

THE ORIGINAL ILIZAROV SYSTEM

General Surgical Technique Brochure

The apparatus described in this brochure is covered in whole or in part by the following patents:

<u>USSR:</u> G. A. Ilizarov: Compression-Distraction Apparatus U.S.S.R. Patent N. 538710 – 3338801 1/28-13

Italy: Patent No. 47890 - A/82

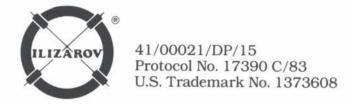
France: 2587612

Belgium: 903258

U.S.: Patent No. 4615338

Great Britain: 2180453

Other patents exist in various countries or are still pending.



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THE ILIZAROV EXTERNAL FIXATOR

General Surgical Technique Brochure

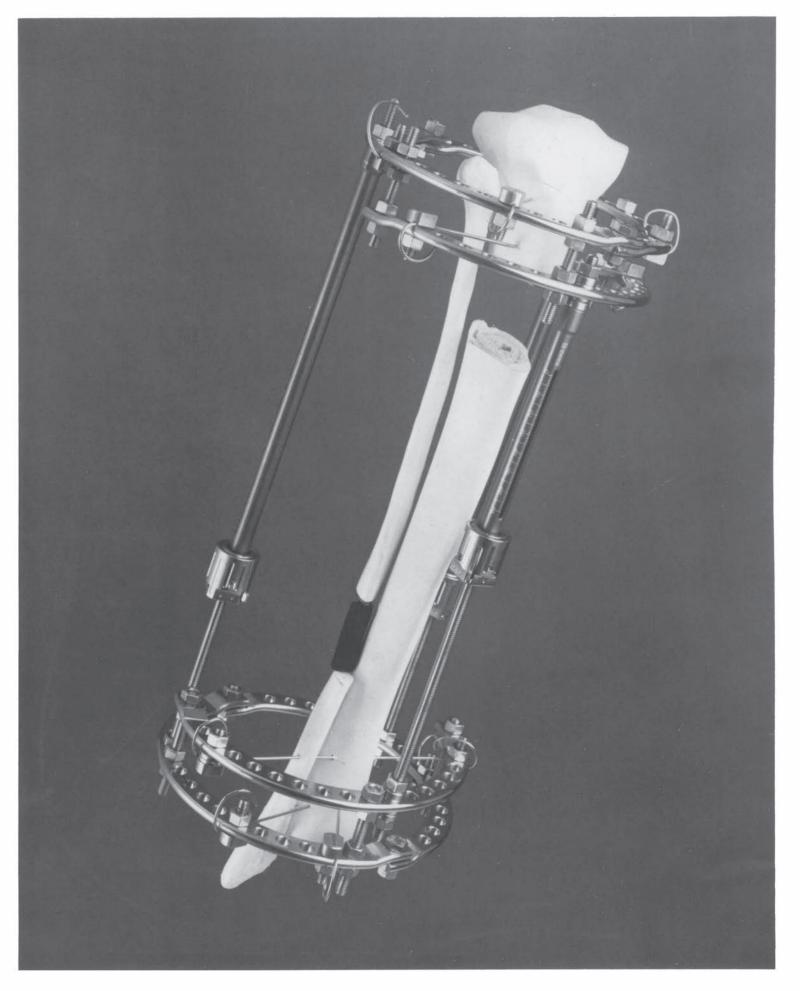
INTRODUCTION

The Ilizarov External Fixator was originally developed in Kurgan, Siberia of the Soviet Union in 1951 by Dr. Gavriil A. Ilizarov. Since that time, this device has been used in a reported 1,000,000 cases worldwide, although only first used in the West in 1981. The Ilizarov External Fixator is often called a Compression-Distraction Apparatus to denote its bone lengthening feature whereby two bony ends are compressed together while at the same time distracting from a corticotomy area. As presently available, the equipment in the system can be assembled in over 600 different ways with each assemblage custom-made for the particular orthopaedic needs of each patient. Because of the complexity of the different methods of assembly, no surgical technique brochure could possibly explain all of the variations of usage. The purpose of this brochure is to describe the steps common to nearly all operations.

The brochure is broken down into three parts. In the first (Part I) the insertion of wires, assembly of the rings of the circular fixator, wire tightening, and rod assembly are described. The second (Part II) shows clinical examples of apparatus assembly. And the third (Part III) explains the corticotomy which would be used if any bone regeneration is needed.

The final method of assembly and selection of parts has to be made by the surgeon at the time of the operation. Because of the complexity, pre-operative planning is a necessity. However, the versatility of the system allows some minor modifications of the assembly after the procedure is complete. The method of use, patient selection, patient post-operative instruction and treatment, and mode of application for each patient are, of course, the final responsibility of the physician. This brochure is meant only to be an introductory guide to the assembly process. The proper assembly process for each patient can only be gained by experience and advanced orthopaedic training of the proper use of the Ilizarov equipment.

Nota Bene: The technique description herein is made available to the healthcare professional to illustrate the author's suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the needs of the specific patient.



PART I

INSTRUCTION FOR WIRE INSERTION AND RING ASSEMBLY

- Select two half rings that are at least 2-3 cm larger than the major diameter of the limb being operated upon.
- 2. Using a bolt (Catalog No. 103200, 103201 or 103202) and a nut (Catalog No. 103300) assemble two ends of the half rings together, such that the major sections of both halves are in the same plane (Fig. 1).
- 3. After placing the two half rings around the limb at the projected area of the final assembly, check that there is at least 2-3 cm clearance from the inside of the ring to all areas of skin. If operating upon the tibia, only 1 cm will be needed anteriorly since swelling (edema) will not occur in this region.

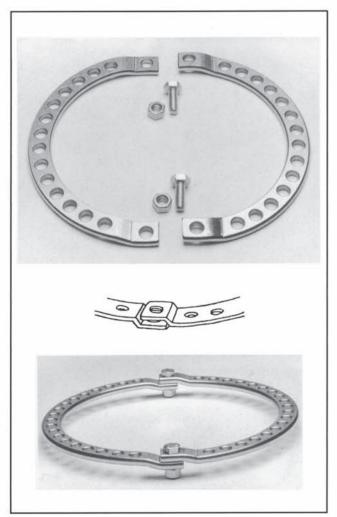


Fig. 1

- 4. Determining the direction and location of the wire insertions relative to the ring should be made with proper attention to anatomical features such as nerves, blood suply, etc. Further information can be found elsewhere. 1-3
- 5. The plane of the insertion of the wires can be determined by two methods.

First, the top and bottom portion of the half ring can be marked on the skin using a skin marker running alongside the ring. These markings on the skin can then help the surgeon determine the angle for the pin insertion.

Second, the half rings can be held in position and the guide wires inserted superior or inferior to the top or bottom of the ring using the ring itself as a guide for wire insertion.

Note: The ring should be held such that it is approximately perpendicular to the midline of the bone in its pre-operative state at that level.

6. If two wires are used, the wires should be inserted approximately 90 degrees relative to each other.

Note: Sometimes anatomical considerations prevent the wires from being inserted 90 degrees relative to each other. For these cases, the wires should be placed as close to 90 degrees apart as anatomically possible.

As already mentioned, if two wires are used, then one wire should run parallel to the top of the ring and the other along the bottom (Fig. 2).

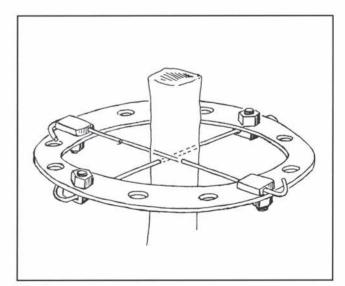


Fig. 2

7. The 1.5 mm or 1.8 mm wires can be inserted using one of several types of powered drills. If possible, the drills should be chucked up as close to the skin as possible and gradually chucked back during the drilling process. Pressing the wire down to the bone is recommended first, then drilling through the bone, and then hammering the end of the wire through the remaining soft tissue to the other side of the limb. Insertion of the wires should be checked using an image intensifier (Fig. 3, Table 1).

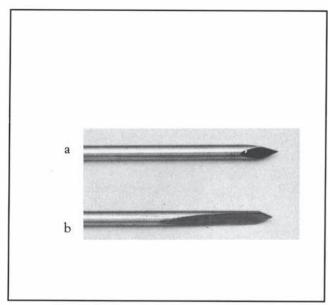


Fig. 3

- a) Tip of Trocar wire for spongy bone
- b) Tip of Bayonet wire for cortical bone

Table 1

Ilizarov wires:

- a) The bayonet point (cortical) wires available are:
 - 1.5 x 170 mm (Catalog No. 102100)
 - 1.5 x 300 mm (Catalog No. 102101)
 - 1.8 x 370 mm (Catalog No. 102102)
- b) The trocar point (cancellous) wires available are:
 - 1.5 x 170 mm (Catalog No. 102103)
 - 1.5 x 300 mm (Catalog No. 102104)
 - 1.8 x 370 mm (Catalog No. 102105)
- c. The Ilizarov wires with stopper or "olive" (bayonet point) available are:
 - 1.5 x 300 mm (Catalog No. 102106)
 - 1.8 x 400 mm (Catalog No. 102107)

The choice of diameters should take into consideration the segment being operated upon and the age and the weight of the patient.

Note: If the wires are not in parallel planes at least 5 mm apart (the width of the ring) (Fig. 4) and 90 degrees to each other, then serious consideration should be given to removing and reinserting one or more of the wires.

Remember: After final assembly, the wires and rings are to be approximately perpendicular to the midline of the bone at that level as seen at the time of surgery.

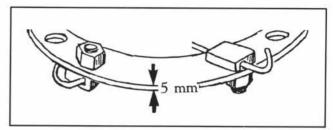


Fig. 4

Note: The Ilizarov wire with stopper (olive) (Catalog No. 102106 or 102107) (Fig. 5) can be used: a) to create interfragmentary compression, b) to add more stability to the assemblage.

