

UniPlasty®

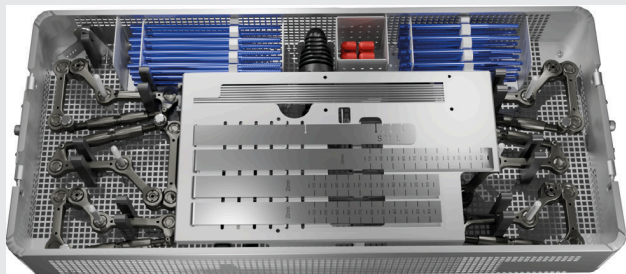
Gradual Opening-Wedge High Tibial Osteotomy

Surgical Technique · UniX® Metaphyseal Hinge Fixator System



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





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Introduction

UniPlasty® is a gradual opening-wedge high tibial osteotomy performed with the UniX® Metaphyseal Hinge Fixator System, a unilateral external fixator that corrects varus and valgus deformities of the proximal tibial metaphysis in the frontal plane, gradually or in a single step.

The fixator corrects up to 20° of varus and up to 10° of valgus, and its hinge can be aligned with the centre of the deformity. With a body only 9 mm thick, an anatomical shape and a dedicated half-pin locking mechanism, it is designed for patient comfort during the correction and consolidation period.

The fixator was conceived and patented by Prof. Rainer Baumgart MD, a trauma surgeon and mechanical engineer. We thank Prof. Baumgart for his work on this surgical technique.

Patient information on bow legs, high tibial osteotomy and the UniPlasty® treatment stages is available at www.UniPlasty.com.

Indications for Use

The Response Ortho Metaphyseal Fixation System is indicated for treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by use of the external fixation.

Prescription use only.

Scope of This Technique

This technique is written for proximal tibial deformities in varus or valgus, particularly when the deformity is combined with knee joint laxity, as seen in medial compartment osteoarthritis.

It can be combined with concomitant procedures such as arthroscopy, cartilage repair or ACL reconstruction.

System at a Glance

Correction capacity	Up to 20° varus · up to 10° valgus
Sizes	X-Small, Small, Medium, Large · left and right
Size by tibial width	XS 56–64 mm · S 64–70 mm · M 70–78 mm · L 78–88 mm
Profile	9 mm body thickness
Bone fixation	Four 6 mm conical half pins, titanium alloy
Body material	Titanium alloy (Ti6Al4V ELI)
Weight	Approximately 125–137 g, depending on size
Correction rate	0.33° per click · 0.66° per day

Regulatory Status

This product is CE-marked and has also been cleared by the FDA for distribution in the United States.

Product Description

The UniX® Metaphyseal Hinge Fixator System is available in four sizes (X-Small, Small, Medium and Large), each for the left or the right side, and is designed for frontal-plane deformities of the proximal tibia. It is fixed to the bone with four 6 mm conical half pins. Its titanium-alloy body keeps the construct light, and it is simpler to care for than a ring fixator.

The fixator sits on the anterior surface of the proximal tibia, where the soft tissue covering the bone is thin and moves little during walking and knee motion.

Why Gradual Correction

With the fixator, the correction is made gradually and new bone forms by callus distraction, the mechanism used in bone lengthening.

- When an osteotomy is fixed acutely with a plate, the response of the ligaments to full weight bearing cannot be fully anticipated; under- or over-correction may result even when the correction was planned accurately.
- Because the angle can be adjusted while the patient bears weight, the final alignment can be set under load.
- Acute correction from valgus to varus may stretch the peroneal nerve and cause drop foot; a gradual correction is intended to reduce this risk.
- In open-wedge osteotomies, gradual distraction may avoid the need for iliac crest bone grafting.

Fixator First, Osteotomy Second

The fixator is applied to the intact tibia before the bone is cut. The half pins are inserted through the fixed-angle cones of the fixator, with the fixator body parallel to the tibial shaft in the sagittal plane, so the tibial head is held from the outset.

The correction then turns about the hinge in the frontal plane only; the construct is designed to leave the posterior tibial slope unchanged.

Preoperative Planning

Correction Angle

On a standing AP radiograph of the whole leg, taken with the patella facing forward, a line joining the centres of the femoral head and the tibiotalar joint shows the patient's preoperative mechanical axis (Figure 1).

