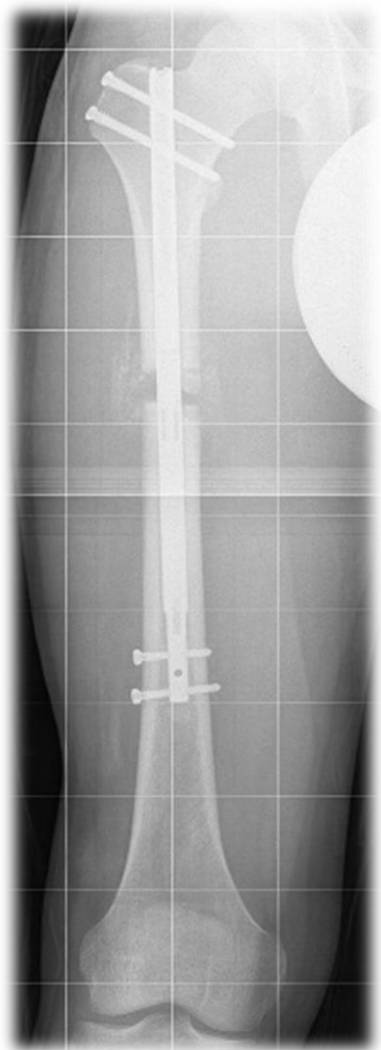


# The Latest Advancements in Limb Lengthening

F. Lalonde, MD  
CHOC Children's Hospital  
Orange, CA



LC0068-A



# Contributing Surgeons

**Stuart A. Green, MD**

Clinical Professor

Department of Orthopaedic Surgery

University of California, Irvine Medical  
Center

Irvine, CA

# Topics for Today

- History of Limb Lengthening
  - Where did we start and where we are heading
- Tips for a Successful Outcome
  - Anatomy and level of osteotomy
  - Tips and tricks (venting, distal fixation)
- Introduction to PRECICE
  - Implant options and instrumentation
- Case Study Review
  - Reason for surgery and clinical outcome
- Discussion + Q&A
  - Open discussion on topics important to the audience

# History of Limb Lengthening

# History of Limb Lengthening

- ❑ 1905 – First published paper on principals and applications of *distraction osteogenesis* techniques by Prof. Alessandro Codivilla (Italy).
  - osteotomy, gradual lengthening through traction, consolidation.
- ❑ 1951 – **Gavril Ilizarov** develops external fixation device, oldest and most common method of limb lengthening.
- ❑ 1987 – Jean-Marc Guichet, MD (France) develops **Albizzia** intramedullary nail which adjusts with rotation of knee and leg (femur) or foot (tibia).

# History of Limb Lengthening (continued)

- ❑ 1996 – First surgeries in Germany using **FitBone**.
- ❑ 1997 – Herzenberg and Paley first describe a technique called **Lengthening Over a Nail (LON)**.
  - Combination of Ilizarov osteosynthesis and intramedullary stabilization.
- ❑ 2001 – Dean Cole, MD (Florida) develops **ISKD** device.
- ❑ 2011 – First case with **PRECICE** in New Zealand.
- ❑ 2012 – ISKD field safety action pulling device from all markets.

# Limb Lengthening Options Methods

## External Fixation (ex-fix):

- Ilizarov – Smith and Nephew.
- Taylor Spatial Frame (TSF) – Smith and Nephew.
- Most orthopedic companies market circular ex-fix frame.

## Hybrid Technique:

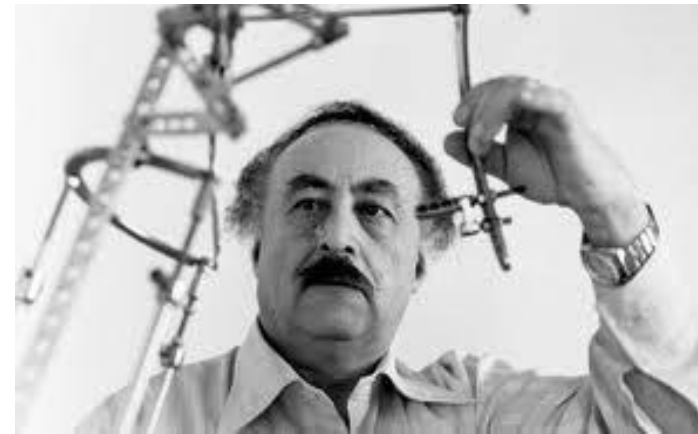
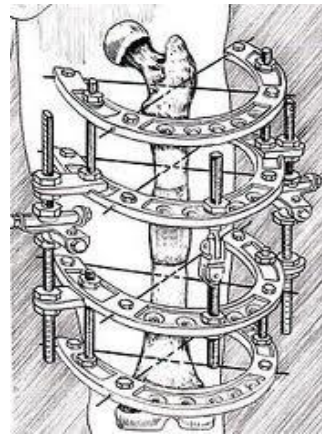
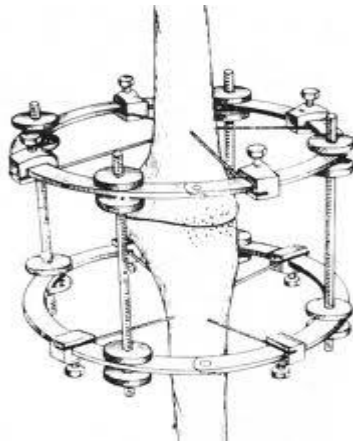
- Lengthening Over Nail (LON).
- External & Internal devices used in combination.

## Intramedullary Nails:

- Minimally invasive intramedullary nailing.
- ISKD Nail – OrthoFix (Recalled but may be re-released in select countries).
- FitBone Nail – Wittenstein Group (CE Mark only & Compassionate Use).
- Guichet Nail – JM Guichet Clinic (1 Location in France).
- PRECICE Nail – Ellipse Technologies Inc. (FDA and CE Mark).

# Ilizarov External Fixation

- ❑ Professor Gavriil Abramovich Ilizarov pioneered the procedure in 1950s in Siberia.
- ❑ Circular fixation device using stainless steel rings with pins that penetrate through skin, muscle tissue and bone.
- ❑ Available in the west since 1981.
- ❑ Lengthening process takes approximately 9-18 months.





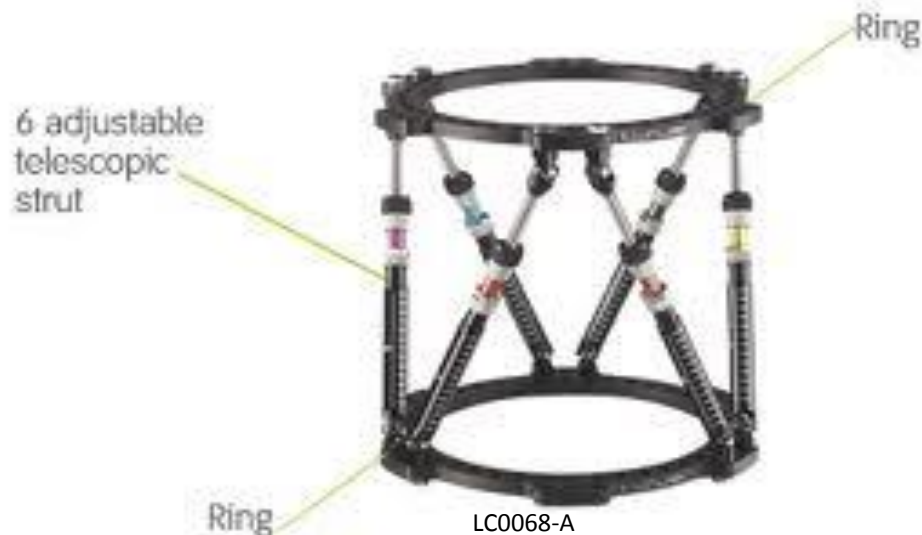
# Ilizarov External Fixation

- ❑ Over 1 million cases worldwide.
- ❑ Can be assembled more than 600 ways.
- ❑ Lightweight and full circular rings.
- ❑ Simplistic nuts, bolts and wires that can be adjusted based up on patients needs.
- ❑ Exposes patient to risk of pin-track infections.
  - Infection requires additional surgery to replace pins and fasteners.
  - 30-60% of cases have complications and require longer hospital stay (Paley, 1990).
- ❑ Limited mobility, may generate nerve and soft tissue irritation, discomfort and pain.
- ❑ Distributed by Smith & Nephew.



# Taylor Spatial Frame (TSF)

- ❑ Advanced circular fixator.
- ❑ Fractures, malunions, non-unions
- ❑ Angular, translational, rotational and length deformities can all be corrected simultaneously with the TSF.
- ❑ Web based software allows preoperatively planning or minor postoperative corrections.
- ❑ Distributed by Smith and Nephew.



# Taylor Spatial Frame

- ❑ Correction of the bone deformity can take 3–4 weeks and done via strut adjustment.
- ❑ Frame is left on leg 3–6 months.
- ❑ Distributed by Smith and Nephew.

