Metaphyseal Hinge Fixator

(designed by Prof. Rainer Baumgart)

RESPONSE ORTH

Response Ortho is a global
orthopaedic trauma solutions manufacturer
offering premium products
created under its founding principles of
innovation, excellence by design

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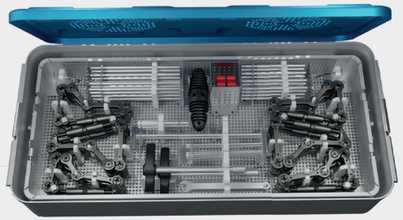

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Introduction

The Metaphyseal Hinge Fixator is a unilateral external fixator special designed for the gradual and acute correction of frontal plane, varus and valgus, metaphyseal deformities of the proximal tibia. The fixator allows for up to 20˚ varus and 10˚ valgus correction with the ability to align the hinge to the center of the deformity. The Metaphyseal Hinge Fixator is one of the lowest profile external fixators in the market. The anatomical design, 9 mm thickness and unique half pin locking mechanism allows for greater patient comfort during the recovery period. The Metaphyseal Hinge Fixator based on the idea and a patent of Prof. Rainer Baumgart MD (trauma surgeon and mechanical engineer).

Response Ortho wishes to thank Prof. Rainer Baumgart for his contribution to the development of this operative technique.

Intended Use

The Response Ortho External Fixation Systems are fixation devices intended for use in the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by use of the external fixation modality.

Indication

The surgical technique has been prepared for the indications: Varus or valgus deformities of the tibia head, especially if knee joint laxity is combined with deformity which occurs in medial osteoarthritis.

Product Descriptions

The Metaphyseal Hinge Fixator is a one way device which is available in 3 different sizes (small, medium, large) and specially designed for the common treatment of tibia head deformities in the frontal, varus and valgus planes. The device is fixed with 4 conical 6mm half pins. All components are made of titanium: This results in a light weight, more comfortable fixation, and easier to maintain than a ring fixator.

With the Metaphyseal Hinge Fixator, gradual correction takes place and bone formation will occur by callus distraction as is used for bone lengthening.
The Metaphyseal Hinge Fixator is positioned in an anatomical location of thin soft tissue coverage of the bone where little soft tissue movements occur during walking and knee motion.

Static fixation with a plate used to secure a proximal tibial osteotomy may not address the reaction of the ligaments in an appropriate way. Acute corrections frequently result in undercorrection or overcorrection after full load bearing, because the ligaments may react more or less as expected even if the amount of the correction was planned accurately.

In cases of corrections from valgus to varus the peroneal nerve may be stretched, resulting in drop foot. Performing a correction gradually with the Metaphyseal Hinge Fixator may avoid this problem. In addition the amount of correction can be adjusted under load.
By using the Metaphyseal Hinge Fixator in case of open wedge osteotomies bone grafting from the iliac crest may be avoided.

Surgical Technique

Equipment Required
The surgical center is responsible for providing the following instruments and equipment for a successful procedure:

- Standard C-arm fluoroscope
- Large bone oscillating saw with thin blade*
- Pin driver
- Chuck drill
- Fine Chisel, 10mm

* ***Important Note:*** The saw blade must meet the following dimensional requirements;

Width : 19-20mm
Thickness: 1.19-1.27mm
Length : 85mm (minimum)

Preoperative Planning for Correction Angle and Implant Size

Using the full-length, standing AP radiograph with patella faced forward, a line from the center of the femoral head to the center of the tibiotalar joint demonstrates the patient's mechanical axis pre-operativly.

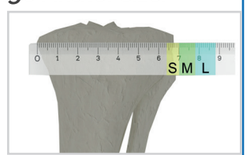
For planning draw a line from the center of the femoral head to the center of the knee joint.

Draw another line from the center of the tibiotalar joint to the center of the knee joint. The angle formed by the intersection of these two lines determines the degree of correction required to return the patient's mechanical axis to normal. Depending on the amount of cartiladge damage and ligament instability over-correction may be needed.