For planning, draw one line between the centres of the femoral head and the knee joint and a second between the centres of the tibiotalar joint and the knee joint. The angle between the two lines is the correction needed to restore the mechanical axis. Some over-correction may be indicated, depending on the state of the cartilage and the stability of the ligaments.

The correction, side and fixator size can also be planned and templated on www.SmartFixator.com.

Fixator Size

Measure the width of the tibial head on the radiograph, using an X-ray calibration marker to correct for magnification, and select the size (Figure 2). The Size Measurement Tool in the set shows the size ranges.

X-Small (XS)	56–64 mm
Small (S)	64–70 mm
Medium (M)	70–78 mm
Large (L)	78–88 mm

The outer end of the transverse arm should not project beyond the outer cortex of the tibial head.

Equipment Required

To be provided by the surgical centre:

- Standard C-arm fluoroscope
- Large oscillating bone saw, thin blade*
- Power driver for the half pins
- Drill with chuck
- Chisel, fine, 10 mm
- Jacobs chuck T-handle (half-pin removal)
- Pin cutter, if available

* Saw blade: width 19–20 mm, thickness 1.19–1.27 mm, length at least 85 mm.

Fixator, half pins and instruments: UniX Metaphyseal Hinge Fixator System Set (Ordering Information, page 13).

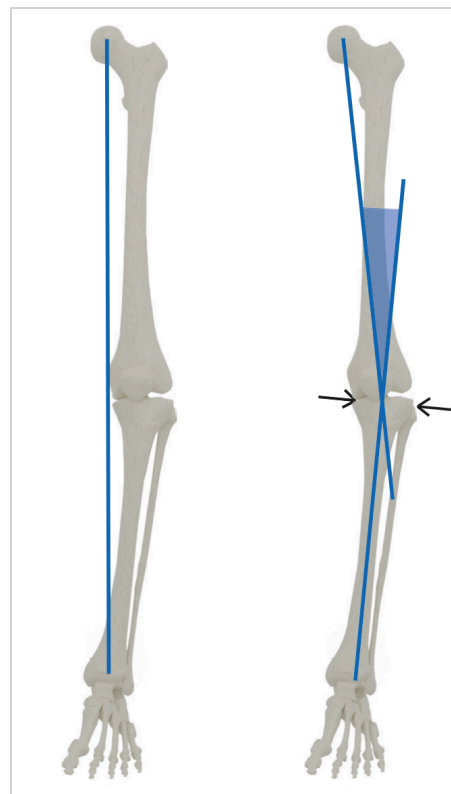


Figure 1 Preoperative mechanical axis (left) and the planned correction (right).

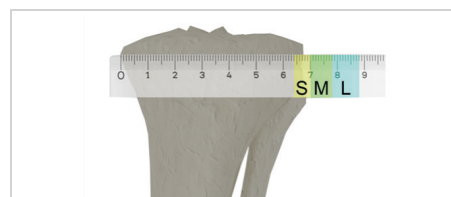


Figure 2 Tibial width read against the XS, S, M and L ranges.

Surgical Technique

Patient Positioning

Place the patient supine, then prepare and drape in the routine sterile fashion. Tilt the operating table 10–20° into the Trendelenburg position so that the tibia lies horizontal; alternatively, support the heel on a pillow so that the tibia lies level and at right angles to the vertical X-ray beam.

Rotate the leg until the patella faces forward. Under fluoroscopy, draw a line along the tibial plateau on the skin to mark the joint level. An assistant holds the leg in position.

1 Hinge Guide Wire

Centre the fixator on the metaphysis and set the insertion distance of the proximal half pins to find the hinge position. Then insert a 3.0 mm guide wire at the hinge position, perpendicular (90°) to the anterior cortex (Figure 3), either through the fixator's hinge hole or with the fixator set aside. The orientation of this wire determines every following step.

2 Positioning the Fixator

If the fixator was set aside, slide it over the 3.0 mm guide wire through its hinge hole. On the AP image, align the transverse arm with the joint line and adjust the distance between the fixator and the skin. Fix the transverse arm with two 2.0 mm guide wires through its oblique holes (Figure 4).

Place the spacers between the fixator and the skin and check the distance on a lateral view. They hold the skin-to-fixator distance constant until the first half pin has been inserted.



Figure 3 Planned hinge position for the 3.0 mm guide wire.

