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Original Research

A Retrospective Cohort Study of the BioPro® Hemiarthroplasty Prosthesis

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ABSTRACT

We reviewed the outcomes of 79 procedures in 76 patients who underwent first metatarsophalangeal joint hemiarthroplasty. The cohort included 23 men (2 bilateral cases) and 53 women (1 bilateral case), with a mean age of 59.6 ± 11.05 years and a mean follow-up of 2.91 years (range, 1.6-4.5 years). Hemiarthroplasty with the BioPro Hemi Implant (BioPro, Inc., Port Huron, MI) was undertaken in all cases, and 34 (43.04%) of the procedures involved long flexor transfer to the proximal phalanx. Mean first metatarsophalangeal joint dorsiflexion increased from 36.13° ± 17.89° to 56.92° ± 9.82° ($P < .0001$), plantarflexion increased from 2.71° ± 8.43° to 9.05° ± 4.52° ($P < .0001$), the first intermetatarsal angle decreased from 8.65° ± 1.17° to 8.41° ± 0.90° ($P = .0009$), and the prevalence of first-ray elevatus went from 52 (65.82%) to 44 (55.70%) ($P = .0047$). Postoperative prevalences included: antalgic gait, 11 (13.92%); normal hallux purchase, 74 (93.67%); satisfaction with the appearance of the great toe, 49 (62.03%); ability to wear conventional shoes, 42 (53.16%); freedom from pain, 45 (56.96%); and satisfaction or high level of satisfaction with the outcome, 68 (86.08%). The mean postoperative American College of Foot and Ankle Surgeons Universal Evaluation score was 94.00 (range, 44-100). Eight (10.13%) cases experienced complications: 2 severe pain (1 required implant removal), 1 sesamoiditis, 1 extensor hallucis longus contracture, 1 hallux subluxation and 1 dislocation, and 2 misaligned implants. Based on these results, use of the BioPro hemi-implant is a useful option for the treatment of first metatarsophalangeal joint degeneration.

Hallux valgus, hallux limitus, and hallux rigidus are common deformities of the adult forefoot, and patients with first metatarsophalangeal joint (MTPJ) osteoarthritis typically experience pain and functional limitations. Conservative treatment of these conditions includes the judicious use of soluble steroid injections, oral antiinflammatory medications, physical therapy, and biomechanical control with either functional or accommodative foot orthoses. When conservative treatment options are exhausted or fail, surgical intervention is indicated. Surgical options for these degenerative conditions of the first MTPJ include synovectomy, cheilectomy, phalangeal and/or metatarsal osteotomy, partial joint resection, joint replacement, and arthrodesis (1). Although combined synovectomy and cheilectomy provide a less aggressive surgical approach, osteotomy may be required to correct joint orientation, metatarsal position, and metatarsal length. Joint reorientation options such as a shortening decompression osteotomy, or an angular osteotomy, can be used to correct osseous deformities of the damaged first MTPJ. In fact, a decompression osteotomy can, in certain instances, be used to reduce the first intermetatarsal angle (IMA) and realign the proximal articular set angle (2), and this may result in increased first MTPJ range of motion. If desired, the surgeon can modify a decompression osteotomy to shorten and plantarflex the first metatarsal. Furthermore, joint destruction procedures such as resection arthroplasty, arthrodesis, or partial or total joint replacement are generally considered surgical options for severely damaged joints. Overall, the procedure of choice for the treatment of first MTPJ degeneration that has not responded satisfactorily to nonsurgical interventions should be based on the functional needs of the patient, the structural characteristics of the joint, and the skills of the surgeon (3). Drago et al. (4) described 4 categories of first MTPJ degeneration (Table 1) and noted that grades 2, 3, and 4 typically warrant surgical repair. Criteria for

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Table 1
Drago, Oloff, and Jacobs scale of hallux limitus (4)

Grade	Description of the joint
1	Functional hallux limitus with minimal adaptive changes
2	Joint adaptation, development of proliferative, destructive joint changes
3	Joint deterioration, arthritis, established arthrosis
4	Ankylosis

joint replacement include severe degenerative joint disease and decreased, painful range of motion. This type of advanced joint disease in patients who have not sustained acute articular injury is more prevalent in patients 50 years of age and older. Contraindications to joint replacement include a history of joint or adjacent bone infection, poor bone stock, inadequate soft tissue coverage, and a joint that can be preserved by means of osteotomy or other reconstructive options. In addition, many surgeons consider implant surgery in a young patient as relatively contraindicated (5). In general, joint replacement or resurfacing procedures should be avoided in young patients, as well as in those who are required to participate in significant weight bearing activities. However, if conservative measures have failed and joint preservation reconstructive surgery is not an option for a symptomatic young patient, we believe that implantation of an endoprosthesis, resection arthroplasty, or fusion should be considered (5).

The BioPro metallic hemiarthroplasty resurfacing prosthesis for the hallux MTPJ (BioPro, Inc.) (Figure 1) was designed by Charles O. Townley, MD. The implant, which has been in continuous use for more than 52 years, replaces the articular surface of the proximal phalanx of the great toe (3). In 1994, Townley reviewed 279 cases that ranged over a 40-year period, and follow-up revealed good to excellent clinical results in 95% of the cases (3). The joint resurfacing prosthesis is designed to simulate the articular surface of the proximal phalanx and thereby restore unconstrained triplanar joint function. Currently, the implant is available in 4 sizes and is made of either cobalt chrome or titanium in both nonporous and porous-coated models. A porous coat on the stem and nonarticular surface of the implant allows cancellous bone in-growth up to the surface of the implant, thereby increasing stability in the phalanx. Although Townley recommended the use of an approximately 2-mm resection of the base of the proximal phalanx (3), we typically resect 4 to 5 mm to shorten the skeletal segment, decompress the joint, and increase range of motion. Moreover, by means of careful dissection of the transected base of the proximal phalanx, the intrinsic musculature attachments and vascularity are preserved (3). In particular, flexor hallucis brevis is preserved intact to maintain the sagittal plane stability and position of the first MTPJ. Furthermore, abductor and adductor hallucis attachments are preserved attached to the periosteum of the proximal phalanx in an effort to further preserve the transverse plane stability of the hallux.

