Association Between Patient Factors and Outcome of Synthetic Cartilage Implant Hemiarthroplasty versus First Metatarsophalangeal Joint Arthrodesis in Advanced Hallux Rigidus

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ABSTRACT (max 250 words)

Background: We evaluated data from a clinical trial of first metatarsophalangeal joint (MTPJ1) implant hemiarthroplasty and arthrodesis to determine the association between patient factors and clinical outcomes.

Methods: Patients ≥18 years with hallux rigidus grade 2, 3, or 4 were treated with synthetic cartilage implant MTPJ1 hemiarthroplasty or arthrodesis. Pain VAS, Foot and Ankle Ability Measure (FAAM) Sports and ADL scores, and SF-36 PF subscore were obtained preoperatively, and at 2, 6, 12, 24, 52 and 104 weeks postoperatively. Final outcome data, great toe active dorsiflexion motion, secondary procedures, radiographs and safety parameters were evaluated for 129 implant hemiarthroplasties and 47 arthrodeses. The composite primary endpoint criteria for clinical success included VAS pain reduction ≥30%, maintenance/improvement in function, no radiographic complications, and no secondary surgical intervention at 24 months. Predictor variables included: hallux rigidus grade; gender; age; BMI; symptom duration; prior MTPJ1 surgery; preoperative hallux valgus angle, ROM, and pain. Two-sided Fisher's Exact test was used ($p<0.05$).

Results: Patient demographics and baseline outcome measures were similar. Success rates between implant MTPJ1 hemiarthroplasty and arthrodesis were similar ($p>0.05$) when stratified by hallux rigidus grade, gender, age, BMI, symptom duration, prior MTPJ1 surgery status, and preoperative VAS pain, hallux valgus and ROM.

Conclusion: Synthetic cartilage implant hemiarthroplasty is appropriate for patients with grade 2, 3 or 4 hallux rigidus. Its results in those with associated mild hallux valgus (≤20°) or substantial preoperative stiffness are equivalent to MTPJ1 fusion, irrespective of gender, age, BMI, hallux rigidus grade, preoperative pain or symptom duration.

Level of Evidence: II, randomized clinical trial

Keywords: First metatarsophalangeal joint; Hallux rigidus; Hemiarthroplasty; Synthetic cartilage implant.

INTRODUCTION

Arthritis of the first metatarsophalangeal joint (MTPJ), or hallux rigidus, is a common problem affecting one in 40 people over 50 years of age[11] and 45% of people aged 75 to 79 years[21]. Moderate to severe hallux rigidus is often treated with arthrodesis, historically considered the most reliable option.[16] However, the loss of motion through the MTPJ following arthrodesis can interfere with activities that require great toe motion, such as jumping and running, or the wearing of high heels, and can lead to transfer metatarsalgia or adjacent joint arthritis. A desire to preserve motion at the first MTPJ has prompted the development of several great toe implants, many of which demonstrated high rates of failure due to loosening, malalignment, dislocation, subsidence, implant fragmentation and bone loss.[23,24]

A polyvinyl alcohol (PVA) hydrogel implant has been developed for use in first MTPJ hemiarthroplasty. The PVA hydrogel has a cartilage-like viscoelasticity,[18] a tensile strength of 17 MPa comparable to that of human articular cartilage,[18] and biomechanical properties (i.e., compression-compressive modulus, shear-shear

modulus, compressive creep-creep and creep recovery, and kinetic friction) very similar to cartilage.[2] Its high biocompatibility with cartilage, bone, synovium and muscle,[18] combined with its compressibility, low friction, and durable bearing surface make it a suitable synthetic cartilage implant.[2,3] Since the implant has similar osmotic, physical and frictional properties to cartilage, replacement of the opposing articular surface is not required, permitting a hemiarthroplasty that maintains articulation through the joint.