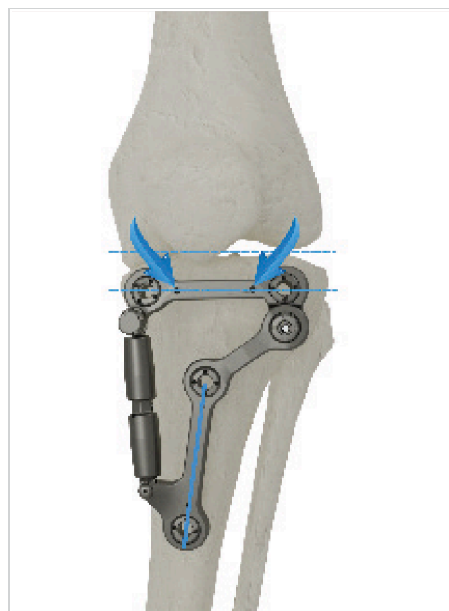


Figure 4 Transverse arm parallel to the joint, fixed with two 2.0 mm guide wires.

3 Aligning the Longitudinal Arm

Turn the spindle to dial the fixator to the angulation of the proximal tibial metaphysis until the longitudinal arm lies directly over the front of the tibial shaft. Fix the longitudinal arm with two 2.0 mm guide wires (Figure 5); this sets the target for the distal half pins.

Once the four 2.0 mm guide wires are in place, the arms can no longer move against the bone, and the skin-to-fixator gap is set (Figure 6). If an arm or the skin distance is not correct, remove the 2.0 mm guide wires and place them again.

4 Drilling

Through small stab incisions, insert one 4.8 mm Drill Guide into each cone; check that each cone is open. Leave the half-pin locking nuts on the fixator body.

***Note:** If a half-pin locking nut is taken off while drilling or inserting a pin, the pin can end up misaligned and the nut may not lock securely afterwards.

Drill with the 4.8 mm drill bit through the tibial head, including the dorsal cortex; a lateral image is recommended.

***Important Note:** Drilling in cancellous bone gives much less tactile feedback than in cortical bone; check where the drill tip is under the image intensifier.

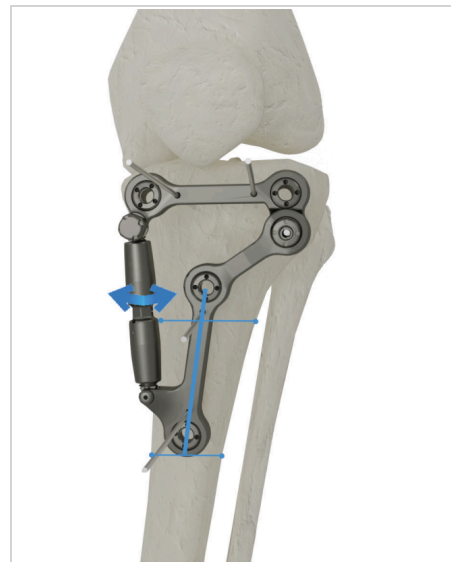


Figure 5 Longitudinal arm over the tibial shaft, fixed with two 2.0 mm guide wires.



Figure 6 Fixator held by the hinge wire and four 2.0 mm guide wires.

5 Half-Pin Insertion

Insert a 6 mm conical half pin into every cone (Figure 7); bicortical purchase is required. The cones set the pin direction, so the surgeon does not angle the pins: by design, the proximal half pins converge to follow the anatomy and run posteriorly with a distal inclination to follow the tibial slope (Figure 8).

***Important Note:** Avoid over-insertion. Because the pins are conical, backing one out loosens its hold in the bone.



Figure 7 Half pin inserted through a cone.



Figure 8 Lateral view: the proximal half pins converge and run posteriorly, inclined distally.

6 Locking and Cutting the Half Pins

Tighten all half-pin locking nuts with the Screw Locking Handle (Figure 9). Then cut the half pins, leaving 8 mm of pin above the locking nut, with a pin cutter if one is available in the operating room.

7 Osteotomy Guide Wires

Aim the MHF Osteotomy Guide at the hinge and use it to insert the 2.0 mm guide wires that define the osteotomy, one wire at a time.

8 Releasing the Spindle

Remove the 2.0 mm temporary fixation wires placed in steps 2 and 3; the osteotomy guide wires stay in place. Open the spindle connection by hand and take the spindle out of its proximal attachment point, so that the osteotomy can be performed freely (Figure 10).



Figure 9 Locking nuts tightened with the Screw Locking Handle.