Fig. 1. The BioPro first MTPJ (BioPro, Inc., Port Huron, MI) implant.

Patients and Methods

Patient Population

A retrospective analysis of the records of 76 consecutive patients who underwent implantation of the BioPro first MTPJ (BioPro, Inc.) implant between January 2002 and December 2004, was undertaken by all of the authors. In order to be included in the cohort, the patient had to have undergone reconstructive first-ray surgery with implantation of the BioPro proximal phalangeal resurfacing hemiprosthesis.

Intervention

All of the operations were performed by two of the coauthors (DCN and MMP) and entailed an incision made over the first MTPJ just dorsal and medial to the extensor hallucis longus tendon (Figure 2). The dissection was then carried down to the capsule of the first MTPJ, where a linear capsulotomy was made over the joint just medial to the extensor hallucis longus tendon. After careful dissection of the first MTPJ, with preservation of the attachments of the flexor hallucis brevis tendons, the joint was evaluated (Figure 3). The base of the proximal phalanx was then resected, taking care to make the thickness of the removed portion of the bone 3 to 4 mm greater than the thickness of the articulating flange of the implant (Figure 4). This was done to accommodate the thickness of the articulating flange of the implant, which was placed in the joint and oriented parallel to the articulating surface of the metatarsal head (Figure 5). Care was taken to avoid release of the attachments of the flexor hallucis brevis tendons to the base of the proximal phalanx when the base was excised. Identification of the flexor hallucis longus (FHL) tendon after resection of the phalangeal base suggested that the attachments of the short flexor had been detached (Figure 6). In such cases, the FHL tendon was attached to the plantar-central aspect of the proximal cortical margin of the proximal phalanx with a 2-0 suture as an adjunct procedure to increase the sagittal plane stability of the great toe.

After resection of the proximal phalangeal base, osteophytic spurs on the metatarsal head were removed dorsally, medially, and laterally, and the metatarsal head contoured to allow for smooth, triplanar translation of the implant over the residual articular cartilage. If indicated, repositioning the distal aspect of the first metatarsal by means of a joint decompression or angulational osteotomy was undertaken, and the position of the first metatarsal evaluated intraoperatively to avoid excessive lengthening, shortening, and elevatus.

After resection of the phalangeal base and preparation of the first metatarsal segment, the medullary canal broach was used to create an intramedullary canal in the proximal phalanx for reception of the stem of the implant. The canal was oriented parallel to the long axis of the phalanx, and it is important to understand that an improperly oriented canal could allow the stem to infringe on and penetrate the adjacent cortical margin, thereby destabilizing the implant and joint. For this reason, checking the orientation and fit of the implant with trial sizers was an important element of the operation (Figures 7, 8, and 9). Because the implant is a press-fit design, the medullary canal broach is actually smaller than the stem of the implant, and the implant has to be steadily tapped into place in the medullary canal to create a tight fit (Figures 10 and 11). Proper fitting required that the articulating base flange of the implant matched the contour of the cortical rim of the remaining portion of the

Fig. 2. Incision placement dorsomedial over the first MTPJ.

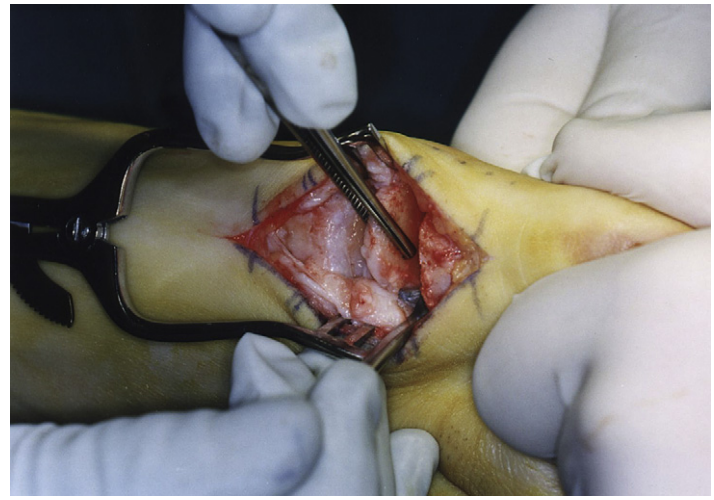

Fig. 4. Removal of the base of the proximal phalanx.

proximal phalanx. If the implant is smaller than the cortical rim, there is increased risk of bony overgrowth and intramedullary subsidence of the implant itself. Moreover, an oversized implant might impinge on the periarticular structures, including the extensor and flexor tendons, and this could lead to the development of tenosynovitis. After assessing the fit of the implant, an assessment of the quality and range of motion was undertaken (Figure 12). Once the fit and function of the implant was satisfactory, the wound was closed in layers and bandaged, after which the patient was allowed to bear weight in a surgical shoe or, if proximal metatarsal osteotomy precluded weight bearing, bracing and non-weight bearing was used. In every case, mobilization of the first MTPJ was initiated within 7 to 10 days of the operation to optimize postoperative joint mobility. If the patient displayed difficulty establishing joint motion, then professional physical therapy was used to enhance range of motion, strength, and function of the first MTPJ hemiprosthesis.