In a recent prospective, randomized, multicenter, clinical trial of 202 patients with moderate to severe hallux rigidus, hemiarthroplasty of the first MTPJ with a synthetic cartilage implant demonstrated equivalent pain relief, functional outcomes and safety to first MTPJ arthrodesis at two years follow-up, with no cases of implant fragmentation, wear or bone loss.[4] First MTPJ active dorsiflexion motion improved by a mean of 6.2° (27.3%) in 152 synthetic cartilage implant hemiarthroplasty patients and was maintained at 24 months. In a subset of 27 implant hemiarthroplasty patients who reached five years follow-up, functional outcomes improved significantly and pain was reduced significantly compared to preoperative measures, and only one implant was removed and converted to fusion at two years postoperative, because of persistent pain.[7]

There is a paucity of data regarding the association between patient factors and clinical outcomes following hallux rigidus surgery. Several studies have directly compared the short- to mid-term outcomes (i.e., 2 to 4 years) of first MTPJ hemiarthroplasty with various implants to MTPJ arthrodesis.[9,10,13,17,19,20,22] However, these studies either did not evaluate the association between patient factors and outcomes,[10,20,22] or the sample sizes were too small to permit such analyses.[9,17,19]

The purpose of this study was to evaluate the longitudinal data from the aforementioned randomized, clinical trial comparing synthetic cartilage implant first MTPJ hemiarthroplasty with arthrodesis,[4] to determine the association between numerous patient factors and the success or failure of these procedures. Success rates were also compared between treatment groups within each category of the patient factors.

PATIENTS AND METHODS

Patients 18 years of age and older who had been diagnosed with Coughlin hallux rigidus grade 2, 3, or 4 based on combined radiological and clinical observations[5] including moderate to severe pain, and who were considered surgical candidates for arthrodesis, were treated with either hemiarthroplasty of the first MTPJ using a synthetic polyvinyl alcohol hydrogel implant (Cartiva® Synthetic Cartilage Implant, Cartiva, Inc., Alpharetta, GA, USA) or first MTPJ arthrodesis in a multicenter, non-inferiority clinical trial, as previously reported.[4] Patients were randomized 72 hours or less prior to surgery, in a 2:1 allotment of implant hemiarthroplasty to arthrodesis. The randomized clinical trial was approved by each site's institutional review board, and all patients provided informed consent. The efficacy and safety data for the clinical trial have been previously reported.[4] For the current study, patient demographic data and preoperative data collected prospectively for the original trial were assessed for the Safety population, comprising 152 hemiarthroplasties and 50 arthodeses (Figure 1). Osseous union was determined by independent radiographic review of foot radiographs, which were taken preoperatively and at 2, 6, 12, 24, 52 and 104 weeks postoperatively. A patient's outcome was deemed successful if composite primary endpoint criteria for

clinical success were met at 24 months, namely: 1) VAS pain reduction ≥30%; 2) maintenance or improvement in function; 3) freedom from radiographic complications; and 4) no secondary surgical intervention. Final outcome data were assessed in the modified Intent to Treat (mITT) population (Figure 1).

The standardized operative technique used for the synthetic cartilage implant and postoperative protocol has been published previously.[4,24] Briefly, the first MTPJ was accessed via a straight dorsal incision, or a standard mid-medial approach. The neurovascular structures and tendons were protected as appropriate and a capsular incision made to expose the first metatarsal (MT) head (Figure 2a). The articular cartilage wear was examined, and the medial, lateral and dorsal osteophytes were carefully removed from the metatarsal head; in some cases, the osteophyte on the dorsal side of the proximal phalanx was also removed (Figure 2b). A central guide wire was placed in the MT head and extended into the shaft, and the MT head was drilled (Figures 2c, 2d). An appropriately sized 8 or 10 mm implant was seated in the MT head to allow approximately 1.5-2.0 mm of the implant to extend beyond the adjacent native cartilage (Figures 2e, 2f). With the implant at the correct depth, range of motion was checked against the implant, ensuring there was no restriction or limitation of the joint movement. Layered closure of the capsule and skin was performed. A soft dressing was applied, and postoperative shoes were used. Patients could bear weight immediately as tolerated. At 2 weeks, skin sutures were removed, range of motion (ROM) exercises were begun, and patients resumed wearing regular shoes, as tolerated.

