Revision of Implant to Great Toe Fusion: Did We "Burn a Bridge" With a Synthetic Implant Hemiarthroplasty?

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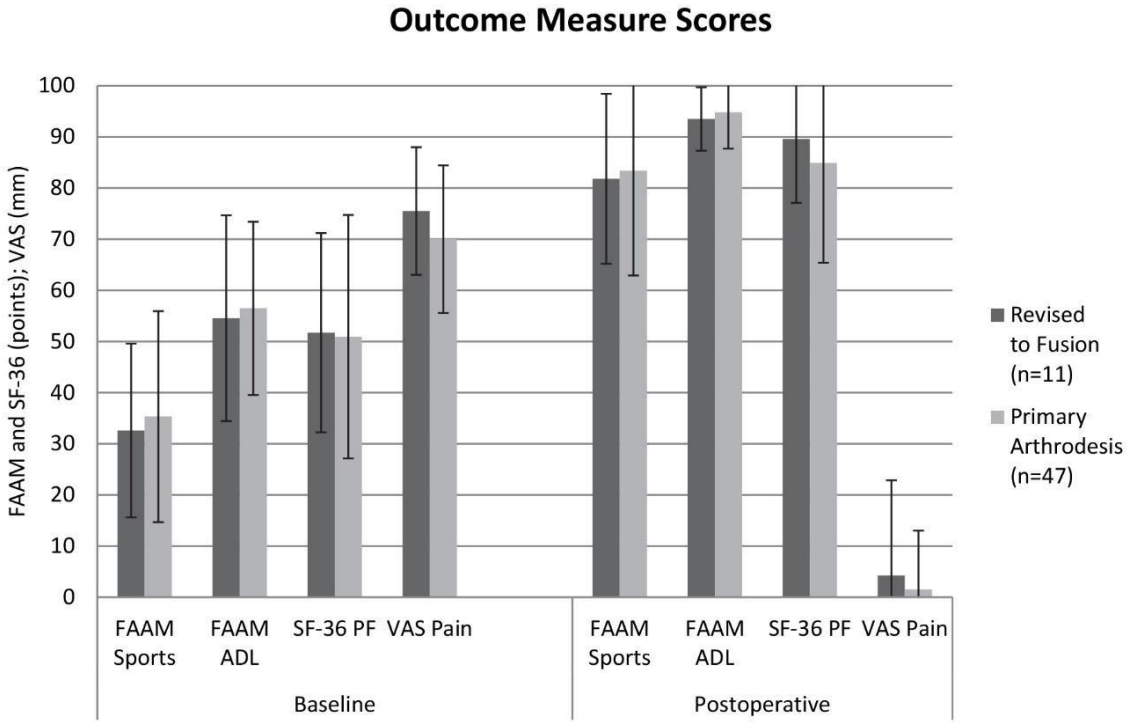
Introduction/Purpose: A prospective, randomized, non-inferiority clinical trial demonstrated that first metatarsophalangeal joint (MTPJ1) hemiarthroplasty with a synthetic polyvinyl alcohol hydrogel implant (Cartiva®) had equivalent pain relief and functional outcomes to MTPJ1 arthrodesis at 2 years. Despite 91% success, there was a 9.2% rate of implant removal and conversion to fusion. Other implants with more bone resection have demonstrated poorer outcomes after conversion to fusion than if a primary arthrodesis was performed. Since bone loss with synthetic cartilage implant hemiarthroplasty is minimal, we hypothesized that outcomes following implant removal and conversion to fusion would be similar to those following primary arthrodesis. We determined the outcomes of revision of synthetic implant hemiarthroplasty of the great toe to MTPJ1 arthrodesis and compared these outcomes to the primary arthrodesis cohort.

Methods: In the original pivotal trial, 152 patients >/=18 years diagnosed with hallux rigidus grade 2, 3, or 4 underwent synthetic cartilage implant MTPJ1 hemiarthroplasty, as previously described (Baumhauer et al., Foot Ankle Int. 2016;37(5):457-69). Outcome measures including the Foot and Ankle Ability Measure (FAAM), pain visual analogue scale (VAS), and Short Form-36 Physical Functioning (SF-36 PF) score were obtained preoperatively, and at 2 weeks, 6 weeks, and 3, 6, 12 and 24 months postoperatively. Revision surgery of the MTPJ1 was performed using the original surgical incision. The medial and lateral capsule was released, the metatarsal head was exposed to permit implant removal, and the void was filled with cancellous autograft or bone graft substitute. Joint compression was achieved using two crossed screws or a compression plate. Patients were non-weightbearing for six weeks. Union was confirmed on radiographs. Patients were followed post-conversion and assessed for pain and functional outcomes.

Results: Fourteen patients (9.2%) underwent implant removal and conversion to MTPJ1 arthrodesis. Mean time to revision surgery was 12.8 (range: 1.8-24.2) months. The removed implants demonstrated no signs of wear, fragmentation, fracture or other defects; the cause for failure was patient-reported pain. Eleven revision patients were followed up for mean 11.6 (range 3.1-22.9) months. Pain VAS decreased by mean 65.2 (range: 19.5-96.0) mm from baseline (i.e., prior to implant hemiarthroplasty). The FAAM ADL and Sports scores increased by mean 39.0 (range: 2.4-73.8) points and 49.2 (range: 5.8-90.6) points, respectively (Figure 1), compared to baseline, with minimal clinically important differences (MCIDs) of 8 and 9 points, respectively. The SF-36 PF subscore improved by mean 37.8 (range: 10-65) points from baseline, with MCID of 3.3 points.

Conclusion: Patients who underwent implant removal and conversion to MTPJ1 arthrodesis exhibited outcome measure scores statistically similar ($p>0.05$ for all scores) to those of the MTPJ1 fusion cohort at 24 months in the original pivotal trial (Figure 1). These results indicate that removal of the synthetic cartilage implant does not "burn a bridge" to having excellent pain relief and a successful functional outcome with a subsequent fusion procedure, if needed. The amount of bone loss with synthetic implant hemiarthroplasty is minimal, as the original joint surface length is maintained.

Figure 1: Baseline and postoperative outcome measure scores for synthetic implant hemiarthroplasty patients who underwent revision to arthrodesis (n=11) and for arthrodesis patients in the original pivotal trial (n=47). FAAM Sports, FAAM ADL and SF-36 PF scores are shown as mean values. VAS pain scores are shown as median values, as they were not normally distributed for revision patients. Lines represent standard deviation.



	Baseline				Post-Operative			
	FAAM Sports	FAAM ADL	SF-36 PF	VAS Pain*	FAAM Sports	FAAM ADL	SF-36 PF	VAS Pain*
Revised to Fusion (n=11)	32.6 (17.0)	54.6 (20.1)	51.7 (19.5)	75.5 (12.5)	81.8 (16.6)	93.5 (6.2)	89.6 (12.5)	4.3 (18.6)
Primary Arthrodesis (n=47)	35.3 (20.6)	56.5 (16.9)	50.9 (23.8)	70.0 (14.4)	83.4 (20.5)	94.8 (7.1)	84.9 (19.5)	1.5 (11.5)

Values are shown as means, with standard deviations in brackets.
*Shown as median values, as they were not normally distributed for revision patients.

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