Outcomes

A successful outcome was defined as the absence of postoperative pain, as well as the patient's satisfaction or high level of satisfaction with the outcome of the operation. Other independent variables that were abstracted from the medical records and radiographs and considered in the analyses included patient age (years) and age category (age $<$ 50 years, age 50 to $<$ 65 years, and age $\geq$ 65 years), sex, the presence in the preoperative state of hallux valgus (yes/no), the Drago, Oloff, and Jacobs grade of hallux rigidus (grade 1—functional hallux limitus with minimal adaptive changes, grade 2—joint adaptation with development of proliferative destructive changes, grade 3—joint deterioration with arthritis and established arthrosis, grade 4—ankylosis) (Table 1) (4), the anatomical side (right or left) of the surgery, adjunct surgical procedures (defined as none, 1 = first ray, 2 = lesser ray, 3 = first and lesser ray), flexor hallucis longus tendon transfer to the proximal phalanx (yes/no), patient comorbidities (defined as none, hypertension, peripheral arterial disease, systemic arthritis or other connective tissue disease, multiple comorbidities including diabetes mellitus, multiple comorbidities excluding diabetes mellitus, or other disorders [skin cancer, mitral valve prolapse, cholecystitis, duodenal ulcer, hypercholesterolemia, anxiety/depression, asthma, lumbar disk disease, mononeuritis]), whether previous surgery had been performed on the operated joint (yes/no), cigarette smoking status (defined as never, previous, or current), preoperative and postoperative first MTPJ dorsiflexion and plantarflexion, preoperative and postoperative first IMA, preoperative and postoperative first metatarsal elevatus (measured as the sagittal plane difference in millimeters between the dorsal cortices at the junction of the middle and distal thirds of the shafts of the first and second metatarsals), postoperative hallux abductus angle, postoperative hallux purchase (yes/no), implant size (small, medium, medium-large, large), postoperative antalgic gait (yes/no), postoperative satisfaction with the appearance of the great toe (neutral, pleased, disliked), postoperative toe function normal (yes/no), postoperative ability to wear normal/desired (excluding shoes with a heel height $>$1.5 inches) shoe gear (yes/no), postoperative pain (none, mild, moderate, severe), postoperative satisfaction with the outcome of the surgery (not satisfied, satisfied, very satisfied), and the duration of postoperative follow-up in years. We also obtained American College of Foot and Ankle Surgeons (ACFAS) Universal Evaluation scores (6) for all of the patients in the postoperative phase (Table 2). All of the postoperative ranges of motion were measured by a physical therapist who did not participate in the surgery or in the study in any other way, and who was unaware of the preoperative measurements. The radiographic measurements were made by one of the coauthors (CCS), who also abstracted the clinical information from the records.

Analyses

All of the independent variables and outcomes were characterized by estimating means and standard deviations, medians and ranges, and by a visual assessment of the distribution of the data with attention paid to skewing. We undertook univariate

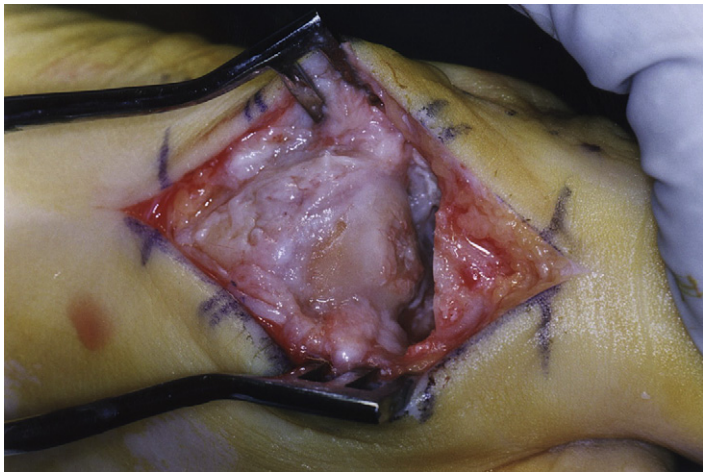

Fig. 3. Evaluation of the first MTPJ joint articular surfaces.

Fig. 5. Comparing the base of the proximal phalanx with the implant.

Fig. 6. Evaluation of the flexor hallucis longus tendon.

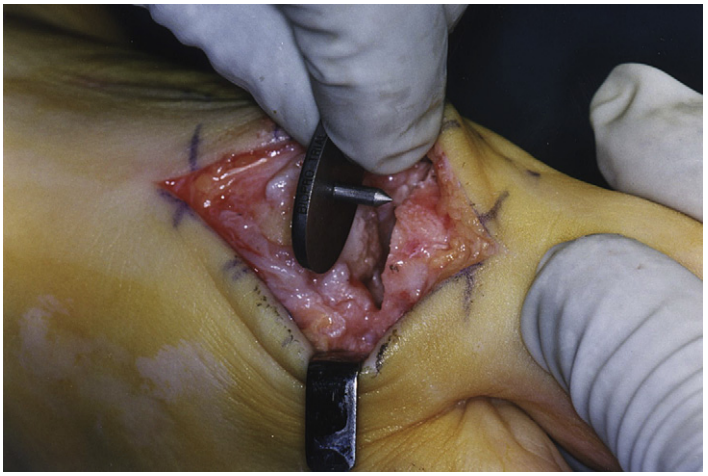

Fig. 8. Trial sizer.