First MTPJ arthrodesis was performed using standard techniques, as described in the literature.[6] For this study, the first MTPJ was exposed as per the synthetic cartilage implant technique. The base of the proximal phalanx and the first MT head were aligned

and positioned in slight dorsiflexion and valgus with neutral rotation and held with K-wires. A simulated weight bearing test was used to confirm grip of the big toe when plantigrade and sufficient lift off to enable comfortable walking. The construct was then stabilized with crossed screws or plate and screws. Layered closure of the capsule and skin were performed. The foot was placed in a sterile dressing and immobilized in a heel wedge shoe or boot for six to ten weeks, or until osseous union occurred, at which time weight bearing was begun at the discretion of the surgeon.

Data Collection

Outcome measures included a pain visual analogue scale (VAS), the Foot and Ankle Ability Measure (FAAM) Sports and Activities of Daily Living (ADL) subscales, and Short Form-36 Physical Functioning (SF-36 PF) subscore, which were prospectively recorded for all study patients preoperatively and at 2 (pain VAS and FAAM only), 6, 12, 24, 52 and 104 weeks postoperatively. The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) consensus group defined a decrease in pain of ≥30% to be a clinically meaningful improvement for patients and recommended this value be reported in clinical trials.[8] The FAAM has been validated in subjects with a leg, foot, or ankle musculoskeletal disorder;[15] the minimal clinically important difference (MCID) is 9 points for the FAAM Sports score and 8 points for the FAAM ADL score.[4] The SF-36 is a generic measure of general health status and has been validated in the end-stage ankle arthritis population;[14] the MCID for the SF-36 PF subscore is 3.3 points.[1] Great toe active dorsiflexion motion, secondary procedures, radiographs and safety parameters were also evaluated.

Patient demographic and preoperative data assessed as predictor

variables included hallux rigidus grade,[5] hallux valgus angle, preoperative ROM, gender, age, body mass index (BMI), preoperative symptom duration, preoperative pain level, and prior first MTPJ surgery (e.g. joint debridement or cheilectomy), all of which were captured prospectively at baseline.

Statistical Analysis

Categorical data are presented as numbers and percentages. Continuous data are presented as means and standard deviations with ranges. Two-sided Fisher's Exact test was used to assess the association between patient demographic and preoperative variables and clinical success, within each treatment group. In secondary analyses, success rates were compared between groups within each level of the patient demographic and preoperative variables. A p-value <0.05 was considered statistically significant.

RESULTS

The original randomized clinical trial reported equivalent pain relief and functional outcomes in the synthetic implant first MTPJ hemiarthroplasty group and the first MTPJ arthrodesis group.[4] Complete data at 24 months follow-up (mITT Completers; Figure 1) included 129 patients with synthetic cartilage implant hemiarthroplasty and 47 patients who underwent an arthrodesis. Patient demographics and baseline outcome measures were similar for both groups (Table 1).

There were no significant differences in success rates for either first MTPJ synthetic cartilage implant hemiarthroplasty or arthrodesis when stratified by hallux rigidus grade, degree of preoperative hallux valgus, extent of preoperative ROM, gender, age, BMI, duration of symptoms, prior MTPJ1 surgery status (including joint

debridement and/or cheilectomy), and preoperative VAS pain score (all $p>0.05$; Table 2). There were also no significant differences between treatment groups within any level of the patient or preoperative factors evaluated (Table 2). Males tended to have greater clinical success with implant hemiarthroplasty versus arthrodesis, but this difference was not statistically significant. Patients with less preoperative motion had marginally higher success rates with hemiarthroplasty versus fusion, but these differences were not statistically significant.

DISCUSSION

In a large, randomized, clinical trial, synthetic cartilage implant hemiarthroplasty of the first MTPJ demonstrated equivalent success rates compared to first MTPJ arthrodesis, regardless of hallux rigidus grade, gender, age, BMI, degree of preoperative hallux valgus, extent of preoperative ROM, preoperative duration of symptoms, prior first MTPJ surgery, and preoperative VAS pain score. Notably, patients with larger BMI, patients with minimal ROM (i.e., stiff joints), and patients with mild hallux valgus had equivalent success rates for both procedures, indicating that synthetic implant first MTPJ hemiarthroplasty could be considered as a reasonable operative option for moderate to severe hallux rigidus.