**Left limb deformity**

	Struts increased	Struts decreased
Medial translation	#2, #5	#1, #4
Lateral translation	#1, #4	#2, #5
Anterior translation	#1, #2, #4, #5	#3, #6
Posterior translation	#3, #6	#1, #2, #4, #5
Varus	#6 (#1, #5)	#3 (#2, #4)
Valgus	#3 (#2, #4)	#6 (#1, #5)
Apex anterior	#4, #5	#1, #2
Apex posterior	#1, #2	#4, #5
Internal rotation	#2, #4, #6	#1, #3, #5
External rotation	#1, #3, #5	#2, #4, #6
Lengthen	ALL	

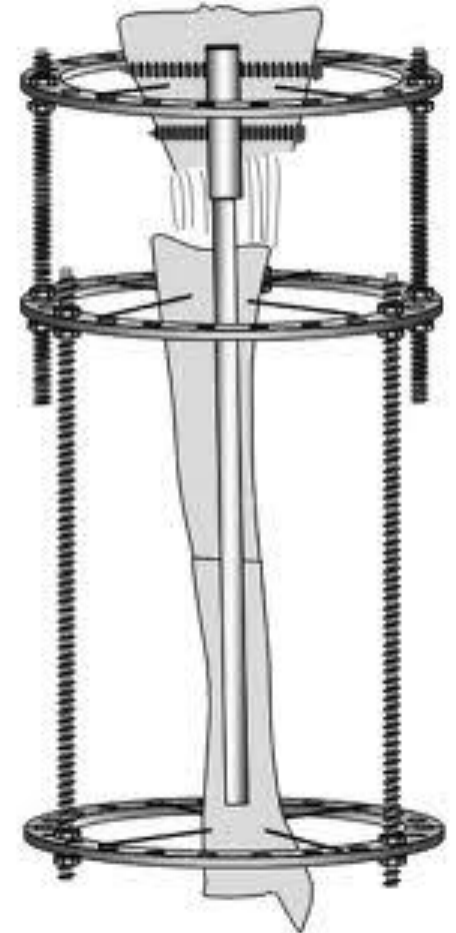
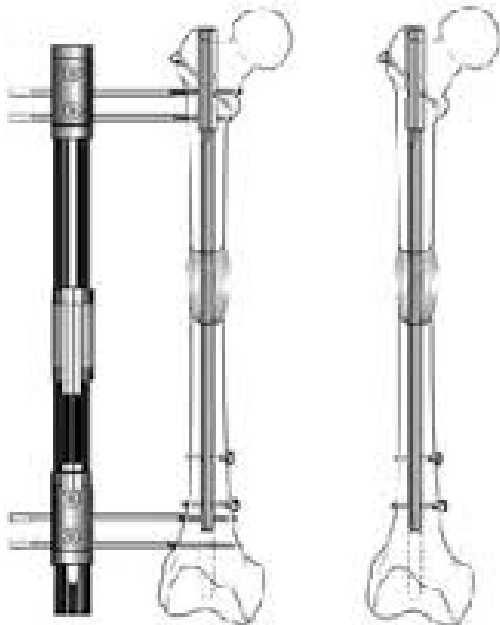
**Right limb deformity**

	Struts increased	Struts decreased
Medial translation	#1, #4	#2, #5
Lateral translation	#2, #5	#1, #4
Anterior translation	#1, #2, #4, #5	#3, #6
Posterior translation	#3, #6	#1, #2, #4, #5
Varus	#3 (#2, #4)	#6 (#1, #5)
Valgus	#6 (#1, #5)	#3 (#2, #4)
Apex anterior	#4, #5	#1, #2
Apex posterior	#1, #2	#4, #5
Internal rotation	#1, #3, #5	#2, #4, #6
External rotation	#2, #4, #6	#1, #3, #5
Lengthen	ALL	



# Lengthening Over Nail - Hybrid Technique

- ❑ Using external fixator with internal nail.
- ❑ Unilateral or circular external fixator.
- ❑ Stable construct.
- ❑ Requires additional surgical procedures.



# Lengthening over Nail – Hybrid Technique (continued)

- ❑ Reduces fixator time as the nail may be distally locked with screws when the desired distraction is reached.
- ❑ May reduce complications such as pin-tract infection.
- ❑ Eliminates post-op casting removal.
- ❑ Prevention of fracture due to stable construct.
- ❑ Faster healing rates seen than just internal alone.
- ❑ External fixation portion is approximately 5-8 months.
- ❑ LON with external fixation requires external fixation during distraction phase which is 1+ month.

# Intramedullary Nail Lengthening

- Minimally invasive surgical approach.
- Eliminates risk of pin-site infections.
- Improved patient comfort and satisfaction vs. external fixation.
- Intramedullary stabilization.
- Surgical time may be reduced.
- Nail removal at 1 – 1.5 years.

# Tips for a Successful Outcome

# Lengthen or Shorten

## When to limb lengthen in the femur and tibia.

- Congenital differences in limbs.
- Trauma.
- Bone tumors.

## Shortening consideration.

- Non-compliance concerns.
- Poor bone regeneration potential.
- Age of the patient.



# Pertinent Anatomy

- ❑ Muscles, tendons and ligaments to remember.
- ❑ Nerves and stretching.
  - *“Nerves are highly viscoelastic tissues and show marked stress relaxation.”*
  - *“Major nerve injury complications also depend on the amount of lengthening; they rarely occur with lengthening of less than 10 cm, but with lengthening of more than 10 cm, 12% of patients developed transient sensory or motor loss.”*



# Pre-Operative Assessment

Careful pre-operative evaluation and planning, proper surgical technique and extended post-operative care by experienced surgeons are essential for success of any lengthening procedure.

## **Pre-operative evaluation is performed to determine:**

- Limb length discrepancy.
- Type of nail approach (antegrade or retrograde).
  - Antegrade: Piriformis Fossa or Greater Trochanter.
- Overall length of nail.
- Diameter of nail (8.5 mm, 10.7 mm or 12.5 mm).

# Case Planning

## Limb Length Discrepancy Measurements

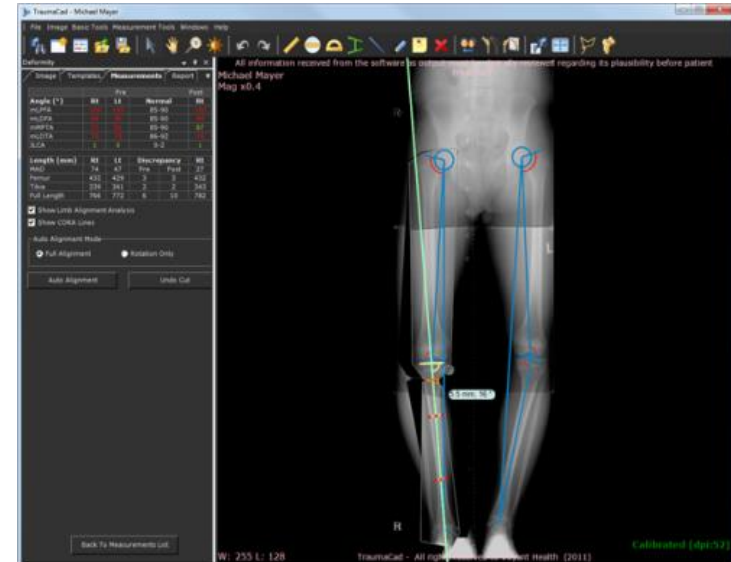
<b>Examination Period:</b>	<input type="checkbox"/> Baseline/pre-operative
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	<b><u>3. Contralateral Limb</u></b>	<b><u>4. Treatment Limb</u></b> <input type="checkbox"/> Left <input type="checkbox"/> Right
	$d_1 = \square\square.\square$ mm	$d_2 = \square\square.\square$ mm
	$F_1 = \square\square.\square$ mm	$F_2 = \square\square.\square$ mm
	$T_1 = \square\square.\square$ mm	$T_2 = \square\square.\square$ mm
		$Lift = \square\square.\square$ mm
	<b><u>5. Limb Length Discrepancy</u></b> = $(d_2 - d_1) + Lift = \square\square.\square$ mm	

Use a magnification marker to ensure accurate measurements.

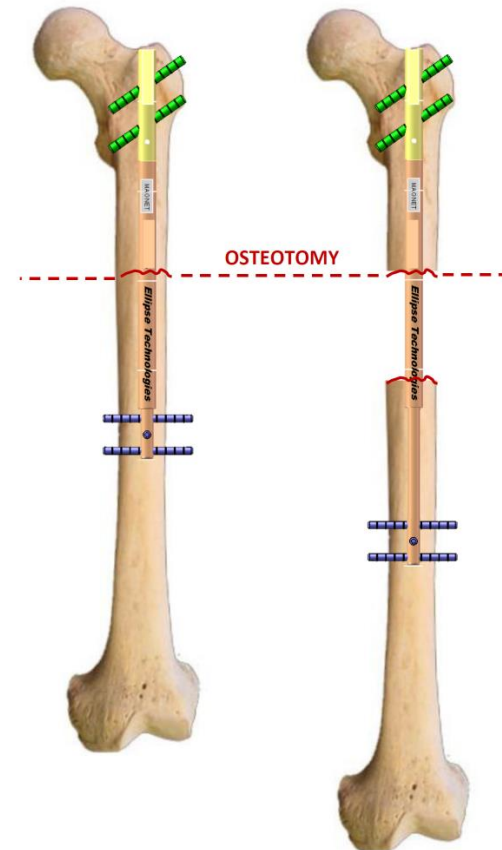
# Case Planning

- ❑ 3D imaging software to plan deformity correction and limb lengthening cases.
  - Perform measurements, fix prostheses, simulate osteotomies and visualize fracture reductions.
- ❑ Over 2,500 implant families are part of the TraumaCad software program.