assessments of association using chi-square statistics and the Wilcoxon rank-sum test, with a focus on estimating the unadjusted incidence of postoperative success after implantation of the BioPro hemi-endoprosthesis. We also estimated the association of various risk factors (independent variables) with the probability that a patient having undergone the surgery would experience a successful outcome during the observation period. Because of the lack of true independence between the independent variables (some of the patients underwent surgery on both feet), rather than using univariate (unadjusted) and multiple variable (adjusted) logistic regression to assess the magnitude of the effect of a given risk factor on the outcome, both fixed effects and random effects models using generalized estimation equations were used to more conservatively calculate the effect estimates (7). In consideration of the potential influence that unmeasured variables may have had on our effect estimates, we also performed a Greenland sensitivity analysis (8) by programming a sensitivity analysis calculator with spreadsheet software (Microsoft Excel 2008 for Mac, Version 12.2.1; Microsoft Corporation, Redmond, WA) and inputting a range of values for the hypothetical prevalence of unmeasured variables, after which we analyzed the effect that these variables could potentially have on our point estimates as determined by our measured variables. With the exception of the sensitivity analysis, all of the analyses were conducted on a personal computer with Stata/SE 9.2 for Macintosh (Stata Corporation, College Station, TX), by one of the coauthors who did not participate in any of the operations or data collection (DSM). Statistical significance was defined at the 5% ($P \leq .05$) level.

Results

The cohort consisted of 76 patients, 23 (30.26%) men and 53 (69.74%) women, who underwent 79 resurfacing hemiarthroplasties of the first MTPJ. Surgical indications for the operation included failure of conservative treatment, chronic first MTPJ pain, degenerative osteoarthritis of the first MTPJ, and decreased ambulation and functional status. All of the implants in this series were cobalt chrome with porous, coated stems. It should be noted that the range of motion of the interphalangeal and MTPJs was measured preoperatively in only 38 (50%) of the 76 patients, and postoperatively in all of the patients. Table 3 shows the overall prevalences of the independent variables for the entire cohort. The mean age of the cohort was 59.6 ± 11.05 years (range, 35-81 years), and there were 25 (31.65%) procedures performed in men and 54 (68.35%) in women. The mean duration of follow-up was 2.91 ± 0.80 years (range, 1.6-4.50 years). A little more than half (50.63%) of the patients displayed Drago, Oloff, Jacobs grade 1 hallux rigidus. Range of motion of the hallux interphalangeal and MTPJ was measured preoperatively in only 39 (49.37%) of the cases, whereas postoperative measurements for these ranges of motion were available for all of the cases. Table 4 reveals the results of the statistical comparisons between the preoperative and postoperative measurements for the entire cohort, which show statistically significant ($P < .0001$) increases in the range of postoperative dorsiflexion and plantarflexion in comparison with the preoperative measurements. Specifically, the mean preoperative first MTPJ dorsiflexion was 36.13 ± 17.89 (range, 0-80), the postoperative

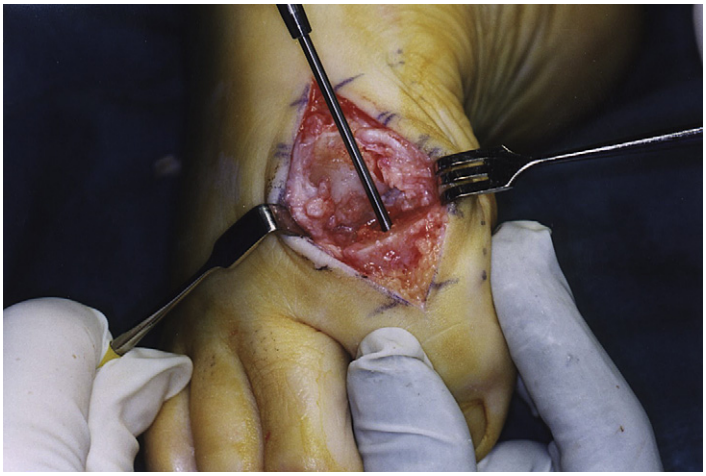

Fig. 7. Preparing the canal for the trial sizer.

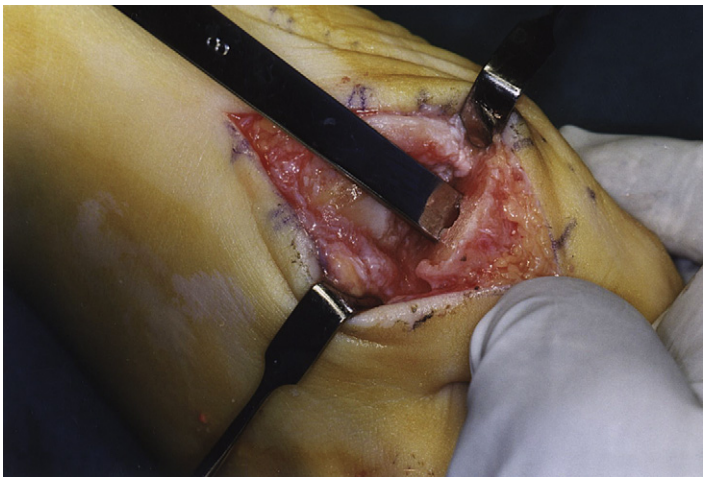

Fig. 9. Preparing the canal for the proximal phalangeal implant.

