Correction of Hammer Toe Deformity with Novel Intramedullary PIP Fusion Device vs K-Wire fixation

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Introduction

- Hammertoe deformity is a common complaint in foot & ankle clinics which leads to common secondary conditions such as corns, callouses, ulcerations, & shoe wear difficulties.

- Gold standard for operative intervention is a PIP resection arthroplasty & fixation with a Kirschner wire.

- K-wires carry inherent complications historically (e.g., pin tract infections, hardware failure, pin migration, & unappealing cosmesis).

- In the past 5-10 years intramedullary implants have both been increasing in number & popularity.
Introduction

- The CannuLink™ (Tornier, Bloomington, MN) intramedullary implant is a one piece titanium alloy device designed as an alternative to the K-wire.

- The goal of this study was to compare K-wire fixation with the CannuLink™ in terms of:
  - (1) need for revision surgery
  - (2) pain control
  - (3) complications (infection, hardware failure)

- We hypothesized the CannuLink™ device has superior outcomes compared to K-wire fixation.
The Intramedullary Device

Intramedullary device prior to implantation

Four sizes of the intramedullary device from left to right in length and width (of inferior segment) 12mm x 2.2mm, 13mm x 2.4mm, 13mm x 2.7 mm, 14mm x 2.9mm

Intramedullary device in situ

AP x-ray of a right foot, toes 3 & 4, with intramedullary implant in the former PIP joints demonstrating good alignment & fusion
Methods

- **Design:** Retrospective review of hammertoe correction by a single surgeon was performed from 06/2011 to 12/2013

- **Data collection:** Manual review of OR books and electronic chart review including complications, revision surgeries, Charlson comorbidity index, BMI, smoking, peripheral neuropathy, bony union percentage, pre and postoperative visual analogue pain scores (VAS)

- **Exclusion criteria:** Revision surgeries, acute injuries, and surgical correction of hammer toe using any other implant than the two aforementioned

- **End-points:** Postoperative VAS, revision rate, complications (hardware & surgery-related), & persistent symptoms

- **Power analysis:** Not performed due to the lack of published data on clinical outcomes within the groups
Methods

- **K wire group:**
  - 60 patients
  - 95 toes
  - 12.9 month follow-up average

- **Intramedullary group:**
  - 39 patients
  - 54 toes
  - 12.3 month follow-up average

- **Statistics:** Non-normal distributions were analyzed using the Wilcoxon rank sum test; normal distributions were analyzed with unpaired t-tests. A significance level of 5% was used for all testing.
# Results

## Baseline demographics & clinical variables for patients in K-wire group & intramedullary device group

<table>
<thead>
<tr>
<th>Variables</th>
<th>Intramedullary</th>
<th>K-wire</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients (n)</td>
<td>39</td>
<td>60</td>
<td></td>
</tr>
<tr>
<td>Age (y) *</td>
<td>61.4 ±10.2</td>
<td>61.7 ± 9.7</td>
<td>0.875‡</td>
</tr>
<tr>
<td>Females [n, (%)]</td>
<td>31 (57.4)</td>
<td>51 (85)</td>
<td>0.587†</td>
</tr>
<tr>
<td>BMI (kg/m²)*</td>
<td>29.3 ± 5.4</td>
<td>28.2 ± 6.0</td>
<td>0.180‡</td>
</tr>
<tr>
<td>ASA **</td>
<td>2 [2, 2]</td>
<td>2 [2, 2]</td>
<td>1‡</td>
</tr>
<tr>
<td>CCI **</td>
<td>3 [2, 3]</td>
<td>3 [2, 3]</td>
<td>0.744‡</td>
</tr>
<tr>
<td>Inflammatory arthritis [n, (%)]</td>
<td>4 (10.3)</td>
<td>3 (5)</td>
<td>0.429†</td>
</tr>
<tr>
<td>Smoker [n, (%)]</td>
<td>2 (5.3)</td>
<td>7 (12)</td>
<td>0.476†</td>
</tr>
<tr>
<td>DM [n, (%)]</td>
<td>0 (0)</td>
<td>1 (2)</td>
<td>1†</td>
</tr>
<tr>
<td>PVD [n, (%)]</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>-</td>
</tr>
<tr>
<td>Neuropathy [n, (%)]</td>
<td>2 (5.3)</td>
<td>3 (5)</td>
<td>1†</td>
</tr>
<tr>
<td>Preoperative pain (VAS) **</td>
<td>4 [2, 7]</td>
<td>5 [3.25, 7]</td>
<td>0.407‡</td>
</tr>
<tr>
<td>Postoperative pain (VAS) **</td>
<td>1 [0, 3]</td>
<td>1 [0.5, 3]</td>
<td>0.589‡</td>
</tr>
</tbody>
</table>

