Complications of ISKD (Intramedullary Skeletal Kinetic Distractor) in Distraction Osteogenesis

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Introduction

- Intramedullary Lengthening Devices
  - Torsionally activated device
    - Albizia (France)
    - ISKD (USA)
  - Electric motorized device
    - Fitbone (Germany)
  - Magnet activated device
    - Precice (USA)
    - Phenix nail (France)
Introduction

- **Albizzia Nail**
  - *Dr. Guichet*
  - torsionally activated
  - need 20° of rotation for rachet
  - criticism: *pain!*
Introduction

- ISKD (Intramedullary Skeletal Kinetic Distractor)
  - Dr. Dean Cole
  - activated by physiologic motion
    - 3 - 9° rotation
    - provide a comfortable lengthening
  - Orthofix. USA
Introduction

- Problems of the ISKD
  - Rate control
    - run-away nail
    - Poor regenerates
  - Mechanical failure
  - Pain -> comfortable lengthening device?

Simpson, JBJS(Br), 2008
Schiedel, JBJS, 2011
Burghardt RD, JBJS(Br), 2011
Wang, JOT, 2012
Purpose

- Evaluate **pain** for lengthening with ISKD
- Evaluate **rate control associated with pain**
- Evaluate **other complications**
Patients and Methods

- Demographics
  - March, 2010 ~ March, 2012
  - 19 patients (M:F=11:8)
  - 35 segments; LLD (3 cases), Familiar short stature (32 cases)
    - Femur 26 cases
    - Tibia 9 cases
  - Age: average, 27.9yrs (range, 17-73)
  - Lengthened length: average, 5cm (range, 4-6)
  - Prospectively collected data
Patients and Methods

- **Procedure**
  - Over-reaming
    - a minimum of 2 mm wider than the nail diameter by flexible reamer
  - Osteotomy
    - Complete transverse
    - Multiple drill hole technique
    - Above 11cm from the tip of the nail
  - Intraoperative pre-distraction
    - 1.5 to 2 mm gap at the osteotomy site
Patients and Methods

- Distraction Rate (DR) Control
  - Normal distraction rate: 0.8 ~ 1.5 mm/day
    (optimal: 0.8 ~ 1.2 / suboptimal: 1.2 ~ 1.5 mm/day)
  - Too rapid distraction rate
    - Keep absolute non-weight-bearing and reduce level of activity
  - Too slow distraction rate
    - Increase the level of activity //if not effective, manipulation
Patients and Methods

- Three Problematic Nails – Difficulty in rate control
  - Runaway nail
    - Distraction rate $\geq 1.5\text{mm/day}$
  - Difficult-to-distract nail
    - Distraction rate $\leq 0.8\text{mm/day}$
    - Require bedside manipulation
  - Non-distracting nail
    - Distraction rate $\leq 0.8\text{mm/day}$
    - Required manipulation under general anesthesia or re-osteotomy
Patients and Methods

- **Factors** that may associate with the rate
  - Age
  - BMI
  - Thigh circumference
  - Degrees of over-reaming (mm)
  - Length of thicker portion of the nail in the distal segment; friction
    
    *(Wang, JOT, 2012)*
Patients and Methods

- Pain - VAS (Visual Analogue Scale)
  - Rest
  - Physiotherapy
  - Rachet motion

- Analyzed correlated with distraction rate (4 groups)
  - normal / runaway / difficult-to-distract / non-distracting
Patients and Methods

- Consolidation Index (days/cm)
  - 1-cortex consolidation index
  - 3-cortex consolidation index
Patients and Methods

- **Complications**
  - Mechanical failure
  - MDRDP
    (Marked Decreased ROM during Distraction Phase)
  - Delayed union
  - Nonunion requiring bone graft
  - Deep infection
## Results

- **Rate Control**

<table>
<thead>
<tr>
<th>Rate control</th>
<th>Femur (n=26)</th>
<th>Tibia (n=9)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal nails (cases)</td>
<td>9 (35%)</td>
<td>5 (56%)</td>
<td>0.48</td>
</tr>
<tr>
<td>Problematic nails (cases)</td>
<td>17 (65%)</td>
<td>4 (44%)</td>
<td>0.43</td>
</tr>
<tr>
<td>- Runaway nails</td>
<td>6 (23%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>- Difficult-to-distract nails</td>
<td>8 (31%)</td>
<td>4 (44%)</td>
<td></td>
</tr>
<tr>
<td>- Non-distracting nails</td>
<td>3 (12%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
</tbody>
</table>
## Results