Figure 10 Spindle released from its proximal attachment point.

9 Osteotomy

Make a straight or curved ventromedial skin incision of sufficient length. Prepare the pes anserinus and perform a sufficient medial release. Place two Hohmann retractors, one ventral and one dorsal, and cut the bone with the oscillating saw while protecting the patellar tendon (Figure 11).

*** Important Note:** The cut begins 7 cm below the knee joint line and runs straight towards the 3.0 mm guide wire. Laterally, the cut stays between the medial edge of the fixator's hinge and the 3.0 mm guide wire, so the lateral hinge is preserved: the far cortex is left intact.

Check that the osteotomy works: watch the open (medial) end move, so that no bone bridge remains. If needed, distract 3–5 mm and confirm the opening under the C-arm, then reverse this test distraction.

10 Closure

Close the incision and clean the operative field. Reposition the spindle and fit the red HalfPin SoftTissueCovers over the pin ends (Figure 12).

Tighten the nut on the hinge to lock the hinge.



Figure 11 Completed osteotomy.



Figure 12 Spindle repositioned, pin ends covered.

Correction Procedure

The correction starts after a latency period of 5–7 days. First loosen the hinge nut by half a turn, otherwise the hinge cannot move; the correction is then carried out by the patient or a carer, who turns the distraction nut by hand. If the nut is hard to turn, the patient is given the Distractor Wrench and makes the adjustment with it.

***Note:** One complete 360° rotation of the distraction spindle opens the fixator hinge by approximately 2°. To allow gradual and controlled adjustment, the distraction nut is divided into six equal increments of 60°. A distinct tactile and audible "click" is generated with each 60° rotation, and each click corresponds to approximately 0.33° of angular correction.

To achieve the recommended 0.66° of correction per day, the distraction nut is rotated a total of two clicks (120°) each day: one click in the morning and one in the evening. Dividing the daily correction in this way supports gradual soft-tissue adaptation and patient comfort, and allows the planned correction to be performed in a precise, controlled and reproducible manner.

Nut rotation	Clicks	Angular correction
60°	1	approx. 0.33°
120° per day	2 (morning + evening)	approx. 0.66° per day
360°	6	approx. 2°

- At the medial cortex, about 55–60 mm from the hinge, 0.66° per day opens the gap by less than 1 mm per day, within the rate used for distraction osteogenesis in limb lengthening.
- A 10° correction takes about 15 days. No acute opening or pre-distraction is intended, following the rules of distraction osteogenesis.
- If a day is missed, the correction continues the next day and takes one day longer; never double the adjustment to catch up.
- Partial weight bearing in daily life during the distraction, typically 2–4 weeks for the average 10–15° deformity; the patient can stand with full weight for the standing radiographs.
- The correction ends when the planned alignment is confirmed on a standing radiograph under weight bearing, not after a fixed number of days. When the correction ends, tighten the hinge nut to lock the hinge.
- Total time in the frame, correction and consolidation, is typically 3–4 months.
- Pin-site care follows the clinic's protocol; the patient should contact the clinic promptly in case of redness or fever.



Figure 13 Before the correction.

Measuring the Angle

The angle of the fixator is read by placing the Angle Measuring Tool on the fixator (Figure 14).



Figure 14 Angle read with the Angle Measuring Tool.

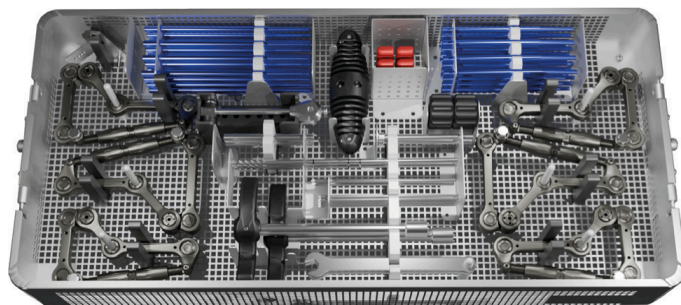
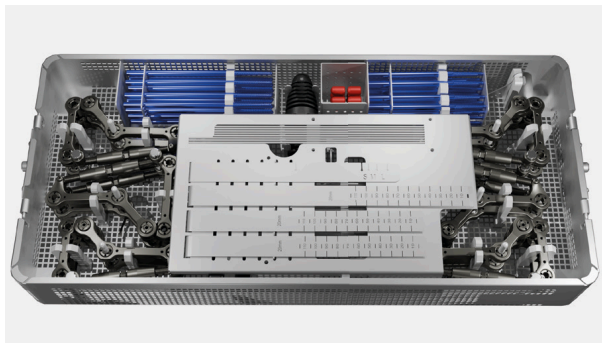
Removal of the Fixator