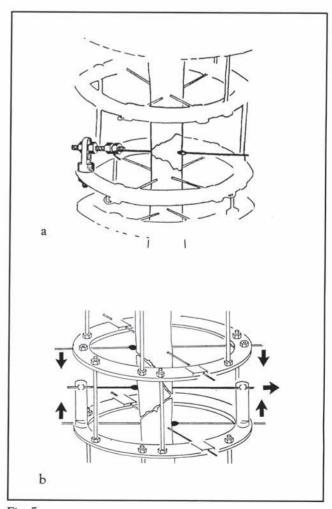
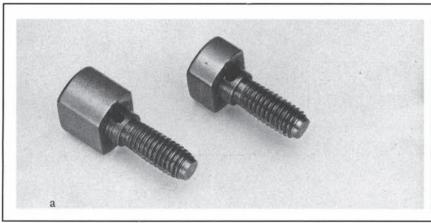


Fig. 5

- 8. As soon as possible after the wires have pierced through the skin on the opposite side of the limb, the tips of the pins should be removed to prevent cutting through surgical gloves, etc. The tips of the pins should be wrapped in gauze or some other suitable material and then cut using a wire cutter.
- If gauze or rubber stoppers are to be used around the wires to help prevent pin tract infection, they should be placed over the ends of the wires and slid toward the surface of the skin.
- 10. The rings should be repositioned around the limb and held approximately two finger breadths away from all areas of the limb, with the possible exception of the anterior part of the tibia where one finger breadth is sufficient. One wire should run along the top of the ring and the other wire should be flush with the bottom.
- 11. Using a bolt (Catalog No. 103200, 103201 or 103202) and nut (Catalog No. 103300) (see Fig. 1), securely fasten the opposite side of the ring. For ease of assembly, the nuts and bolts holding the two half rings together should be positioned over the most anterior and posterior parts of the limb. All the nuts and bolts can be securely tightened by attaching two wrenches, one to the nut and one to the bolt, and turning simultaneously in opposite directions.
- 12. Extreme care should be taken so as not to bend or scratch the wires at any time. If this occurs, the wires should be replaced. If necessary, washers or other metal spacers should be used to build the ring to the wire. The natural temptation to bend the wire to the ring should be avoided. If the wire is out of position or if excessive amounts of washers or spacers are needed, then serious consideration should be given to removing and repositioning the wire.

- 13. At this point the wires should be assembled to the ring, using either cannulated (Fig. 6a) or slotted (Fig. 6b) bolts (Catalog No. 100600 or 100700) and nuts (Catalog No. 103300). The choice of a cannulated or a slotted bolt is determined by the position of the wire relative to the hole over which it passes. Selection should be made so as to minimize or eliminate bending of the wire.
- 14. The nuts and bolts on the rings should be loosely attached at first. All the wires, nuts and bolts should be examined relative to each other, checked for proper alignment and selection of components, and oriented according to preoperative planning.
- After checking out the assembly, securely tighten the wire bolts and nuts farthest away from the surgeon.
 - Caution: Whenever tightening wires to rings, hold the head of the bolt stationary with one wrench and turn the nut with another. If the bolt on the wire turns during tightening, the wire will bend. This action may damage the wire or change the tension.
- 16. If wires with stoppers (olives) are used (Catalog Nos. 102106 and 102107), then the ends of the wire with the stopper or olive should be noted and marked (such as bending one end in a different manner) to prevent the possibility of accidentally pulling the wire through the bone in the wrong direction.
 - Note: Wires with stoppers may or may not be placed under tension depending upon the particular technique and surgeon preference.
- 17. After marking wires where appropriate, checking to see if gauze and/or stoppers are in proper position, and confirming the proper orientation and alignment of the rings and wires, the wires are then ready to be placed under tension.



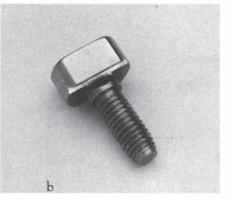


Fig. 6

INSTRUCTIONS FOR PROPER USE OF DYNAMOMETRIC WIRE TENSIONER

Catalog No. 103101

Although the original Russian design for the tensioner is available (Catalog No. 103100), its proper use in tensioning can be determined only by feel (Fig. 7a). To solve this problem, the Italians have developed a special wire tensioner specifically for use in this surgical procedure. This instrument (Fig. 7b) (Catalog No. 103101) is a calibrated spring wire tensioner. After the ring has been assembled around the wires,

one end of the wire is securely fastened using a bolt and nut, and another bolt and nut are loosely attached to the wire on the side closest to the surgeon. The wire tensioner handle is first turned all the way to the left or counter-clockwise. This action opens the jaws of the wire tensioner to the fullest degree.

To protect the ring from warping during the tightening process, two wire tensioners may be used simultaneously, one on each of the two wires. The wire tensioner should be slid over one end of the wire and the special prong on the end of the wire tensioner fitted onto the ring (Fig. 8).

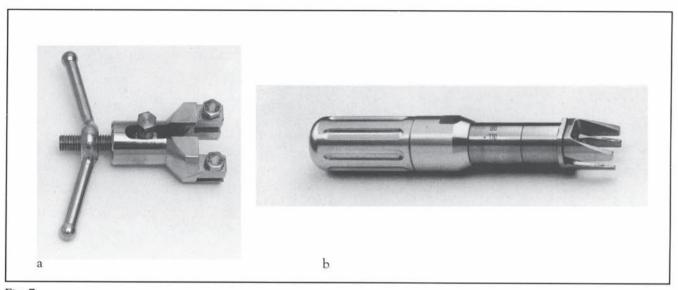


Fig. 7

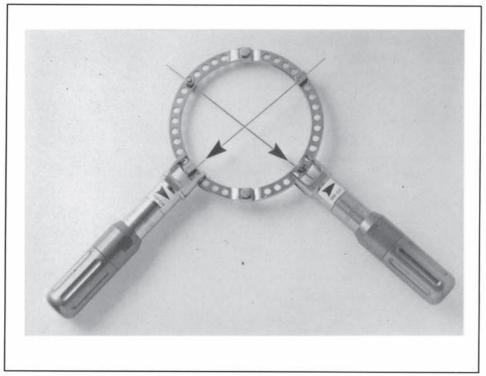


Fig. 8

Note: The prong will go on only one way. If for some reason (such as the presence of a threaded rod) the wire tensioner cannot be placed directly onto the ring, then a spacer such as a threaded socket (Catalog Nos. 100900, 100901) can be slid over the end of the wire to give the tensioner a surface to work against. Demonstration of the use of the spacer is shown in the diagram (Fig. 9).

After the wire tensioner (or tensioners) is placed against the ring, the handle of the wire tensioner is turned clockwise or to the right. After several turns the handle of the wire tensioner begins to move toward the ring. The most upper part of the handle will gradually pass over the numbers inscribed on the wire tensioner. (The wire tensioner is calibrated from 50 to 130 kilograms) (Fig. 9). As the wire tensioner handle passes over the numbers and dots, the value read indicates the tension in kilograms being applied to the wire. After the wire tensioner has reached the desired tension, the loosely fitting bolt and nut nearest to the surgeon should be securely tightened using two wrenches. One wrench holds the bolt stationary while the other tightens the nut. Only after securely tightening the nut and bolt should the wire tensioner handle be turned counter-clockwise (to the left) and removed.

It is most important to tension all the wires during frame assembly. Increasing the tension on the wire increases the stiffness of the assemblage and decreasing the tension on the wire increases the amount the fracture site telescopes during normal loading. Too much tension on the wires can lead to premature breakage during use. Too little tension on the wires (or none at all) may allow too much movement at the fracture site during loading. To maintain a safe balance between the axial stiffness and the stability of the fixator, it is recommended that the wire tension used be between 100 and 130 kilograms, with the actual selection depending upon the diameter of the wire, the body weight of the patient, and the bone being operated upon. (Table 2)

It is absolutely imperative to check the tension on the wire on the days following surgery and during the course of treatment. Loss of wire tension decreases stability and causes pain. Decreased stability also invokes an inflammatory response around the wire sites and leads to pin tract infection. If the tension on the wires is too great, the external fixator rings may warp or go out of alignment during the course of treatment. To prevent this occurrence, at least two transosseous wires must be used for each ring of the assembly, with one fixed on the proximal side of the ring and the other fixed on the distal side.

Table 2

The approximate tension to be applied to the wires:

a) Half rings: 50 Kgs

b) One single wire attached to the ring: 70 Kgs

c) Young patients: 100-110 Kgsd) Adult patients: 120-130 Kgs

e) Heavy patients: 130 Kgs (with an additional number of wires)

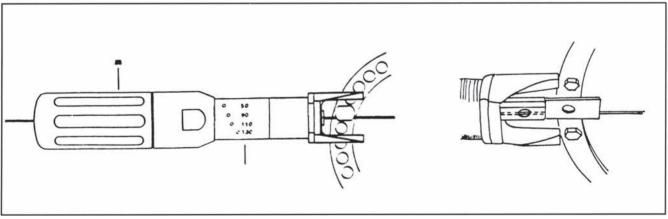


Fig. 9

MAINTENANCE AND PRECAUTIONS ON USE OF THE DYNAMOMETRIC WIRE TENSIONER

The Dynamometric wire tensioner is made principally of stainless steel. It is a delicate instrument and should be handled with great care. Maintenance is also a concern. Following surgery, the apparatus should be cleaned with a soapy solution and brushed. If cleaned with a disinfectant, a cleaning agent should be selected that is well tolerated by the stainless steel. The Dynamometric wire tensioner can withstand repeated sterilization using proper and normal autoclaving techniques.

Note: Dynamometric wire tensioners should never be stored with the handle turned all the way to the left. Any position other than this position increases the useful life of the product. The tensioner should be stored in a dry, protected environment. The apparatus should be checked periodically for damage, although nicks on the pronged end of the tensioner where it attaches to the ring are normal and do not affect the utilization of the instrument. If the instrument becomes damaged it should be replaced.

If it is difficult to achieve the desired level of tension on the wire during the tightening process, then there are a number of possible explanations. First, the wire could be damaged, preventing an accurate grip on the wire. Second, the tensioner could be damaged.

<u>Note</u>: To check for this possibility, try using another wire tensioner.

The most common problem is that the wire is slipping from the bolt and nut on the opposite side of the ring. An indicator of this condition is that as the tension goes up on the tensioner, a clicking sound is heard, and the level of tension suddenly decreases on the handle. To prevent this from occurring, be sure that the bolt and nut on the opposite side of the ring are extremely well secured by using two wrenches, one on the bolt and one on the nut, and turning the nut firmly.

After the desired level of tension is reached and the nut and bolt nearest to the wire tensioner is securely tightened, the tensioner is removed after first turning the handle counterclockwise. The ends of the wire should be either cut off and a protector put on the ends of the wire or preferably the wire should be bent around the ring in the opposite direction from the side to which it is attached. Leaving a long end on the wire allows for the possibility of retightening at a later date if the tension is lost.

Note: After the first ring is tightened, all the other rings should be held such that after tightening, their most anterior section will be approximately parallel to the surface of the skin. Taking this step will make it easier to assemble the threaded rods to the rings later.