**Factors** that may interrupt distraction rate in femur

<table>
<thead>
<tr>
<th>Pain VAS</th>
<th>Normal nails (n=9)</th>
<th>Runaway nails (n=6)</th>
<th>Difficult-to-distract nails (n=8)</th>
<th>Non-distracting nails (n=3)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>28±8.4</td>
<td>33±20.0</td>
<td>26±7.2</td>
<td>24±9.2</td>
<td>0.48</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>23±4.6</td>
<td>22±2.7</td>
<td>22±5.2</td>
<td>23±8.2</td>
<td>0.87</td>
</tr>
<tr>
<td>Thigh circ. (mm)</td>
<td>406±25</td>
<td>409±32</td>
<td>402±21</td>
<td>405±21</td>
<td>0.81</td>
</tr>
<tr>
<td>Over-reaming (mm)</td>
<td>13±0.6</td>
<td>1.0±0.6</td>
<td>1.4±0.6</td>
<td>1.4±0.8</td>
<td>0.35</td>
</tr>
<tr>
<td><em>Length of thicker portion</em></td>
<td>94.8±6.2</td>
<td>92.7±5.9</td>
<td>99.9±7.4</td>
<td>100.0±4.0</td>
<td><strong>0.03</strong></td>
</tr>
</tbody>
</table>

*Length of thicker portion of the nail in the distal fragment*
## Results

- Pain VAS (0-10 points)

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<th>Pain VAS</th>
<th>Normal nails (n=9)</th>
<th>Runaway nails (n=6)</th>
<th>Difficult-to-distract nails (n=8)</th>
<th>Non-distracting nails (n=3)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rest</td>
<td>1.7±0.8</td>
<td>2.3±0.8</td>
<td>1.9±0.7</td>
<td>1.6±0.5</td>
<td>0.58</td>
</tr>
<tr>
<td>Physiotherapy</td>
<td>2.5±1.2</td>
<td>3.0±1.7</td>
<td>2.0±0.7</td>
<td>1.9±1.4</td>
<td>0.73</td>
</tr>
<tr>
<td>Distraction</td>
<td>3.0±1.0</td>
<td>6.7±1.7</td>
<td>6.5±0.7</td>
<td>7.7±1.0</td>
<td>0.02</td>
</tr>
<tr>
<td>P-value</td>
<td>0.01</td>
<td>0.01</td>
<td>&lt;0.01</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Results

- **Consolidation Index**

<table>
<thead>
<tr>
<th>Consolidation Index (days/cm)</th>
<th>Femur (n=26)</th>
<th>Tibia (n=9)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 cortex</td>
<td>14±6.0 (6.2-35.0)</td>
<td>26±13.8 (15.1-50.7)</td>
<td>0.002</td>
</tr>
<tr>
<td>3 cortices</td>
<td>17±11.3 (8.3-35.0)</td>
<td>36±8.2 (31.6-96.7)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

*3/9 (33%) of tibia

; Consolidation index > 60 days/mm
## Results

### Other Complications

<table>
<thead>
<tr>
<th>Complications</th>
<th>Femur</th>
<th>Tibia</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanical failure (cases)</td>
<td>0</td>
<td>1 (11%)</td>
<td>0.26</td>
</tr>
<tr>
<td>*MDRDP (cases)</td>
<td>0</td>
<td>5 (56%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Delayed union (cases)</td>
<td>1 (4%)</td>
<td>3 (33%)</td>
<td>0.05</td>
</tr>
<tr>
<td>Nonunion requiring bone graft (cases)</td>
<td>0</td>
<td>0</td>
<td>0.99</td>
</tr>
<tr>
<td>Deep infection (cases)</td>
<td>0</td>
<td>0</td>
<td>0.99</td>
</tr>
</tbody>
</table>

*MDRDP: Marked decrease of ROM during distraction phase*
Conclusion

- ISKD was not a comfortable lengthening device, if distraction rate is uncontrollable.

- The rate control was difficult in ISKD.
  - out of normal distraction rate (66% femur; 44% tibia)

- Tibia
  - Tendency of slow consolidation;
    - 3/9(33%), CI > 60 days/mm; ‘small sample size’
  - Marked equinus during lengthening period
Thank you for your attention!