

# **HSS Experience: ISKD vs. PRECICE**

**Internal Lengthening Nail Course  
Baltimore Deformity Precourse  
Baltimore, MD; August 27, 2015**

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SPECIAL  
SURGERY

# Disclosures

Ellipse: Consultant

Smith and Nephew: Consultant

Stryker: Consultant and Royalties

# Clinical Outcomes of Internal Lengthening Nails

- Successful (good to excellent) outcomes
  - Cole et al., Injury 2001; Guichet et al., JBJS, 2003; Hankemeier et al., Arch Orthop Trauma Surg. 2004
- Complications
  - Papanna et al., Acta Orthop Belg 2011; Mazeau PJ Pediatr Orthop B. 2012; Kenawey et al., CORR 2011; Mahboubian et al., CORR 2012
  - “*run away nails*”
  - Inaccurate and unreliable distraction
  - Premature consolidation
  - Nonunions
  - Nerve injuries
  - Joint contractures
- Need for more accurate distraction

CLINICAL RESEARCH

# Femoral Lengthening with Lengthening over a Nail has Fewer Complications than Intramedullary Skeletal Kinetic Distraction

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## Abstract

**Background** Lengthening over a nail and internal lengthening nails have been developed to minimize or eliminate patients' time wearing a frame during femur lengthening. However it is unclear whether either of these two approaches results in faster times to union or fewer complications over the other.

**Questions/purposes** We asked which technique better achieved: (1) the lengthening goals, (2) the distraction rate control, (3) quality of the regenerate bone, (4) fewer complications, and (5) if SF-36 scores and American Academy of Orthopaedic Surgeons Lower Limb Module (AAOS LLM) scores differ in each treatment modality?

**Methods** We retrospectively reviewed the records and radiographs of 11 patients who had 12 Intramedullary

Skeletal Kinetic Distractor (ISKD) procedures between 2002 and 2005, and 21 patients with 22 femoral lengthenings performed as lengthening over nail procedures between 2005 and 2009. Details such as leg length discrepancies, operative time, time of removal of the external fixator or ISKD, and any complications encountered were recorded. SF-36 and AAOS LLM scores also were compiled. The minimum followups for the ISKD and the lengthening over nail cohorts were 62 months (average, 76 months; range, 62–93 months) and 13 months (average, 27 months; range, 13–38 months), respectively.

**Results** We observed no difference in achieving the lengthening goals between the two procedures. Distraction was not well controlled in the ISKD group; the distraction rates were 1.7 mm per day for the fast group (distraction rate greater than 1 mm/day) and 0.84 mm per day for the slow group (less than 1 mm/day). The lengthening over nail group had an average distraction rate of 0.88 mm per day. One of 20 of the patients who had lengthening over a nail had complications requiring additional unanticipated surgeries whereas six of 12 patients who had femoral lengthening in the ISKD group had such complications.

**Conclusions** Based on our observations, we believe the lengthening over nail technique for femoral lengthening is associated with fewer complications than the ISKD.

**Level of Evidence** Level III, therapeutic study. See the Guidelines for Authors for a complete description of levels of evidence.

## Introduction

Distraction osteogenesis has become a widely used and accepted method for limb lengthening. Since the classic Ilizarov method of using an external ring fixator for limb

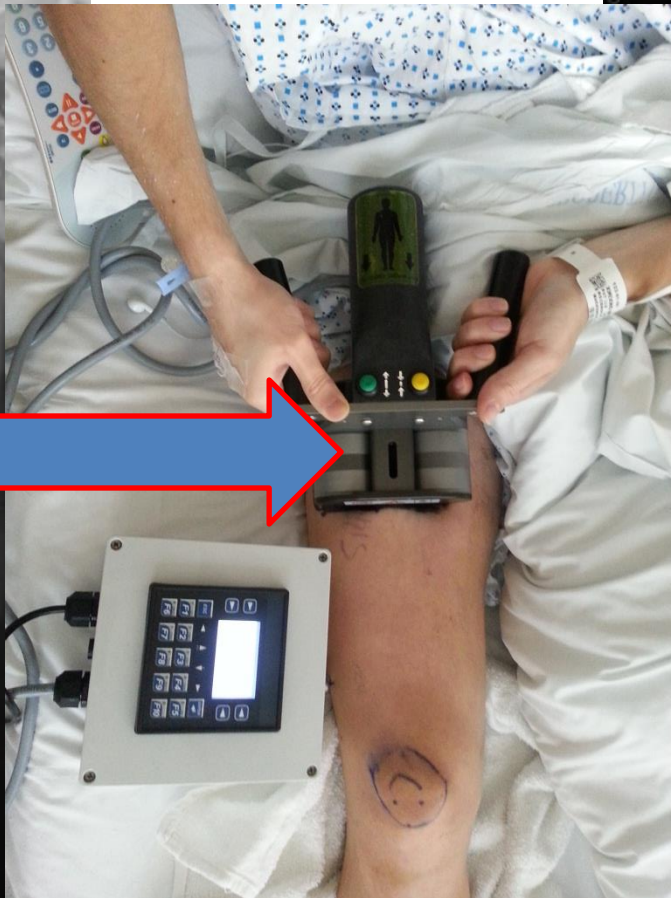
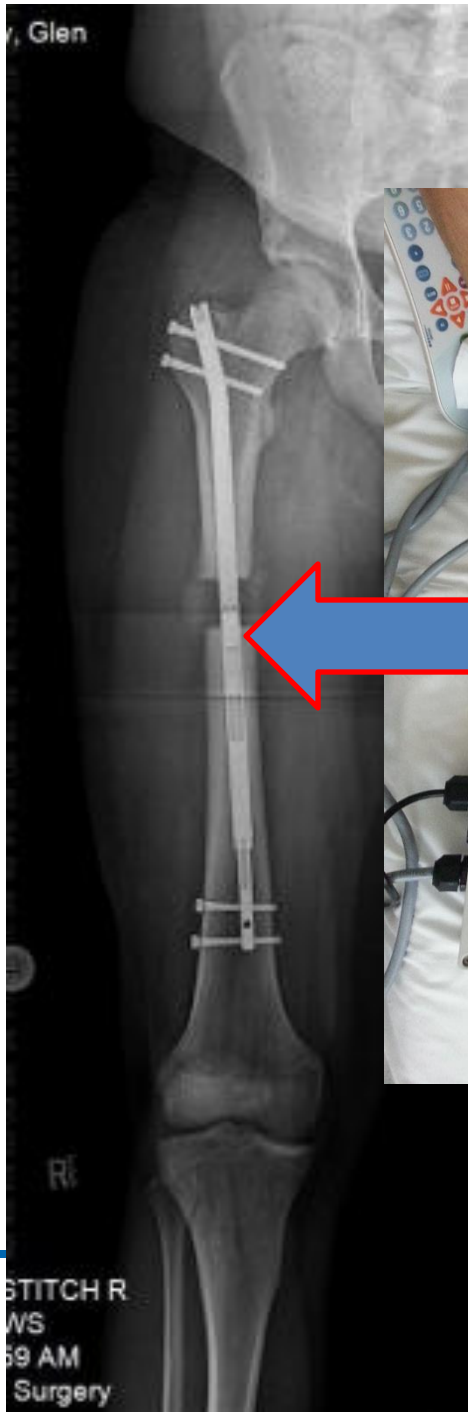
- ISKD distraction was poorly controlled
  - 1.7 mm/ day in fast group (> 1 mm/day)
  - 0.84 mm/day in slow group (< 1 mm/day)
- Complications
  - 50% of ISKD patients required unanticipated surgeries
- Conclusion
  - LON was more predictable and with fewer complications

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Trochanteric Entry  
Good for adolescent  
< 18 yrs.





