A Prospective Comparison of a Permanent Intramedullary Device to K-Wire Fixation for Proximal Interphalangeal Joint Fusion: Early Results

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Summary:
A prospective randomized controlled trial comparing the SmartToe device to kirschner wire to treat fixed hammer toe deformity, with 12 months follow-up.

Introduction:
Arthrodesis of the proximal interphalangeal joint (PIPJ) is the standard treatment for hammertoe deformity correction. The use of Kirschner wires is associated with problems such as rotational instability, loosening, pin track infections and loss of alignment. Intramedullary implants statistically have superior outcomes when compared to Kirschner wires. The purpose of this study was to compare clinical and radiological outcomes of PIPJ arthrodesis using Kirschner wires and the Smart Toe intramedullary implant.

Methods:
Patients requiring PIPJ arthrodesis for hammertoe deformity were randomized into a control group treated with Kirschner wire fixation (15 pts – 44 toes) and a study group treated with the Smart Toe implant (48 pts-85 toes). The primary endpoint was PIPJ fusion, and the secondary endpoints were pain scores, alignment, AOFAS scores and SF-36 scores at 12 months. Significance was assessed at $p \leq 0.05$.

Results:
Both groups were similar with regards to age, sex, work status and medical co-morbidities. At 12 months follow up, the Smart Toe implant showed significantly higher AOFAS scores (mean 81.8) versus Kirschner wire (mean 74.4) ($p=0.012$). Smart Toe also had significantly lower rates of footwear pain at the end of 12 months (6/48) as compared to Kirschner wire (6/15) ($p=0.028$). The two groups had similar pain scores on the VAS ($p=0.532$), fusion rates ($p=0.324$), and malalignment ($p>0.999$). There were no statistically significant differences between the SF-36 scores for the two groups ($p=0.988$), nor the various components of the SF-36 scores. It should be noted that one patient expired as a result of pulmonary thromboembolism after surgery.

Conclusion:
PIPJ arthrodesis with Smart Toe yields higher AOFAS scores and lower rates of footwear pain as compared to Kirschner wires at the end of 12 months. Both devices show similar pain scores, fusion rates, SF 36 scores and malalignment rates at 12 months.