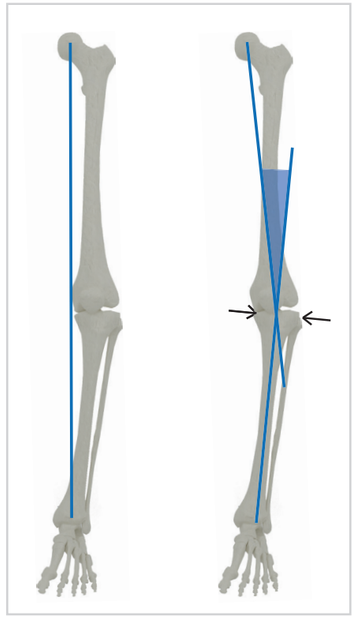
Measure the tibial width on the X-ray image. Use an X-ray calibration tool to verify the magnification factor.

Estimate the Metaphyseal Hinge Fixator size:

- Small (S) 64-70mm
- Medium (M) 70-78mm
- Large (L) 78-88mm



The outer line of the transverse arm of the fixator should not overstand the outer cortex of the tibia head.



Metaphyseal Hinge Fixator Kit (S, M, L,) – Left or Right

- Metaphyseal Hinge Fixator
- Guide Wire, 3.0mm x 120mm
- Guide Wire, 2.0mm x 120mm (4 pcs)
- Drill Guide, 4.8mm
- Drill Bit, 4.8 x 200mm
- T-Handle
- Half Pin, 6.0/110/40mm, Blunt (4 pcs)
- Screw Locking Handle
- Distractor Wrench
- Goniometer
- Half Pin SoftTissueCover, 6mm (4 pcs)

Surgical Approach

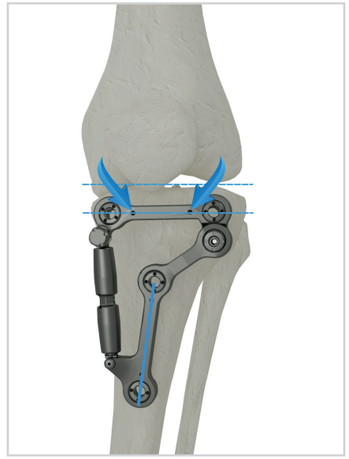
Position the patient

Patients should be placed in the supine position and prepped and draped in routine sterile fashion with the operating table set 10-20 degrees in the Trendelenburg position to level the tibia horizontically.

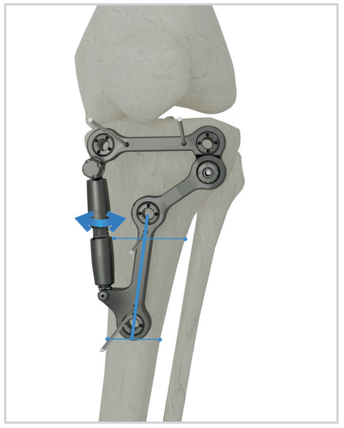
Alternatively, placing a pillow under the heel will make the tibia horizontal and therefore perpendicular to the vertical image beam. Once the leg is rotated so that the patella is faced forward, utilize fluoroscopy and a marking pen to draw a line parallel with the tibial plateau to identify the level of the joint. Assistent should fix the leg in position.

Bone Screw Insertion and Positioning the Fixator

Position a 3.0mm Guide Wire exactly 90° to the frontal cortex in the planned hinge position. The correct orientation of the wire is essential for all following steps. Position the Metaphyseal Hinge Fixator with the hinge-hole over the Guide Wire



Adjust the transverse arm parallel to the knee joint using AP X-ray. Adjust the distance to the skin and place 2 Guide Wires (2.0mm) through the oblique transverse arm to fix it in position.



The fixator is now dialed out to match the amount of angulation on the proximal tibial metaphysis. Turn the fixator spindle until the longitudinal arm is exactly in front of the tibial shaft and adjust the longitudinal arm with 2 Guide Wires (2.0mm). This will facilitate distal bone screw targeting.

It is important to note, that after insertion of the 4 Guide Wires, the position of the arms to the bone and the distance between fixator and skin is fixed. If one of the arms or the distance to the skin is not in appropriate position take off the 2.0mm Guide Wires and place again.

Make small skin incisions and insert the drill guides, each in one cone, (make sure that the cones are open)

Use a 4,8mm drill bit and perforate the tibia head including the dorsal cortex (lateral X-ray recommended).

Insert 6mm conical half pins in all cones.

