orthopaedics*, (1998), 12: 159-166.
- GIEBEL G., Resektions - Débridement mit kompensatorischer Kallusdistraction. *Unfallchirurg.*, (1991), 94: 401-408
- GIEBEL G., In *Callus Distraction: Clinical Applications*. 1992. Georg Thieme Verlag, Stuttgart, New York.
- GLOWACKI J., MULLIKEN J.B., Demineralised bone implants. *Clin. Plast. Surg.*, (1985), 12: 233.
- JUDET R., PATEL A., Muscle pedicle bone grafting of long bones by osteoperiosteal decortication. *Int. Ortop.*, (1972), 87: 74-80.
- KREIBICH D.N., WELLS J., SCOTT I.R., SALEH M., Nonunion Donor site morbidity at the iliac crest: comparison of percutaneous and open methods. *J. Bone Joint Surg.*, (1994), 76-B: 847-848.
- MAGYAR G., TOKSVIG-LARSEN S., MORONI A., Hydroxyapatite coating of threaded pins enhances fixation. *J. Bone Joint Surg.*, (1997), 79-B (3): 487-489.
- POULIQUEN J. C., LANGLAIS J., CEOLIN J.L., PAUTHIER F., The use of the Dyna-ring in lengthenings of the lower limb. Presented at the second Riva Congress on Current Perspectives in External and Intramedullary Fixation, Riva del Garda, Italy, 27-31 May 1992.
- RIBBANS W.J., STUBBS D.A., SALEH M., Non-union surgery. Part II. The Sheffield experience – one hundred consecutive cases. Results and lessons. *International Journal of Orthopaedic Trauma*, (1992), 2: 19-24.
- SALEH M., External fixation of long bone fractures in children. British Orthopaedic Association Autumn Meeting, Cambridge, 25-27 September 1991 (Abstract in the *J. Bone Joint Surg.*, (1992), 74-B Orthopaedic Proceedings Supplement 2, page 152).
- SALEH M., Non-union Surgery. Part I. Basic principles of management. *International Journal of Orthopaedic Trauma*, (1992), 2: 4-18.
- SALEH M., Non-union treated with the Dynamic Axial Fixator: Results. Presented at the second Riva Congress on Current Perspectives in External and Intramedullary Fixation, Riva del Garda, Italy, 27-31 May 1992.
- SALEH M., Bone Grafting Harvesting: a percutaneous technique. *J. Bone Joint Surg.*, (1991), 73-B: 867-868.
- SALEH M., Editorial - Mini symposium on bone loss. *Current Orthopaedics*, (1994), vol. 8 no 3: 141-143.
- SALEH M., The management of bone loss. In C. Court-Brown and D. Pennig (eds): *Tibia and Fibula*. Butterworth - Heinemann, 1997: 143-159.
- SALEH M., BURTON M., Leg Lengthening: Patient Selection and Management in Achondroplasia. *Orthopaedic Clinics of North America*, (1991), 22:589-599.
- SALEH M., FLOWERS M.J., Bifocal Comment article "Limb Lengthening". *Current Medical Literature*. *Orthopaedics*, (1994), 7 (3): 71-73.
- SALEH M., HAMER A., Bifocal lengthening - preliminary results. *J. Paed. Orthop.*, (1993), 2[B]: 42-48.
- SALEH M., HOWARD A.C., Improving the appearance of pin site scars. *J. Bone Joint Surg.*, (1994), 76-B, 906-908.
- SALEH M., MEFFERT R.H., STREET R.J., Bifocal Verlängerung der unteren Extremität mit dynamisch-axialer externer Fixation nach der Technik von Vilarubias. *Tagliche Praxis*, (1994), 35 (1): 83-90.
- SALEH M., REES A.R., Bifocal surgery for deformity and bone loss - bone transport and compression distraction compared. *J. Bone Joint Surg.*, (1995), 77-B: 429-434.
- SALEH M., ROYSTON S., Management of nonunion of fractures by distraction with correction of angulation and shortening. *J. Bone Joint Surg.*, (1996), 78-B: 105-109.
- SALEH M., STREET R., RIBBANS W.J., Lower limb reconstruction using the Ilizarov technique. British Orthopaedic Association Spring Meeting, Brighton, 24-26 April 1991 (Abstract in the *J. Bone Joint Surg.*, (1991), 73-B Orthopaedic Proceedings Supplement 2, page 188).
- SVESNIKOV A.A., BARABASH A.P., CHEPLENKO T.A., SMOTROVA L.A., LARIONOV A. A., Radionuclide studies of osteogenesis and circulation in substitution of large defects of the leg bones in experiment. *Ortop. Travmatol. Protez.*, (1984), 11:33.
- TRUETA J., Muscle contraction and interosseus circulation. *J. Bone Joint Surg.*, (1965), 47-B: 186.

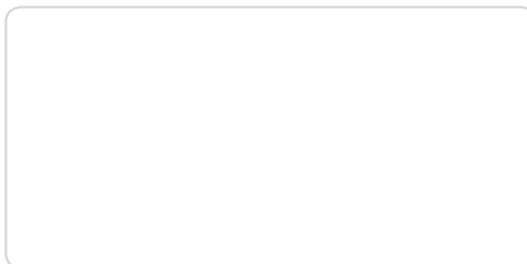
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