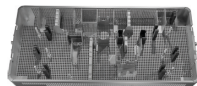
The fixator is removed once radiographs confirm sufficient bone healing. Loosen the half-pin locking nuts by turning them counter-clockwise with the Screw Locking Handle (Figure 15). Then remove the half pins with a Jacobs chuck T-handle; once the half pins are out, the fixator comes off.

Removal is minimally invasive and is typically performed as an outpatient procedure; no internal implant remains in the body.



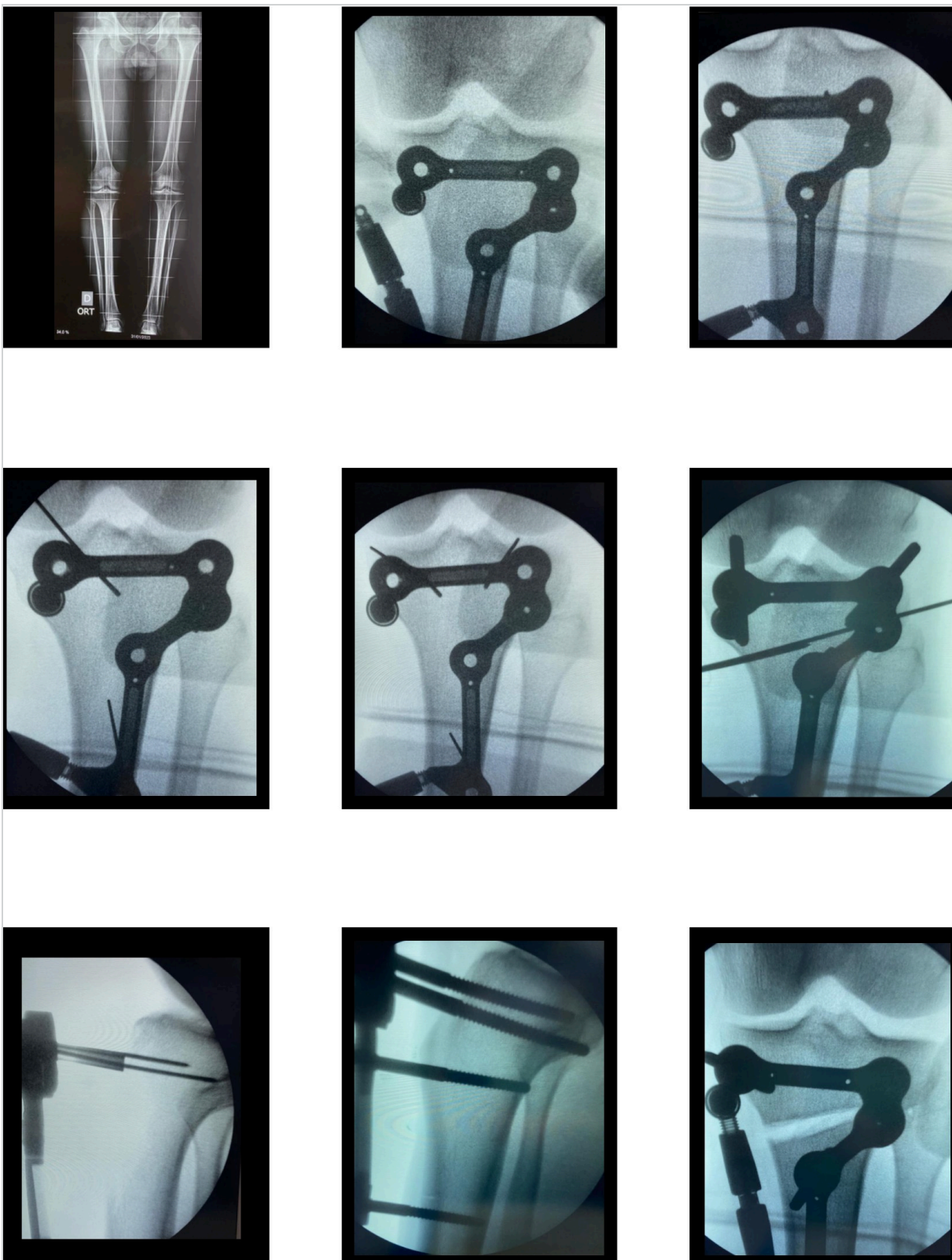
Figure 15 Locking nuts loosened for removal.