Only one other study has compared the short-term outcomes (i.e., 2 to 3 years) of metatarsal head-resurfacing hemiarthroplasty to those of MTPJ arthrodesis. Erdil et al[9] retrospectively reviewed patients with advanced hallux rigidus who underwent resurfacing hemiarthroplasty with the HemiCAP (n=14) or arthrodesis with 2 cannulated compression screws (n=12). They also had a third cohort of patients who underwent total joint arthroplasty with the ToeFit-Plus (n=12), They reported similar functional

outcomes following arthroplasty and hemiarthroplasty, and less function due to less range of motion in arthrodesis patients, who also had less pain, at 28 to 35 months follow-up. However, they did not evaluate the association between patient factors and clinical outcomes; there is a notable lack of such data available in the literature.

To be included in the original clinical trial, patients had to be diagnosed with Coughlin grade 2, 3, or 4 hallux rigidus, which is based on a combination of radiological and clinical observations,[5] and all patients had to be considered surgical candidates for arthrodesis. It is important to point out that Coughlin grade 2 includes moderate to severe pain and stiffness, which may be constant.[5]

The literature generally holds that joint-sparing procedures should be reserved for mild to moderate osteoarthritis, and that fusion should be used in late-stage moderate to severe osteoarthritis.[5,12,23] Our findings do not support this proposition, as we found no significant difference in outcome between the groups, irrespective of the hallux rigidus grade, preoperative presence of a stiff toe, a high BMI, or the presence of mild hallux valgus (≤20°).

Synthetic implant first MTPJ hemiarthroplasty can be used to successfully treat patients with mild hallux valgus; however, patients with >20° hallux valgus were excluded from the clinical trial, and concomitant valgus correction procedures were also not permissible. Hence, we are unable to comment on the outcome of synthetic cartilage implant first MTPJ replacement in cases with >20° hallux valgus.

We acknowledge the limitations of this study. The original clinical trial was powered for non-inferiority to demonstrate equivalence of the two procedures, whereas the current study retrospectively analyzed success rates for variations in patient factors within each treatment group and may not have been sufficiently

powered for some patient factors, thus a type II error cannot be excluded in the subgroup analysis. Some patient factors that may be associated with clinical outcomes may not have been recorded in the original trial. Exclusion criteria for the original trial also excluded some patient factors that would have been of interest to evaluate within the current study, such as the presence of hallux valgus >20° or an associated deformity correction. Another limitation is the loss of 15 patients who initially consented to randomization and treatment and subsequently withdrew from the original trial following randomization to arthrodesis; statistical analyses were therefore performed on the modified intent to treat population, so as to address the potential bias in favor of the implant. The current study did not assess surgeon factors such as type of approach, type of fixation used, or position of construct in the arthrodesis group, which could be confounding variables, and we intend to assess these in a subsequent study. Finally, this study evaluated association of patient factors based on two-year outcomes. As data for five years and longer follow-up become available, it is possible there may be some failures, which could potentially modify some of the associations observed here.

Strengths of this study include the rigorous quality of the longitudinal data obtained as part of a large, multicenter, well controlled, randomized clinical trial, the large sample sizes (hemiarthroplasty n=129; arthrodesis n=47) and the low rate of patients lost to follow-up (2%). Most previous comparative studies of operative treatment for hallux rigidus have small numbers in each treatment arm.[9,10,16,17,19,22] The data from this study are broadly generalizable, as they represent patients enrolled by 49 surgeons from 12 centers across two countries. This study provides the first thorough evidence of the association between patient factors and clinical outcomes following hallux rigidus surgery.

In conclusion, **based on our short-term data of two-year follow-up,** synthetic cartilage implant hemiarthroplasty is an appropriate treatment for patients with hallux rigidus of Coughlin grade 2, 3 or 4. Our results demonstrate that it is a reasonable choice in hallux rigidus associated with mild hallux valgus (≤20°), and in patients with a high degree of preoperative stiffness, irrespective of gender, age, BMI, hallux rigidus grade, preoperative pain, or duration of symptoms, in contrast to what might have been expected.