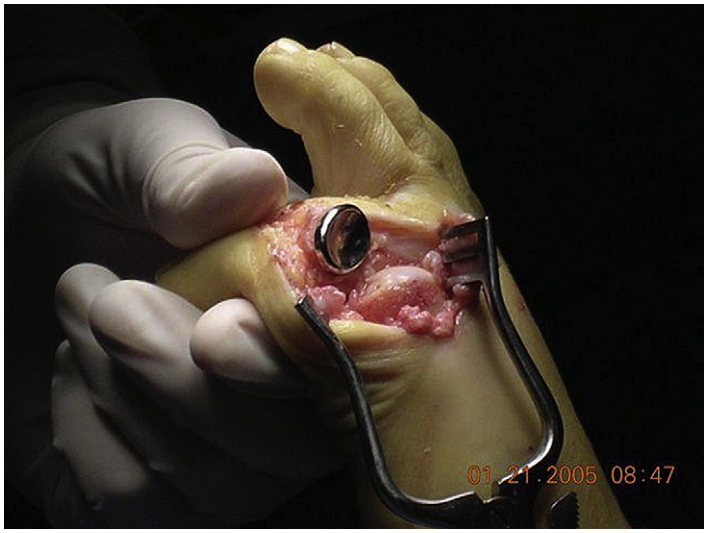

Fig. 10. Placement of the proximal phalangeal hemiarthroplasty resurfacing implant.

range was 56.92 ± 9.82 (range, 25-80), and the increase in dorsiflexion was statistically significant ($P < .0001$). The mean preoperative first MTPJ plantarflexion was 2.71 ± 8.43 (range, 10 to 25), the postoperative range was 9.05 ± 4.52 (range, 5 to 25), and this increase was statistically significant ($P < .0001$). The mean preoperative first IMA was 8.65 ± 1.17 (range, 7-13) the postoperative IMA was 8.41 ± 0.90 (range, 7-12), and this decrease was statistically significant ($P = .0009$). Still further, in the preoperative state, 52 (65.82%) of the patients displayed first-ray elevatus, whereas 44 (55.70%) displayed elevatus in the postoperative period, and this difference was statistically significant ($P = .0047$).

We identified 8 (10.13%) procedures that were associated with postoperative complications. Of these, 2 (2.53%) cases were associated with persistent joint pain, and 1 (1.27%) of these required a return to the operating room for removal of the implant. One (1.27%) other patient experienced sesamoiditis due to implant impingement, and another patient (1.27%) experienced extensor hallucis longus contracture. Two (2.53%) patients experienced hallux malposition, one of which was subluxation and the other dislocation at the implant-metatarsal articulation. Two (2.53%) other cases displayed radiographic evidence of implant malposition without clinical malposition, one of which involved transverse plane misalignment, and the other involved plantarflexion of the implant.

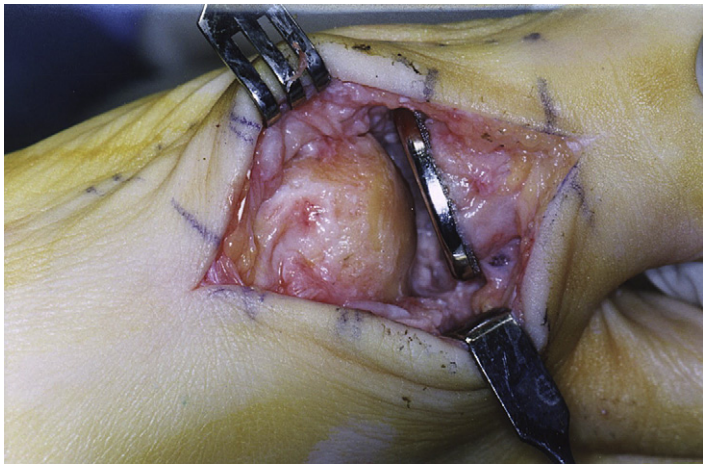

Fig. 11. The endoprosthesis in place.

Fig. 12. Testing the tension and range of motion.

For the purposes of the investigation, a successful outcome was defined as experiencing no postoperative pain, as well as subjectively the patient's subjective satisfaction or high level of satisfaction with the results of the operation. In regard to patient satisfaction during the postoperative period, none of the cases in the successful group were associated with patient dissatisfaction with the outcome, whereas 9 (20.93%) of the successful cases were associated with patient satisfaction and 34 (79.07%) were associated with a high level of patient satisfaction. Keep in mind that there were some patients with residual pain who were subjectively satisfied with the outcome of the operation. Specifically, 24 (35.29%) of the satisfied or very satisfied patients reported mild postoperative pain, 1 (1.47%) had moderate pain, and none had severe pain. The unadjusted incidence of the primary outcome, namely a successful result after implantation of the BioPro first MTPJ hemi-implant was 54.43% (43/79) of the operations over the 2.91 ± 0.80 month duration of the postoperative observation period. Table 5 shows that the patients who experienced a successful outcome were very similar at baseline to those who experienced failure. Specifically, the mean age of the patients in the group that achieved success was 59.14 ± 11.74 years, and in the failure group 60.14 ± 10.31, and this difference was not statistically significant ($P = .6084$). There were 15 (34.88%) men in the success group, and 10 (27.78%) in the failure group, and this difference was not statistically significant ($P = .5016$). The mean duration of follow-up for the overall group was 2.91 years (range, 1.6-4.5 years); and that for the success group was 2.77 ± 0.73 years, and for the failure group 3.07 ± 0.86, and this difference was not statistically significant ($P = .1346$). Statistically significant differences were not observed between the success and failure groups in regard to a number of other baseline characteristics, including the presence of hallux valgus, the Drago, Oloff, and Jacobs grade of hallux rigidus (4), adjunct procedures performed in conjunction with the implant surgery, transfer of the flexor hallucis longus tendon to the base of the proximal phalanx, the side on which the surgery was performed, the size of the implant, the presence of comorbidities, and whether previous first-ray surgery had been performed. Table 5 also shows that active smoking was statistically significant (P=.0205); it was more prevalent in the group of patients who experienced a successful outcome. Moreover, normal postoperative function ($P = .0136$), the ability to wear regular shoes ($P < .0001$), and subjective satisfaction ($P = .0001$) were, as one might expect, statistically significantly more prevalent in the group of patients who experienced a successful outcome. On the other hand, the presence of an antalgic postoperative gait was statistically significantly ($P = .0012$) more prevalent in the group that failed to