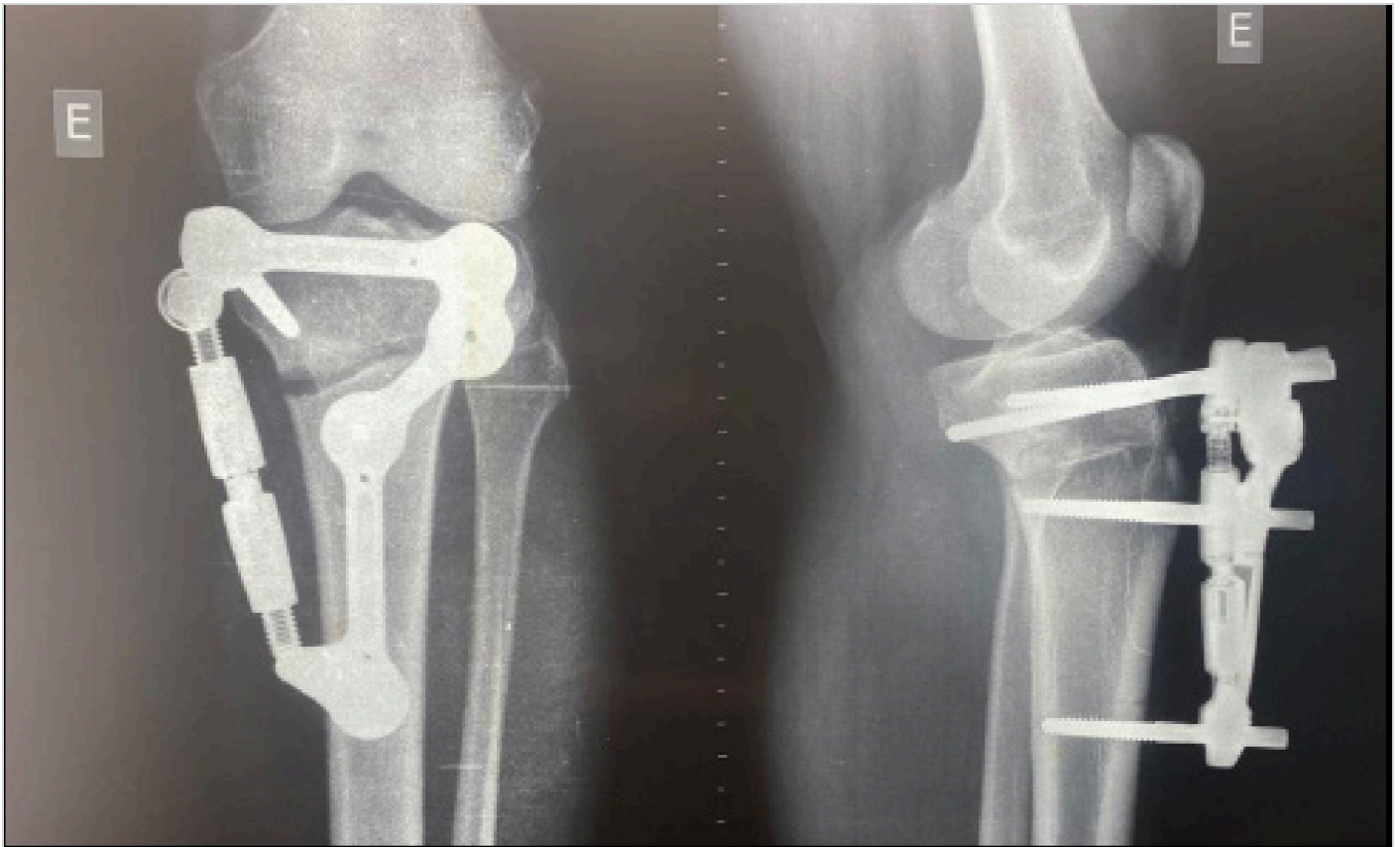
00-9069-17	UniX Metaphyseal Hinge Fixator System Set	1	Set	
00-8109-17	Metaphyseal Hinge Fixator System Tray	1	Instrument	
00-0141-03	Size Measurement Tool	1	Instrument	
40-4301-12	Guide Wire, 3.0mm x 120mm, Trocar	2	Instrument	
50-5016-11	Metaphyseal Hinge Fixator, Anterior, Small, Left	1	XF Component	
50-5016-12	Metaphyseal Hinge Fixator, Anterior, Medium, Left	1	XF Component	
50-5016-13	Metaphyseal Hinge Fixator, Anterior, Large, Left	1	XF Component	
50-5016-21	Metaphyseal Hinge Fixator, Anterior, Small, Right	1	XF Component	
50-5016-22	Metaphyseal Hinge Fixator, Anterior, Medium, Right	1	XF Component	
50-5016-23	Metaphyseal Hinge Fixator, Anterior, Large, Right	1	XF Component	
00-7057-00	2.0mm X 250mm Non-Threaded Guide Wire	8	Instrument	
00-0059-60	4.8mm Drill Guide	2	Instrument	
00-3483-21	Drill Bit, 4.8x200mm	2	Instrument	
00-1043-00	Multiple T-Handle	1	Instrument	