Age 16  
LLD = 36 mm  
LLD = 1.5 inches



## MAGNETIC INTERNAL LENGTHENING NAIL



Equal leg lengths  
2 months  
Minimal pain  
No frame

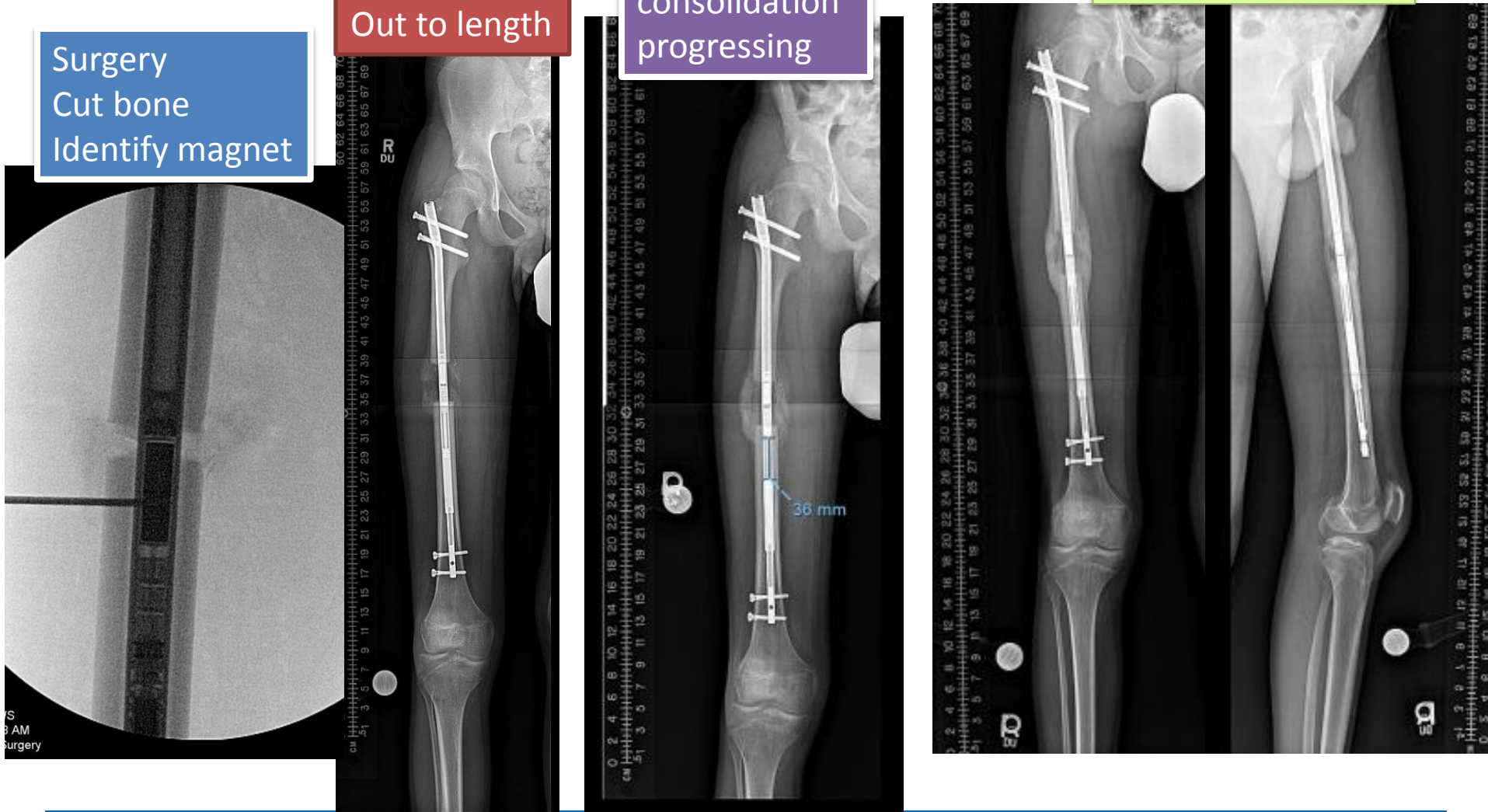


Surgery  
Cut bone  
Identify magnet

5 weeks  
Out to length

2 months  
Bone  
consolidation  
progressing

3 months  
All healed  
Full weight bearing







Advanced  
arthrosis



LLD=35 mm



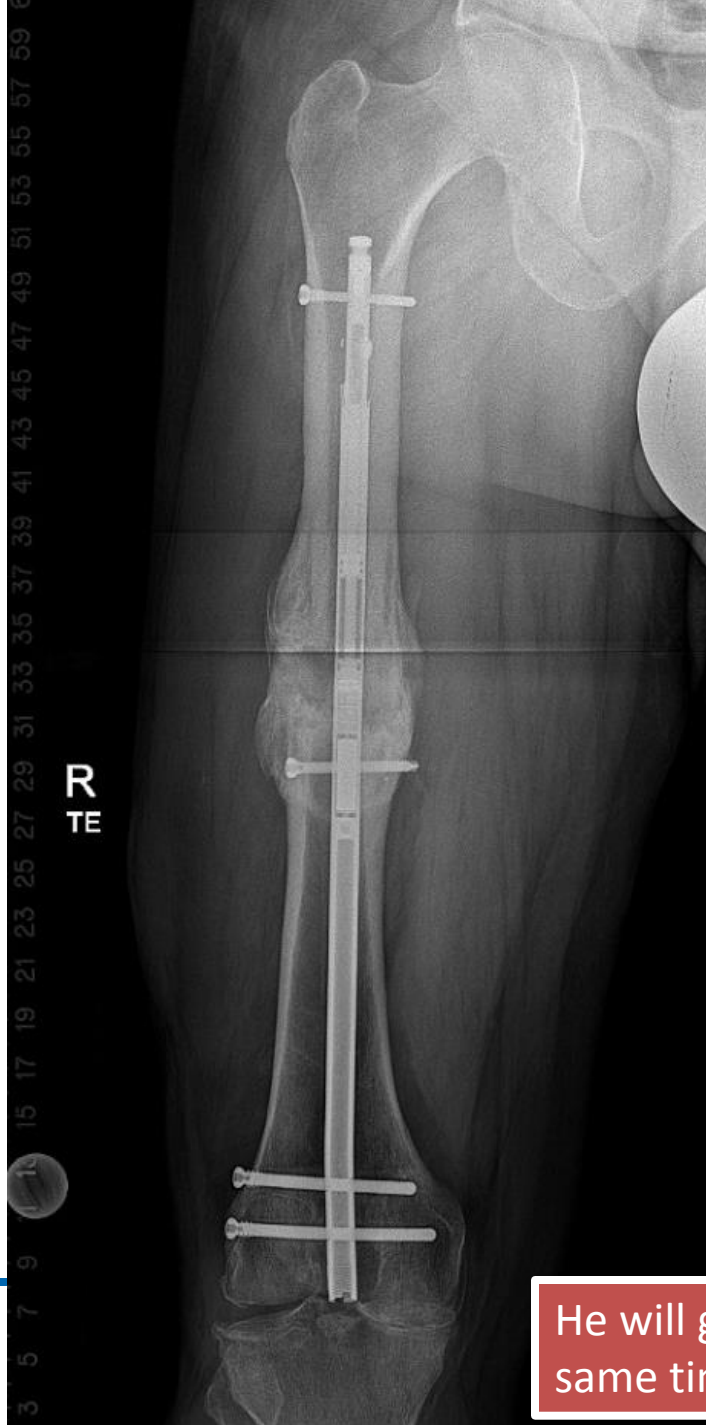
Malunion with varus and  
procurvatum



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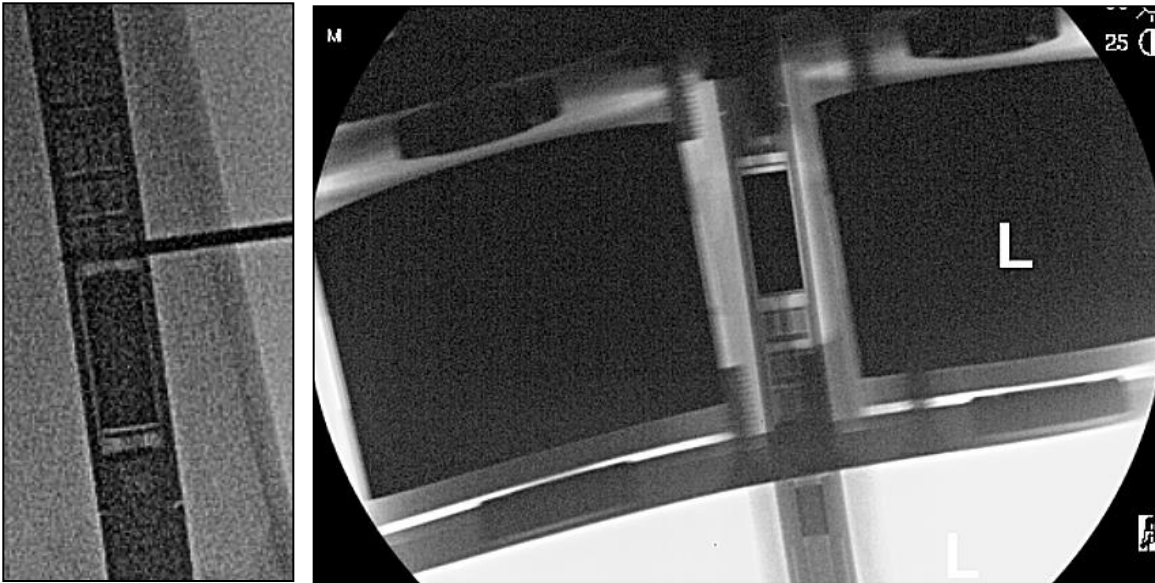




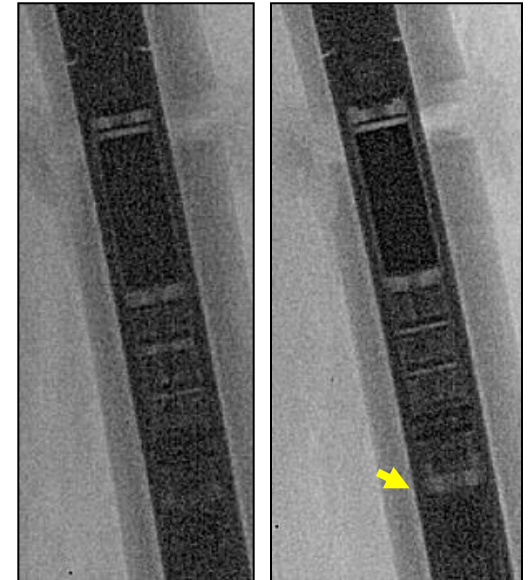
He will get staged TKR with removal of nail at same time

# Intraop Magnet Localization & Distraction

Localization of the internal magnet



Intraop distraction





## Precision of the PRECICE® Internal Bone Lengthening Nail

Yatin M. Kirane MBBS, DOrtho, PhD,  
Austin T. Fragomen MD, S. Robert Rozbruch MD

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**Abstract**

**Background** Previous designs of internal bone lengthening devices have been fraught with imprecise distraction, resulting in nerve injuries, joint contractures, nonunions, and other complications. Recently, a magnet-operated PRECICE® nail (Ellipse Technologies, Inc, Irvine, CA, USA) was approved by the FDA; however, its clinical efficacy is unknown.

**Questions/purposes** We evaluated this nail in terms of (1) accuracy and precision of distraction, (2) effects on bone alignment, (3) effects on adjacent-joint ROM, and (4) frequency of implant-related and non-implant-related complications.

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Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

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**Methods** We reviewed medical and radiographic records of 24 patients who underwent femoral and/or tibial lengthening procedures using the PRECICE® nail from August 2012 to July 2013 for conditions of varied etiology, the most common being congenital limb length discrepancy, post-traumatic growth arrest, and fracture