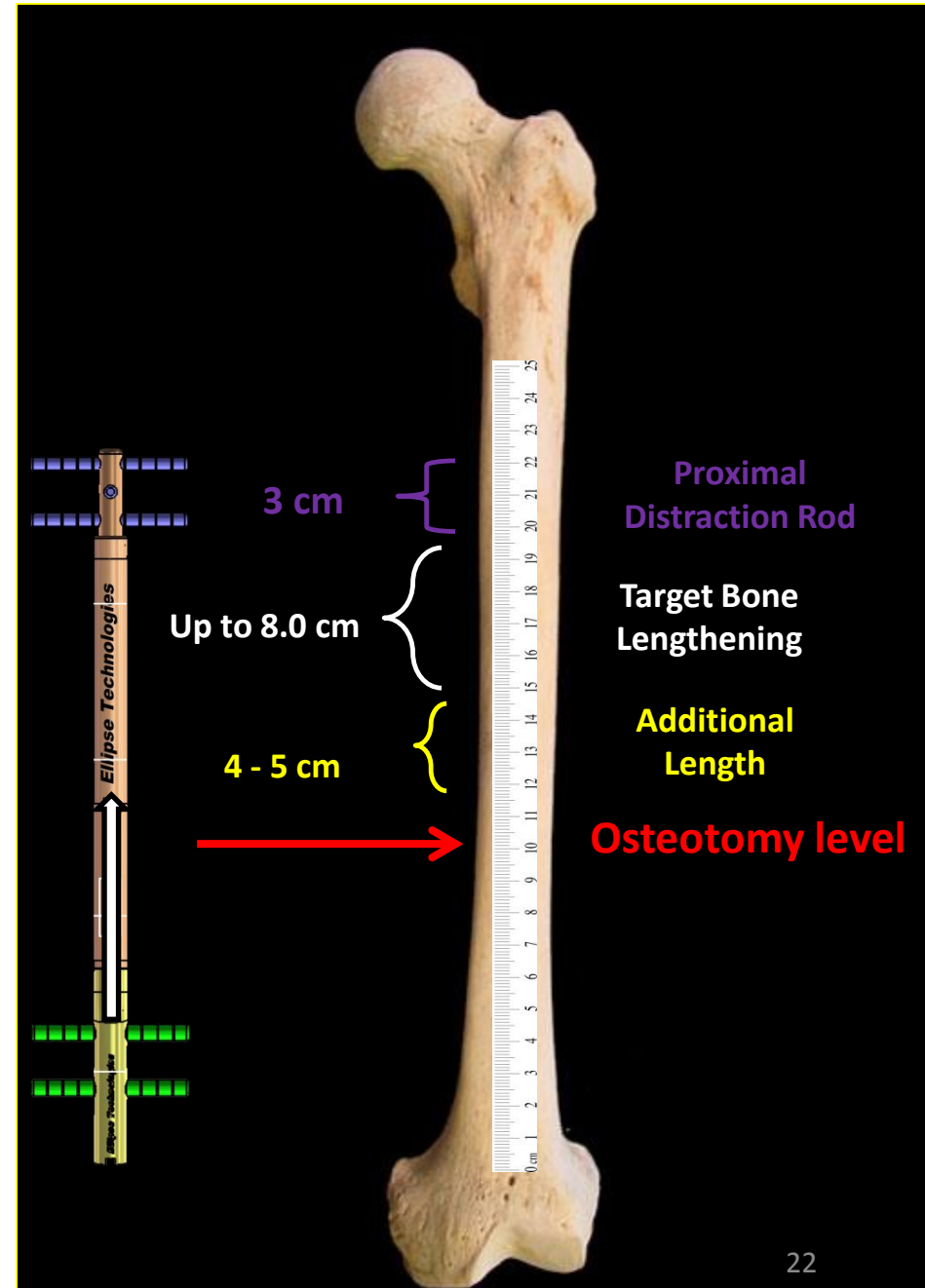
# Level of Osteotomy

- ❑ General rules to follow.
- ❑ Situations where changing osteotomy site should be considered.



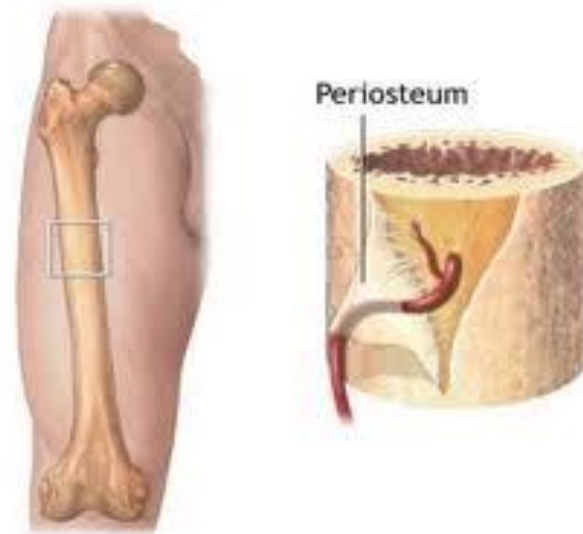
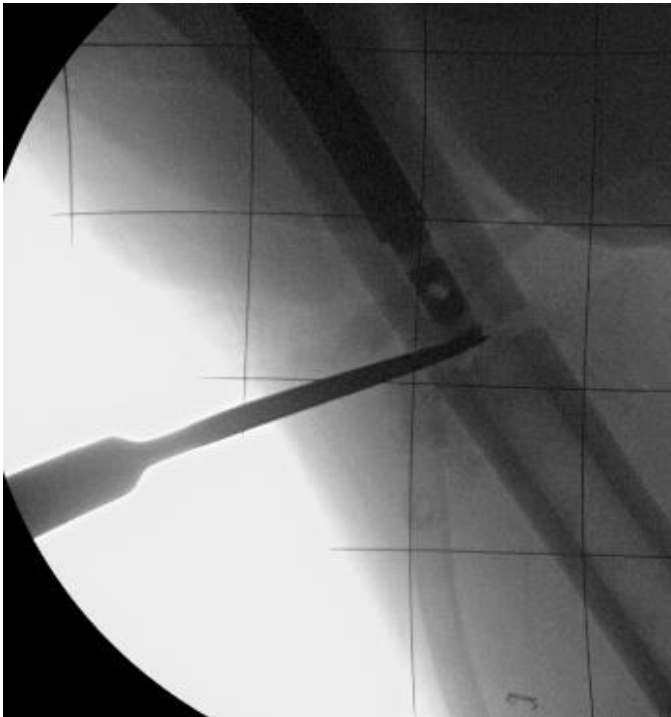
# Osteotomy Calculation

- ❑ 3 cm (proximal distraction rod) + the desired amount of bone lengthening (up to 8.0 cm) + an additional 4-5 cm.
- ❑ This measurement is the distance from the tip of the proximal distraction rod to the osteotomy.
- ❑ This measurement may need to be modified if there is a deformity to be addressed in the frontal or sagittal plane.



# Intramedullary Corticotomy

- ❑ Importance of intact intramedullary blood supply.
- ❑ Preserving the periosteum.



# Venting and Reaming

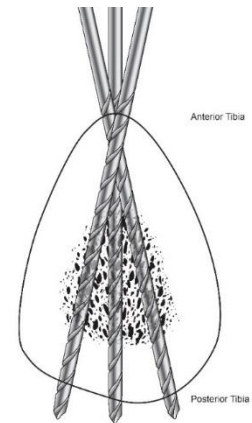
Intramedullary reaming of a closed bone generates high intramedullary pressures that have been associated with complications such as fat embolism\*

❑ Place multiple venting holes at the planned osteotomy site prior to reaming.

- Egress for bone marrow at osteotomy site.
- Osteotomy site facilitation.
- Avoid fat embolism.

❑ Avoiding thermal necrosis

❑ 2 mm or more over the outer diameter of the nail



1. Intramedullary pressure and bone marrow fat intravasation in unreamed femoral nailing. Kröpfl A, Berger U, Neureiter H, Hertz H, Schlag G. JTrauma. 1997 May;42(5):946-54



# Entry Points and Tips and Tricks

## ❑ Entry points.

- Piriformis Fossa or Greater Trochanter.
- Tibia.

## ❑ Shanz pins / ex-fix.

- Manipulation and control.
- Prevents mal-rotation.

## ❑ Blocking screws.

- Ensures proper seating of the nail.
- May allow for minor angular deformity correction.

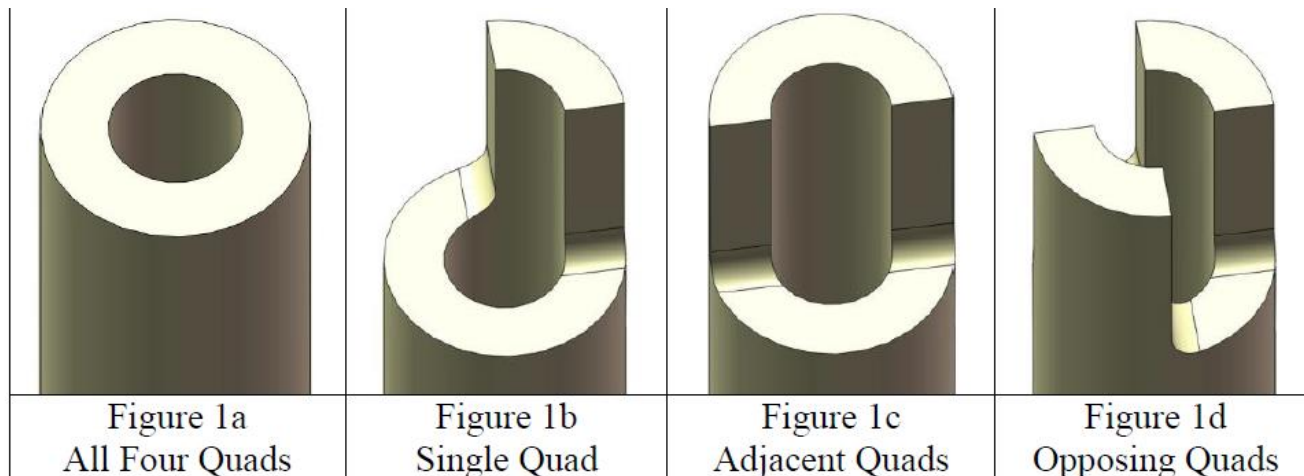


# General Rules

- ❑ **Consolidation Phase** is twice as long as **Distraction Phase**.
- ❑ **Latency** and the **quality of bone** produced.
- ❑ **1 mm per day** of distraction / 0.33 mm 3 x per day.
  - When 1 mm a day is too little / much.
- ❑ Weekly X-Ray imaging.
- ❑ *Lengthening too quickly*: overstretches soft tissues and inability of bone to form in gap.
- ❑ *Lengthening too slowly*: early consolidation prior to lengthening being achieved.
- ❑ Consider using a A/P screw distally to provide two planes of fixation and added rotational control (especially on smaller diameter implants).

