Prospective, Randomized, Multi-Centered Clinical Trial Assessing Safety and Efficacy of a Synthetic Cartilage Implant versus First Metatarsophalangeal Arthrodesis in Advanced Hallux Rigidus

Summary: A prospective, randomized (2:1), controlled, non-inferiority clinical trial was performed to compare the safety and efficacy of a small synthetic cartilage bone implant to first MTP arthrodesis in patients with advanced stage hallux rigidus. This study has shown equivalent pain relief and functional outcomes. The synthetic implant is an excellent alternative to arthrodesis in patients who wish to maintain 1st MTP motion. The percentage of secondary surgical procedures was similar between groups. Less than 10% of the implant group required revision to arthrodesis at 2 years.

Introduction: Hallux rigidus is the most common arthritic condition of the foot. Patients complain of symptoms such as pain, loss of 1st MTP motion, functional and shoe wear limitations. Although a variety of great toe implants have been tried in an attempt to maintain toe motion, the majority have failed with loosening, malalignment/dislocation, implant fragmentation and bone loss. In these cases, salvage to arthrodesis is more complicated and results in shortening of the ray or requires structural bone graft to establish length. This prospective study compares the efficacy and safety of this small (8/10 mm) hydrogel implant to the gold standard of a great toe arthrodesis for advanced stage hallux rigidus.

Methods: In this prospective, randomized non-inferiority study, patients from 12 centers in Canada and the UK were randomized (2:1) to a synthetic cartilage implant or 1st MTP arthrodesis. VAS pain scale, validated outcome measures (FAAM sport scale), great toe active dorsiflexion motion, secondary procedures, radiographic assessment and safety parameters were evaluated. Analysis was performed using Intent-to-Treat (ITT) and modified ITT methodology. The primary endpoint for the study consisted of a single composite endpoint utilizing the three primary study outcomes (pain, function, and safety). The individual subject's outcome was considered a success if all of the following criteria were met: 1) Improvement (decrease) from baseline in VAS Pain of ≥30% at 12 months; 2) Maintenance of function from baseline in FAAM Sports subscore at 12 months and 3) absence of major safety events at 2 years. The proportion of successes in each group was determined and one-sided 95% confidence interval for the difference between treatment groups was calculated. Non-inferiority of the implant to arthrodesis was considered statistically significant if the one-sided 95% lower confidence interval was greater than the equivalence limit (<15%).

Results: 236 patients were initially enrolled, 17 patients withdrew prior to randomization, 17 patients withdrew after randomization and 22 were non-randomized training patients, leaving 152 implant and 50 arthrodesis patients. Standard demographics and baseline outcomes were similar for both groups. Mean and standard deviation for pain and FAAM sports sub-score is reported in Table 1 for the mITT population. VAS pain scores decreased significantly in both the implant and arthrodesis groups from baseline at 12 and 24 months. Similarly, the FAAM sports and FAAM ADL scores improved significantly at 12 and 24 months in both groups. First MTP active dorsiflexion motion improved an average of 4° at 3 months after implant placement and was maintained at 24 months. Secondary surgeries occurred in 17 (11.2%) implant patients (17 procedures) and 6 (12.0%) arthrodesis patients (7 procedures). Fourteen (9.2%) implants were removed and converted to arthrodesis and 6 (12.0%) arthrodesis patients (7 procedures (14%)) had painful hardware requiring removal. There were no cases of implant fragmentation,

wear, or bone loss. When analyzing the ITT and mITT population for the primary composite outcome of VAS pain, function (FAAM sports) and safety, there was statistical equivalence between the implant and arthrodesis groups.

Conclusion: In patients requiring surgery for advanced stage hallux rigidus, treatment with a small synthetic cartilage implant resulted in comparable clinically important pain relief and functional outcomes compared to 1st MTP arthrodesis while preserving and often improving great toe motion. Secondary surgical intervention was similar in the implant and arthrodesis groups. Revision from a small implant plug to arthrodesis can be performed if needed with comparable outcomes to primary fusion.

Table 1. Modified ITT: Pain and Functional Outcomes Means (SD) Measurements for Implant and Arthrodesis

	Synthetic Cartilage Implant	1st MTP Arthrodesis
Demographics: No Between Group Differences		
VAS Baseline (0) (SD)(pts)	68.00 (13.8)	69.32 (14.3)
VAS 12 months (SD) (pts)	18.08 (23.5)	6.76 (10.8)
VAS 24 months (SD) (pts)	14.17 (21.7)	6.88 (13.4)
FAAM Sports Sub-score Baseline (0 mo.) (SD) (pts)	36.64 (21.1)	35.56 (20.5)
FAAM Sports Sub-score 12 months (SD) (pts)	72.81 (26.9)	83.22 (18.9)
FAAM Sports Sub-score 24 months (SD) (pts)	76.96 (29.2)	82.22 (21.5)

VAS = Visual Analog Scale; SE = Standard Error; FAAM = Foot and Ankle Ability Measure; MCID = Minimal Clinically Important Difference; pts = points; mo. = months; * clinically significant change