INSTRUCTIONS FOR ASSEMBLING THE THREADED AND TELESCOPIC RODS TO THE RINGS*

- —The threaded rods (Catalog Nos. 102300, . . . 102314) are placed parallel to each other and in line with the longitudinal axis of the bone. The rods should be equidistant from each other on the ring.
 - a) In fracture cases, if the apparatus has been mounted properly and the fragments aligned, the tightening of the nuts automatically produces a perfect reduction (Fig. 10a).
 - b) In angular deformity cases, hinges (Catalog Nos. 101600, 101700) should be used, or in cases of slight angular deformities, conical washers (Catalog No. 201700) can be selected (Fig. 10b) (Fig. 12).

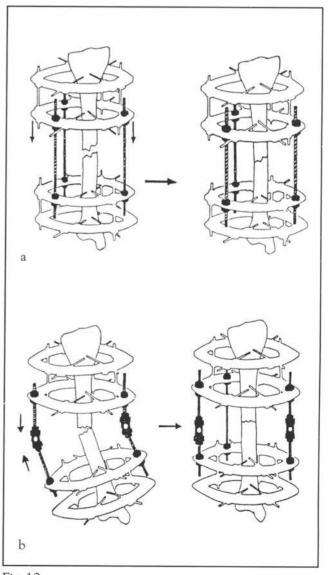


Fig. 10

^{*}See Part II for clinical examples.

c) In cases with an oblique positioning of the rods, a lateral displacement of the fragments on the frontal plane and a rotational displacement on the sagittal plane is produced (Fig. 11).

Once the apparatus has been assembled, an X-ray is taken. If the position of the rods is incorrect, an immediate modification is necessary.

Ideally, the rods should pass through the corresponding holes of the rings. If the position of the rods is not correct, when the nuts are tightened the rods will not be perpendicular to the rings, producing a lateral force. This force will lead to a medial-lateral displacement.

If a rod needs to be repositioned, another rod should be placed nearby first to ensure alignment and stability of the mounting. This second rod is removed once the proper position of the primary rod is obtained. If a rod cannot easily fit into the holes of the ring, correcting plates should be used.

Note: To aid in assembling the Graduated Telescopic Rods to the archs and rings, Conical Washer Couples (Catalog No. 201700) are used (Fig. 12a). The couple is composed of a concave and convex washer which when loose act like a universal joint. When tightened down using nuts, the Conical Washer Couple provides good stability and allows non-parallel rings to be easily connected with the rods.

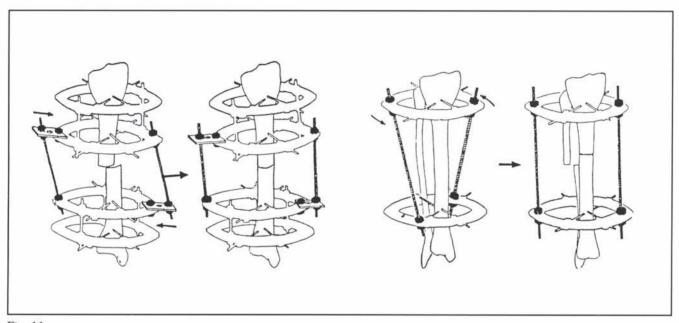


Fig. 11

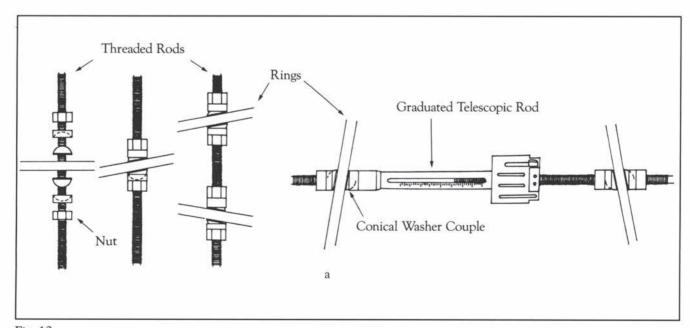


Fig. 12

PART II

CLINICAL EXAMPLES OF APPARATUS ASSEMBLY*

FRACTURES OF THE HUMERUS

Transverse fractures at different levels

a) In the proximal humerus a pair of wires is inserted. The exact angle between the wires depends upon anatomical considerations. Since it is impossible to insert the wires at a 90 degree angle, a third wire inserted below the first two is recommended to increase the stability of the mounting. The wires are then connected to the half ring with curved extremities (Catalog Nos. 101332, 101333,

101335) (Fig. 13a).

b) In the distal humerus, after inserting the wires connect a 5/8 ring (Catalog Nos. 101323, 101325, 101326) (Fig. 13b) in a posterior position, in such a way as to permit a free anterior movement of the elbow.

The fixation and the reduction of the fracture are obtained by applying two half rings or rings in the middle third above and below the fracture site to which two wires with stoppers are connected (Fig. 14).

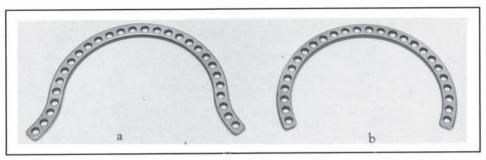


Fig. 13

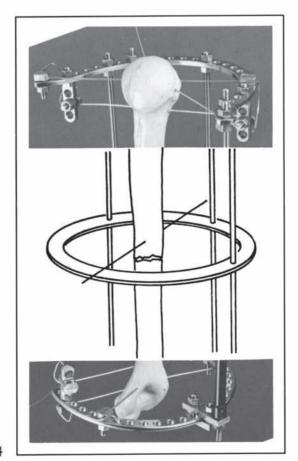


Fig. 14

^{*}Condensed from "Manual of Transosseus Osteosynthesis According to G. A. Ilizarov" in press (Authors: A. Bianchi Maiocchi, M. Catagni, R. Cattaneo, A. Villa).

PSEUDOARTHROSIS OF THE HUMERUS

Assembling of the apparatus

Follow the general rules already discussed. As described previously for humeral fractures, apply the half ring with curved extremities and the 5/8 ring to the proximal and distal ends. The diagrams in Figure 15 illustrate the mountings.

1) Oblique pseudoarthrosis of the middle third

Variation A

Assemble the mountings according to previous scheme. Interfragmentary compression can be exerted by two wires under tension above and below the fracture site. The assembly may be completed with a slight distraction, depending on the case.

Variation B

The interfragmentary compression can be obtained with two wires with stoppers on the transverse or oblique plane.

2) Pseudoarthrosis requiring correction of the longitudinal axis

Variation A

In a case of pseudoarthrosis with a slight (10 degrees-15 degrees) angular deformity and satisfactory apposition of the fragments, assembly is as follows: The proximal half ring is placed perpendicular to the axis of the upper fragment of the humerus (oblique to longitudinal axis of the arm). The distal half ring is placed in the distal fragment also perpendicular to the axis of the humerus at its site of insertion. The correction of the deformity is obtained by the compression-distraction mechanism of the rings. A third or fourth wire with stoppper is inserted into the middle third to strengthen the mounting (Fig. 15a).

Variation B

The correction of the angular deformity and the healing of the pseudoarthrosis are obtained with a mounting similar to the one previously described. The gradual correction of the deformity is achieved by the use of the wires with stoppers. If the angular deformity is moderate, the correction may be achieved at the time of surgery with the Dynamometric wire tensioner (Fig. 15b). In more severe cases, apply a gradual "traction" during the post-operative course by using a slotted threaded rod. With the Ilizarov technique in a stabilized pseudoarthrosis, compression and distraction forces that stimulate the osteogenesis can develop.

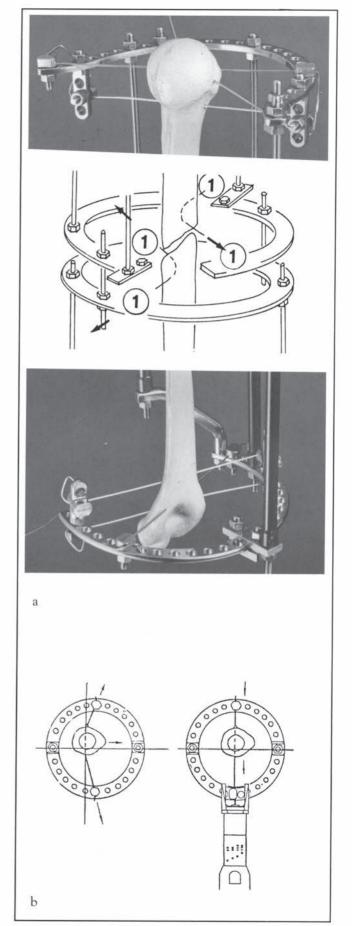


Fig. 15

FRACTURES OF THE FOREARM

Fracture of the radius and ulna at the middle third

The forearm must be in a neutral position. The fracture is almost always of the oblique type.

- 1) Insert the wires in the proximal and distal epiphysis, as described in the previous case. It is always necessary to use four rings (Fig. 16).
- 2) To maintain the reduction of the radius, a wire with stopper is applied in the metaphysis; the wire is bent and traction is applied. For the ulna, a simple wire with stopper acting in the opposite direction can be used.

The number of additional wires that can be transfixed in the diaphysis, and the site of their insertion, depend upon the type of the fracture.

Fracture of the radius and ulna at the distal third

The technique for insertion of the wires is similar

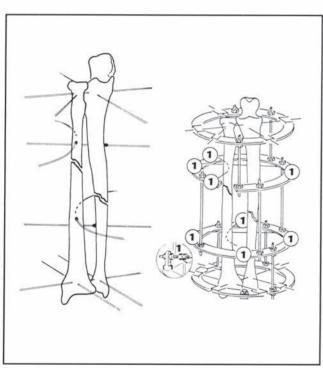


Fig. 16

to the ones previously described. To achieve and maintain the reduction a three-ring mounting is used (Fig. 17).

Fracture of the ulna with dislocation of the head of the radius (Monteggia fracture)

First, the dislocation must be reduced and the forearm placed in a neutral position, over a proper support.

- Two wires are inserted into the radius and ulna in the proximal metaphysis; a wire with stopper is drilled in the radial site.
- 2) Another pair of wires is inserted in the distal epiphysis.
- The rings are applied and connected with threaded rods.

Distraction can then be applied to achieve reduction of the fracture and the dislocation.

The reduction of the head of the radius is maintained by the wire with stopper.