malunion. This group represented 29% of patients (24 of 82) who underwent a limb lengthening procedure for a similar diagnosis during the review period. At each postoperative visit, the accuracy and precision of distraction, bone alignment, joint ROM, and any complications were recorded by the senior surgeon (SRR). Accuracy reflected how close the measured lengthening was to the prescribed distraction at each postoperative visit, while precision reflected how close the repeated measurements were to each other over the course of total lengthening period. No patients were lost to followup. Minimum followup from surgery was 3 weeks (mean, 14 weeks; range, 3–29 weeks).

**Results** Mean total lengthening was 35 mm (range, 14–65 mm), with an accuracy of 96% and precision of 86%. All patients achieved target lengthening with minimal unintentional effects on bone alignment. The knee and ankle ROM were minimally affected. Of the complications requiring return to the operating room for an additional surgical procedure, there was one (4%) implant failure caused by a nonfunctional distraction mechanism and six (24%) non-implant-related complications, including premature consolidation in one patient (4%), delayed bone healing in two (8%), delayed equinus contracture in two (8%), and toe clawing in one (4%).

**Conclusions** We conclude that this internal lengthening nail is a valid option to achieve accurate and precise limb lengthening to treat a variety of conditions with limb shortening or length discrepancy. Randomized, larger-sample, long-term studies are required to further confirm

- These were first 24 patients (August 2012–July 2013)
- 29% of patients who underwent limb lengthening surgery during that time period

# Primary Outcome Variables

## I. Accuracy of Lengthening

- Distraction distance & accuracy measured using a calibrated digital radiology system (PACS, OnePacs LLC, New York, NY)

$$A) \% \text{ Error} = \frac{\text{Distraction prescribed} - \text{Lengthening measured}}{\text{Distraction prescribed}} \times 100$$