* mean ± standard deviation  
** median [25th, 75th percentiles]  
† Fisher’s exact test  
‡ Wilcoxon rank sum test

## Clinical outcomes of toes fixed with intramedullary device & K-wire

<table>
<thead>
<tr>
<th>Variables</th>
<th>Intramedullary</th>
<th>K-wire</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toes (n)</td>
<td>54</td>
<td>95</td>
<td></td>
</tr>
<tr>
<td>Right [n, (%)]</td>
<td>29 (54)</td>
<td>58 (61)</td>
<td>0.393†</td>
</tr>
<tr>
<td>Second [n, (%)]</td>
<td>35 (65)</td>
<td>28 (30)</td>
<td>&lt;0.001†</td>
</tr>
<tr>
<td>Third [n, (%)]</td>
<td>17 (32)</td>
<td>21 (22)</td>
<td></td>
</tr>
<tr>
<td>Fourth [n, (%)]</td>
<td>2 (4)</td>
<td>21 (22)</td>
<td></td>
</tr>
<tr>
<td>Fifth [n, (%)]</td>
<td>0 (0)</td>
<td>25 (26)</td>
<td></td>
</tr>
<tr>
<td>Time to union (months) *</td>
<td>9.58 ± 6.4</td>
<td>14.3 ± 9.3</td>
<td>0.916‡</td>
</tr>
<tr>
<td>Complications [n, (%)]</td>
<td>3 (5.6)</td>
<td>18 (19)</td>
<td>0.027†</td>
</tr>
<tr>
<td>-Infection</td>
<td>0 (0)</td>
<td>3 (3.2)</td>
<td>0.554†</td>
</tr>
<tr>
<td>Symptomatic [n, (%)]</td>
<td>3 (5.6)</td>
<td>15 (15.8)</td>
<td>0.183†</td>
</tr>
<tr>
<td>Revision surgery [n, (%)]</td>
<td>0 (0)</td>
<td>5 (5.2)</td>
<td>0.159†</td>
</tr>
<tr>
<td>Recurrent deformity [n, (%)]</td>
<td>1 (1.9)</td>
<td>9 (9.5)</td>
<td>0.095†</td>
</tr>
</tbody>
</table>

* mean ± standard deviation  
† Fisher’s exact test  
‡ Wilcoxon rank sum test
## Results

### Complication Comparison between intramedullary Implant & K-wire

<table>
<thead>
<tr>
<th>Complication</th>
<th>Intramedullary Implant</th>
<th>K-wire</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRPS, DVT, PE</td>
<td>1 patient</td>
<td>Continued pain – 3 patients</td>
</tr>
<tr>
<td>Recurrent deformity – 1 toe</td>
<td></td>
<td>DVT and peroneal neuritis – 1 patient</td>
</tr>
<tr>
<td>Wound dehiscence – 1 toe</td>
<td></td>
<td>Foot drop – 1 patient</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Recurrent deformity – 9 toes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Infection – 3 toes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Partial toe numbness – 1 toe</td>
</tr>
</tbody>
</table>
Discussion

- Pain levels decreased between both groups although not significantly between the two
  - This is in line with other studies such as Angirasa et al 2012
  - Likely due to small sample size and both procedure removing pain generating joint

- Deformity recurred more frequently with K wires (9.5%) compared to the intramedullary device (1.5%)
  - P value trended toward significance and like due to sample size was unable to reach this
  - In the largest study by Kramer et al 2015 K-wire recurrent deformity rate was 5.6% so the intramedullary device was still superior

- Infection rate was higher in the K-wire group: 3% vs 0% in the intramedullary group
  - Infections are one of the driving factors for physicians to switch to an intramedullary device
  - Rates of infection in the literature range from 0.3%-18%
  - This result was not significant in our study likely due to the very low rate of overall infections and sample size
Discussion

- There were no revision surgeries necessary in the intramedullary group compared to 5 revisions in the K-wire group (0% vs 5.2%, p=0.159)
  - Likely only due to limited sample size
  - Revision rates for K-wires in other studies have ranged from 3.5-6.7%
  - A lower revision rate will increased patient satisfaction, keep costs lower, and make for a better practice

- Overall Complication rate was significantly different between the two groups
  - Intramedullary device 5.6% vs K-wire 19%, p = 0.027
  - The reason this value is significant while the individual subgroups were not is likely due to pooled effect and more power

- Cost is on the minds of most if not all orthopedic practices whether they be private, hospital owned or academic
  - K-wire is less expensive as an implant (roughly $10-$20 per wire)
  - Cost of intramedullary devices vary from $500-$1500
  - True cost effectiveness is yet to be determined over the long term