The proximal half pins are orientated to distal and to the center to the tibia according to the anatomical conditions (tibia slope).

In children penetration of the physis must be provided.

Important Note:

- *Unlike cortical bone, the tacticle sensation of drilling in cancellous bone is much softer. Image intensification is recommended to confirm the position of the drill bit.*
- *Care should be taken to avoid over penetration as the half pins are tapered and will loose purchase if they are backed out.*

Lock all the half pin fixation nuts and shorten it to 8mm.

Performing the Osteotomy

Remove all 2.0mm Guide Wires and open the proximal fixation of the Metaphyseal Hinge Fixator by hand.

Make a 5cm straight or curved skin incision ventromedial. Preparate the Pes anserinus and make a sufficient medial release. Place 2 Hohmanns – one ventral and one dorsal. Perform the osteotomy with the oscillating saw. Preserving the patella tendon.

Important Note: *The osteotomy should begin 7cm distal to the knee joint and should be directed straight to the 3.0mm Guide Wire – not lateral.*

Check if osteotomy is completed by careful manipulation

Close the wound and clean the operation field. Re-position the spindle.

Use the red protection cups to cover the ends of the half pins.

Correction procedure:

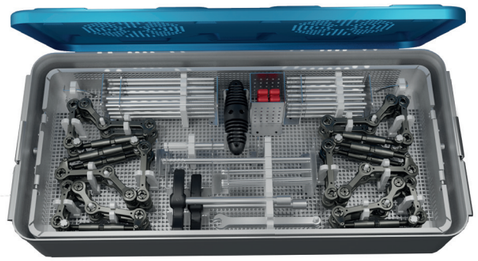
The patient starts correction one day after surgery by turning the spindle

Note: *One 360 degree rotation of the spindle will change the gap about 2 degree.*

The angle of the fixator can be read by placing the goniometer on the fixator.

Removal of the Metaphyseal Hinge Fixator

The Metaphyseal Hinge Fixator can be easily removed after bone healing. Turn half pin locking nuts counter clockwise to loosen. Remove half pins.



00-9069-17	Metaphyseal Hinge Fixator Set			
00-8109-17	Metaphyseal Hinge Fixator Tray	1	instrument	
50-5016-11	Metaphyseal Hinge Fixator, Anterior Small, L	2	XF Component	
50-5016-12	Metaphyseal Hinge Fixator, Anterior, Medium, L	2	XF Component	
50-5016-13	Metaphyseal Hinge Fixator, Anterior, Large, L	2	XF Component	
50-5016-21	Metaphyseal Hinge Fixator, Anterior, Small, R	2	XF Component	
50-5016-22	Metaphyseal Hinge Fixator, Anterior, Medium, R	2	XF Component	
50-5016-23	Metaphyseal Hinge Fixator, Anterior, Large, R	2	XF Component	
40-4301-12	Guide Wire, 3.0mm x 120mm, Trocar	2	instrument	
40-4201-12	Guide Wire, 2.0mm x 120mm, Trocar	8	instrument	
00-0059-60	Metaphyseal Hinge Fix. 2.0mm Wire, 4.8mm Drill Guide	1	instrument	
00-3483-21	Drill Bit, 4.8x200mm, Can.	2	instrument	
00-1043-00	Multiple T-Handle	1	instrument	
00-1041-00	Metaphyseal Hinge Fixator Screw Locking Handle	2	instrument	

00-1041-01	Distractor Wrench	2	instrument	
00-0141-01	Goniometer, R	1	instrument	
00-0141-02	Goniometer, L	1	instrument	
50-1070-07	HalfPin SoftTissueCover,6mm(4-pack),Red	16	Accessory	
50-1076-113B	Half Pin, 6.0/110/30mm, Blunt, Ti	8	Implant	
50-1076-114B	Half Pin, 6.0/110/40mm, Blunt, Ti	8	Implant	
50-1076-153B	Half Pin, 6.0/150/30mm, Blunt, Ti	8	Implant	
50-1076-154B	Half Pin, 6.0/150/40mm, Blunt, Ti	8	Implant	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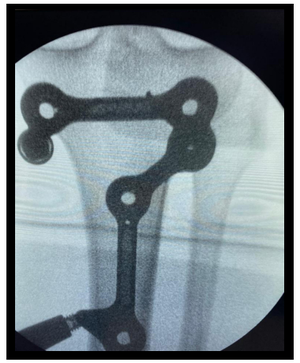