$$B) \text{ Accuracy of distraction} = 100 - \% \text{ Error}$$

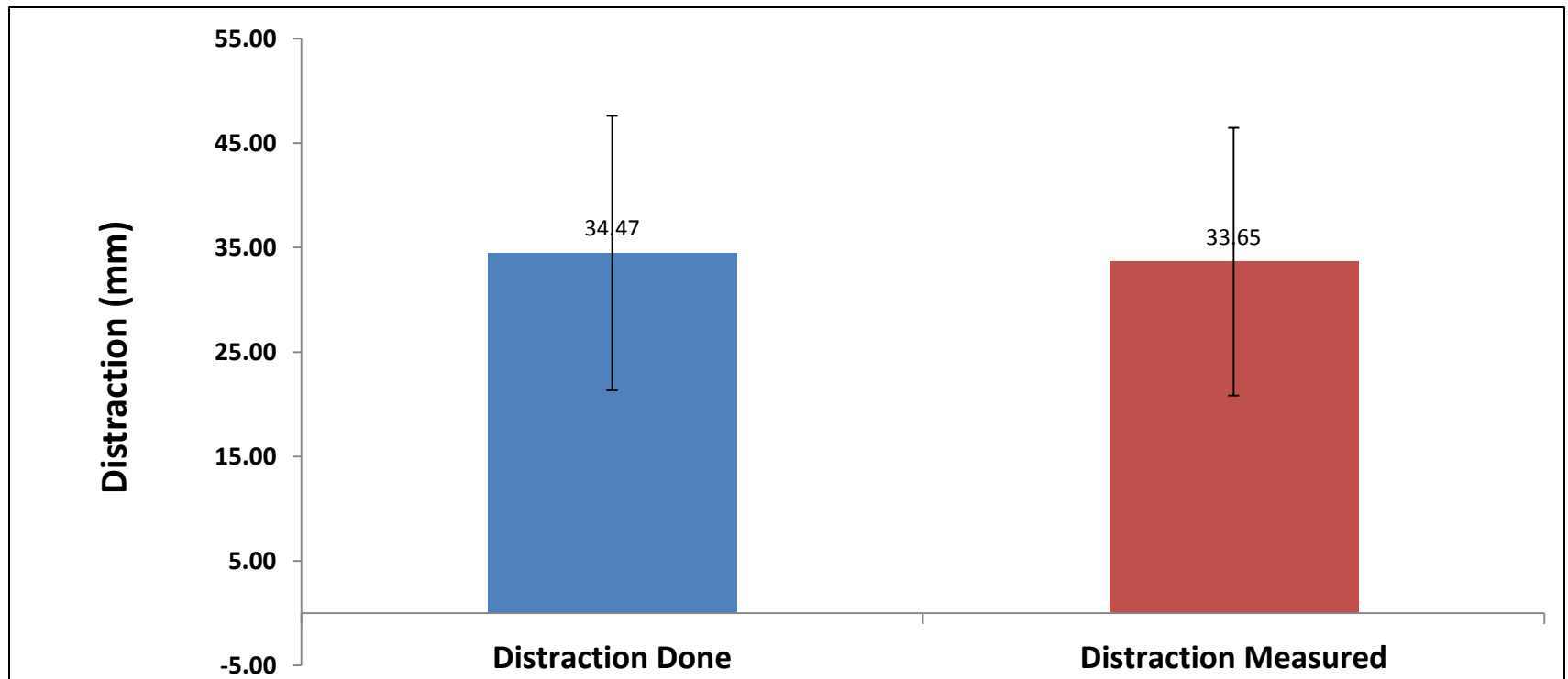
## II. Change in bone alignment

## III. Effect on adjacent joint ROM

# I. Accuracy of Lengthening

At 19 weeks follow-up (range, 1-42 weeks):

- Average lengthening was **35 mm** (range, 14mm-65mm)
- Accuracy was **96%**



## II. Absolute Change in Bone Alignment

BONE	ANGLE	ABSOLUTE CHANGE (degrees)	
		Mean	Range
Femur	Lateral distal femoral angle (LDFA)	2	0-4
	Procurvatum/Recurvatum	6	0-12
Tibia	Medial proximal tibial angle (MPTA)	3	0-6
	Procurvatum/Recurvatum	3	1-5

- Intentional reduction of femur bow (5/17)
- Blocking screws (4/17 femur & 6/8 tibia)



# III. Joint ROM

- Hip, knee and ankle ROM well maintained
- Temporary loss of motion in early postop period

MOTION	ABSOLUTE LOSS (degrees)	
	Mean	Range
Knee Flexion	13	0-30
Knee Extension	0	0-2
Ankle Dorsiflexion	3	0-15
Ankle Plantarflexion	6	0-20

- ITB release (10/17 femur)
- Gastrocnemius recession (5/8 tibia)

# Overall Clinical Outcomes

- All femur cases had excellent bone healing
- In 2 tibia cases, BMAC was injected for delayed bone healing
- There was 1 case of failure of the magnet mechanism requiring nail exchange
- One case of premature consolidation

# Conclusions

- All patients achieved lengthening goal
- Minimal (insignificant) unwanted change in bone alignment
- Adjacent joint ROM was minimally affected
  - Mild temporary loss of motion that resolved
- Implant failure 4%
  - Change of nail led to excellent outcome
- Excellent bone healing in femur
  - Tibia requires slower distraction
- Blocking screws useful in tibia and retrograde femur
  - When nail does not fill IM canal adjacent to osteotomy site

# Summary

- The new Precice® nails have **excellent clinical efficacy** with **~ 96% accuracy**
  - **Implant failure: 4% (1/25)**
  - **No other major complications**
  - Use of remote control was **straightforward**
  - Acute **rotational and angular correction** was possible
  - **Malalignment was prevented** by using correct nail size, osteotomy level and blocking screws
  - **Length of the thicker nail segment** beyond the osteotomy is **critical** to ensure stability and prevent iatrogenic deformities
-



# Example 2: Retrograde Femur



- 30M
- 3.6 cm LLD
- 7° genu valgum (MAD 14 mm lateral)
- 10° ER deformity
- Post-traumatic growth arrest after R femur Fx
- Lower back and R LL pain

# Example 2: Retrograde Femur



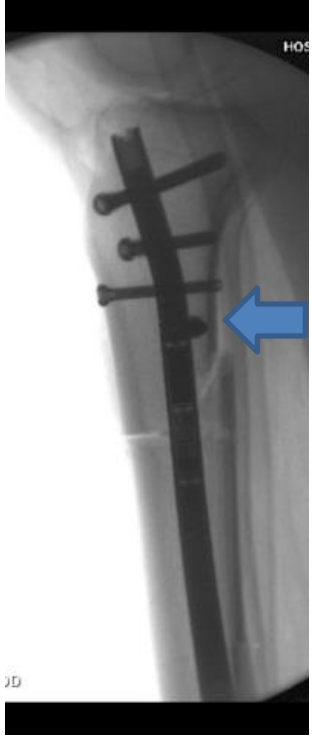


68 y/o male

LLD 4 cm

Dysplastic Ankle







BMAC Injection@  
end distraction

# Femur lengthening: a comparison of internal lengthening with a remote controlled magnetic internal lengthening nail *versus* lengthening over a nail

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## INTRODUCTION

Lengthening over a nail (LON) has been shown to be superior to lengthening with a previous generation of mechanical internal lengthening nail in the femur.<sup>1</sup> It is unclear, however, whether a newer generation of remote controlled magnet driven internal lengthening nail (MILN) has overcome the weaknesses of earlier technologies.<sup>2</sup>

## OBJECTIVES

We asked which technique (LON or MILN) better achieved:

1. The lengthening goals,
2. The distraction rate control,
3. Optimal quality of the regenerate bone, and
4. Fewer complications.