50-1076-133B	Half Pin, 6.0/130/30mm, Blunt, Ti	4	Implant	
50-1076-134B	Half Pin, 6.0/130/40mm, Blunt, Ti	8	Implant	
50-1076-135B	Half Pin, 6.0/130/50mm, Blunt, Ti	4	Implant	
50-1076-153B	Half Pin, 6.0/150/30mm, Blunt, Ti	4	Implant	
50-1076-154B	Half Pin, 6.0/150/40mm, Blunt, Ti	8	Implant	
50-1076-155B	Half Pin, 6.0/150/50mm, Blunt, Ti	4	Implant	
00-0141-04	Spacer	2	Instrument	
00-1041-00	Metaphyseal Hinge Fixator Screw Locking Handle	2	Instrument	
00-7041-20	Osteotome, 20mm	2	Instrument	
00-7041-21	Osteotome, 20mm, Long	1	Instrument	
00-0141-00	Angle Measuring Tool	1	Instrument	
00-1041-01	Metaphyseal Hinge Fixator Distractor Wrench	2	Instrument	
50-1070-07	HalfPin SoftTissueCover,6mm(4-pack),Red	16	Instrument	
00-0141-05	MHF Osteotomy Guide	1	Instrument	
Optional Items				
50-5016-10	Metaphyseal Hinge Fixator, XSmall, L	1	XF Component	
50-5016-20	Metaphyseal Hinge Fixator, XSmall, R	1	XF Component	

Case Studies



Full-length standing radiograph and intraoperative fluoroscopy. Courtesy of Dr. Marcelo Fumio



AP and lateral radiographs with the fixator in place. **Courtesy of Dr. Marcelo Fumio**