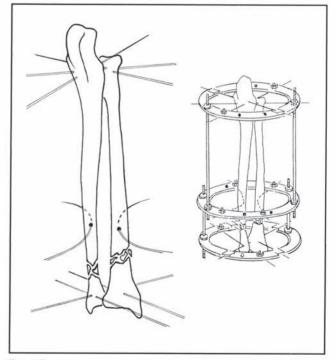


Fig. 17

PSEUDOARTHROSIS OF THE FOREARM

Pseudoarthrosis of the distal third of the radius

Note: This condition may be complicated by radial club-hand with dislocation of the epiphysis of the ulna.

These conditions usually have a combination of an angular and a rotatory (in pronation) displacement of the distal fragment.

Figure 18a shows how one ring has been set per-

pendicular to the axis of the radius and ulna. Another ring has been set perpendicular to the axis of the radius. Consequently, the angular displacement must be corrected by three hinges connected to the distal ring with threaded rods (Fig. 18a).

To reach the final correction and improve the stability it is necessary to put a fifth wire with stopper on the distal ring using two supports (Fig. 18b). The gradual movement of hinges and the strength of the wire allow the correction of the pseudoarthrosis to be obtained.

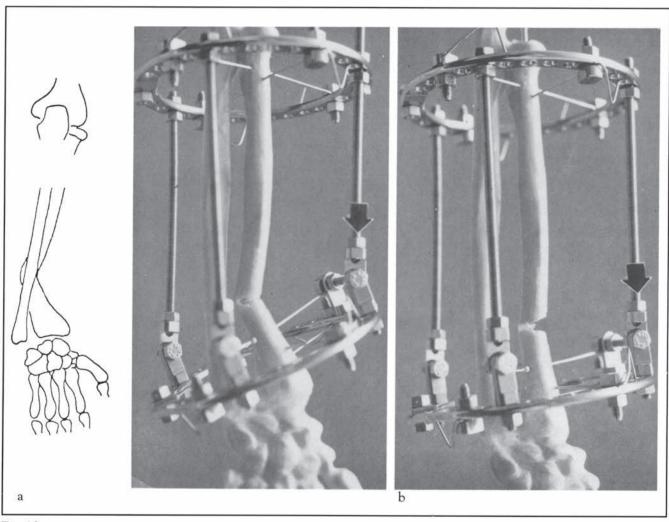


Fig. 18

FRACTURES OF THE FEMUR

Assembling of the original Ilizarov's apparatus.

1) In the proximal area

For the fixation of the proximal fragment, the wires must pass from the anterior surface of the femur, at the level of the lesser trochanter. Five to six wires are used; the two with stopper have to be transfixed in opposite directions. (This act prevents any possible secondary movement of the arch when the patient is lying on his back.) The wires are connected to the upper femoral arches and put under tension (Fig. 19).

2) In the distal area

Since the proximal femoral arch has a diameter that does not correspond to the diameter of the distal ring, a short connection plate (3-4 holes) can be used to "augment" the diameter of the distal ring (Fig. 19). A couple of Ilizarov wires inserted in the usual manner, plus one or two additional wires for added stability placed in the metaphysis, are connected to two rings or to one ring and one half ring (Fig 20).

<u>Note</u>: In the femur it is better to connect the third wire to a half ring, instead of any other kind of support.

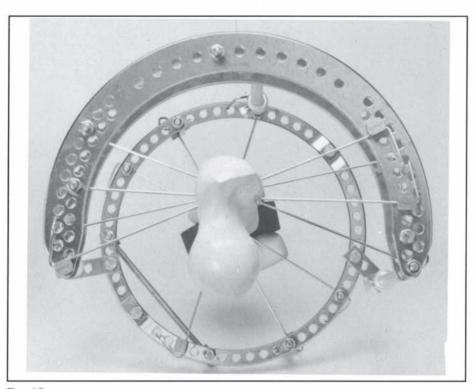


Fig. 19

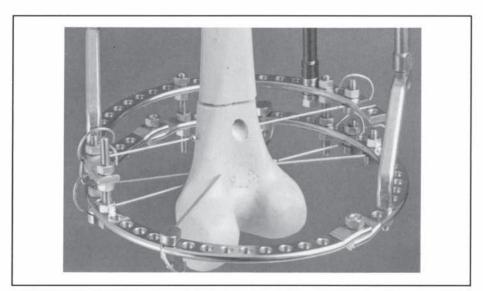


Fig. 20

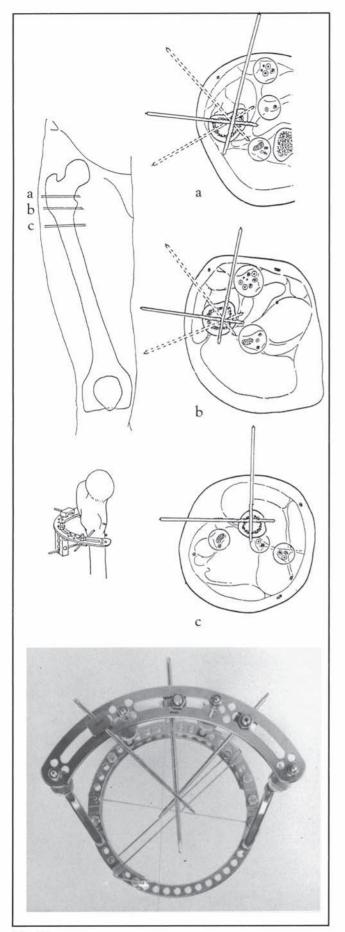


Fig. 21

Special apparatus for proximal side of the femur adaptable to external circular fixators.

Dr. M. Catagni and Prof. R. Cattaneo from Lecco Hospital (Italy) have developed a new special apparatus for the proximal side of the femur. These modifications allow correct assemblage with all the other original elements of the original Ilizarov External Fixator.

The modifications consist of special arches 90 degrees and 120 degrees (Catalog Nos. 201002, 201004, 201006, 201008), Single Pin-Fixation Bolt (Catalog No. 201100) and Multiple Pin-Fixation Bolt (Catalog No. 201200).

Assemblage is facilitated by insertion of the Half Pins (Catalog Nos. 201400, 201401, 201402, 201502) in the anterior and lateral subtrochanteric regions at different levels, thus providing a higher grade of stability (Fig. 21).

If more stability is needed a second series of Half Pins can be added.

The Graduated Telescopic Rods and Oblique Support connections spread the load along the circumference (280 degrees - 300 degrees) of the distal ring (Fig. 22).

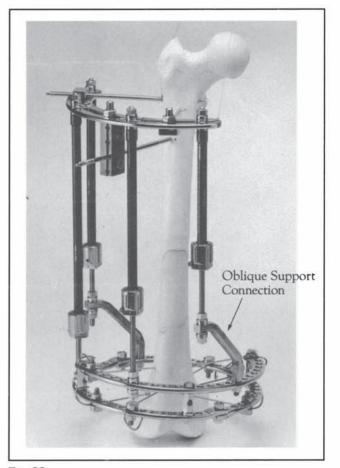


Fig. 22

Comminuted fractures

To reinforce the stability of the fixation in comminuted fractures, it is necessary to transfix two pairs of wires in the diaphyseal or metaphyseal site above and below the comminuted area. The site of introduction of the wires depends upon the location of the fracture and the method of treatment. Figures 23 and 24 show:

a) Distraction osteosynthesis in comminuted fractures (Fig. 23).

b) Interfragmentary compression osteosynthesis with one or more wires with stopper (Fig. 24).

Note: In order to maintain continuous traction on the wire with stopper (interfragmentary compression) slotted threaded rods (Catalog Nos. 102400, 102401, 102402, 102403) are used. These rods are connected to one or more hinges (Catalog No. 101600) or Supports (Catalog Nos. 101400, 101401, 101402) (See Fig. 25).

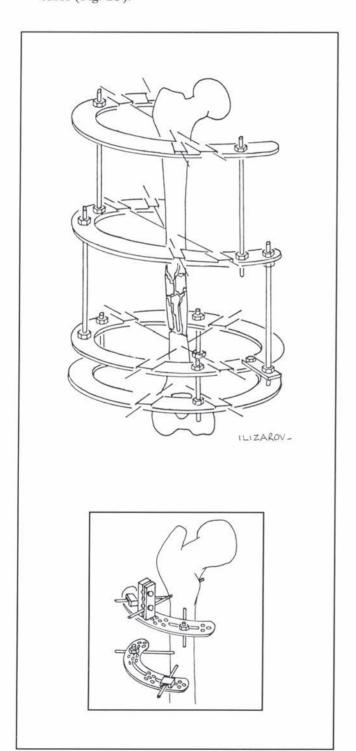


Fig. 23

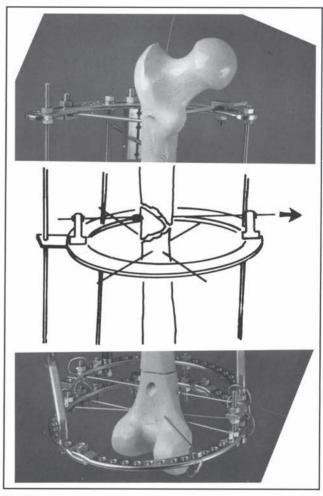


Fig. 24

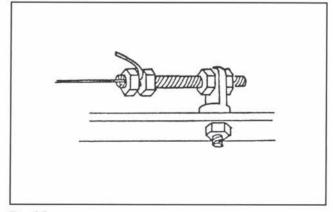


Fig. 25

PSEUDOARTHROSIS OF THE FEMUR: EXAMPLE OF TREATMENT

Compression osteosynthesis and contemporary correction of the deformities

This method is indicated in cases of hypertrophic pseudoarthrosis, angular deformities of the fragments and unilateral cone-shaped bone-defects at the extremities of the fragments, with a shortening less than 3 cm.

Avoid a single level lengthening in cases of atrophic pseudoarthrosis; in cases with the extremities of the fragments incongruent, atrophic or thin; in cases with shortening greater than 3 cm and a bone defect; or in cases of sequestrae and fistulous osteomyelitic. In these cases it is better to adopt the technique of two level lengthening in distraction and consequent compression (see "Pseudoarthrosis of the Tibia with Bone Defects" on page 23).

Note: Figure 26 demonstrates a gradual correction of varus deformity of the femur.