Table 2
American College of Foot and Ankle Surgeons Universal Evaluation Scoring Scale (100 points total)

Category (points)	Question or measurement (points)		Answer (points)
Pain (30)	Over the past month how has your foot pain limited your daily activities? (30)		No pain with normal activity (30) Slight or occasional pain, no compromise in activities (22) Moderate pain, slight effect on activities (14) Pain with serious limitation of activities (6) Severe pain with total limitation of activities (0)
Appearance (5)	How do you rate the appearance of your big toe joint? (5)		I like it very much (5) I mostly like it (4) I'm not sure either way (neutral) (3) I mostly don't like it (2) I dislike it very much (0)
Functional capacities (15)	How frequently do you have pain while wearing shoes? (15)		I am able to continuously wear any type of shoe (15) I am able to wear any type of shoe most of the time (10) I am able to wear only walking, athletic, or casual shoes (5) I am able to wear only special order, orthopedic, or custom shoes (0)
Radiographic (18)	Hallux abductus angle (°) (6)		0° to 20° (6) 21 to 30 (3) –1 to –3 (2) < –3 or > 31 (0)
	First intermetatarsal angle (°) (6)		≥ 20 (0) 11 to 19 (3) 0 to 10 (6) < 0 (0)
	First metatarsal declination angle (°) (6)		16 to 24 (6) 10 to 15 (3) 25 to 29 (3) < 10 (0) > 29 (0)
Function (32)	Hallux purchase (paper pull-out) (10)		Not movable (10) Resistant (5) Easy (0)
	First ray range of motion (°) (17)	Dorsiflexion first MTPJ (11)	≥ 60 (11) 46 to 59 (8) 36 to 45 (4) < 36 (0)
		Plantarflexion first MTPJ (4)	≥ 0 (4) < 0 (0)
		Extension hallux IPJ (2)	≥ 0 (2) < 0 (0)
	Limp due to foot pain (unshod) (5)		No (5) Yes (0)

Abbreviations: MTPJ, Metatarsophalangeal joint; IPJ, interphalangeal joint.

Table 3
Overall prevalences of independent variables for the entire cohort (N = 79 feet in 76 patients)

Variable	Mean ± standard deviation (minimum, maximum) for continuous numeric data, or count (%) for categorical data
Age (y)	59.6 ± 11.05 (35, 81)
Age < 50 y	15 (18.99)
Age 50 to < 65 y	39 (49.37)
Age ≥ 65 y	25 (31.65)
Male sex	25 (31.65)
Hallux valgus	9 (11.39)
Drago, Oloff, Jacobs grade 1	40 (50.63)
Drago, Oloff, Jacobs grade 2	15 (18.99)
Drago, Oloff, Jacobs grade 3	14 (17.72)
Drago, Oloff, Jacobs grade 4	10 (12.66)
Any adjunct surgery	39 (49.37)
Flexor transfer	34 (43.04)
Right side	40 (50.63)
Any comorbidity	57 (72.15)
Previous first MTPJ surgery	12 (15.19)
Current smoker	6 (7.59)
Preop dorsiflexion (°)*	36.13 ± 17.89 (0, 80)
Postop dorsiflexion (°)	56.53 ± 9.82 (25, 80)
Preop plantarflexion (°)*	2.71 ± 8.43 (–10, 25)
Postop plantarflexion (°)	9.05 ± 4.52 (–5, 25)
Preop intermetatarsal angle (°)	8.65 ± 1.17 (7, 13)
Postop intermetatarsal angle (°)	8.41 ± 0.90 (7, 12)
Preop elevatus	52 (65.82)
Postop elevatus	44 (55.70)
Postop hallux abductus angle normal	77 (97.47)
Hallux purchase	74 (93.67)
Implant small	42 (53.16)
Implant medium	21 (26.58)
Implant medium-large	12 (15.19)
Implant large	4 (5.06)
Postop antalgic gait	11 (13.92)
Postop appearance neutral	24 (30.38)
Postop appearance pleased	49 (62.03)
Postop appearance disliked	6 (7.59)
Postop function normal	66 (83.54)
Wears regular shoes	42 (53.16)
No postop pain	45 (56.96)
Mild postop pain	26 (32.91)
Moderate postop pain	5 (6.33)
Severe postop pain	3 (3.80)
Postop satisfied or very satisfied	68 (86.08)
Follow-up duration (y)	2.91 ± 0.80 (1.6, 4.50)

Abbreviation: MTPJ, Metatarsophalangeal joint.
* Only 39 (49.37%) cases of preoperative dorsiflexion and plantarflexion first MTPJ and interphalangeal joint range of motion measurements were available for use in the analyses.

experience a successful outcome. Furthermore, a statistically significant ($P = .001$) trend for a greater prevalence of patients to be satisfied with the appearance of their operated foot existed in the group that experienced a successful outcome. Similarly, there was a statistically significant ($P < .0001$) trend for a greater prevalence of patients without postoperative to be in the group that experienced a successful outcome.

In regard to the ACFAS Universal Evaluation Scoring Scale (6) for the first MTPJ and first ray, this measurement was only obtained for patients in the postoperative period (data not shown), and the mean value was 94.00 (range, 44-100).