Left – Preop



End of Correction



PostOp

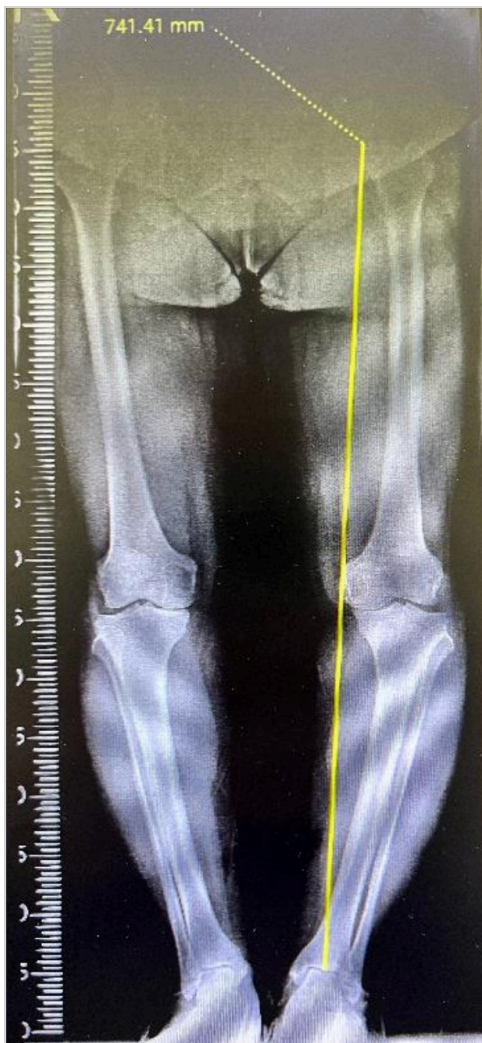


Right – PreOp



Courtesy of Dr. Ahmet Kekeç

Valgus Deformity Under Load



8 Weeks Postoperative, Gradual Correction

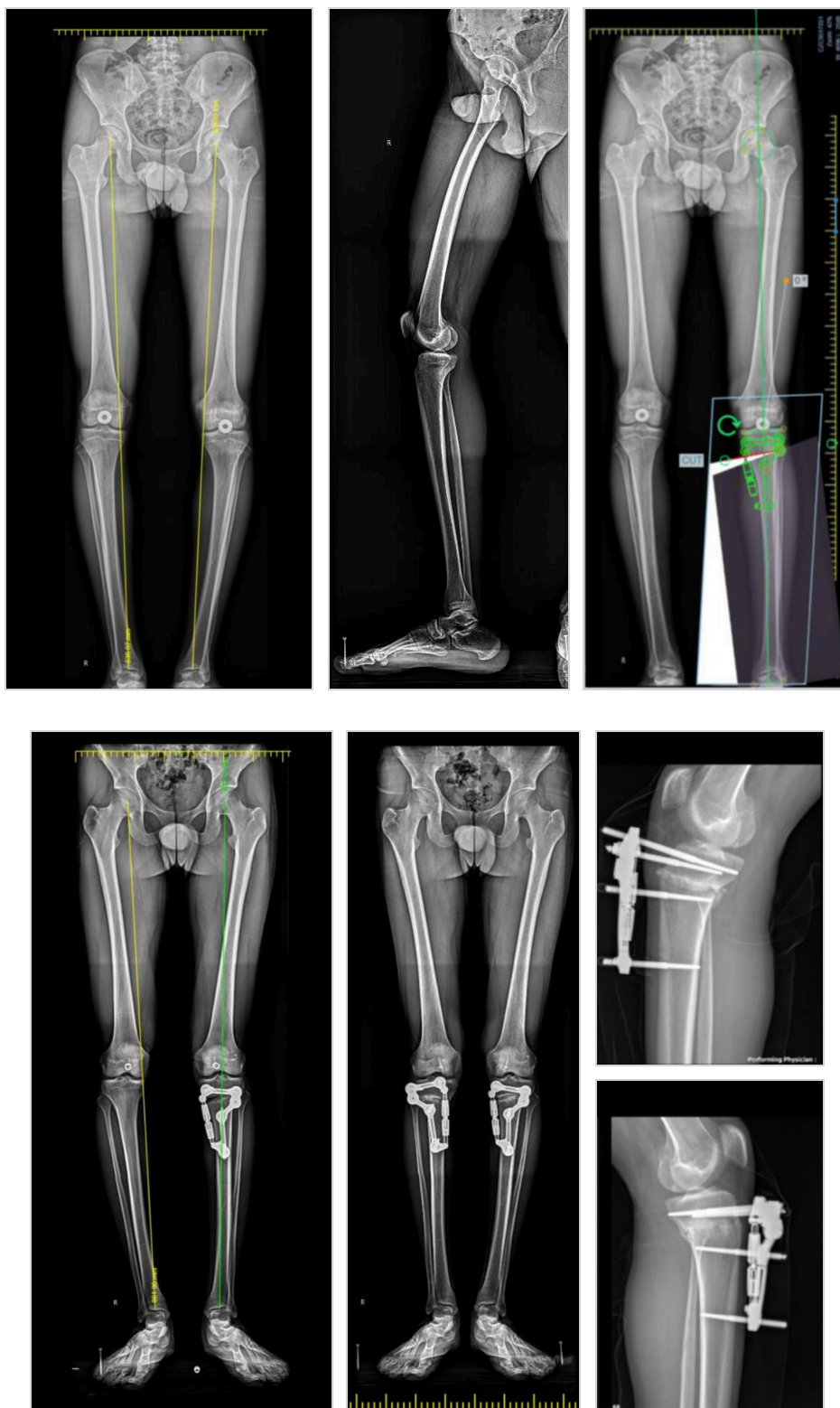


IntraOp



Courtesy of Prof. Rainer Baumgart

Bilateral Application



Courtesy of Dr. Levent Eralp

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www.ResponseOrtho.com

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