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Figure 1: Pivotal Trial Study Enrollment

Subject accountability tree. The Safety Population consisted of 152 patients (22 roll-in and 130 randomized) treated with synthetic cartilage implant hemiarthroplasty and 50 control patients treated with arthrodesis. The modified Intent to Treat (mITT) Population included 130 patients randomized and treated with synthetic cartilage implant hemiarthroplasty and 50 patients randomized and treated with arthrodesis, of whom 129 hemiarthroplasty and 47 arthrodesis patients had complete data available at 24 months follow-up (mITT Completers)

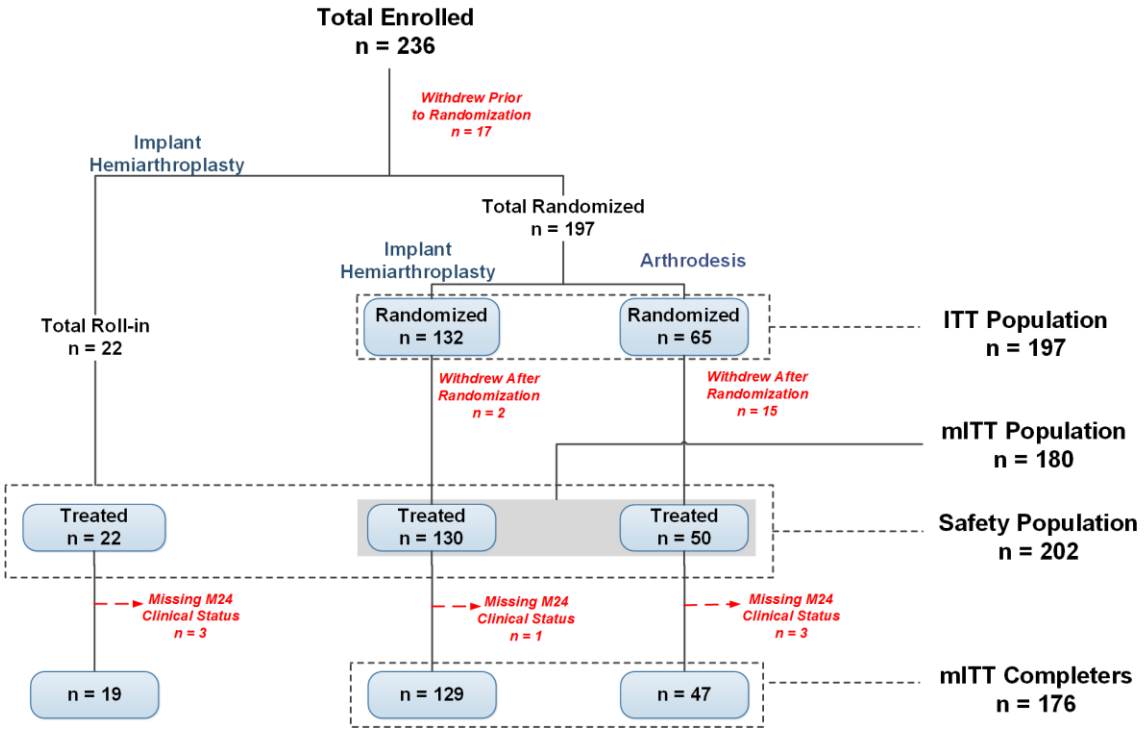

Figure 2: Overview of operative technique for synthetic cartilage implant first metatarsophalangeal joint hemiarthroplasty: (a) Straight dorsal or medial incision and exposure of the entire joint to gain access to the first metatarsal head; (b) Resection of osteophytes from the metatarsal head; (c) Guide wire placement and advancement of the cannulated drill bit; (d) Drilling of metatarsal head to produce cavity for the implant; (e) Implant compressed within the introducer tube and positioned for insertion into the metatarsal head cavity; (f) Implant seated into metatarsal head with expected 1.5 to 2.0 mm implant prominence.