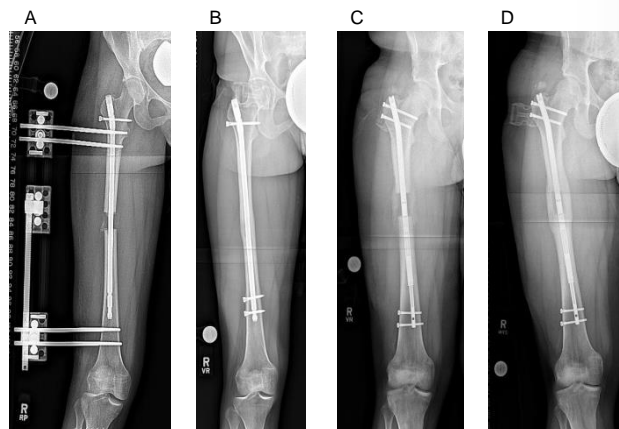
## METHODS

We conducted a retrospective comparison study between LON and MILN techniques. We reviewed the records and radiographs of 21 consecutive patients with 22 femoral LONs between 2005 and 2009, and 35 consecutive patients with 40 femoral lengthenings using a remote controlled magnetic internal lengthening nail between 2012 and 2014. Details such as limb length discrepancy (LLD), etiology, time to bony union, knee range of motion, regenerate quality, and any complications encountered were compiled. The minimum follow-up times for the LON and MILN cohorts were 13 months (mean, 27 months; range, 13–38 months) and 10 months (mean 19.9 months; range, 10–31 months), respectively.

## RESULTS

1. Patients treated with MILN had a significantly smaller post-treatment residual LLD (0.0 mm) than those treated with LON (3.6 mm) ( $p=0.003$ ).
2. Rate of distraction was closer to the goal of 1 mm/day and more tightly controlled for the MILN cohort (0.9 mm/day, SD 0.1 mm/day) than for the LON group (0.84 mm/day, SD 0.19 mm/day) ( $p=0.044$ ).
3. Regenerate quality (as measured with the modified Li score), and healing index (months/cm) were not significantly different between the cohorts. Time to union, however, was shorter in the MILN group (3.3 months) than in the LON group (4.5 months) ( $p=0.001$ ).
4. Knee flexion at the end of distraction was significantly greater for MILN patients (105 degrees) than for LON patients (88.8 degrees) ( $p=0.033$ ). The percentage of patients who experienced a complication was not different in the MILN group (15.8%) than in patients treated with LON (20%) ( $p=0.724$ ).

Below: (A) LON at end of distraction, (B) LON fully healed, (C) MILN at end of distraction, (D) MILN fully healed.



## CONCLUSIONS

Femoral lengthening with the MILN is safe and well controlled, offering the limb lengthening surgeon greater accuracy in achieving lengthening goals, tighter distraction rate control, faster time to union, and greater knee mobility during treatment as compared to lengthening with the LON technique while maintaining an acceptable risk of complications and reliable healing. Though not documented specifically in this study, MILN patients typically require less pain medication during treatment. Additionally, MILN requires one less surgery than LON and eliminates external fixation-related complications like pin infections.

## REFERENCES

1. Mahboubian S, Seah M, Fragomen AT, Rozbruch SR. Femoral lengthening with lengthening over a nail has fewer complications than intramedullary skeletal kinetic distraction. Clin Orthop Relat Res. 2012;470(4):1221–1231.
2. Rozbruch SR, Birch JG, Dahl MT, Herzenberg JE. Motorized intramedullary nail for management of limb-length discrepancy and deformity. J Am Acad Orthop Surg. 2014;22(7):403–409.



# Methods

- Retrospective comparison LON vs. PRECICE
- LON: 22 femurs in 21 patients (2005-2009)
  - Same control group used for ISKD study
  - Follow-up: 27 months (13-38 months)
- PRECICE: 40 femurs in 35 patients (2012-2014)
  - Follow-up: 20 months (10-31 months)

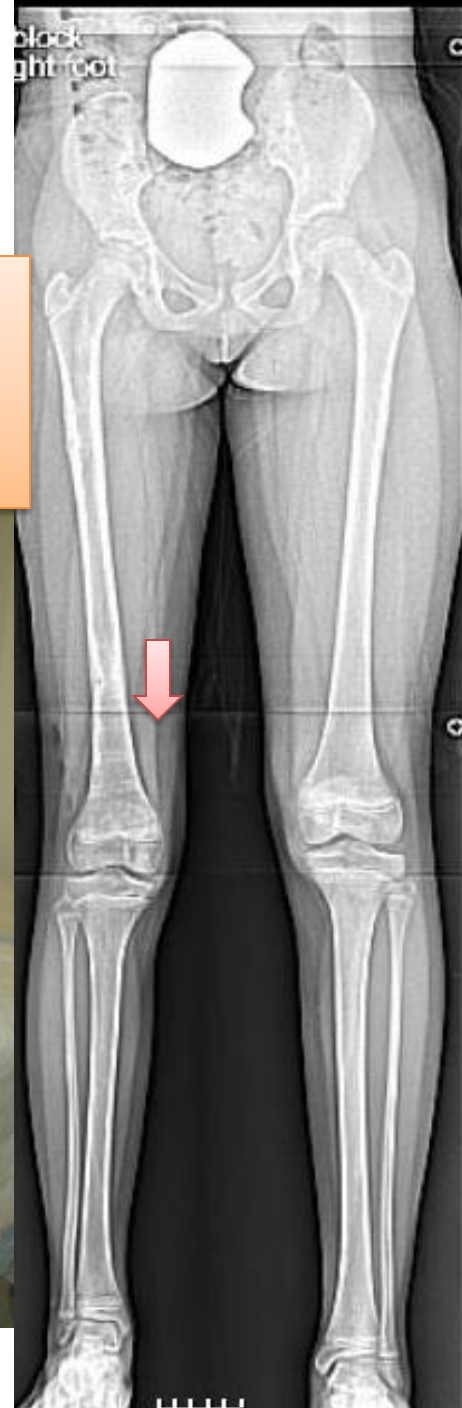
# Results

- PRECICE had significantly smaller post-treatment residual LLD (0 vs. 3.6 mm)
- Rate of distraction closer to goal of 1mm per day in PRECICE
  - Precice: 0.9 mm/day, SD 0.1 mm/day
  - LON: 0.84 mm/day, SD 0.14 mm/day
  - ISKD distraction was poorly controlled
    - 1.7 mm/ day in fast group ( $> 1$ mm/day)
    - 0.84 mm/day in slow group ( $< 1$  mm/day)
- Time to union significantly shorter in PRECICE
  - (3.3 vs. 4.5 months)
- Knee flexion significantly greater at end distraction
  - 105 vs 89 degrees
- PRECICE had one less surgery than LON