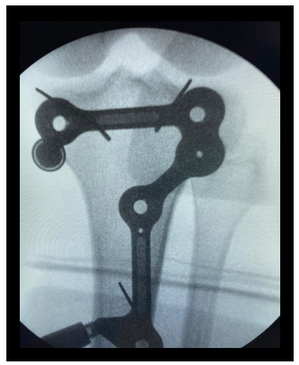

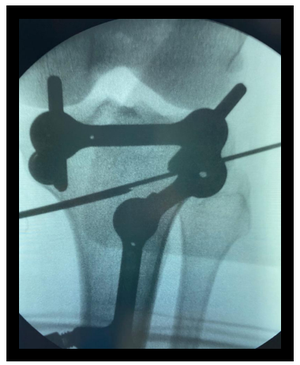

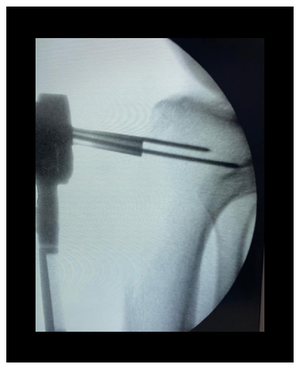

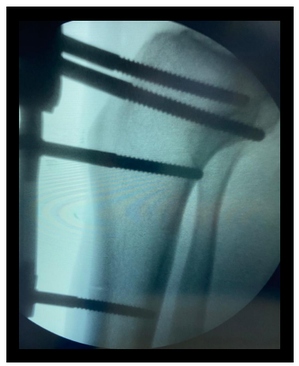

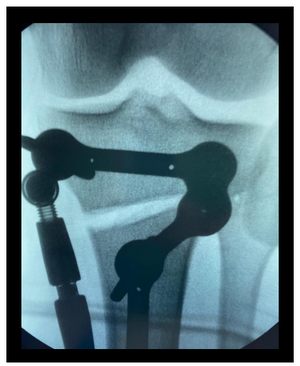

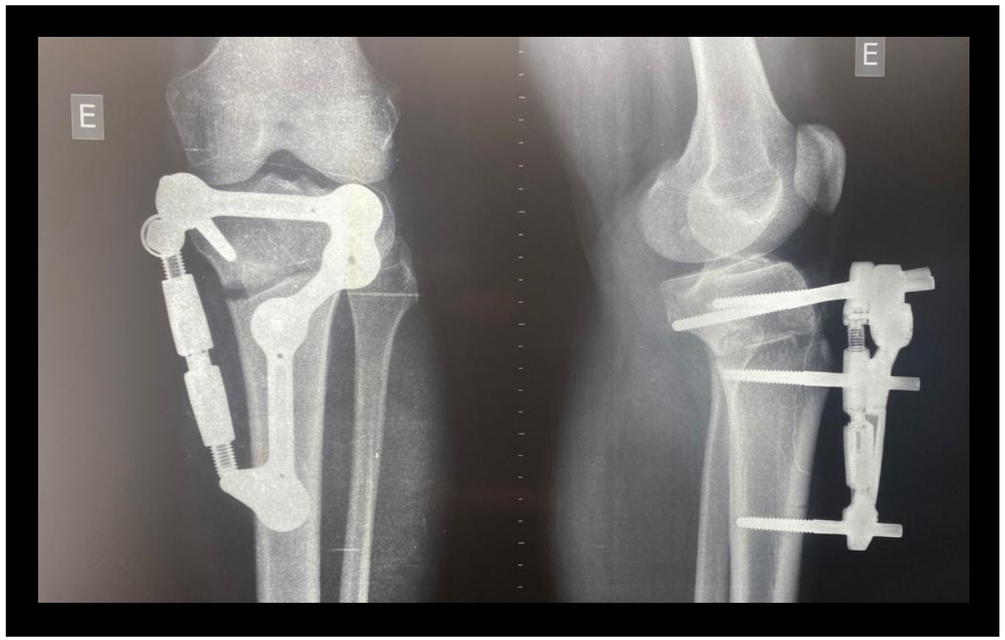
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