

## Five-year Outcomes of a Synthetic Cartilage Implant for the First Metatarsophalangeal Joint in Advanced Hallux Rigidus

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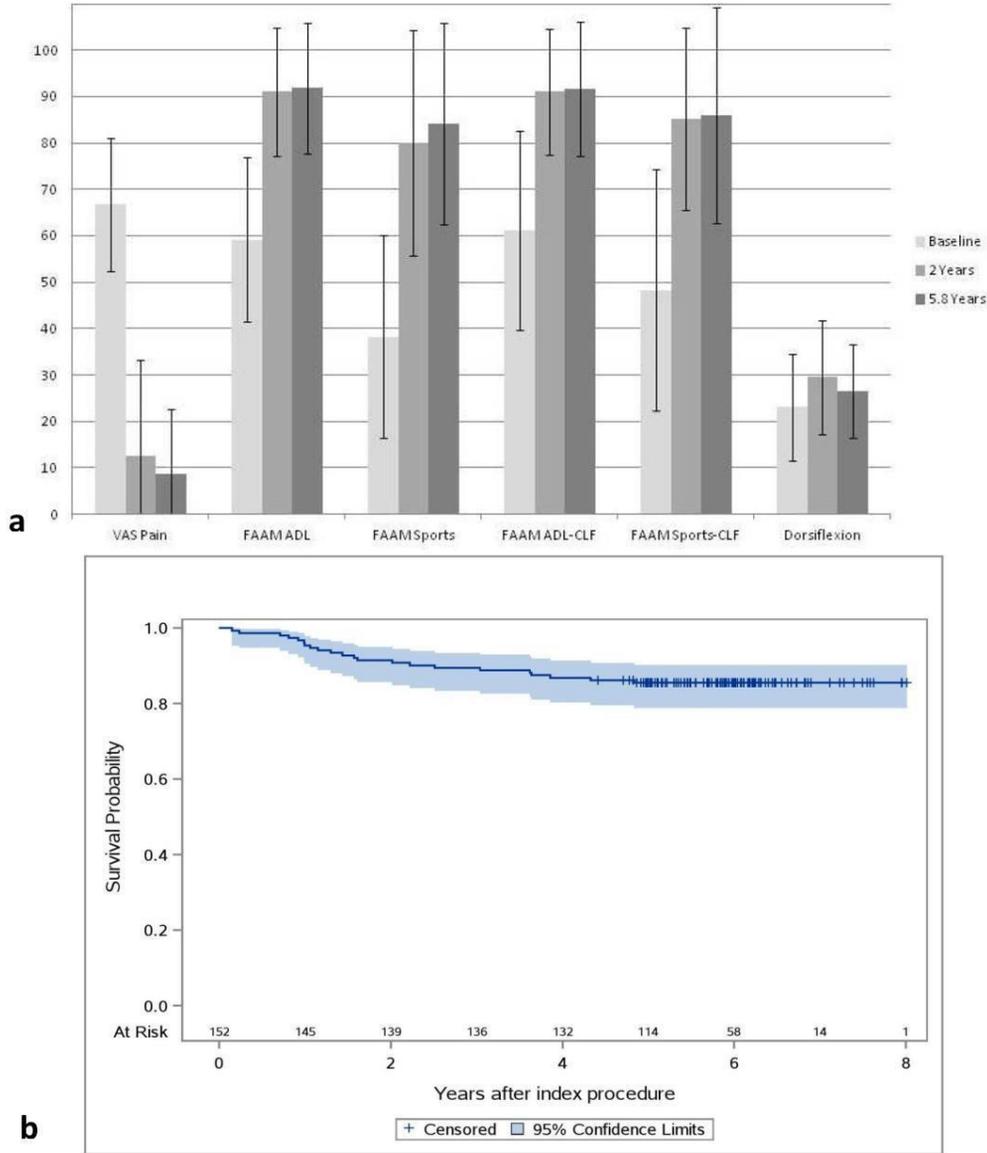
**Introduction/Purpose:** Hallux rigidus is the most common arthritic condition of the foot. A prospective, randomized, non-inferiority clinical trial of first metatarsophalangeal joint (MTPJ) hemiarthroplasty with a synthetic polyvinyl alcohol hydrogel implant, for moderate to severe hallux rigidus, demonstrated maintenance of MTPJ active dorsiflexion motion and excellent pain relief; additionally, the trial showed functional outcomes and safety equivalent to first MTPJ arthrodesis at 24 months (Baumhauer et al. 2016; *FAI*:37(5):457-469). Recognizing that many hemiarthroplasty and total toe implants have initially good results that deteriorate over time, the purpose of this study was to prospectively assess the safety and efficacy outcomes for the synthetic cartilage implant population and to determine if the excellent outcomes were maintained at >5 years.