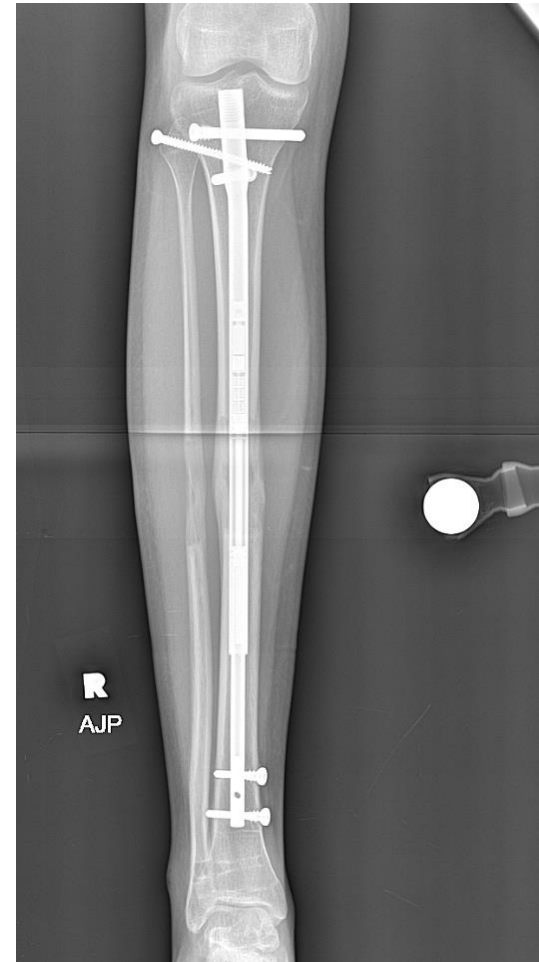
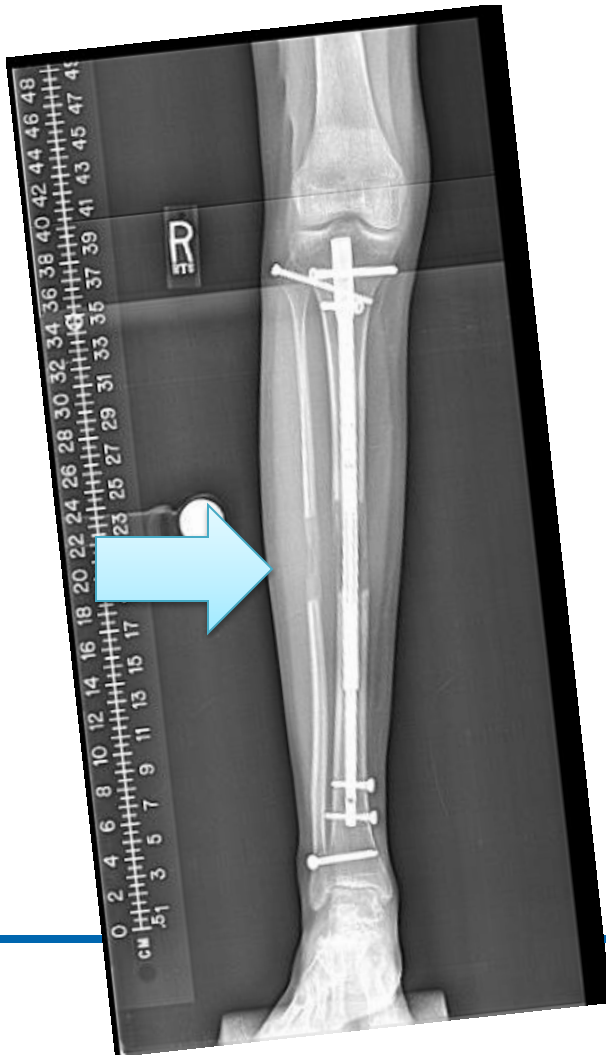


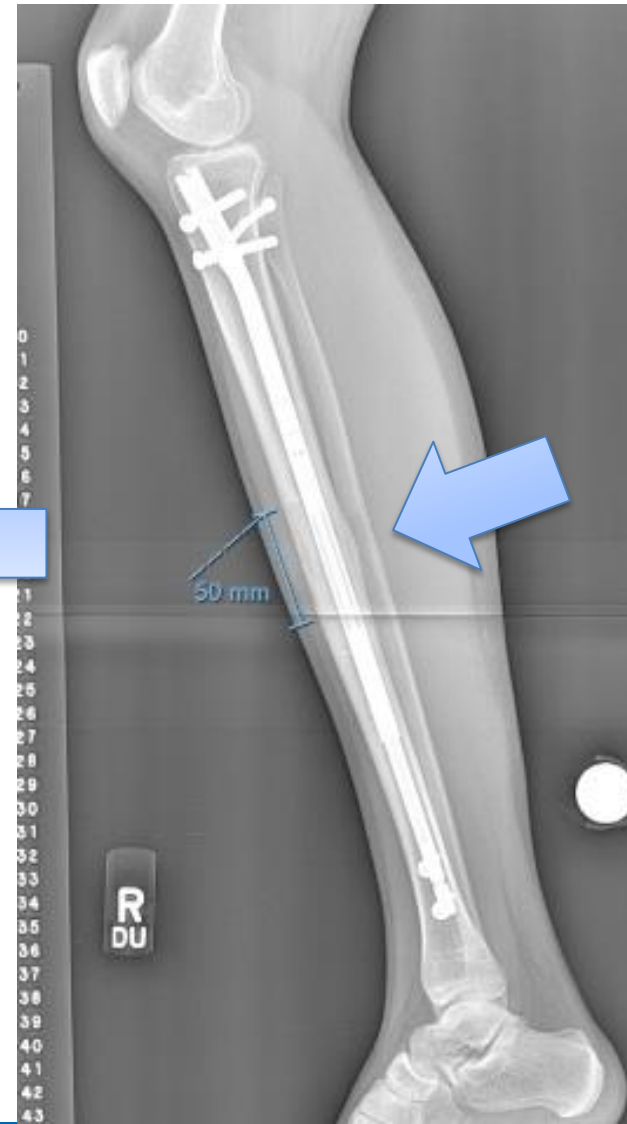
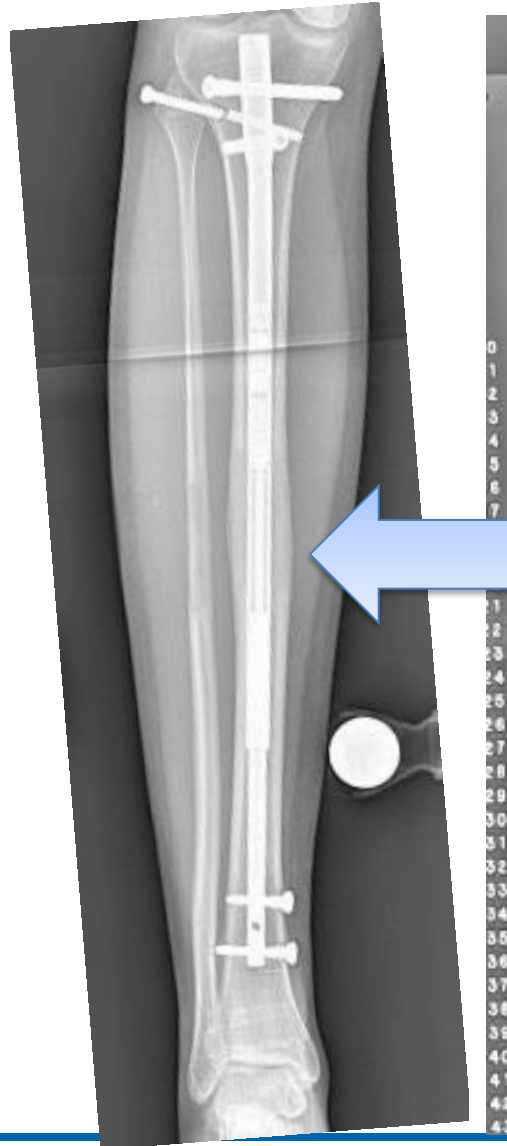
Age 8, congenital  
LLD 5.5 cm , femur /tibia  
PLLD= 9.5 cm

