

Clinical and Radiographic Evaluation of a One-Piece Intramedullary Device for Interphalangeal Joint Arthrodesis

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Introduction: Hammertoe deformities are commonly treated by foot and ankle practices to alleviate pain and secondary conditions including corns, callouses, ulcerations and shoe wear difficulty¹. While k-wire fixation is the most common operative treatment, intramedullary implants can alleviate risks associated with k-wires¹. New one-piece intramedullary devices have been FDA cleared and CE marked for the use in corrective procedures of lesser toes but have limited clinical data to date. The objective of this study was to assess safety, effectiveness, clinical performance, and fusion rate for subjects undergoing interphalangeal joint arthrodesis with new one-piece intramedullary devices.

Methods: Institutional Review Board approval was obtained to perform a retrospective and prospective registry to gather clinical and radiographic data on subjects treated for interphalangeal joint arthrodesis with one-piece intramedullary devices. Subjects were evaluated for radiographic fusion and clinical healing with patient reported outcome measurements captured by the Visual Analog Scale (VAS) and the 36-Item Short Form Survey (SF-36). Statistical significance was calculated between pre-op and final post-op measurements using a two-tailed, paired T-test with significance set at $p < 0.05$.

Results Section: Procedurally, 33 subjects and 43 toes were treated for interphalangeal joint arthrodesis. Results demonstrated 96.97% (32/33) of subjects achieved radiographic fusion defined as bridging bone across the fusion site. One obese patient developed pseudarthrosis by 6-weeks post-operative. All other subjects were void of pseudarthrosis, radiolucency, loosening, breakage, or motion and there were no reported cases of revision surgery at final clinic assessment. Subjects achieved a mean time to fusion of 8.65 ± 11.65 weeks and demonstrated significant ($p < 0.05$) improvement in VAS pain scores and SF-36 Pain scores at final visit and a trend ($p = 0.068$) in improvement in SF-36 Physical Functioning Scores (Table 1).

Discussion: This early analysis in an on-going study is the first to evaluate the effectiveness of one-piece intramedullary devices for interphalangeal joint arthrodesis and show improved patient functionality and pain following treatment. While additional research is required to fully evaluate this new one-piece intramedullary device, early evidence supports its ability to obtain successful clinical and radiographic outcomes.

Significance/Clinical Relevance: To our knowledge, this study was the first to evaluate the safety of one-piece intramedullary devices implanted during forefoot joint arthrodesis. Study results demonstrated the success of the one-piece intramedullary devices to provide early structural support and ultimately obtain solid boney fusion resulting in both radiographic and clinical success. Moreover, outcomes demonstrate that a one-piece intramedullary device alleviates associated risks with k-wires, provides limited dissection, and reduced complications, supporting that physician preference of such device yields a high level of satisfactory results.

Table 1: Pre-operative and Final Patient Reported Outcome Measurements

	Pre-Operative	Final Visit	P-Value
VAS Pain (n=28)	63.18 \pm 25.21	0.00 \pm 0.00	<0.00001
SF-36 Physical Functioning (n=30)	66.80 \pm 23.91	75.33 \pm 16.86	0.068
SF-36 Pain (n=30)	75.58 \pm 19.99	90.43 \pm 13.03	<0.001

References:

1. Coughlin et al. Foot & Ankle International, 21(2), 94-104.