Figure 2

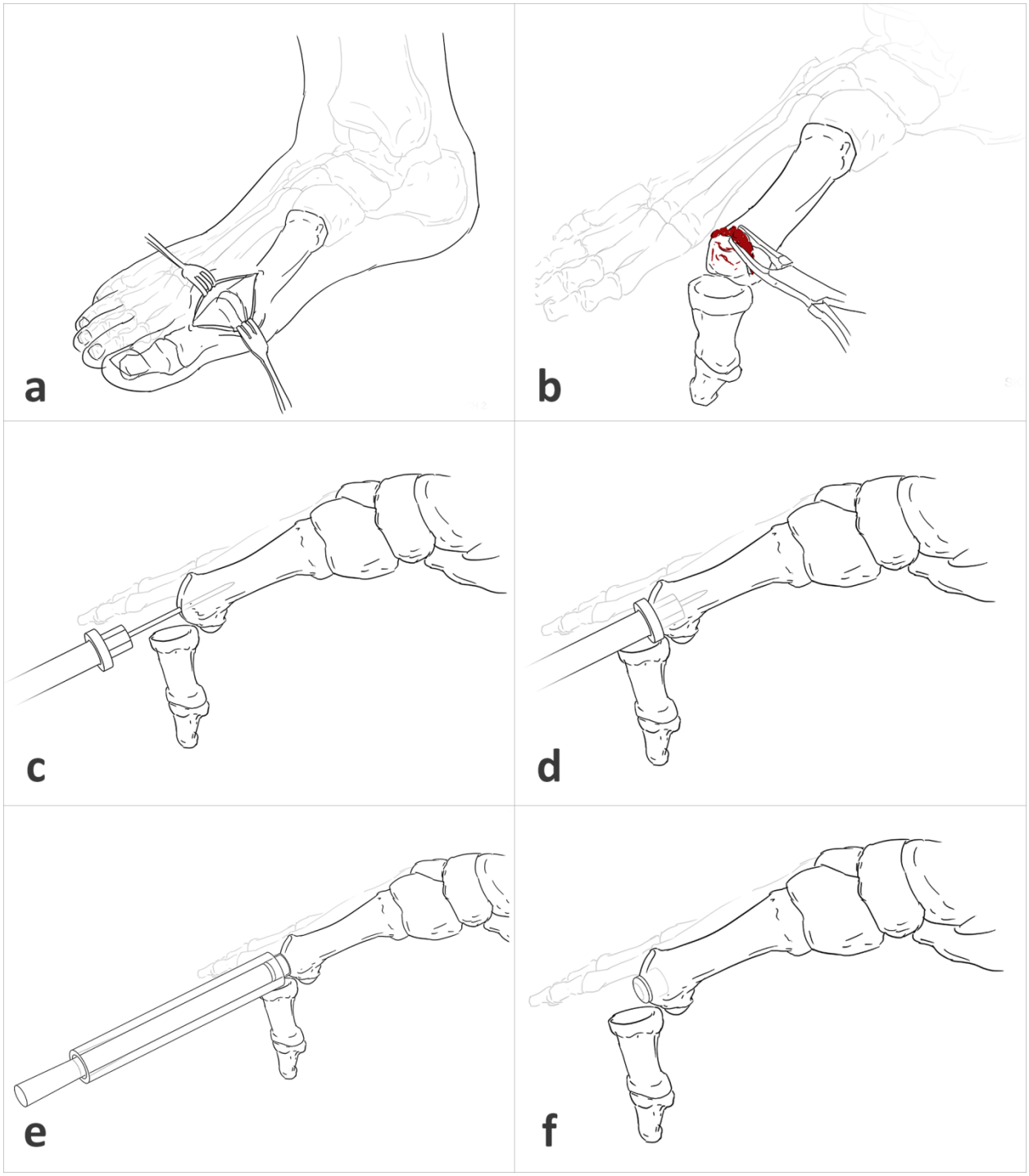

Table 1: Baseline demographics and outcome measure scores of implant hemiarthroplasty and arthrodesis modified Intent to Treat (mITT) cohorts, shown as mean ± standard deviation, with the range in brackets

