Magnetic Resonance Imaging for Safety and Bio-Integration of a Fiber-Reinforced Proximal Interphalangeal Joint Fixation Implant: Prospective Multicenter Study with 2-Year Follow-Up
Jurij Stalc; Luke D. Cicchinelli; Stuart D. Miller, MD; Carolyn M. Sofka; Martinus Richter, MD, PhD

Category: Midfoot/Forefoot; Lesser Toes; Other

Keywords: Internal Fixation; Hammertoe Correction; Fusion

Introduction/Purpose: Bio-integrative implants, uniquely designed with high mineral fiber content, were developed to encourage paced, gradual degradation while enhancing bio-integrative response. Previous publications demonstrated the safe use of these fiber-reinforced implants in both in vivo preclinical models and in clinical use. The main focus of this study was to assess the longer-term clinical outcomes and to evaluate implant bio-integration, using a newly developed Magnetic Resonance Imaging (MRI) scoring system. The device used in this study was a Proximal Interphalangeal Joint (PIP) fixation implant. The scoring system implemented in this study was developed based on the review of existing literature describing MRI evaluation of degradable orthopedic implants, concentrating on various local tissue reactions and the implant-to-bone interphase characteristics.

Methods: Twenty-four patients were enrolled in this multicentre study, all previously treated for a single hammertoe deformity using the fiber-reinforced, bio-integrative fixation implant. Implant material is composed of continuous reinforcing mineral fibers (SiO2, Na2O, CaO, MgO, B2O3, and P2O5), bound together by a degradable polymer [poly (L-lactide-co-D,L-lactide), PLDLA] in a 50% w/w ratio. Final study visit took place two years post-operatively. X-ray was used to assess radiographic PIP fusion, defined as at least 50% bridging across the osteotomy site. MRI scans were reviewed by an independent radiologist, using a newly developed bio-integration score on a scale of 0-10. The score focused on material bio-integration defined by the evaluation of implant and bone border visibility, and parameters for local tissue response; fluid accumulation, cyst formation and local bone edema. Patient Reported Outcomes of Visual Analogue Scale (VAS) for pain, were also collected. Results were analysed and compared to previously published data.

Results: Radiographic PIP fusion rate was 96% (n=23) at the 2-year follow-up. MRI was performed and analyzed for all patients. The border between implant and surrounding bone was scored as not visible in 88% of subjects (n=21) and partially visible in remaining 12% (n=3) (100% partially visible at the 1-year). Mild bone edema was detected in 4% (n=1) (29% at 1-year). The edema findings were not evaluated as adverse implant-related. There were no cyst formation or fluid accumulation findings. The mean bio-integration score was 9.70+-0.69 at the 2-year timepoint (7.71+-0.46 at 1-year). Patient reported outcomes showed improvement from baseline with pain score reduced to 0.04+-0.20 compared to the initial score of 5.3+-2.5 at screening. No implant-related adverse effects were reported.

Conclusion: Study results provide evidence of safe bio-integration of the fiber-reinforced implants, with favourable clinical outcome at 2-years follow-up. MRI scans did not detect fluid accumulation, cyst formation or adverse implant-related edema findings. Primarily, these study results represent a first long-term follow-up for these implants in a clinical setting. The advanced bio-integration results at 2-years corelate well with substantial degradation previously demonstrated in animal models at a similar timepoint. Proven to provide the mechanical strength and safe elimination of the material without adverse local inflammation, this technology shows promising potential to be implemented on broader applications in orthopaedic surgery.
Fig. 1. A-F: Case study of a 74-year-old female with 2nd toe hammertoe deformity correction.

[A&B] – Coronal inversion recovery MRI scans at 1-year [A] and 2-years [B].

[C&D] – Parasagittal proton density fast spin echo MRI scans at 1-year [C] and 2-years [D].

[E&F] – Coronal proton density fast spin echo MRI scans at 1-year [E] and 2-years [F].

The bio-integration score calculates as follows,

1-year: Border between implant and bone, partially visible, 2 points; bone edema, none, 2 points; cyst formation, none, 2 points; fluid accumulation, none, 2 points. Total score 8.

2-years: Border between implant and bone, not-visible, 4 points; bone edema, none, 2 points; cyst formation, none, 2 points; fluid accumulation, none, 2 points. Total score 10.