# General Rules (continued)

- ❑ After the bony distraction has been completed, the patient's weight bearing status must still continue at 20% load on the implanted leg not to exceed 50 pounds.
- ❑ Once two sides of regenerate bone (anterior, posterior, medial, lateral) have completely healed with bridging bone, the patient may begin loading more weight onto the implanted leg.

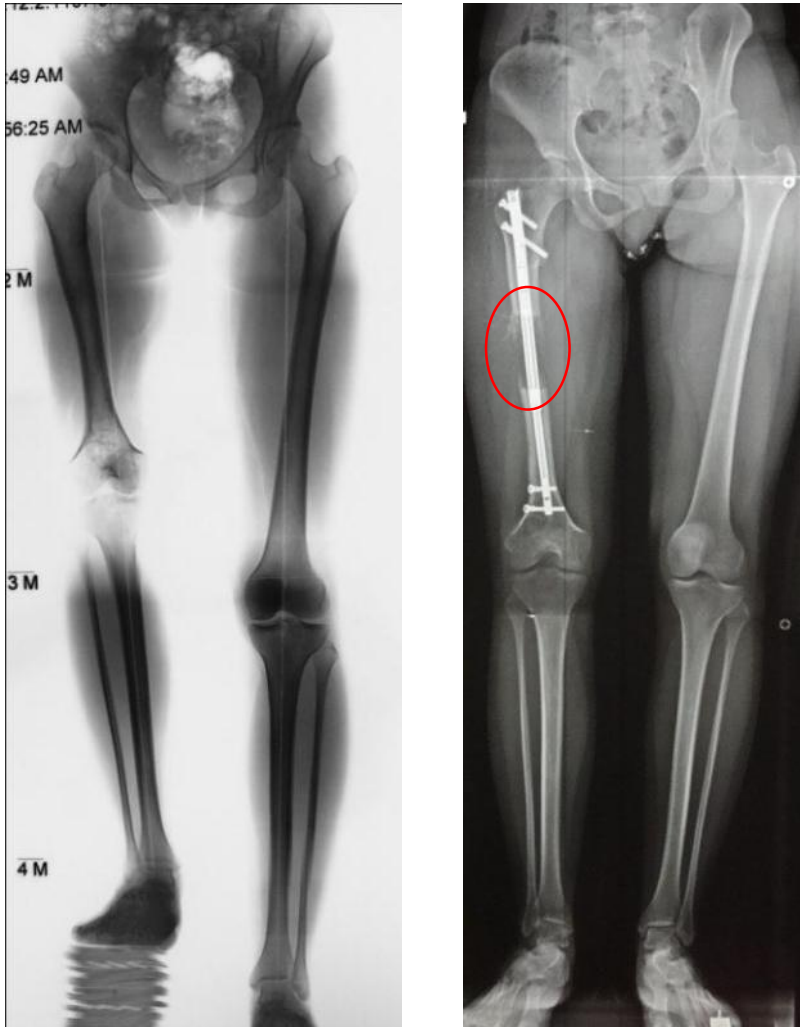


# **Introduction to Ellipse Technologies and the PRECICE<sup>®</sup> System**

# Ellipse Technologies, Inc.

- ❑ The company is dedicated to the design, development and successful commercialization of noninvasively adjustable implants for orthopedic deformity and trauma procedures.
- ❑ The company is based in Irvine, CA and was incorporated in 2005.
- ❑ Two target markets:
  - Spine = MAGEC<sup>®</sup>
  - **Limb Lengthening = PRECICE<sup>®</sup>**

# PRECICE<sup>®</sup> Limb Lengthening System

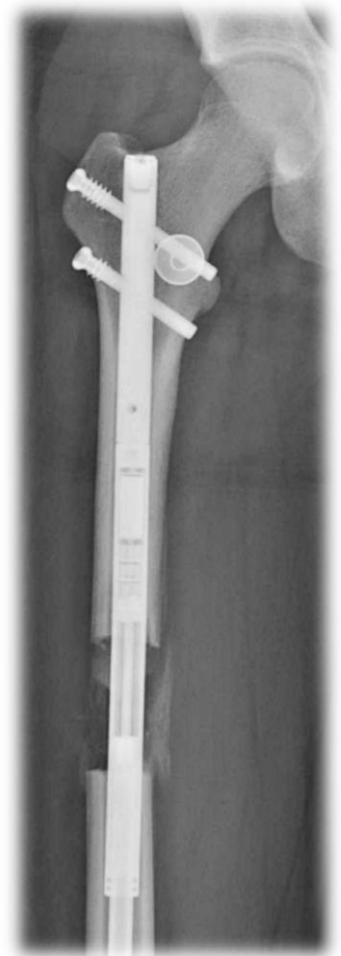


**PRECICE<sup>®</sup>** is designed to eliminate the need for external fixation devices in linear limb lengthening procedures, now considered the gold standard of care.

- Adjustable intramedullary nail incorporating patented magnetic remote control technology.
- Designed for the lengthening of the tibia and femur.

# PRECICE Limb Lengthening System

- ❑ Minimally invasive implant + IM Nailing  
Benefits (eliminates pin-site infection, etc.).
- ❑ Lengthening up to 80 mm.
- ❑ Reversible if necessary for delayed healing (accordion maneuver).
- ❑ Targeting limb lengthening procedures of femur and tibia:
  - Legs shortened due to congenital abnormalities.
  - Major fractures due to trauma or disease.
  - Malunion and non-union.



# PRECICE Limb Lengthening System

- Typical PRECICE limb lengthening procedures of the femur and tibia include:
  - Legs shortened due to congenital abnormalities.
  - Major fractures due to trauma or disease.
  - Malunion and non-union.
  - Stature lengthening.
- Customizable Lengthening Protocol.
- Non-invasive Distraction via External Remote Controller.
- Patient Preferred Treatment Option.\*
- Novel Magnetic Technology.
- Up to 80 mm of Distraction.
- Nail May Be Reversed.



\* Herzenberg JH, Standard SC and Specht SC. Limb lengthening in children with a new, controllable internal device. European Paediatric Orthopaedic Society (EPOS); April 17-20, 2013; Athens, Greece.



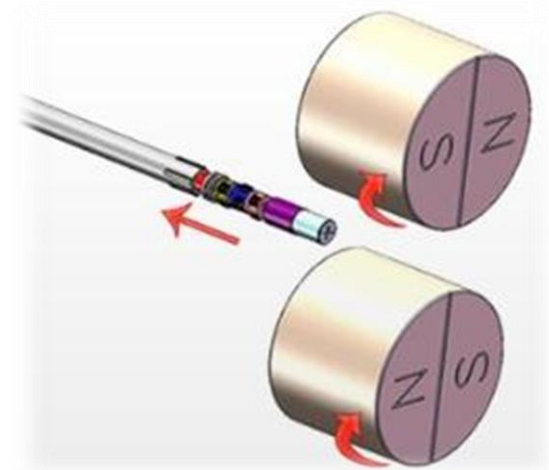
# Rare Earth Magnet

□ The key to the Ellipse platform technology is the interaction between the PRECICE intramedullary nail and the ERC. This interaction between magnets precisely modifies the length of the implant.

▪ Rotational Force ———→ Axial Force.

▪ Rare Earth Magnets.

Neodymium Iron Boron (NdFeB)



# Rare Earth Magnet (continued)

## □ NdFeB.

- Developed in 1982 by General Motors.
- Most powerful permanent magnet.

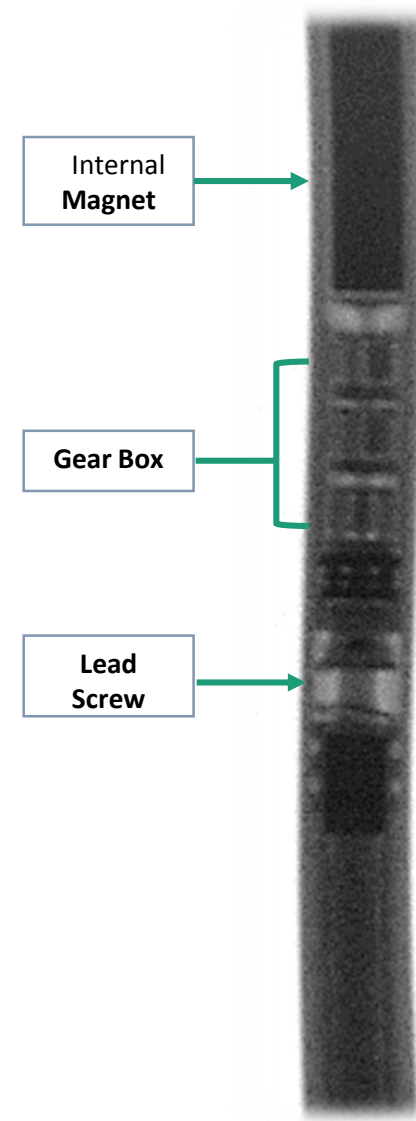


The PRECICE system involves the use of high strength magnets. Improper handling of magnets can result in severe personal injury or damage to equipment.

\*PRECICE has not been tested for use with Magnetic Resonance Imaging (MRI) machines.

# Internal Components

- ❑ The proprietary technology includes a complex internal gear system wirelessly powered and controlled by permanent magnets.
  - Internal magnet.
  - Complex gear box system.
  - Lead screw which lengthens the intramedullary nail.