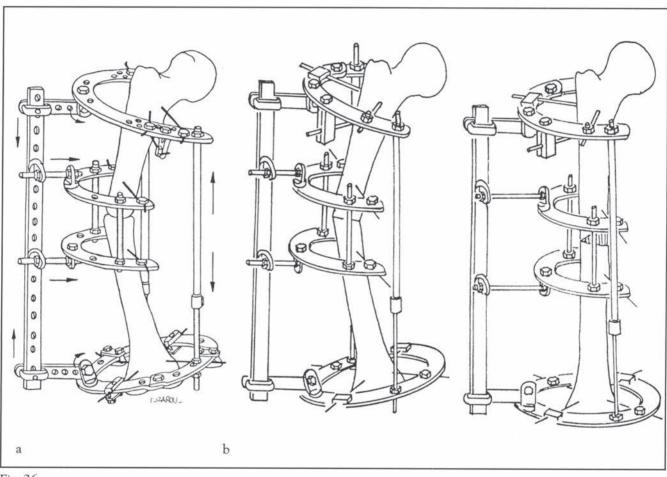


Fig. 26

FRACTURES OF THE TIBIA

Transverse fracture of the proximal third of tibia: example of treatment

1) Two wires are transfixed through the proximal epiphysis of the tibia, (the head of the fibula may or may not be transfixed, depending on the case). Use caution so as to prevent injury to the peroneal nerve (Fig. 27).

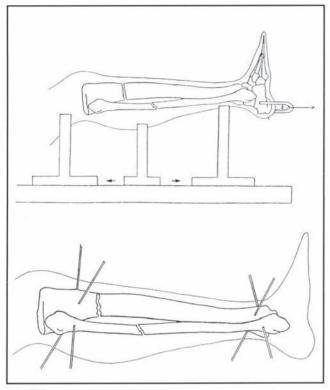


Fig. 27

2) Two wires are positioned through the distal epiphysis (with or without the fibula). The planes formed by the two pairs of wires must be perpendicular to the axis of the fracture fragments.

In order to maintain the ankle joint motion, follow this method: when transfixing the wires from the flexor surface, the limb has to be extended; when the wire exits from the opposite side, the limb has to be flexed (Fig. 28).

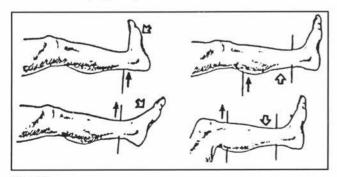


Fig. 28

3) A proximal and a distal ring (each one formed by two half rings) are then assembled and positioned by the manner described in Part I (see Fig. 29).

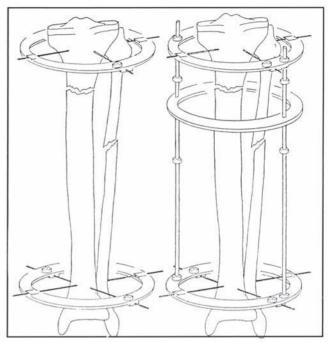


Fig. 29

Note: Observe the correct rotation of the foot. The tensioning process described in Part I should be followed with the foot in the correct position.

- 4) To add more stability to the mounting, two additional wires can be added to the proximal epiphysis. These additional wires can be held parallel to the others by:
 - a) a 4-hole support (Catalog No. 101402) (Fig. 30), or
 - b) a slotted washer (Catalog No. 102600) connected to the base of a support.
- 5) An intermediate ring is then attached to threaded rods and moved towards the desired position, just below the site of the fracture. The ring is fixed in position with two more wires.

Finally, reduction of the fragments is achieved by applying axial compression to the bone fragments.

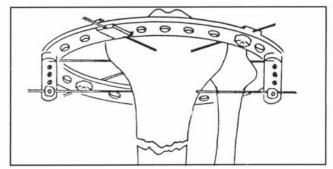


Fig. 30

DIAPHYSEAL FRACTURE WITH THREE OR MORE FRAGMENTS

In the presence of three or more fragments, a manual reduction associated with a transcalcaneal traction is performed.

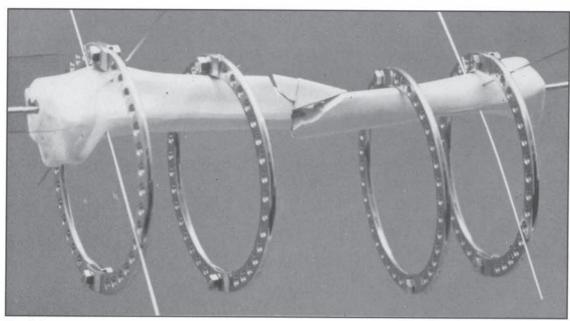


Fig. 31

1) Assembling of the apparatus using four rings. The setting of the rings was pre-operatively determined according to the site of the fracture as seen on an X-ray.

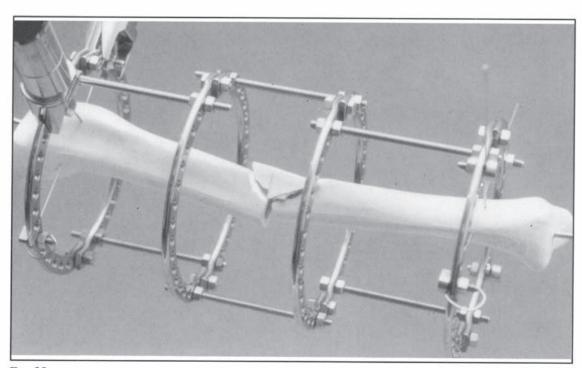


Fig. 32

2) The four rings are joined by threaded rods. Wires are fixed on the rings and stretched by two Dynamometric wire tensioners.

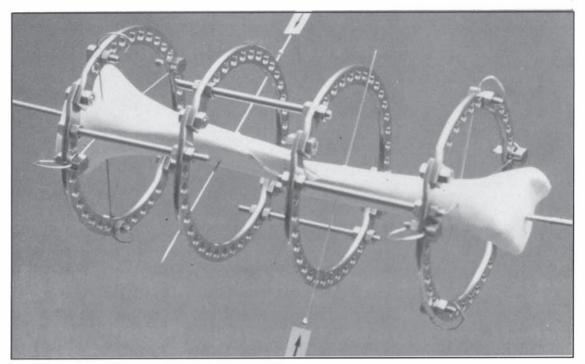


Fig. 33

3) Correction of the axis is made by two wires with stopper inserted in opposite positions.

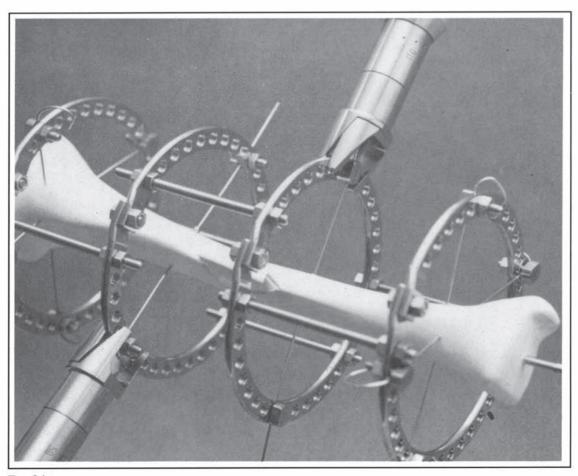


Fig. 34

4) The axis of the tibia has been corrected by tension of the wires with stopper.

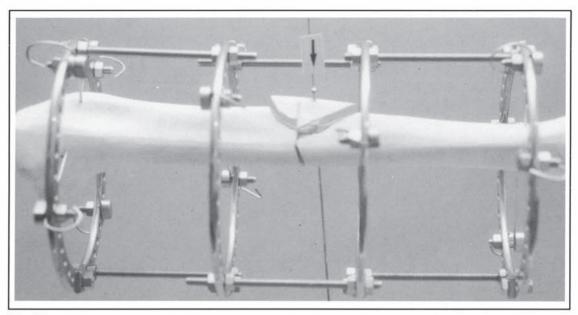


Fig. 35

5) By using two threaded rods to connect the central rings and adding a wire with stopper (as shown), the fracture can be reduced.

Note: One or more wires with stoppers may be used, if necessary.

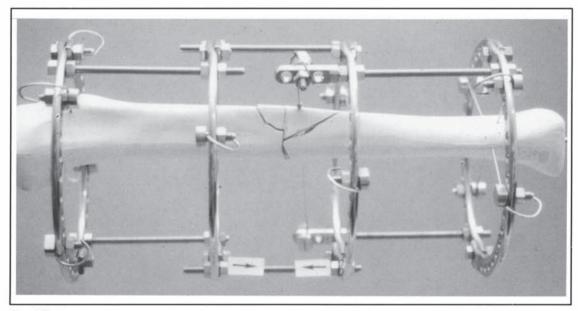


Fig. 36

6. Reduction of the third fragment with interfragmentary compression and light axial compression will improve stability.

Note: The traction can be gradual and checked often during the post-operative treatment.

In the U.S. a special wire with stopper is available. It is machined from one piece of stainless steel and is pictured in Figure 37.

- 7) Figure 38 shows how two wires with stopper (A) in opposite positions increase the stability of the assemblage. The wire with stopper (B), connected and put in tension on a Support Masculine End, compresses the interfragmentary fragment.
- 8) Final assemblage of the apparatus (Fig. 39).

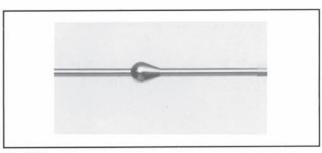


Fig. 37

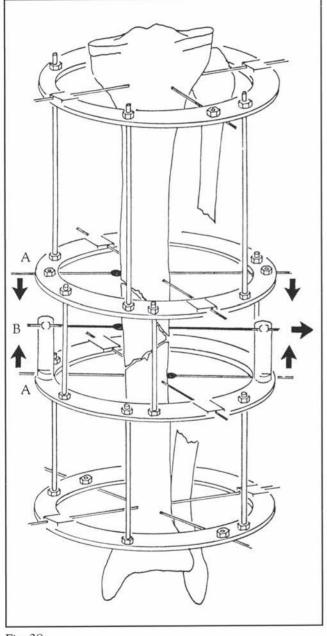


Fig. 38

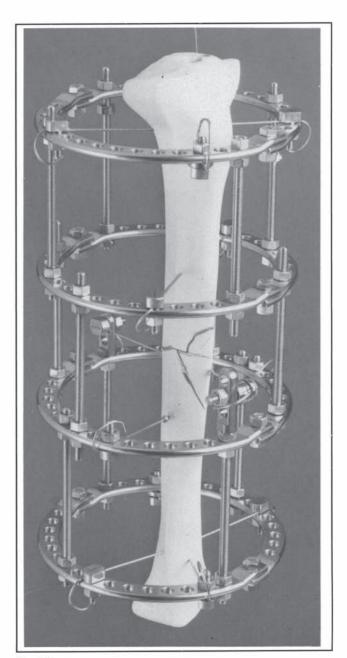


Fig. 39

PSEUDOARTHROSIS OF THE TIBIA WITH BONE DEFECTS

1) Atrophic pseudoarthrosis with bone defect but with maintenance of the leg length

Proximal corticotomy, without resection of the fibula, and a gradual descent of the distal corticotomized fragment toward the other extremity of the pseudoarthrosis will fill the bone defect. Once the filling of the gap has been completed, compression is applied to stabilize the pseudoarthrosis and the regenerate bone. (See Treatment Techniques in Figures 40, 41 and 42.)

