Hammertoe Correction Options:

Nextra® vs. K-Wire
58 patients were randomized to receive either K-wire or Nextra® for hammertoe correction. Patient populations are:

- Equivalent - similar numbers of each sex and age
- Represent typical hammertoe patients

Pre-surgery (baseline) versus 6-month patient outcome measures were compared.

Six-month data included objective and subjective measurements:

- Arthrodesis - independent scoring of x-rays for fusion, contact or gap
- Quality of Life - using two patient outcome measures (Bristol Foot Score and Foot Function Index)

Level 1, Prospective, Multi-Center, Randomized Controlled Trial.

Data analysis and statistics performed by independent clinical research organization, Milestone Clinical Research, Inc.
58 Hammertoe Patients:

Randomize

**29** Kwire Patients

<table>
<thead>
<tr>
<th>Gender</th>
<th>Number</th>
<th>Average Age</th>
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<tbody>
<tr>
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<td>61.56</td>
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<td>F</td>
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**29** Nextra Patients

<table>
<thead>
<tr>
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<th>Number</th>
<th>Average Age</th>
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</thead>
<tbody>
<tr>
<td>M</td>
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<td>61.56</td>
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<td>F</td>
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Baseline Bristol Foot Score

Monthly Baseline Bristol Foot Score

Foot Function Score

**6 Months** Baseline Bristol Foot Score

Foot Function Score

**6 Months** Baseline Bristol Foot Score

Foot Function Score

**6 Months** Baseline Bristol Foot Score

Foot Function Score

**6 Months** Baseline Bristol Foot Score

Foot Function Score

**6 Months** Baseline Bristol Foot Score

Foot Function Score

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Definitions

**UNION**

Radiographic evidence shows a high probability that a fusion has occurred. This contact and union of the bone is known as “bone-to-bone apposition”.

**GAP**

Radiograph evidence indicates that no contact was made and a space exists between the two bones.
Results by the Numbers

Nextra® vs. K-Wire Arthrodesis: Fusion

Scoring of patient x-rays at 6 months found:

82.8% of Nextra® patients achieved union versus 14.3% of K-wire patients...a 5.8 X higher rate for bone fusion with Nextra®.

Statistically significant via ANOVA analysis p<0.001 for gap, contact and union
Patient self-assessments of Quality of Life at Baseline and 6 Months found statistically significant **reductions in pain, reductions in disability and improvements in activity**.

26% improvement in quality of life for K-wire patients versus a 61% improvement for Nextra® patients.

Over **2.3 x** improvement in quality of life compared to K-Wire.

Statistically significant via ANOVA analysis, p=0.006.
Foot Function Index: **Pain Reduction**

- **40%** decrease in pain for K-wire patients versus a **64%** decrease for Nextra® patients.
- **60%** better pain reduction compared to K-wire.

Statistically significant via ANOVA analysis $p=0.02$
Foot Function Index: **Disability Reduction**

19% decrease in disability for K-wire patients versus a 63% decrease for Nextra® patients.

**3.3 X** better at decreasing patients’ level of disability compared to K-wire.

Statistically significant via ANOVA analysis $p=0.02$
Foot Function Index: *Activity Improvement*

5.5% decrease in activity for K-wire patients versus a 43% improvement in activity for Nextra® patients.

8.8 X better at improving patients’ activity levels compared to K-wire.

INCREASE IN **Activity**

- **Nextra®**: 43%
- **K-wire**: -5.5%

Statistically significant via ANOVA analysis, p=0.036
In a cohort of poor healers (morbidly obese, smokers and diabetics), 82% of Nextra® patients achieve union versus 23% of K-wire patients.

**3.6 X** higher rate of bone fusion compared to K-wire.
“Are K-wires still the standard of care for hammertoe proximal interphalangeal joint (PIPJ) fusion? ... Lamm and colleagues similarly showed a 20 percent nonunion rate with PIPJ fusion and K-wire fixation.² It seems that we should not be satisfied with any operation yielding a 20 percent failure rate.

There are benefits to this technique. K-wires are inexpensive and easy to use. There are, however, many downsides to K-wires, including wire failure (breakage/bending), greater risk of infection, patient anxiety with removal, lack of compression and lack of rotational stability.”

Based on the results of this study, surgeons who use Nextra® will potentially have better results than those who use a K-wire, which is a very old treatment method. The implant Nextrremity Solutions® provides is a fast procedure, uses no wires, has a quicker recovery rate and less pain.

Provide your patients with a new standard of care. Contact us at Nextra® today:

http://www.nextremity.com/contact-us