Precision of the Precice® Internal Lengthening Nails

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

Limb Lengthening and Complex Reconstruction Service
Hospital for Special Surgery, New York, NY
Disclaimer

- I have nothing else to disclose
Introduction: Bone Lengthening Techniques

- **External Fixators** – Paley et al., JBJS 1997; Herzenberg et al., JBJS 1997

- **Hybrid Techniques**
  - LON (*lengthening over nail*) – Paley et al. JBJS 1997; Mahboubian et al., CORR 2012
  - LATN (*lengthening and then nailing*) – Rozbruch et al., CORR 1997

- **Internal lengthening Devices (ILD)**
  - ISKD (Orthofix) – Cole et al., Injury 2001; Mahboubian et al., CORR 2012; Kenawey et al., CORR 2011;
Clinical Outcomes of ILD

- 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 ILD
Precice® Nail  Ellipse Technologies Inc., Irvine, CA

- Telescopic, magnet-operated device
- Recent FDA approval
- Clinical efficacy not established
Surgical Technique

- Rotation marker pins
- Vent hole & multiple drill hole osteotomy
- Osteotomy completion before advancing the nail
Intraop Magnet Localization & Distraction

Localization of the internal magnet

Intraop distraction
Methods

- 17 femur and 8 tibia lengthening cases
- Medical records were reviewed for:
  - Patient characteristics
  - Etiology
  - Surgery details
  - Distraction process
  - Bone alignment
  - Adjacent joint range of motion (ROM)
  - Any complications
## Demographics

<table>
<thead>
<tr>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>18</td>
<td>5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Etiology</th>
<th># of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Congenital/Developmental</td>
<td>10</td>
</tr>
<tr>
<td>Post-traumatic growth arrest</td>
<td>5</td>
</tr>
<tr>
<td>Fracture malunion</td>
<td>4</td>
</tr>
<tr>
<td>Short stature</td>
<td>4</td>
</tr>
<tr>
<td>Post-arthrodesis</td>
<td>1</td>
</tr>
<tr>
<td>Tumor resection</td>
<td>1</td>
</tr>
</tbody>
</table>
Primary Outcome Variables

I. Accuracy of Lengthening
   ◦ Distraction distance & accuracy measured using a calibrated digital radiology system (PACS, OnePacs LLC, New York, NY)

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

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

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 **33.65 mm** (range, 14mm-61mm)
- Accuracy was **99.3% ± 0.23%**
II. Absolute Change in Bone Alignment

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

- 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

<table>
<thead>
<tr>
<th>MOTION</th>
<th>ABSOLUTE LOSS (degrees)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
</tr>
<tr>
<td>Knee Flexion</td>
<td>13</td>
</tr>
<tr>
<td>Knee Extension</td>
<td>0</td>
</tr>
<tr>
<td>Ankle Dorsiflexion</td>
<td>3</td>
</tr>
<tr>
<td>Ankle Plantarflexion</td>
<td>6</td>
</tr>
</tbody>
</table>

- 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
Example 1: Anterograde Femur

- 14M
- 3.8 cm LLD
- 20° ER deformity
- Progressive LLD since birth
- Back and hip pain
- Difficulty playing sports
Example 1: Anterograde Femur

24 weeks after surgery
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

24 weeks after surgery
Example 3: Tibia

- 37F
- 7 cm LLD
- Pain in the left leg
- h/o multiple hip surgeries including THR
Example 3: Tibia

12 weeks after surgery

218 mm
237 mm

13 mm

18 mm

726 mm
655 mm

70 mm
123 mm

65 mm

65 mm

12 weeks after surgery
The new Precice® nails have excellent clinical efficacy with ~100% 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
Thank you for your attention!