Variation A

In a case with a severe bone defect, to decrease

the time of filling the gap and compressing the pseudoarthrosis, a second corticotomy can also be performed distally.

Variation B

In a case without any shortening or axial deviation, there is not any need for an osteotomy of the fibula. An intact fibula will insure a higher grade of stability.

Variation C

In a case with a severe bone defect where the tibia is extremely atrophied and the chances of obtaining good regenerate bone through a corticotomy appear doubtful, part or all of the fibula can be transported toward the tibial defect. This process, which literally widens the fibula, is called transosseous osteosynthesis with lateral transportation. The procedure is completed by axial compression.

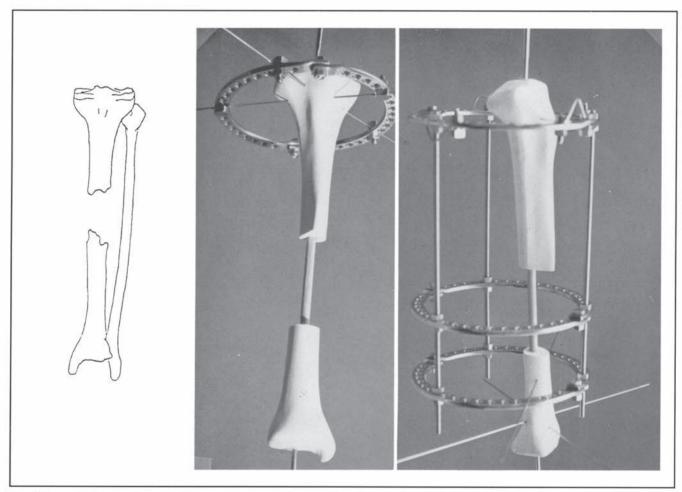


Fig. 40

Atrophic type of pseudoarthrosis with bone defect but with maintenance of the leg length.

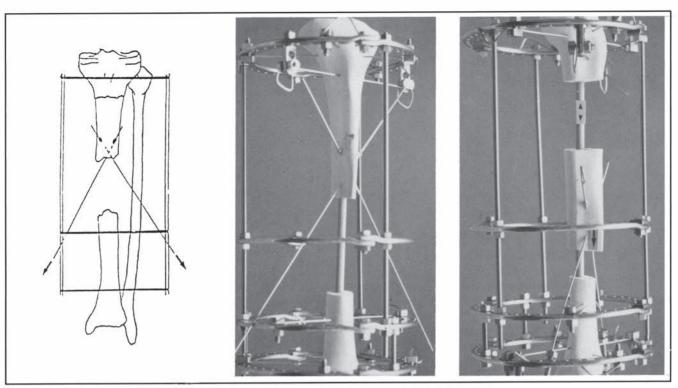


Fig. 41

These figures show a proximal corticotomy, without resection of the fibula, and the use of two wires with stoppers to descend the distal corticotomized fragment and fill the bone defect.

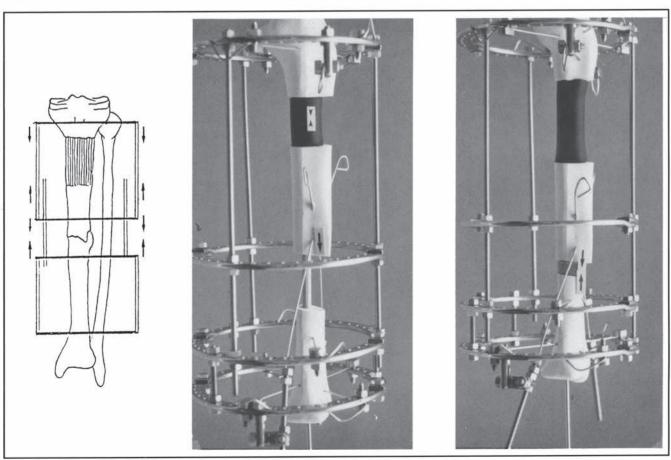


Fig. 42

Once the filling of the gap has been completed, axial compression is applied.

Variation D

The treatment technique shown in Figure 42 can also be achieved by first performing a proximal corticotomy and then lowering the tibial fragment using two wires connected to a central ring. Once the gap has been filled, axial compression is applied to stabilize the pseudoarthrosis and regenerate bone (see Fig. 42a).

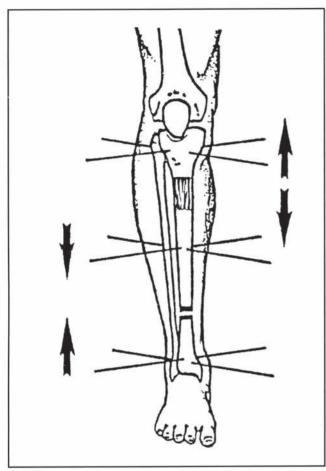


Fig. 42a

2) Atrophic pseudoarthrosis with bone defect and shortening

The leg length is restored by a proximal corticotomy, osteotomy of the fibula and a progressive, gradual lengthening of the regenerate bone.

Once the filling of the gap is completed, compression is applied to stabilize the pseudoarthrosis and regenerate bone.

Variation A

In a case with a severe bone defect a double corticotomy (proximal and distal) is performed.

3) Atrophic pseudoarthrosis with bone defect, severe shortening and axial deviation

A proximal corticotomy and distraction will fill the defect and restore the desired leg length.

<u>Note</u>: To prevent the fibula from consolidating too soon, resect 2 cm of the fibula.

Variation A

In a case with severe skin conditions or configurations of the fragments, the principle is the same: distraction osteogenesis, except that only some portions of the diaphysis can be transported.

Conclusions: Treatment of pseudoarthrosis

To perform the methods illustrated, it is important to know all the technical details of transosseous osteosynthesis. While the general principles must be known and understood, a strict, standard list of technical rules cannot be made since each clinical case will always be slightly different. The procedure must be varied to meet the needs of the individual patient. Further variations are discussed elsewhere.⁴⁻⁷

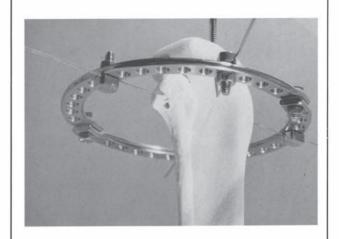
PART III

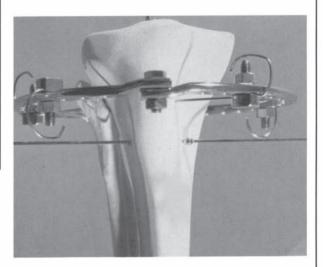
BONE LENGTHENING - CORTICOTOMY

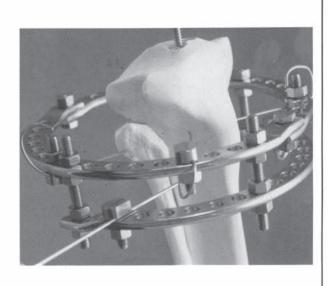
As opposed to an osteotomy, a corticotomy (or compactotomy) involves the cutting of only the cortex of the bone. If properly performed, the medullary canal will not be violated. A corticotomy is performed only in those cases where bone lengthening is needed.

The corticotomy is an extremely critical step in the procedure. Performance of this step should be attempted only by those surgeons who have had special training. For those unfamiliar with procedure, practicing on cadavers is recommended so that the accuracy of the procedure can be checked by anatomical dissection. During surgery the achievement of a complete corticotomy should be confirmed by an image intensifier. Extreme care should be taken to ensure that there will not be any damage to any critical anatomical structures such as nerves.

The corticotomy procedure can be performed in several ways. The following describes one method of the tibia (Figs. 43, 44, and 45). (Caution: Before cutting the tibia, the fibula should be transsected at a different level). Other methods could be learned with advanced training.







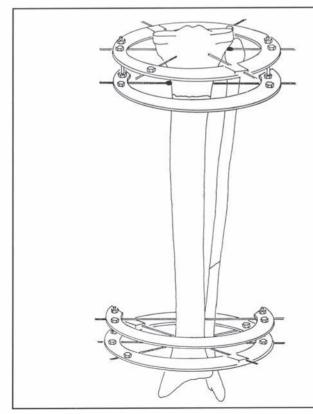


Fig. 43
Wire insertion and apparatus assembly for the proximal side of the tibia, as previously described.

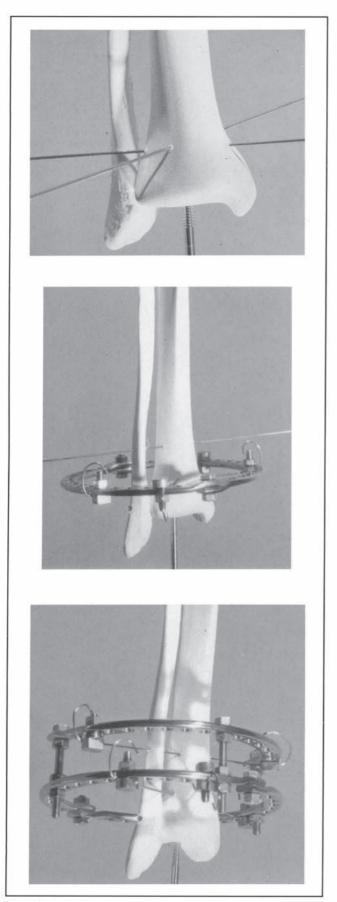


Fig. 44
Wire insertion and apparatus assembly for the distal side of the tibia. The third proximal wire transfixes the fibula.

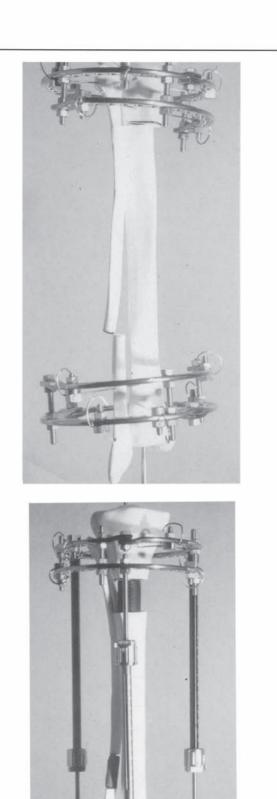


Fig. 43
Final assemblage of the apparatus. The lengthening can begin two to three days after the corticotomy.

