The Influence of Patient Factors on the Outcome of Synthetic Cartilage Implant Hemiarthroplasty versus First Metatarsophalangeal Joint Arthrodesis

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Introduction/Purpose: Many studies have compared the outcomes of MTPJ1 hemiarthroplasty and arthrodesis, but there is a paucity of data on the influence of patient factors on clinical outcomes. A prior prospective, randomized, clinical trial compared the efficacy and safety of first metatarsophalangeal joint (MTPJ1) hemiarthroplasty with a synthetic polyvinyl alcohol hydrogel implant (Cartiva®) and MTPJ1 arthrodesis for moderate to severe hallux rigidus. The current study evaluated the data from this clinical trial to determine the impact of numerous patient variables, including osteoarthritis grade, hallux valgus angle, preoperative range of motion (ROM), gender, body mass index (BMI), preoperative duration of symptoms, and preoperative pain level, on the success or failure of MTPJ1 hemiarthroplasty and arthrodesis.

Methods: Patients =18 years diagnosed with hallux rigidus grade 2, 3, or 4 were randomized and treated with synthetic cartilage implant MTPJ1 hemiarthroplasty (n=129) or arthrodesis (n=47). Outcome measures included a pain visual analogue scale (VAS), Foot and Ankle Ability Measure (FAAM) Sports and Activities of Daily Living (ADL) scores, and Short Form-36 Physical Functioning (SF-36 PF) subscore, obtained preoperatively and at 2, 6, 12, 24, 52 and 104 weeks postoperatively. Great toe active dorsiflexion motion, secondary procedures, radiographs and safety parameters were evaluated. A patient's outcome was deemed successful if composite primary endpoint criteria for clinical success (pain, function and safety) were met at 24 months. Predictor variables included: osteoarthritis grade; hallux valgus angle; preoperative ROM; gender; body mass index (BMI); preoperative symptom duration; prior surgery; and preoperative pain level. Two-sided Fisher's Exact test was used to assess the impact of these variables on success of surgery ($p<0.05$).

Results: Standard patient demographics and baseline outcome measures were similar for both groups; both procedures demonstrated equivalent pain relief and functional outcomes.1 There was no significant difference ($p>0.05$) in success rates (i.e., VAS pain reduction >/=30%, maintenance/improvement in function, freedom from radiographic complications, and no secondary surgical intervention) between synthetic cartilage implant MTPJ1 hemiarthroplasty and arthrodesis when stratified by osteoarthritis grade, degree of preoperative hallux valgus, extent of preoperative ROM, gender, BMI, duration of symptoms, prior MTPJ1 surgery status, and preoperative pain VAS score (Table 1). Notably, patients with minimal ROM and mild hallux valgus had equivalent success rates for both procedures. Males tended to have greater clinical success with implant hemiarthroplasty versus arthrodesis, but this difference was not statistically significant.
1Baumhauer et al., FAI, 2016;37(5):457-69

Conclusion: Synthetic cartilage implant hemiarthroplasty is an appropriate treatment for patients with hallux rigidus of Coughlin grade 2, 3 or 4. Its results in those with associated mild hallux valgus (<20 degrees) and in those with a high degree of preoperative stiffness are equivalent to MTPJ1 fusion, irrespective of gender, BMI, osteoarthritis grade, or preoperative pain or duration of symptoms, in contrast to what might have been expected.

Table 1: Success rates of synthetic cartilage implant hemiarthroplasty of the first metatarsophalangeal joint (n=129) and first metatarsophalangeal joint arthrodesis (n=47), stratified by patient variables.

Patient Variable	Stratification	Synthetic Implant Hemiarthroplasty			Arthrodesis			P-value*
		N^	n~	% Success	N^	n~	% Success	
Osteoarthritis Grade	2	36	26	72.2	18	12	66.7	0.756
	3	73	61	83.6	20	17	85.0	>0.999
	4	20	16	80.0	9	8	88.9	>0.999
Preoperative Hallux Valgus Angle	0 to <15°	101	81	80.2%	34	28	82.4%	0.999
	≥15° to ≤20°	28	22	78.6%	13	9	69.2%	0.698
Preoperative Active Peak Dorsiflexion	≥40° to ≤60°	10	7	70.0%	4	2	50.0%	0.580
	≥30° to <40°	21	16	76.2%	10	9	90.0%	0.634
	>10° to <30°	68	53	77.9%	24	19	79.2%	>0.999
Gender	Female	104	81	77.9%	36	29	80.6%	0.817
	Male	25	22	88.0%	11	8	72.7%	0.343
Body Mass Index (BMI)	<30 kg/m^2	94	76	80.9%	39	30	76.9%	0.640
	≥30 kg/m^2	34	27	79.4%	8	7	87.5%	1.000
Duration of Symptoms Prior to Surgery	<24 months	15	10	66.7%	3	3	100%	0.522
	≥24 months	114	93	81.6%	44	34	77.3%	0.655
Prior MTPJ1 Surgery Status	Prior surgery[1]	12	8	66.7%	4	4	100%	0.516
	No prior surgery	117	95	81.2%	43	33	76.7%	0.513
Preoperative Pain VAS Score	Mild (0 to <40 mm)[2]	2	1	50.0%	2	1	50.0%	>0.999
	Moderate (≥40 to ≤58 mm)	27	24	88.9%	7	7	100%	>0.999
	Severe (≥58 to 100 mm)	100	78	78.0%	38	29	76.3%	0.823

* P-values were determined using Fisher's Exact test.

^ N = total number of patients in the treatment cohort with that variable.

~ n = total number of patients in the treatment cohort with that variable who met the composite primary endpoint criteria for clinical success (i.e., VAS pain reduction ≥30%, maintenance or improvement in function, freedom from radiographic complications, and no secondary surgical intervention).

[1] Prior surgery other than arthroplasty or arthrodesis, for example, joint debridement or cheilectomy

[2] VAS pain <40mm was an exclusion criterion for the study; these patients should not have been enrolled or treated and were protocol violations.

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