Table 6 shows the unadjusted (univariate) likelihood (odds ratio), and 95% confidence interval for the estimate, of experiencing a successful outcome for selected independent variables. These results indicate that the presence of hallux valgus in the preoperative period, as well as each additional 1° range of postoperative dorsiflexion, and the presence of first metatarsal elevatus in the postoperative phase, were not statistically significant in association with achieving the outcome. However, the presence of a postoperative complication, as well as the presence of an antalgic gait in the postoperative phase, was statistically significant in association with a decreased likelihood of experiencing a successful outcome

Table 4
Statistical comparisons between preoperative and postoperative measurements for the entire cohort (N = 79 cases in 76 patients)*

Variable	Preoperative	Postoperative	*P* value†
First MTPJ dorsiflexion (°)	36.13 ± 17.89	56.92 ± 9.82	< .0001
First MTPJ plantarflexion (°)	2.71 ± 8.43	9.05 ± 4.52	< .0001
First intermetatarsal angle (°)	8.65 ± 1.17	8.41 ± 0.9	.0009
First ray elevatus (yes/no)	52 (65.82)	44 (55.70)	.0047

Abbreviation: MTPJ, Metatarsophalangeal joint.
* Only 39 preoperative dorsiflexion and plantarflexion first MTPJ range-of-motion measurements were available for use in the analyses.
† Wilcoxon rank-sum (Mann-Whitney *U*) or signed ranks test.

Table 5
Prevalences of independent variables by outcome (N = 79 feet in 76 patients)

Independent variable	Success* (n = 43)	Failure (n = 36)	*P* value
Age (y [mean ± SD])	59.14 ± 11.74	60.14 ± 10.31	.6084^
Age < 50 y (count [%])	10 (23.26)	5 (13.89)	.486†
Age 50 to < 65 y (count [%])	19 (44.19)	20 (55.56)	
Age ≥ 65 y (count [%])	14 (32.65)	11 (30.56)	
Male sex (n = 25) (count [%])	15 (34.88)	10 (27.78)	.5016^
Hallux valgus (count [%])	7 (16.28)	2 (5.56)	.1377^
Drago, Oloff, Jacobs grade 1	21 (48.84)	19 (52.78)	.874†
Drago, Oloff, Jacobs grade 2	8 (18.60)	7 (19.44)	
Drago, Oloff, Jacobs grade 3	9 (20.93)	5 (13.89)	
Drago, Oloff, Jacobs grade 4	5 (11.63)	5 (13.89)	
Adjunct surgery (count [%])	18 (41.86)	21 (58.33)	.1473^
Flexor transfer (count [%])	19 (44.19)	15 (41.67)	.8229^
Right side (count [%])	25 (58.14)	15 (41.67)	.1473^
Any comorbidity (count [%])	31 (72.09)	26 (72.22)	.9899^
Previous first MTPJ surgery (count [%])	4 (9.3)	8 (22.22)	.1134^
Current smoker (count [%])	6 (13.95)	0	.0205^
Preop dorsiflexion (°) (mean ± SD)§	36.88 ± 16.94	34.93 ± 19.87	.5924^
Postop dorsiflexion (°) (mean ± SD)	58.74 ± 9.66	54.75 ± 9.69	.06^
Preop plantarflexion (°) (mean ± SD)§	1.7 ± 7.61	4.27 ± 9.61	.3590^
Postop plantarflexion (°) (mean ± SD)	9.07 ± 4.42	9.03 ± 4,69	.5773^
Preop intermetatarsal angle (°) (mean ± SD)	8.68 ± 1.17	8.61 ± 1.18	.6481^
Postop intermetatarsal angle (°) (mean ± SD)	8.47 ± 1.11	8.35 ± 0.69	.9522^
Preop elevatus (count [%])	32 (74.42)	20 (55.56)	.0802^
Postop elevatus (count [%])	26 (60.47)	18 (50.00)	.3541^
Postop hallux abductus angle normal (count [%])	43 (100)	34 (94.44)	.1198^
Hallux purchase (count [%])	42 (97.67)	32 (88.89)	.1125^
Implant small (count [%])	27 (62.79)	15 (41.67)	.308†
Implant medium (count [%])	9 (20.93)	12 (33.33)	
Implant medium-large (count [%])	5 (11.63)	7 (19.44)	
Implant large (count [%])	2 (4.65)	2 (5.56)	
Postop antalgic gait (count [%])	1 (2.33)	10 (27.78)	.0012^
Postop appearance neutral (count [%])	9 (20.93)	15 (41.67)	.001†
Postop appearance pleased (count [%])	34 (79.07)	15 (41.67)	
Postop appearance disliked (count [%])	0	6 (16.67)	
Postop function normal (count [%])	40 (93.02)	26 (72.22)	.0136^
Wears regular shoes (count [%])	34 (79.07)	8 (22.22)	< .0001
No postop pain (count [%])	43 (100)	2 (5.56)	< .0001†
Mild postop pain (count [%])	0	26 (72.22)	
Moderate postop pain (count [%])	0	5 (13.89)	
Severe postop pain (count [%])	0	3 (8.33)	
Postop satisfied or very satisfied (count [%])	43 (100)	25 (69.44)	0.0001^
Follow-up duration (y) (mean ± SD)	2.77 ± 0.73	3.07 ± 0.86	0.1346^

Abbreviation: MTPJ, Metatarsophalangeal joint.
* Success defined as no pain, and either satisfied or highly satisfied (there were patients with residual pain who were satisfied: 24 [35.29%] had mild pain, 1 [1.47%] had moderate pain, and none had severe pain).
^ Wilcoxon rank sum (Mann Whitney-*U*) test.
† Chi-square test for trend across ordered groups.
§ Only 39 preoperative dorsiflexion and plantarflexion first metatarsophalangeal joint range-of-motion measurements were obtained.

(odds ratio < 1, and 95% confidence interval crossing unity). Satisfaction with the postoperative appearance of the hallux, normal function, and the ability to wear normal shoes, were statistically significantly associated with an increased likelihood of experiencing a successful outcome; and this association was particularly strong with regard to the ability to wear normal shoes after the operation. Furthermore, analyses for the presence of confounding, as determined by >10% to 15% change in the regression coefficients, showed that the ability to wear normal shoes in the postoperative phase was confounded by the presence, in the postoperative phase, of an antalgic gait, less than full function, and dissatisfaction with the appearance of the foot.