Factor	Implant Hemiarthroplasty (n=130)	Arthrodesis (n=50)	t-test *p*-value[a]	Wilcoxon *p*-value[b]
Age at surgery (years)	57.4 ± 8.8 (30.5 – 79.2)	54.9 ± 10.5 (32.4 – 78.2)	0.115	0.097
Gender, n (%)			0.558	0.535
Male	26 (20%)	12 (24%)		
Female	104 (80%)	38 (76%)		
BMI (kg/m^2)	27.2 ± 4.4 (19.1 – 37.1)	26.3 ± 4.7 (19.1 – 41.6)	0.222	0.175
Outcome Measures				
VAS Pain	68.0 ± 13.9 (27.8 – 100.0)	69.3 ± 14.3 (38.0 – 97.5)	0.571	0.529
FAAM Sports	36.9 ± 20.9[d] (0.0 – 100.0)	35.6 ± 20.5 (0.0 – 87.5)	0.694	0.502
FAAM ADL	59.4 ± 16.9[c] (7.1 – 100.0)	56.0 ± 16.8 (22.6 – 95.2)	0.222	0.152
SF-36 PF	52.4 ± 22.8 (0.0 – 100.0)	49.8 ± 23.6 (15.0 – 100.0)	0.499	0.352

Abbreviations: BMI, body mass index; FAAM, Foot and Ankle Ability Measure; ADL, Activities of Daily Living; SF-36 PF, Short Form-36 Physical Function subscore

[a]Two-sample pooled t-test *p*-value (chi-square test for gender).

[b]Two-sample Wilcoxon rank-sum test *p*-value (Fisher's exact test for gender).

[c] n=129 for this score only.

[d] n=127 for this score only

Table 2: Success rates of synthetic cartilage implant hemiarthroplasty of the first metatarsophalangeal joint (n=129) and first metatarsophalangeal joint arthrodesis (n=47), stratified by patient factors.

Patient Variable	**Stratification**	**Synthetic Implant Hemiarthroplasty**				**Arthrodesis**				***p*-value‡**
		N^	**n~**	**% Success**	***p*-value***	**N^**	**n~**	**% Success**	***p*-value***	
Coughlin[5] Hallux Rigidus Grade	2	36	26	72.2%	0.364	18	12	66.7%	0.331	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%	0.797	34	28	82.4%	0.429	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%	0.308	4	2	50.0%	0.357	0.580
	≥30° to <40°	22	17	77.3%		10	9	90.0%		0.637
	>10° to <30°	72	56	77.8%		26	21	80.1%		0.999
	≤10°	25	23	92.0%		7	5	71.4%		0.201
Gender	Female	104	81	77.9%	0.405	36	29	80.6%	0.679	0.817
	Male	25	22	88.0%		11	8	72.7%		0.343
Age	≥65 years	22	20	90.9%	0.243	9	9	100%	0.172	0.999
	<65 years	107	83	77.6%		38	28	73.7%		0.659
Body Mass Index (BMI)	<30 kg/m^2	94	76	80.9%	0.629	39	30	76.9%	0.667	0.640
	≥30 kg/m^2	35	27	77.1%		8	7	87.5%		0.999
Duration of Symptoms Prior to Surgery	<24 months	15	10	66.7%	0.183	3	3	100%	1.000	0.522
	≥24 months	114	93	81.6%		44	34	77.3%		0.655
Prior MTPJ1 Surgery	Prior surgery[1]	12	8	66.7%	0.259	4	4	100%	0.564	0.516

Status	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%	0.196	2	1	50.0%	0.140	0.999
	Moderate (≥40 to ≤58 mm)	27	24	88.9%		8	8	100.0%		0.999
	Severe (>58 to 100 mm)	100	78	78.0%		37	28	75.7%		0.819

* *p*-values were determined using Fisher's Exact test, within group.

‡ *p*-values were determined using Fisher's Exact test, between groups within strata.

^ 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 <40 mm was an exclusion criterion for the study; these patients were protocol violations.

[3]Coughlin MJ, Shurnas PS. Hallux rigidus. Grading and long-term results of operative treatment. *J Bone Joint Surg Am.* 2003;85-A(11):2072-2088.