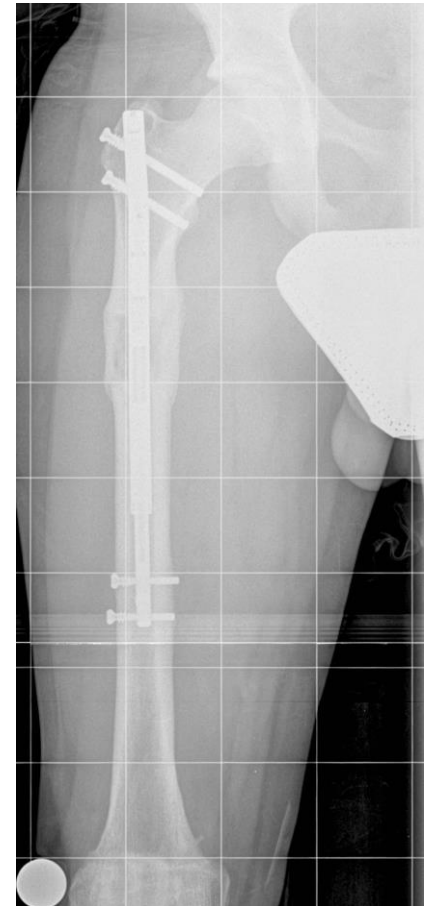
# External Remote Controller (ERC)

- ❑ Adjusts PRECICE system after implantation.
- ❑ Contains two magnets which rotate when activated.
- ❑ Daily lengthening sessions performed by the patient at the comfort of their home.
- ❑ Weekly clinical and radiographic evaluation during the distraction phase confirms lengthening & new bone formation.
- ❑ Distraction can be changed and is customizable based on surgeons prescription.



# PRECICE Results to Date

- ❑ Over 950 cases performed since December 2011 – April 2014.
  - 80% femur cases.
  - 20% tibia cases.
  - Over 135 surgeon users.
  - 14+ Countries.
  
- ❑ Nail Sizes available.
  - 8.5 mm with 3.5 mm distal screws
  - 10.7 mm with 4.0 mm distal screws.
  - 12.5 mm with 5.0 mm distal screws.



# PRECICE<sup>®</sup> Clinical Data

# Clinical Studies

- ❑ Prospective, multi-center, single arm study (no control group).
- ❑ Unilateral limb lengthening with 2-year follow up after consolidation phase completed.
- ❑ 6 clinical sites with 30 total patients.
- ❑ First patients enrolled August 2012.
- ❑ Performance outcomes include:
  - Achievement of lengthening goals.
  - Distraction rate control.
  - Quality of regenerate bone.
  - Patient Quality of Life assessments.



# Poster #1

**Limb Lengthening in Children with a New, Controllable, Internal Device**  
 John E. Herzenberg, MD, FRCS(C), Stacy C. Specht, MPA, Shawn C. Standard, MD  
 International Center for Limb Lengthening, Rubin Institute for Advanced Orthopedics, Jewish Hospital of Baltimore, Baltimore, Maryland, USA

**Background**

- Lengthening with external fixation can result in scarring, pain, decreased range of motion, and pin-site infection.
- Internal devices have been developed to address some of these issues.
- The Precice system (Ellipse Technologies, Irvine, CA, USA) became available in the U.S. in late 2011.
- The lengthening process is controlled with an external remote control (ERC), which is placed on the leg several times throughout the day.
- We report our preliminary clinical results with the Precice device in children.

**Methods**

- 20 children underwent insertion between January 2012 and March 2013.
- 27 limb segments (22 femora, 5 tibiae).
- Average patient age: 13.3 years (range, 7-16 years).
- Average goal of lengthening: 5.2 cm (range, 2.5-5.5 cm).
- Etiology
  - Congenital femoral/ulnar/humeral/tarsal/tibia/fibula hemimelia: 10
  - Post-traumatic growth arrest: 4
  - Acroostopasia: 3
  - Other disease: 2
  - Unknown etiology: 1
- Patients who underwent lengthening with external fixation as well as with the Precice were sent questionnaires and asked to compare their experiences.

**Results**

- 20 of 27 limbs have completed lengthening.
- 16 of the 20 have completely healed.
- 4 of 20 limbs are still in the consolidation phase.
- Target lengths programmed into the ERC closely matched radiographic measurements (average of 0.2 cm vs. 5.5 cm, respectively).
- Range of motion was well maintained throughout the lengthening and consolidation phases.
- Of the 16 patients who have completely healed:
  - Average distance index: 2.4 (range, 1.2-3.25 (cm/month))
  - Average healing index: 1.12 (range, 0.46-2.0 (months))
  - 3 complications occurred and resolved:
    - 1 prominent screw treated with revision
    - 1 proximal nerve entrapment treated with decompression
    - 1 tonyr valgus fracture treated with ligament reconstruction
- 9 of 13 children who had prior lengthening with external fixation completed a questionnaire comparing their experience with internal and external fixation.
- All reported that the Precice allowed for easier physical therapy, better cosmetic results, and a higher rate of overall satisfaction.
- When asked which device they would choose if another surgery was needed, all 9 patients said they would choose the Precice.

**Conclusions**

- The device is accurate, allows for good range of motion, results in few complications, and is an attractive alternative to external fixation.
- Current size availability (10.7-mm diameter rod with bone sleeves 12.0- to 12.5 mm) may limit use in small-boned children.
- More patients and long-term follow-up are still needed.

**Disclosures:** John E. Herzenberg is an unpaid consultant and receives research support from Ellipse Technologies. Shawn C. Standard is a paid consultant, receives royalties, and receives stock options from Ellipse Technologies. Stacy C. Specht does not have any disclosures.

Figure 1: X-ray images showing limb lengthening procedures. The first image shows a rod with dual femoral pins. The second image shows a limb during lengthening. The third image shows a limb after consolidation.

## Limb Lengthening in Children with a New, Controllable, Internal Device

EPOS: April 2013, Athens, Greece

John Herzenberg, MD  
 Shawn Standard, MD  
 Stacy Specht, MPA

## Study Design

- Retrospective, non randomized, single center performed by 2 surgeons.
- 20 patients (27 nails) underwent lengthening procedures between 01/2012-03/2013.
- Procedures included 22 femur and 5 tibia.
- Mean age was 13.5 years and mean pre-operative length discrepancy was 5.2 cm.\*

## Methods

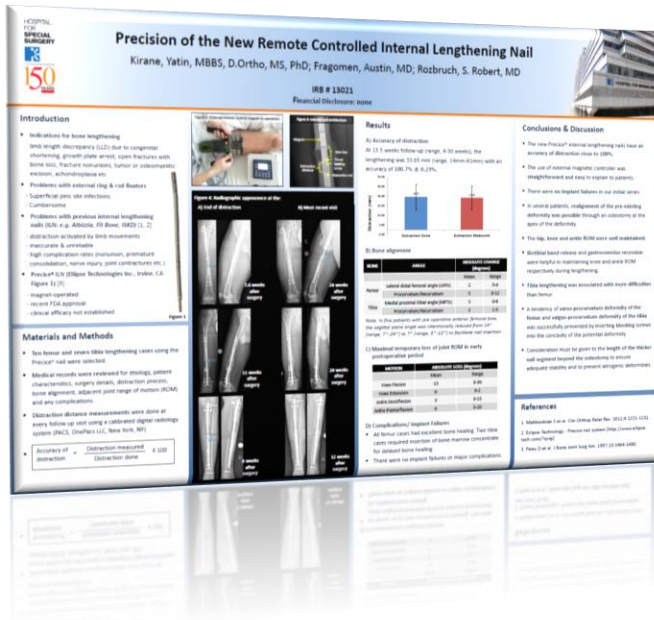
- X-Rays were used to evaluate bony consolidation.

## Results

- 20 of 27 patients completed lengthening at time of study with 1 device related complication.
- Target lengths programmed into ERC closely matched radiographic measurements (5.2 vs. 5.6 cm).
- Range of motion was maintained.
- 9 patients who had prior lengthening with an external fixator completed questionnaire comparing their experiences:
  - 9/9 reported easier physical therapy, better cosmetic results and higher overall satisfaction.
  - 9/9 would choose internal fixation over external fixation.



# Poster #2



## Precision of the New Remote Controlled Internal Lengthening Nail

HSS Research Symposium: June 2013, New York, NY  
Yatin Kirane, MD,  
Austin Fragomen, MD  
Robert Rozbruch, MD

### Study Design

- Retrospective, non randomized, single center performed by 2 surgeons.
- 17 patients (17 nails) underwent lengthening procedures.
- Procedures included 10 femur and 7 tibia.

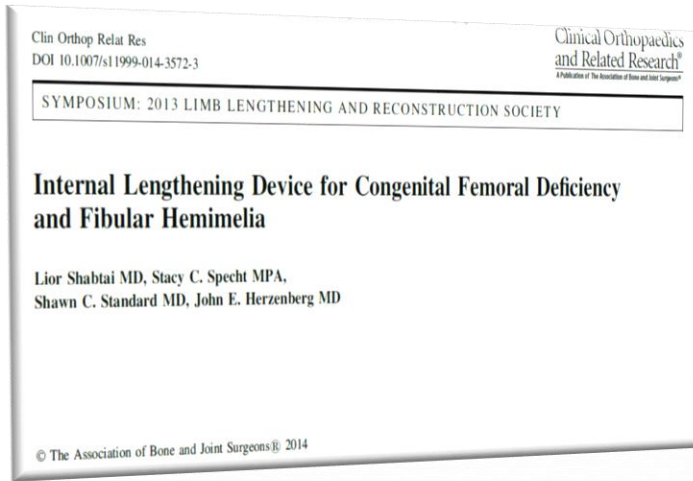
### Methods

- X-Rays were used to evaluate bony consolidation.
- Calibrated digital radiology system was used to measure distraction distance during each patients follow-up appointment.

### Results

- 0 device related complications or failures.
- 100.7%±0.23% lengthening accuracy (33.65 vs. 34.47 mm) at mean 13.5 week follow-up (4-30 weeks).
- Overall temporary range of motion loss of 5° was noted.
- 100% of femurs had excellent bone healing.
- 2 out of 7 tibias were injected with BMA for delayed healing.