**Methods:** One hundred and fifty-two patients underwent implant hemiarthroplasty in the original trial; 14 underwent implant removal and conversion to fusion and 3 were lost to follow-up during the first 24 months, leaving 135 eligible for this study. One hundred patients were evaluated at 5+ years; 5 could not be reached for follow-up. Thirty are pending consent, follow-up, and/or data entry; their status will be available for inclusion at the conference presentation. Patients completed a pain visual analogue scale (VAS) and Foot and Ankle Ability Measure (FAAM) Sports and Activities of Daily Living (ADL) scores, preoperatively and at 2, 6, 12, 26, 52, 104 and 260 weeks postoperatively. Minimal clinically important differences are: =30% difference for pain VAS, 9 points for FAAM Sports, and 8 points for FAAM ADL. Great toe active dorsiflexion, weight-bearing radiographs, secondary procedures, and safety parameters were evaluated.

**Results:** Of 100 synthetic cartilage implant hemiarthroplasty patients available at mean 5.8 years follow-up (SD  $\pm 0.7$ ; range: 4.4-7.4), 5 underwent implant removal and conversion to fusion in years 2-5 (Figure 1), and 2 underwent subsequent surgical interventions during the pivotal trial and were censored, leaving 93 patients for evaluation. Pain and function outcomes observed at 5.8 years were similar to those at 2 years (Figure 1). VAS Pain and FAAM Sports Scores were maintained or improved at 5.8 years follow-up, but these differences were not clinically significant. Joint motion was maintained at 5.8 years. No evidence of avascular necrosis, device migration or fragmentation was observed upon independent radiographic review. Eighty-six percent of patients agreed their overall well-being had improved, and 92% would have the procedure again.

**Conclusion:** Clinical and safety outcomes of patients having undergone synthetic cartilage implant hemiarthroplasty for the surgical treatment of hallux rigidus were previously demonstrated to be non-inferior to the gold standard treatment, MTPJ fusion, at 2 years. Prospectively determined outcomes for 100/135 of these implant hemiarthroplasty patients at 5.8 years are similar to those reported at 2 years. Longer-term results demonstrate that clinical and safety outcomes for synthetic cartilage implant hemiarthroplasty are durable, and that the implant remains a viable treatment option to decrease pain, improve function and maintain motion for advanced hallux rigidus.

Figure 1: Outcomes of a synthetic cartilage implant of the first MTP joint for advanced hallux rigidus at a mean of 5.8 years postoperative: (a) VAS pain (mm), FAAM Sports (points), FAAM ADL (points), FAAM Sports-Current Level of Function (CLF) (%), FAAM ADL-CLF (%), and Active MTP Peak Dorsiflexion (degrees); (b) Kaplan-Meier survivorship curve, with data censored at the most recent post-approval study follow-up visit (for consented patients) or the date of database closure (November 13, 2017) for patients awaiting consent; bars represent standard deviation.



ADL = Activities of Daily Living; CLF = Current Level of Function; FAAM = Foot and Ankle Ability Measure; MTP = metatarsophalangeal; VAS = Visual Analogue Scale