

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 nonunions, tumor or osteomyelitis excision, achondroplasia etc.

Problems with external ring & rod fixators

- Superficial pins site infections
- Cumbersome

Problems with previous internal lengthening nails (ILN; e.g. Albizzia, Fit Bone, ISKD) [1, 2]

- distraction activated by limb movements
- inaccurate & unreliable
- high complication rates (nonunion, premature consolidation, nerve injury, joint contractures etc.)

Precice® ILN (Ellipse Technologies Inc., Irvine, CA Figure 1) [3]

- magnet-operated
- recent FDA approval
- clinical efficacy not established



Figure 1

Materials and Methods

- Ten femur and seven tibia lengthening cases using the Precice® 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 (PACS, OnePacs LLC, New York, NY)

$$\text{Accuracy of distraction} = \frac{\text{Distraction measured}}{\text{Distraction done}} \times 100$$



Figure 2: External remote control magnet in operation

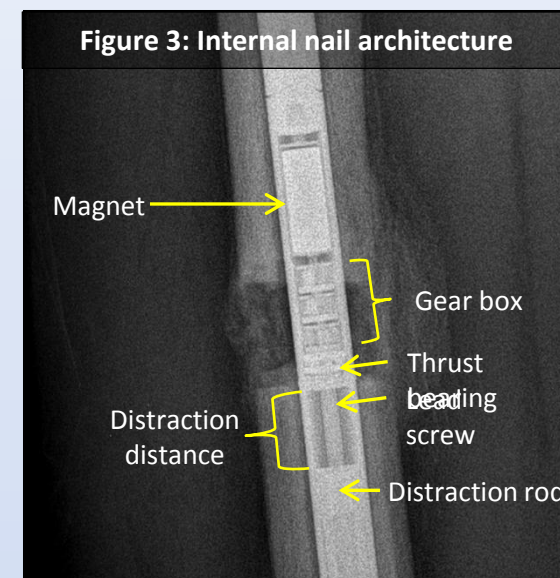


Figure 3: Internal nail architecture



Figure 4: Radiographic appearance at the:

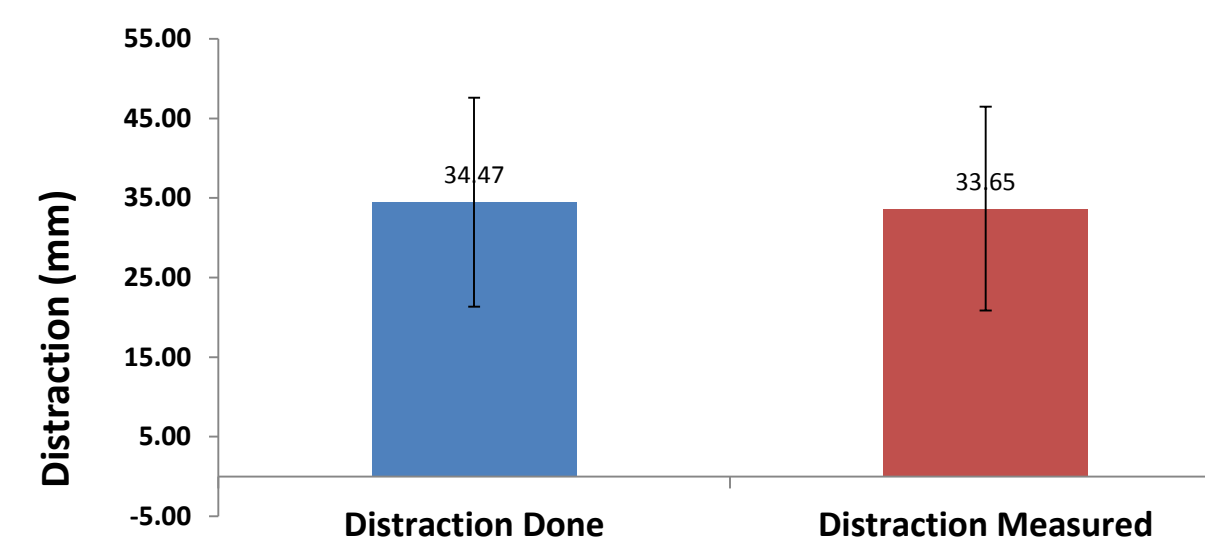
A) End of distraction

B) Most recent visit

Results

A) Accuracy of distraction

At 13.5 weeks follow-up (range, 4-30 weeks), the lengthening was 33.65 mm (range, 14mm-61mm) with an accuracy of $100.7\% \pm 0.23\%$.



B) Bone alignment

BONE	ANGLE	ABSOLUTE CHANGE (degrees)	
		Mean	Range
Femur	Lateral distal femoral angle (LDFA)	2	0-4
	Procurvatum/Recurvatum	5	8-12
Tibia	Medial proximal tibial angle (MPTA)	3	0-6
	Procurvatum/Recurvatum	3	1-5

Note: In five patients with pre-operative anterior femoral bow, the sagittal plane angle was intentionally reduced from 14° (range, 7° - 24°) to 7° (range, 3° - 13°) to facilitate nail insertion

C) Maximal temporary loss of joint ROM in early postoperative 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

D) Complications/ Implant Failures

- All femur cases had excellent bone healing. Two tibia cases required insertion of bone marrow concentrate for delayed bone healing.
- There were no implant failures or major complications.

Conclusions & Discussion

- The new Precice® 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.
- Iliotibial 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 tendency of varus-procurvatum 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 osteotomy to ensure adequate stability and to prevent iatrogenic deformities.

References

1. Mahboubian S et al. Clin Orthop Relat Res. 2012;4:1221-1231.
2. Eclipse Technology - Precice nail system [http://www.ellipse-tech.com/?q=ip]
3. Paley D et al. J Bone Joint Surg Am. 1997;10:1464-1480.