# Peer Reviewed Paper #1



## ***Internal Limb Lengthening Device for Congenital Femoral Deficiency and Fibular Hemimelia***

Clinical Orthopaedics and Related Research:

March 25, 2014

Lior Shabtai, MD

Stacy Specht, MPA

Shawn Standard, MD

John Herzenberg, MD

## □ Study Design

- Institutional review board-approved, non randomized, prospective study, single center, performed by 2 surgeons.
- 18 patients (21 nails) underwent lengthening procedures between 01/2012-05/2013.
- Procedures included 6 femur and 2 tibia.
- 10 female and 8 male patients with a mean age of 19 years (9-49 years).\*
- Limb length discrepancy of 2 cm or more and a intramedullary canal capable of withstanding a device at least 12.5 mm in diameter and 230 mm in length.
- 19 bone segments received a 10.7 mm diameter nail and 2 bone segments received a 12.5 mm device.

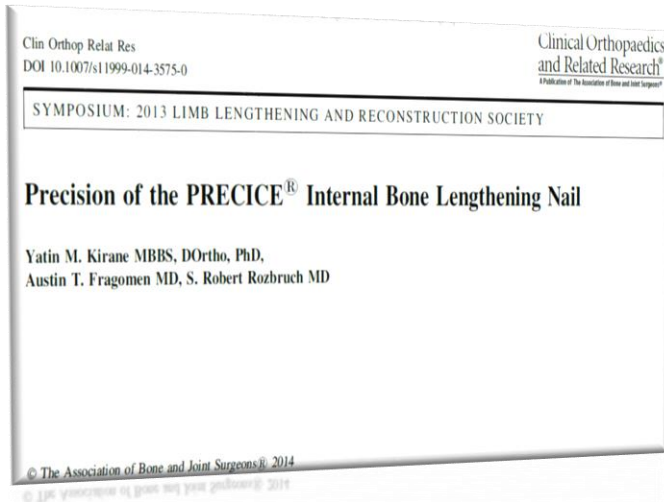
## □ Methods

- X-Rays were used to evaluate bony consolidation.
- All PRECICE nails were lengthened 1-3 mm intra-operatively.

## □ Results

- 0 device related complications.
- Mean healing index was 0.91 months/cm (0.2-2.0 months/cm); no statistical difference in healing times between femurs and tibias (0.81 vs. 1.1 months/cm; p=0.54).
- 4 patients had delayed healing resulting in bone grafting operations; are now fully healed.
- ERC was accurate  $\leq 2$  mm's of discrepancy; may be due to measurement error or magnification.

# Peer Reviewed Paper #2



## ***Precision of the PRECICE® Internal Bone Lengthening Nail***

Clinical Orthopaedics and Related Research:

March 28, 2014

Yatin Kirane, MBBS

Austin Fragomen, MD

Robert Rozbruch, MD

### ❑ Study Design

- Retrospective, non randomized, single center performed by 2 surgeons.
- 24 patients (25 nails) underwent lengthening procedures between 08/2012-07/2013.
- Procedures included 17 femur and 8 tibia.
- 5 female and 19 male patients with a mean age of 31 years (13-67 years).\*
- Target lengthening of no more than 65 mm (maximum allowed in 1<sup>st</sup> generation PRECICE).

### ❑ Methods

- Follow-up protocol involved clinical and radiographic examinations at 2-weekly intervals during the active lengthening phase.
- 1-monthly intervals during the consolidation phase until complete bony healing was achieved; to measure length and bone alignment.

### ❑ Results

- All patients completed target lengthening.
- Mean total lengthening for all patients was 35 mm (14-65 mm).
- Accuracy of distraction was 96% ± 15% and the precision was 86%.
- ROM was temporarily affected but ROM and gait were normal within 2 months after surgery.
- 1 (4%) implant related complication was reported when the nail failed to distract; an exchange nailing was performed.

# Clinical Studies (continued)

**Limb lengthening with a new, internal magnetic device for post-traumatic injury**

John E. Herzenberg, MD\*, Stacy C. Specht, MPA\*\*, Shawn C. Standard, MD\*\*\*, Janet D. Conway, MD\*\*\*

*\*Senior Clinical Center for Limb Lengthening, \*\*Fellow in Orthopaedics, Cleveland Orthopaedics, Cleveland Hospital of Good Samaritan, Cleveland, Ohio; \*\*\*Fellow in Orthopaedics, Cleveland Hospital of Good Samaritan, Cleveland, Ohio*

**Indications:**

- post-traumatic limb lengthening
- congenital limb lengthening
- limb lengthening for bone loss
- limb lengthening for bone nonunion
- limb lengthening for bone infection

**Advantages:**

- a fully internal device
- no external magnets or wires
- no external wires or magnets
- no external magnets or wires
- no external magnets or wires
- no external magnets or wires

**Methods:**

- Patient selection
- Preoperative planning
- Intraoperative technique
- Postoperative care
- Patient selection
- Preoperative planning
- Intraoperative technique
- Postoperative care

**Complications:**

- Infection
- Hardware failure
- Malalignment
- Bone loss
- Nonunion
- Limb lengthening

**Conclusions:**

- The new remote controlled internal lengthening nail
- The new remote controlled internal lengthening nail
- The new remote controlled internal lengthening nail
- The new remote controlled internal lengthening nail



## Limb Lengthening with a New Internal Magnetic for Post-Traumatic Injury

John Herzenberg, MD  
Stacy Specht, MPA  
Shawn Standard, MD  
Janet Conway, MD

**Precision of the New Remote Controlled Internal Lengthening Nail**

Kirane, Yatin, MBBS, D.Ortho, MS, PhD; Fragomen, Austin, MD; Rozbruch, S. Robert, MD

IRB # 13021  
Financial Disclosure: none

**Introduction:**

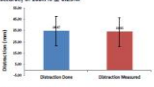
- Indications for bone lengthening
- limb length discrepancy (LLD) due to congenital shortening, growth plate arrest, open fractures with bone loss, fracture nonunion, tumor or osteomyelitis excision, achondroplasia etc.
- Problems with external ring & nail fixators
- Superficial pin site infections
- Cumbersome
- Problems with previous internal lengthening nails (e.g. intramedullary, Intraosseous, etc.)
- distraction activated by limb movements
- inaccurate & unreliable
- high complication rates (nonunion, premature consolidation, nerve injury, joint contractures etc.)
- Precise™ Nail (Eclipse Technologies Inc, Irvine, CA) (Figure 1)
- magnet-operated
- recent risk approval
- clinical efficacy not established

**Materials and Methods:**

- Ten femur and seven tibia lengthening cases using the Precise™ nail were selected.
- Medical records were reviewed for etiology, patient characteristics, surgery details, distraction process, bone alignment, adjacent joint range of motion (ROM) and any complications.
- Distraction distance measurements were done at every follow up visit using a calibrated digital radiology system (RSC, Omnicare LLC, New York, NY)

**Results:**

**A) Accuracy of distraction:** At 23.5 weeks follow-up (range, 4-30 weeks), the lengthening nail 33.63 mm (range, 33mm-35mm) with an accuracy of 100.7% ± 0.23%.



**B) Bone Alignment:**

Measure	Mean	Range
Anterior-Posterior	2	0-4
Medio-Lateral	2	0-4
Distraction Done	33.63	33-35
Distraction Measured	33.63	33-35

**C) Maximal temporary loss of joint ROM in early postoperative period:**

Measure	Mean	Range
Flexion	12	0-20
Extension	0	0-2
Abduction	2	0-2
Internal Rotation	2	0-2

**Conclusions & Discussion:**

- The new Precise™ internal lengthening nails have an accuracy of distraction close to 100%.
- The use of external magnetic controller was straightforward and easy to explain to patients.
- There were no implant failures in our initial series.
- In several patients, realignment of the pre-existing deformity was possible through an osteotomy at the apex of the deformity.
- The hip, knee and ankle ROM were well maintained.
- Distal band release and gastrocnemius recession were helpful in maintaining knee and ankle ROM respectively during lengthening.
- Tibia lengthening was associated with more difficulties than femur.
- A hollowing of talar-proximal deformity of the femur and valgus procurvatum deformity of the tibia was successfully prevented by inserting blocking screws into the concavity of the potential deformity.
- Consideration must be given to the length of the thicker nail segment beyond the indications to ensure adequate stability and to prevent iatrogenic deformities.