CORTICOTOMY PROCEDURE:

- 1. Determine the level of the corticotomy from preoperative X-rays. Assemble and tighten the wires for at least two sets of rings on either side of the metaphyseal bone nearest the bone defect or above and below the level of lengthening selected as the point of the corticotomy. Then make a 1 cm longitudinal incision just off the tibial crest at the level of the corticotomy.
- 2. Dissect tissue down to the selected area (Fig. 46b). With the use of a periosteal elevator the periosteum is incised longitudinally. The periosteum is elevated from the medial and lateral aspects of the tibia back to the posteromedial and posterolateral corners. Using either a chisel, 1 cm osteotome or drill, penetrate into the cortex. Insert a periosteal elevator along the medial aspect of the tibia. Place a hexagonal handled 5 mm

- osteotome (or one the thickness of the cortex) into the opening and twist the osteotome 90 degrees using a wrench or vice grip on the end of the osteotome.
- 3. Carefully chisel down the side of the cortex to the second corner of the tibia. Fracture the second corner using the same procedure described above Caution: Do not disrupt the medullary contents or vessels by excessive movement of the osteotome.
- 4. To complete the fracturing of the cortex, take the two assembled rings and turn in opposite directions until a cracking sound is heard (Fig. 46a).

<u>Note</u>: For the tibia use only an external rotation to avoid damage to the peroneal nerve.

5. To confirm that a complete corticotomy has been achieved, use an image intensifier.

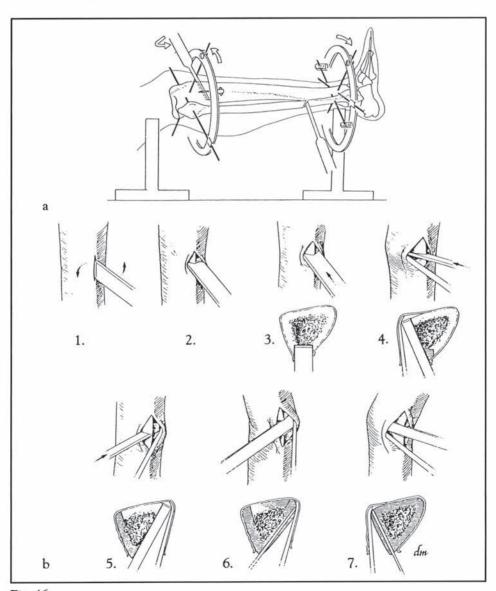


Fig. 46

Fig. 46b: Corticotomy procedure (as described by D. Paley).

COMMENTS

The method of alignment and usage of threaded rods, buckles, side plates, etc., will vary depending upon the patient size, the bone quality and the presence of other orthopaedic and soft tissue problems, as well as the original correction being treated. Preoperative planning is a necessity.

All needed parts and equipment should be located before surgery begins. For example, the proper length threaded rods should be on hand. However, if necessary, some of the parts and equipment can be improvised by adding and subtracting components so as to achieve essentially the same biomechanical structure (Fig. 47-48).



Fig. 47
Example of assembly for the lengthening of the tibia.

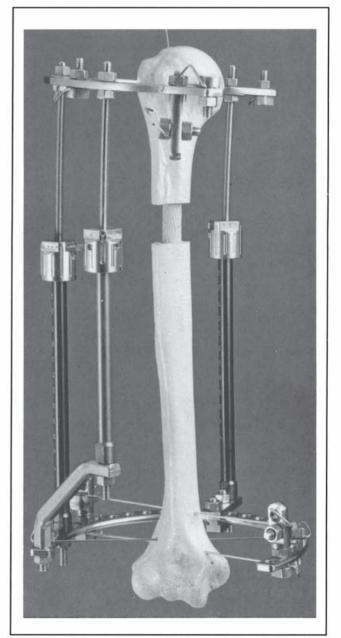


Fig. 48
Example of assembly for the lengthening of the humerus.

For bone lengthening three or four extension rods can be used. The extension process can be achieved by two methods. <u>First</u>, a telescoping rod (Catalog No. 100100, 100101, 100102, or 100103) can be assembled on a threaded rod with the nut being advanced using a wrench.

<u>Note</u>: Which nuts and what direction to turn them should be clearly marked for the patient.

Second, the advancement can be achieved more easily using a graduated telescopic rod, whereby the 0.25 mm turns are achieved by the patient turning a "clicker" (Fig. 49b).

The length of advancement can be monitored by examining the markings on the sides of the rod (See Fig. 49a). Four lengths of the graduated telescopic rods are available (Catalog Nos. 100105, 100106,

100107, and 100108). The original length and extension distances for each are as follows:

Catalog No.	Original Length	Calibrated Extension Distance	
100105	100 mm	40 mm	
100106	150 mm	70 mm	
100107	200 mm	110 mm	
100108	250 mm	110 mm	

Caution: No matter which telescopic rod or graduated telescopic rod is used, the threaded rod should be inserted at least 35 mm into the rod to maintain stability during use.

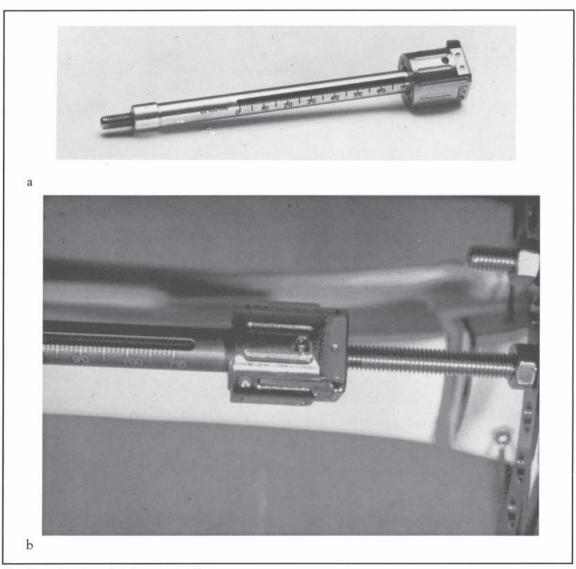


Fig. 49a: Graduated Telescopic Rod.

Fig. 49b: Closeup of "clicker" component.

The distraction process can be achieved in several ways. For advanced users a two level or bifocal corticotomy can be used so as to speed up the bone lengthening process (Fig. 50). When this method is properly performed there will be less risk of fracture of the bone and less chance of soft tissue problems. However, two sets of telescopic rods will be needed.

Two factors affect the lengthening process: rate and rhythm. The rate is the distance traveled per day and the rhythm is the frequency of movement per day. What day after surgery and how fast to undergo the distraction process depends upon the patient age, type and quality of bone, and general health of the patient. In general, at least three days after surgery, and preferably seven in most cases, the distraction process can begin. Some surgeons build up to 1 mm/day

distraction; others start out at that rate, using a rhythm of 0.25 mm increments, four times per day.

Periodic X-rays of the patient are needed. If calcification of the bone lengthening site is not noticed, then consolidation can usually be achieved by reversing the distraction to a compression movement for several days and then proceeding with distraction.

Hinges can also be used for rotary and translatory movements of the bone segments. Proper use of these products (Catalog Nos. 101600 and 101700) requires special training (Fig. 51). The best explanation of their use is described in References 5, 8 and 9.

Widening of bones and correction of foot deformities can also be achieved with special assembly techniques, surgical procedures, and post-operative care.

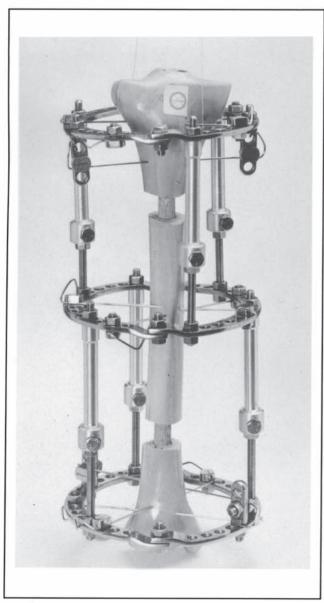


Fig. 50
An example of bifocal corticotomy of the leg.

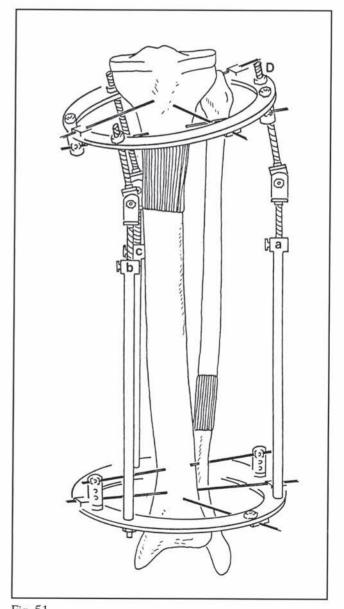


Fig. 51

An example of the use of hinges for correction of axial deviations during the lengthening of the leg.

CONCLUSION

With proper training and assembly, the Ilizarov External Fixator can be a powerful tool for orthopaedic surgeons to correct bone problems that before could not be corrected with traditional methods of treatment.

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- 8. Paley, D.: "Hinges: Theoretical Aspects." Abstracts from the International Conference on the Ilizarov Techniques for Management of Difficult Skeletal Problems. Hospital for Joint Disease, No. 1-3, 1987, New York.
- 9. Paley, D.: "Current Techniques of Limb Lengthening" J. Ped. Ortho., 8: 73-92, 1988.

The books of References 4, 6, and 7 are available at: LIBRERIA SCIENTIFICA GHEDINI Via F. Sforza, 14 20122 MILAN – Italy Telex: 353 113

Reprints of Reference 9 can be obtained by ordering reprint request No. 62-2805 from:
Customer Service Department
Smith & Nepew, Inc.
1450 Brooks Road
Memphis, TN 38116
USA

IMPORTANT MEDICAL INFORMATION

Warnings and Precautions

EXTERNAL FIXATION SYSTEM

SPECIAL NOTE

External fixation should be used only under the directions of physicians who have a thorough knowledge of the anatomy, physiology and surgical principles involved. Physicians are strongly encouraged to obtain instruction from experienced clinicians or to observe surgical application of the apparatus prior to its initial use.