Plan: 4.5 cm lengthening  
Of femur  
Second future lengthening  
tibia



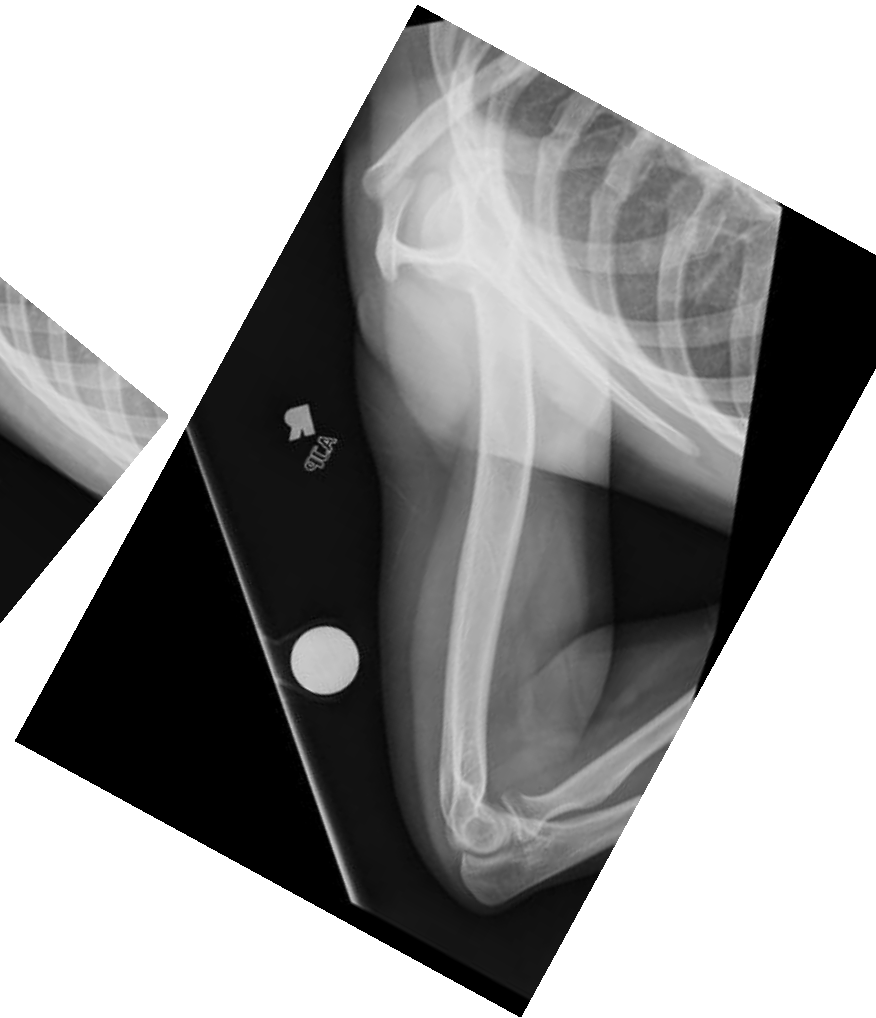
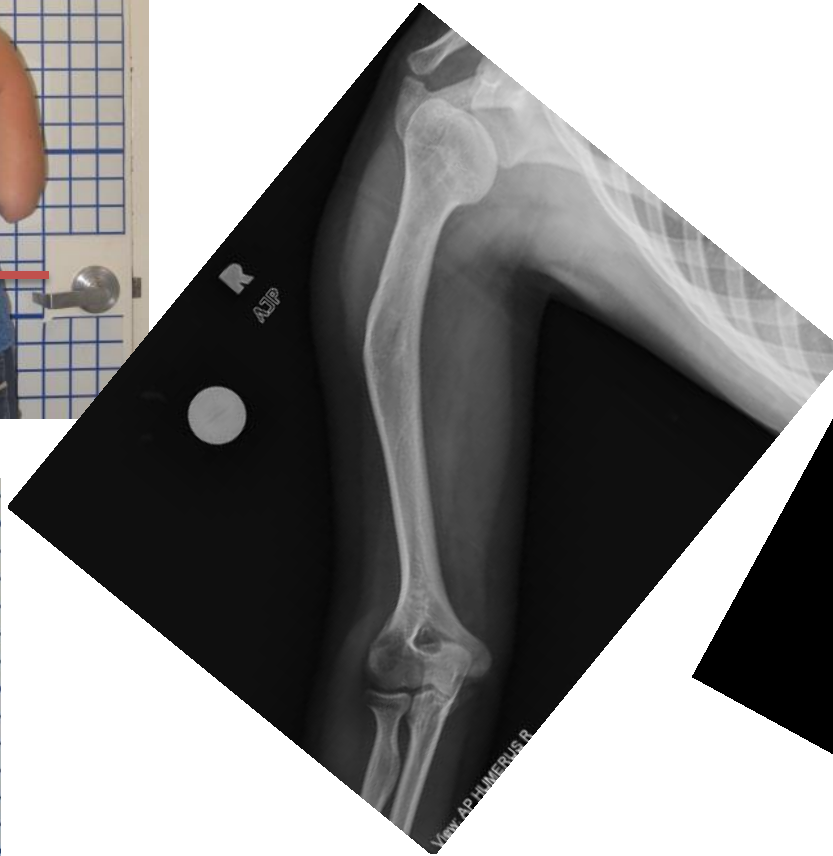
# 5 cm lengthening with Precice at age 14 after skeletal maturity