**References:**

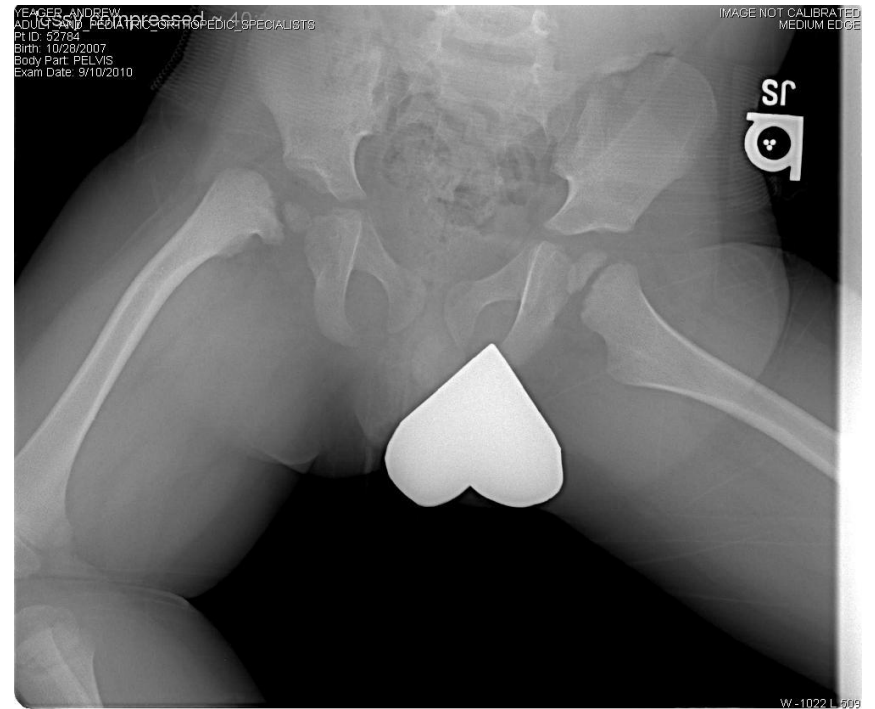
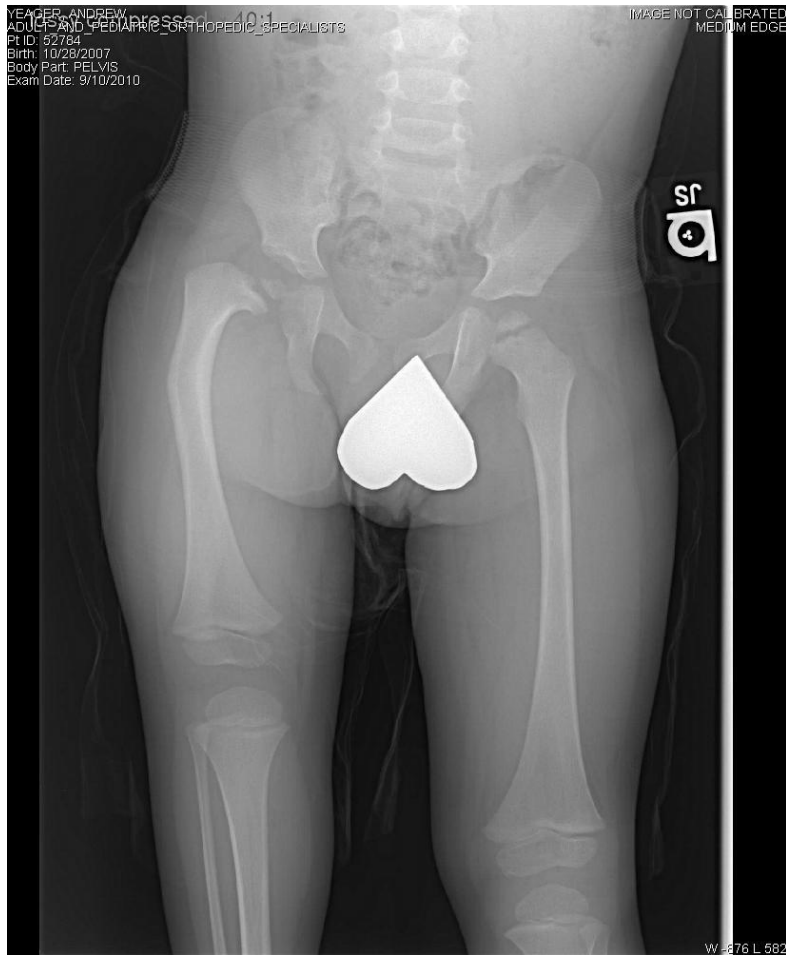
1. Mathabalan S et al. Clin Orth Rel Res. 2012;6:221-231.
2. Eclipse Technology - Precise™ nail system <http://www.4lifer.com/html/>
3. Pany D et al. J Bone Joint Surg Am. 1997;39:1440-1440.

## Precision of the New Remote Controlled Internal Lengthening Nail

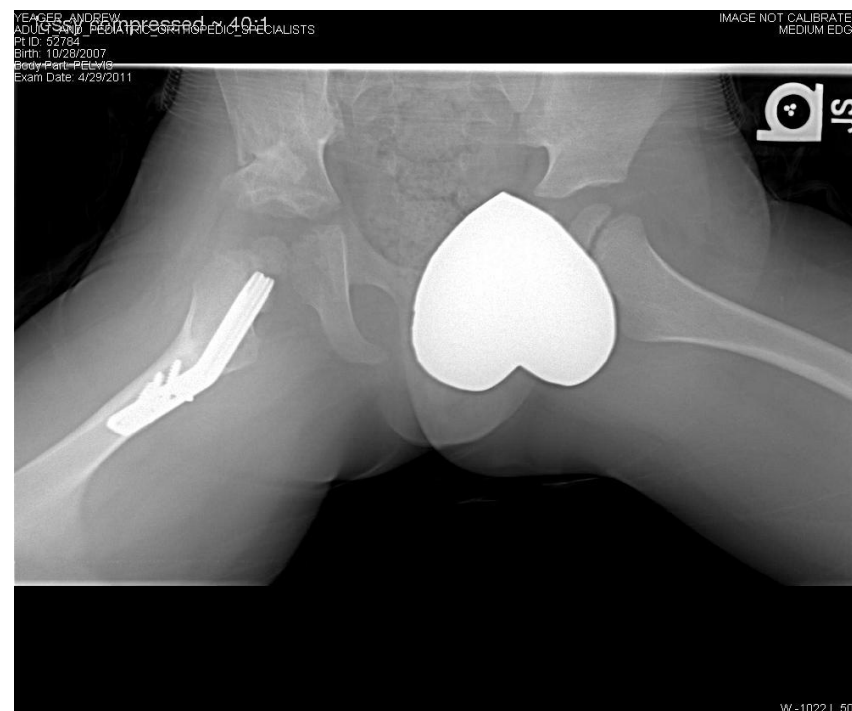
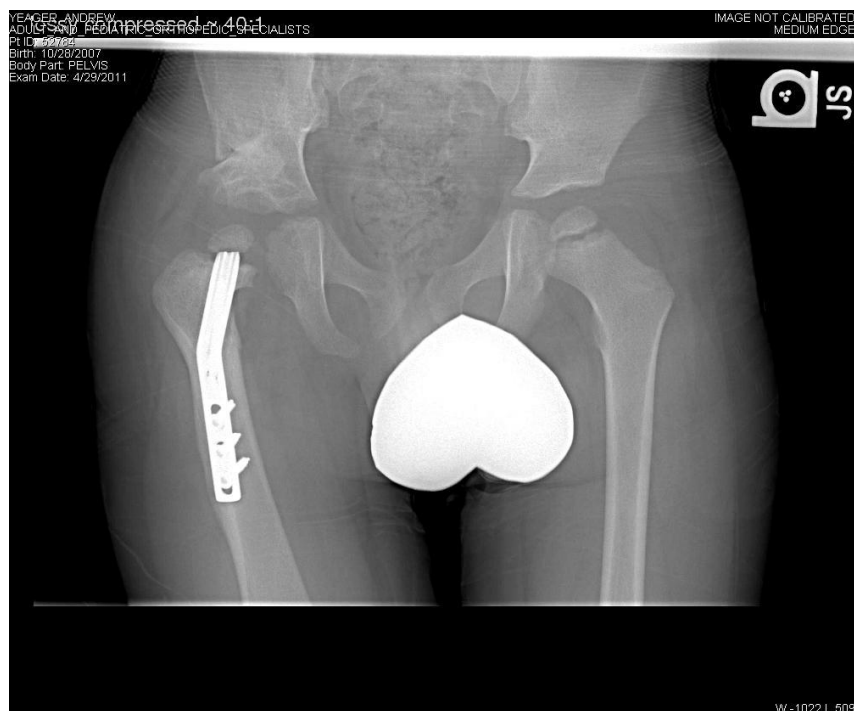
Yatin Kirane, MD,  
Austin Fragomen, MD  
Robert Rozbruch, MD

# Clinical Experience and Results

# Case Study #1



# Pre-op Lengthening

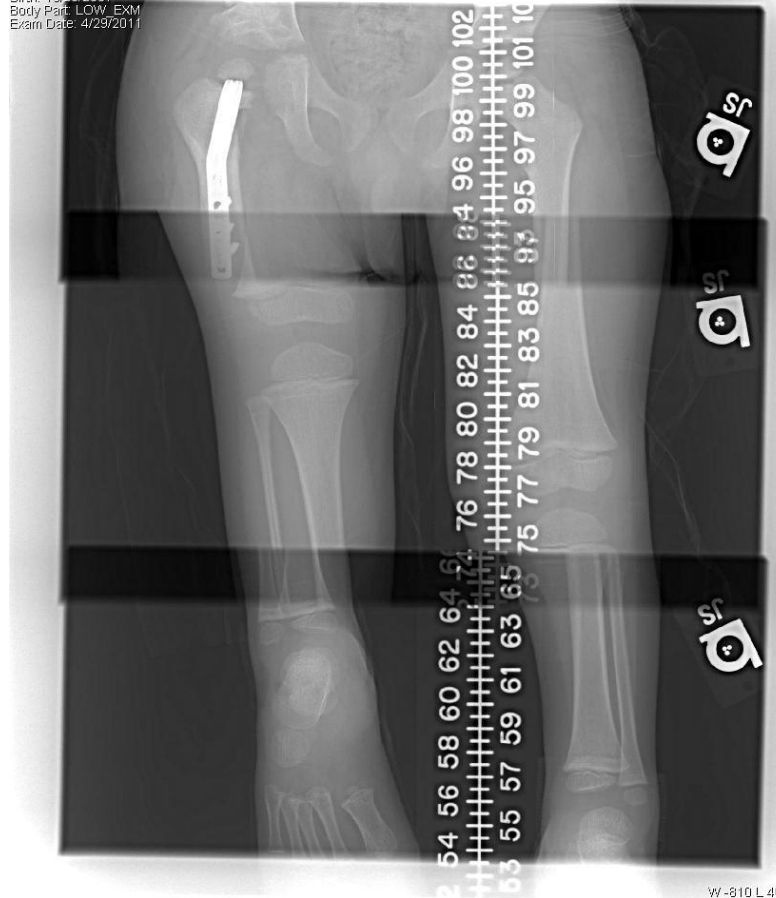




# Pre-op Scanogram

YEAGER, GREGORY  
ADULT PEDIATRIC ORTHOPEDIC SPECIALISTS  
lossy compressed ~ 40:1  
Pt ID: 52784  
Birth: 10/29/2007  
Body Part: LOW\_EXM  
Exam Date: 4/29/2011