DESCRIPTION

External Fixation Systems consist of various components used to build constructs to treat the indications listed below. External Fixation Systems are modular, therefore, different frame configurations are possible. An individualized configuration should be designed for each case to suit the specific application. Refer to supporting instruction information provided by Smith & Nephew or component information assembly instructions, and surgical techniques for each individual external fixation system. All External Fixation System components are designed for single use only.

Unless outlined in supporting instructional information, each External Fixation System is designed as a system and does not allow the substitution of components from other systems or manufacturers.

External Fixation Systems are made from various types of metal, plastic, and composite materials. The component material is provided on the outside carton label.

The Compass® Universal Hinge is used with the Ilizarov External Fixator to control distraction and rotation of an injured joint to regain, maintain, or increase the range of motion of the joint. It utilizes circular frame and half-pin fixation techniques and procedures for placement of the device. The device is intended to be centered on the axis of rotation. The device allows some adjustability to permit adjustment on the axis. Please refer to the surgical technique for complete details of the recommended procedures.

The Taylor Spatial Frame™ utilizes computer software to recommend adjustments to the fixation frame based on surgeon-derived measurements and examination.

INDICATIONS

- Post-Traumatic joint contracture which has resulted in loss of range of motion (not applicable for Hex-Fix).
- Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction.
- 3. Open and closed fracture fixation
- 4. Pseudoarthrosis of long bones.
- Limb lengthening by epiphyseal or metaphyseal distraction (not applicable for Compass Universal Hinge).
- 6. Correction of bony or soft tissue deformities (not applicable for Compass Universal Hinge)
- 7. Correction of segmental bony or soft tissue defects.
- 8. Joint arthrodesis.
- 9. Infected fractures or nonunions.
- The Distal Radius and Colles Fracture Frame are indicated for the management of comminuted intra-articular fractures of the distal radius.
- 11. Calandruccio devices are indicated for arthrodesis of the ankle or subtalar joints, as well as some select fractures, nonunion, or osteotomy of the distal tibia; and acute transverse fractures or nonunion of the distal tibia.

CONTRAINDICATIONS

External fixation devices are contraindicated for use in uncooperative or mentally incompetent patients who are unable to follow the postoperative regimen.

Calandruccio devices are also contraindicated for fractures that will most likely heal satisfactorily with noninvasive conservative management, either casting or cast bracing without loss of joint function. Other contraindications include fractures or nonunions which do not permit multiple pin fixation in the coronal plane and patients with medical problems that require weight-bearing on the extremity.

WARNING

- The correct selection of device components is extremely important. The appropriate type and size should be selected for the patient based on injury, weight, compliance, etc.
- Preliminary frame assembly is recommended to reduce operative times and to assure an adequate supply of components prior to surgery.
- Intraoperative fracture or instrument breakage can occur. Instruments which have been used extensively or with excessive force are susceptible to fracture. Examine all instruments for wear and damage prior to surgery. Replace where necessary.
- Correction of varus, valgus, procurvatum, and recurvatum movement of limb segments during distraction should be planned preoperatively by selecting an appropriate prophylactic ring tilt and strategically positioning wires with stoppers, fulcrums, half pins, and hinges.
- Wire and pin placement requires strict anatomical consideration to avoid damage to nerves, muscles, tendons, and vessels. Wires should be gently pushed through soft tissue, not drilled, to reduce the possibility of injury.
- Wire drilling through the bone should be done slowly to avoid heat necrosis of surrounding tissues and bone.
- Use caution when handling the sharp tips of wires. The tip of the wire should be held when clipped. Eye protection is recommended for operating room personnel.
- 8. Pin/wire site care is crucial in reducing infections.
- 9. Periodic postoperative follow-up and radiographs are recommended during the distraction phase

PRECAUTIONS

- 1. Use extreme care in handling and storing components. Cutting, bending, or scratching the surface of components can reduce the strength and fatigue life of the device. Any components damaged during the course of the treatment should be replaced. Wire bending can be avoided by using various types of washers to build the ring to the wire.
- Surgical technique information is available upon request. The surgeon should be familiar with the devices, instruments and surgical technique prior to surgery.
- Unless specified, only components from the same system should be used together. Refer to supporting instruction information for details on each external system.
- Proper fixation and assembly of components are essential. All wires and miscellaneous parts should be securely fastened with the appropriate instrument. Wires should be tensioned as specified in product literature.
- 5. The proper wire diameter should be used to ensure sufficient wire strength and to maintain appropriate axial stiffness of the apparatus. The 1.8 mm wires are usually recommended for the tibia and femur in normal adults, while the 1.5 mm wires are usually recommended for the upper limbs and pediatric lower limb applications.
- The diameter of the rings, assembled half rings or frames, are recommended to be about 4 cm larger than the maximum diameter of the operated limb segment to accommodate swelling.
- Wire/pin security in bone, wire tension, and device frame integrity should be routinely checked. The gap at a fracture site should be reassessed during healing. Adjustments should be made as necessary.
- The patient should be instructed to report any adverse or unanticipated effects to the physician as soon as possible and should also be advised of the distraction and adjustment requirement.

- 9. Preoperative planning for the Taylor Spatial Frame requires special software and programs. Accurate inputs are critical for accurate results. Verify and double check all input parameters. The computer program should be run twice to verify that the parameters have been correctly entered into the software. The Taylor Spatial Frame can be used as a template to compare the adjusted frame to the deformity to verify fit. Output of strut lengths from the program can exceed any strut length for a particular preassembled frame. If this occurs, refer to Surgical Technique and Instruction Manuals.
- 10. Intraoperative placement of the Taylor Spatial Frame according to preoperative plans is imperative to achieve predetermined results. If intraoperative conditions require a change to frame placement (eccentricity) or size (parameters), new strut lengths should be calculated by entering the new inputs into the program. Small changes may affect accuracy of outcome.
- Touch down weight bearing may be allowed postoperatively. Weight bearing may be increased as the callus thickens.
- 12. For patients with Calandruccio devices, postoperative care and physical therapy should be structured to prevent weight bearing on the operated leg until sufficient healing is evident on the x-ray.

ADVERSE EFFECTS

- 1. Damage to nerves or vessels resulting from insertion of wires and pins.
- Infection including persistent drainage of the pin tracts, or after wire removal; chronic pin/wire site osteomyelitis.
- 3. Edema or swelling, possible compartment syndrome
- 4. Joint contracture, loss of range of motion or reduction, joint subluxation or dislocation.
- 5. Septic arthritis and osteomyelitis.
- Loosening or breakage of the pins, wires, or other components including inadvertent injury to the patient or operating room personnel caused by the wire (e.g. protective wire from tip cutting during surgery).
- 7. Intractable pain or delayed unions or both.
- 8. Persistence or reoccurrence of the initial condition requiring treatment.
- 9. Reoperation to replace a component or the entire apparatus.
- 10. Foreign body reaction to pins, wires, or other components
- 11. Tissue necrosis occurring during pin or wire insertion or at the pin/wire tissue junction.
- 12. Excessive operative bleeding or muscle tendon impalement.
- 13. Skin pressure problems caused by external components.
- 14. The intrinsic risks associated with anesthesia.
- 15. Premature consolidation during bone elongation.
- 16. Secondary equinus contracture.
- Failure of bone to regenerate satisfactorily; development or persistence of nonunion or pseudoarthrosis.
- 18. Fracture of regenerated bone or fracture through a hole after removal of the device
- Abnormal growth plate development in patients who are not skeletally mature, including premature fusion, and slowed or accelerated growth.
- 20. Loss of bone mass due to "stress shielding."
- 21. Limb length discrepancy.
- Bone sequestration secondary to rapid drilling of the bony cortex, with heat build-up and bone necrosis.
- 23. Excessive motion at the fracture site due to failure to tighten the component parts of the device; improper tensioning of wires, flexion from use of too few pins or pins that are too small.
- 24. Ankle stiffness if multiple transfixion pins are used in tibial fractures.
- 25. Thrombosis, late erosion or arteriovenous fistulas.
- 26. Persistent drainage after wire removal; chronic wire site osteomyelitis.
- 27. Bone deformity.

PACKAGING

28. Inability to compress the bone surface if the pins are not securety seated in the bone.

Components should only be accepted if received by the hospital or surgeon with the factory packag-

ing and labeling intact.

STERILIZATION/RESTERILIZATION

Unless specifically labeled sterile, the implants and instruments are supplied nonsterile and must be sterilized prior to use. "In-a-Box" components (Hex-in-a-Box, Universal-in-a-Box, Pelvic-in-a-Box, etc.)

are supplied sterile and have been sterilized by ethylene oxide gas. All radiation sterilized components have been exposed to a minimum of 25 kiloGrays of gamma radiation. The method of sterilization is noted on the package label.

Metal components may be initially sterilized or resterilized, if necessary, by steam autoclaving in appropriate protective wrapping, after removal of all original packaging and labeling. Protect the devices, particularly mating surfaces, from contact with metal or other hard objects which could damage the product. The following process parameters are recommended for these devices:

age the product. The following process parameters are recommended for these devices:

• Prevacuum Cycle: 4 pulses (maximum = 26.0 psig (2.8 bars) & minimum = 10.0 inHg (339 millibars)) with a minimum dwell time of 4 minutes at 270°F to 275°F (132°C to 135°C), followed by a 1 minute purge and at least 15 minutes of vacuum drying at 10 inHg (339 millibars) minimum.

Smith & Nephew does not recommend the use of gravity cycles or flash sterilization

If the "In-a-Box" components are to be resterilized in their packaged containers, they should be resterilized by ethylene oxide gas. Plastic components may also be sterilized by ethylene oxide gas. The following parameters are recommended as starting points for cycle validation by the health care facility:

Sterilant	Temperature	Humidity	Maximum Pressure	Concentration	Exposure Time
10% EtO 90% HCFC	130°F (55°C)	40-60%	28 PSIA (1930 millibar)	550-650 mg/L	120 Minutes
10% EtO 90% HCFC	100°F (38°C)	40-60%	28 PSIA (1930 millibar)	550-650 mg/L	6 hours
100% EtO	131°F (55°C)	30-60%	10 PSIA (689 millibar)	736 mg/L	30 Minutes

Suggested initial aeration starting point for aeration validation is 12 hours at 122°F (50°C) with power aeration. Consult aerator manufacturer for more specific instructions.

INFORMATION

For further information, please contact Customer Service at 1-800-238-7538 for calls within the continental USA and (901) 396-2121 for all international calls.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Smith Plephew First Choice in Orthopaedics