# Humerus lengthening with Precice Nail





LLD= 6 cm

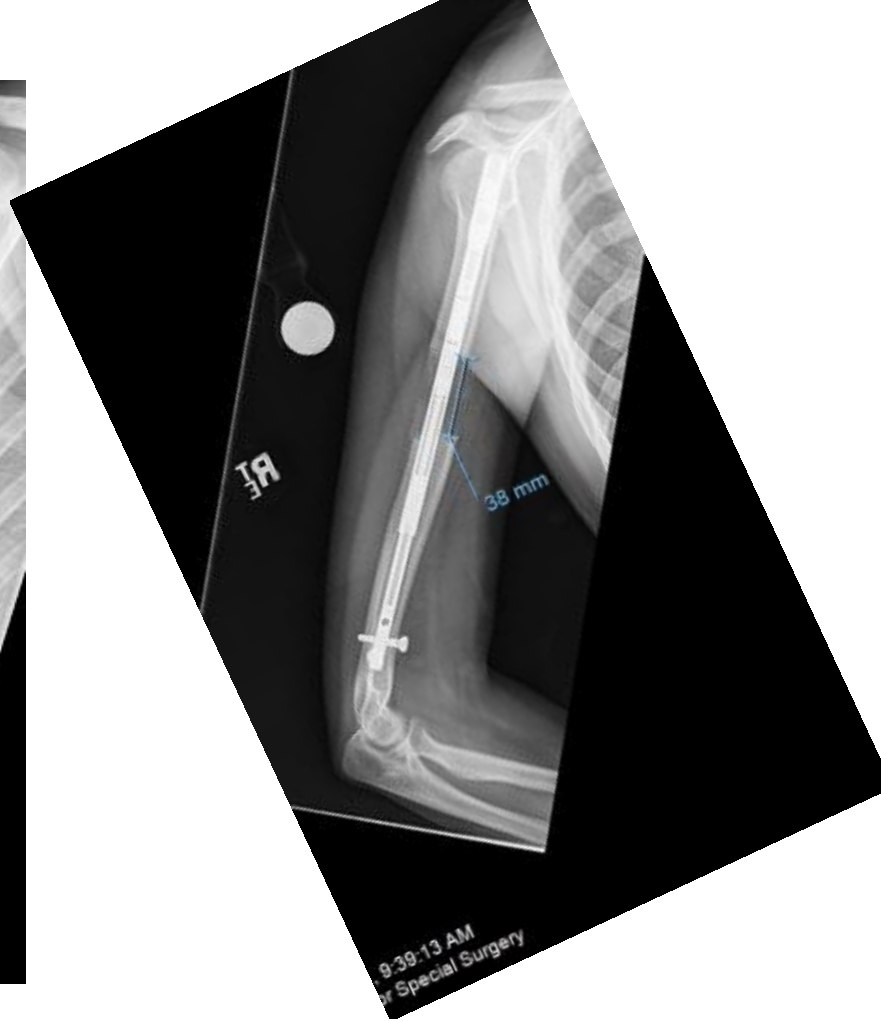
Deformity: varus and apex anterior



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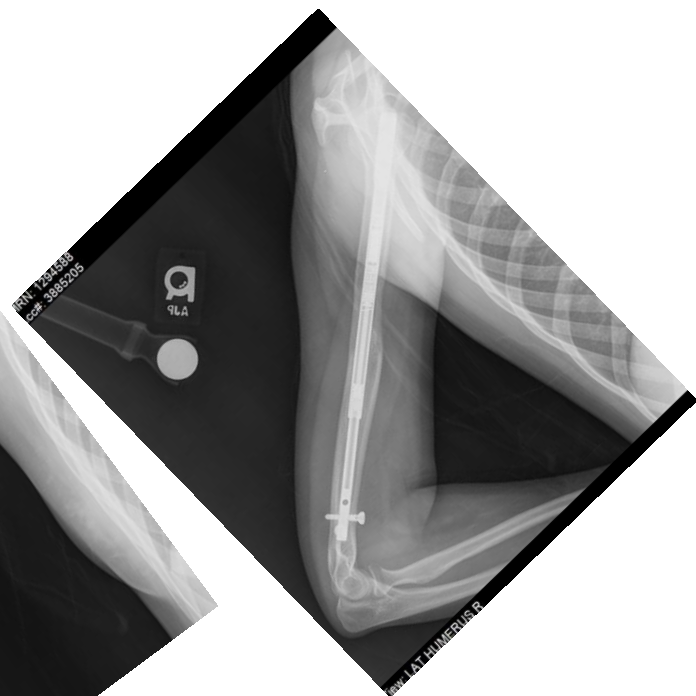
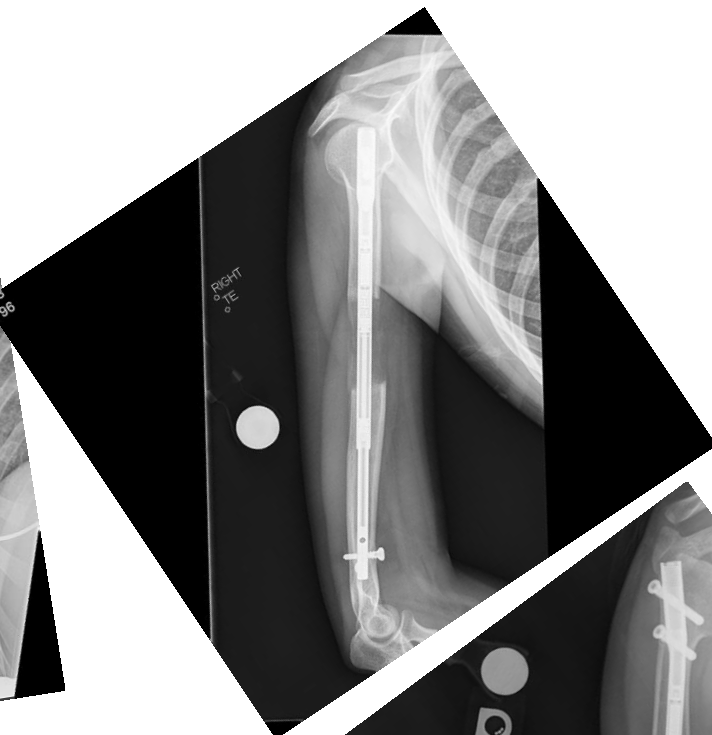
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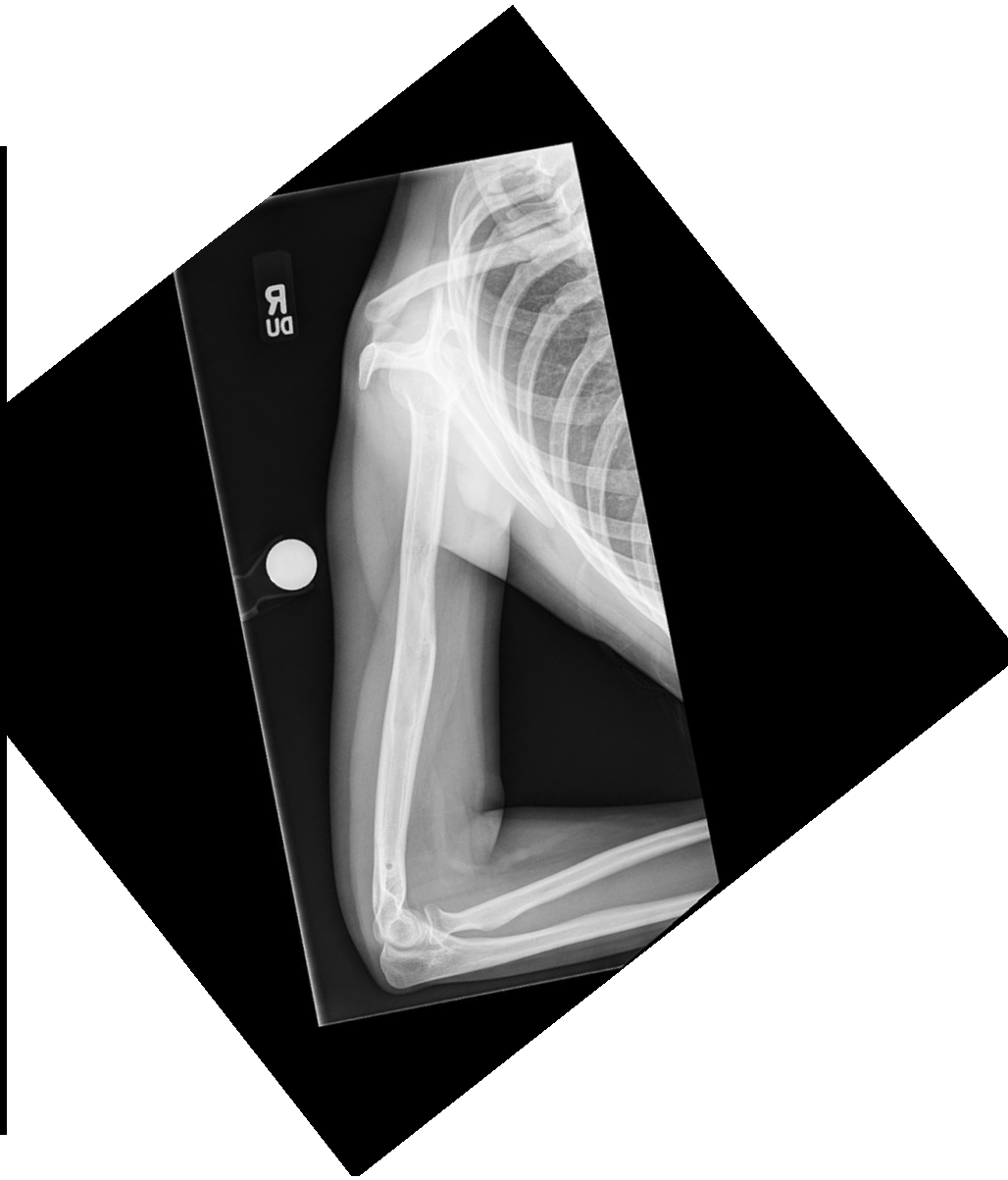


11 mm to go  
50 mm max on this nail (8.5 x 215 femur nail)  
Distraction rate 0.25 mm 3x/day











# Thank You



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