IMAGE NOT CALIBRATED  
MEDIUM EDGE



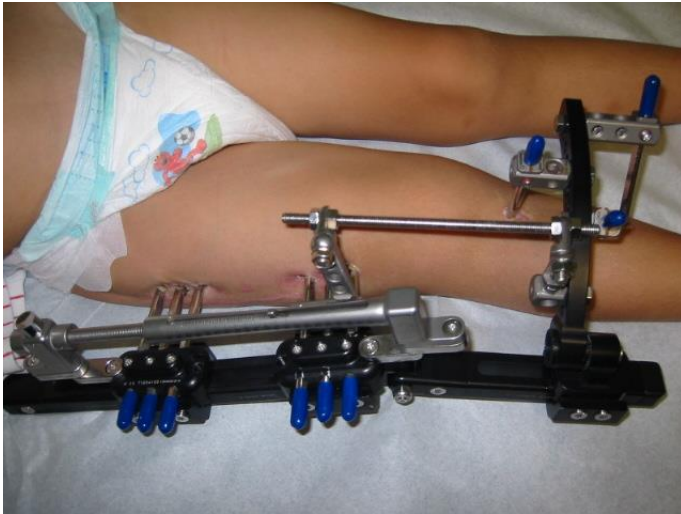
W-810 L 403



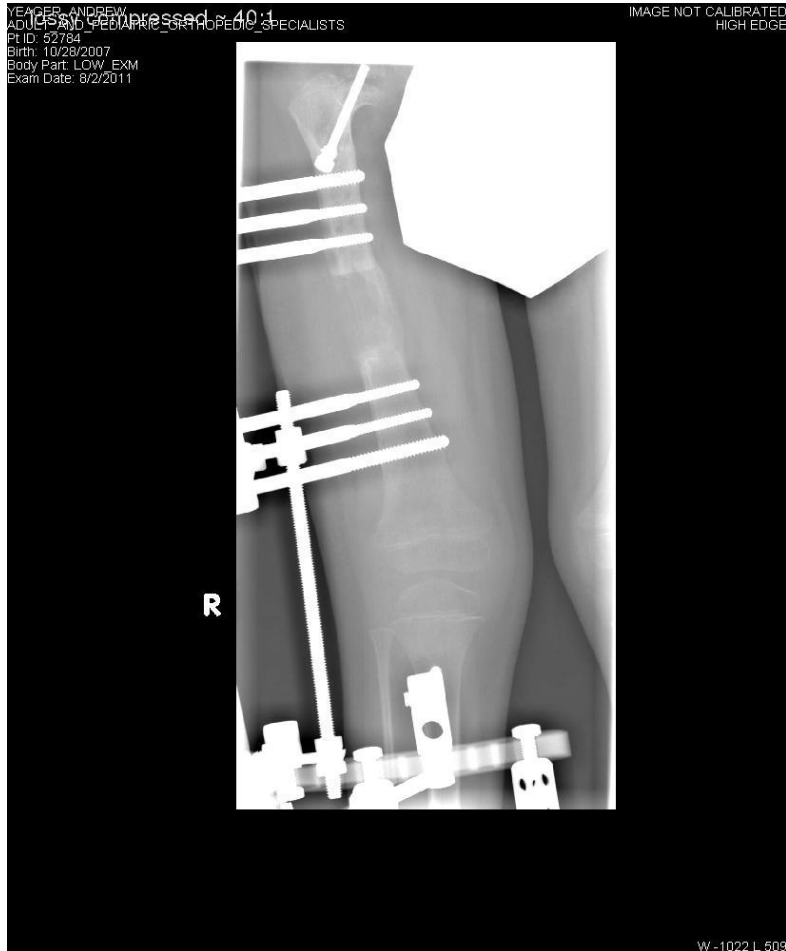
# Initial Post-op



# Clinical Photos

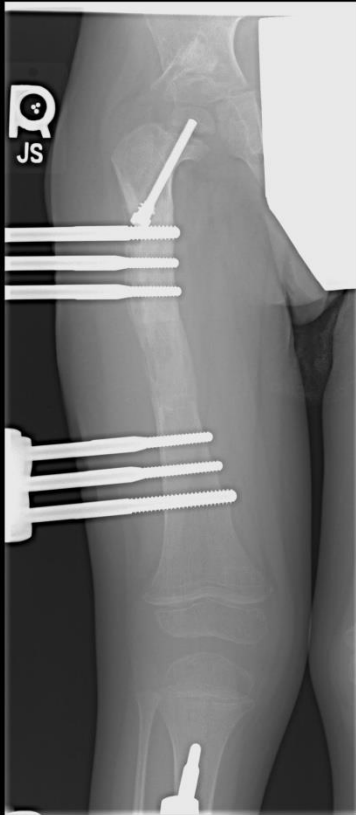


# Two Months Post-op

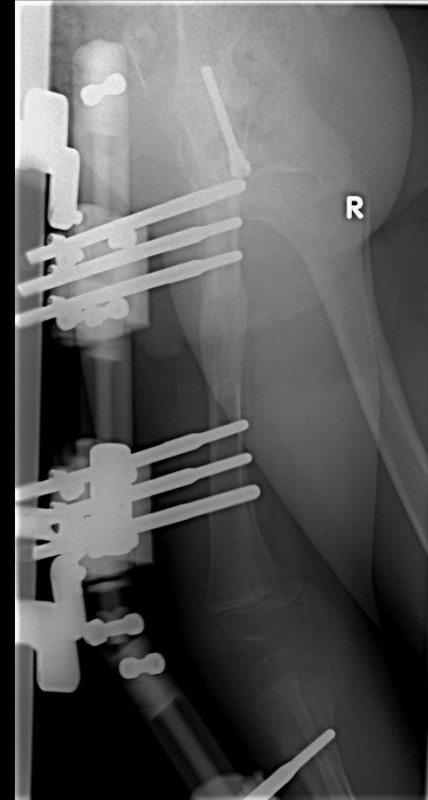


# Three Months Post-op

YEAGER ANDREW  
ADULT AND PEDIATRIC ORTHOPEDIC SPECIALISTS  
P.I.D. 52784  
Birth: 10/28/2007  
Desc: LEG, PEDIATRICS / LOW\_EXM  
Exam Date: 9/30/2011



YEAGER ANDREW  
ADULT AND PEDIATRIC ORTHOPEDIC SPECIALISTS  
P.I.D. 52784  
Birth: 10/28/2007  
Desc: LEG, PEDIATRICS / LOW\_EXM  
Exam Date: 9/30/2011



# Case Study #2

## Early Post-op



# Six Weeks Post-op



# Three Months Post-op



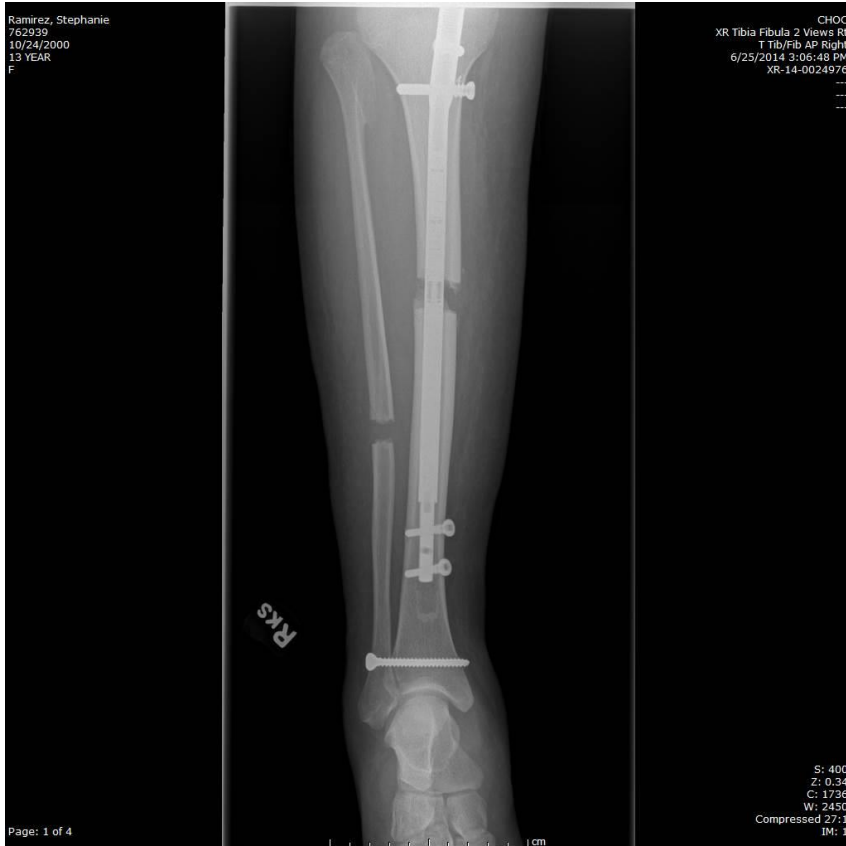


# Four Months Post-op





# Case Study #3



# One Month Post-op Suboptimal Regenerate Bone



# Four Months Post-op



# Contraindications

## ***Contraindications:***

- Infection or Pathologic conditions of bone such as osteopenia which would impair the ability to securely fix the device.
- Metal allergies and sensitivities.
- Patients whose distance from the surface of the treated limb to the intramedullary canal is greater than 51 mm.
- Patients with an irregular bone diameter that would prevent insertion of the IMLL.
- Patients in which the IMLL would cross joint spaces or open epiphyseal growth plates.
- Patients in which there is an obliterated medullary canal or other conditions that tend to retard healing such as blood supply limitations, peripheral vascular disease or evidence of inadequate vascularity.
- Patients unwilling or incapable of following postoperative care instructions.
- Patients weighing in excess of 114 Kg for the 10.7 mm diameter implant.
- Patients weighing in excess of 57 Kg for the 8.5 mm diameter implant.

**Thank You**