Table 7 shows the adjusted (multiple variable) likelihood of experiencing a successful outcome for all of the independent variables that, in the univariate analyses, were statistically significant at the 10% ($P \leq .1$) level. With the exception of the ability to wear normal shoes in the postoperative period, none of the independent variables, when considered together, were statistically significant. As for the ability to wear normal shoes in the postoperative period, this remained highly statistically significant (odds ratio [OR] = 2.1284925, 95% confidence interval = 0.29217568, 15.506015) when all of the other independent variables were taken into consideration.

Finally, the results of the Greenland sensitivity analysis (results not shown) revealed our effect estimates to be resistant to the potential

Table 6
Univariate logistic regression via generalized estimation equations with success* as the outcome (dependent) variable (N = 79 cases in 76 patients)

Independent variable	Odds ratio	95% confidence interval
Preoperative hallux valgus	0.4375	0.7965057, 24.03075
Antalgic gait postoperative	0.0619048	0.0074828, 0.5121372
Satisfied with postoperative appearance	3.777778	1.35454, 10.53613
Postoperative function normal	5.128205	1.288272, 20.41376
Postoperative wears normal shoes	13.22222	4.509462, 38.76896^
Each additional 1° of postoperative dorsiflexion	1.044771	0.9953332, 1.096664
Preoperative first ray elevatus	2.909091	0.8377727, 10.10156
Any postoperative complication	0.0833333	0.009872, 0.7034451

* Success meant no pain, and either satisfied or highly satisfied (there were patients with residual pain who were satisfied: 24 [35.29%] had mild pain, 1 [1.47%] had moderate pain, and none had severe pain).
^ Statistically significant ($P = .02$).

Table 7
Multiple variable logistic regression via generalized estimation equations clustered on patient with success as the outcome (dependent) variable (N = 79 cases in 76 patients)

Independent variable	Odds ratio	95% confidence interval
Preoperative hallux valgus	2.1284925	0.29217568, 15.506015
Satisfied with postoperative appearance	3.2240618	0.88015328, 11.809957
Postoperative wears normal shoes	10.196158	3.0020008, 34.630784^
Each additional 1° of postoperative dorsiflexion	1.0271488	0.96050518, 1.0984164
Preoperative first ray elevatus	1.610373	0.84137502, 3.0822166
Any postoperative complication	0.11728657	0.00776268, 1.7720851

*Success meant no pain, and either satisfied or highly satisfied (there were patients with residual pain who were satisfied: 24 [35.29%] had mild pain, 1 [1.47%] had moderate pain, and none had severe pain).
^ Statistically significant ($P < .001$).

influence of hypothetical unmeasured variables. For instance, in regard to the ability to wear normal shoes in the postoperative period, the estimated OR did not change more than 10% up to an OR of >10 for the unmeasured confounder relative to the likelihood of achieving the outcome. Similarly, with regard to satisfaction with the appearance of the hallux after the operation, the effect estimate resisted significant change up to an OR of >9 for the unmeasured variable relative to the likelihood of achieving the outcome.

Discussion

For the purposes of the investigation, a successful outcome was defined as a patient experiencing no postoperative pain, as well as subjectively being either satisfied or highly satisfied with the results of the operation. We felt that this was a suitable outcome in that patients can be subjectively satisfied without actually being completely pain free. Of course, it was not likely that any patients with severe postoperative pain would report subjective satisfaction, and this was the case with our series of patients. Specifically, 24 (35.29%) of the patients in the success group reported mild postoperative pain, 1 (1.47%) had moderate pain, and none of the satisfied patients had severe postoperative pain. Unfortunately, we did not have preoperative subjective foot-related quality-of-life measurements that could have been used to make within-patient comparisons between the preoperative and postoperative states. Moreover, our primary outcome measurement, namely a successful outcome, was not a measurement that, to our knowledge, has been shown to convey intra-rater and inter-rater reliability. Nonetheless, we felt that our composite outcome was, at face, valid. We also felt that our definition of postoperative success was rather stringent; patients had to be subjectively satisfied or very satisfied without any postoperative pain. Despite the stringent nature of the requirements needed to define a successful outcome, the majority (54.43%, Table 5) of the patients who underwent the proximal phalangeal resurfacing hemiarthroplasty experienced success. Furthermore, we obtained postoperative ACFAS Universal Evaluation scores (6) for the first MTPJ and first ray, and although we are not aware of a published report that depicts the reliability coefficients or normative scores for any population for this outcome measurement, expert consensus seems to support the acceptability of the score. For this reason, we reported the overall mean ACFAS score of 94.00 (range, 44-100), which we feel is suggestive of a satisfactory outcome, and this information may be useful to future investigators interested in designing a prospective cohort study that focuses on the proximal phalangeal resurfacing hemiarthroplasty procedure.

With regard to the baseline characteristics of the cohort, there were no statistically significant differences between those patients who experienced a successful outcome versus those who experienced failure. Independent variables measured in the postoperative phase, namely the presence of an antalgic gait, patient satisfaction with the appearance of the toe, normal function of the hallux, the ability to wear regular shoes, the degree of postoperative pain, and subjective satisfaction with the results of the operation, were statistically significant in association with success or failure in a way that, once again, seemed to be intuitively obvious to experienced foot surgeons. And, although most of the independent variables that were statistically significant or more likely to be associated with a successful outcome were, in our opinion, rather intuitively obvious, it was interesting to note that active cigarette smoking was statistically significantly more prevalent in the group of patients who experienced a successful outcome; however, the precise meaning of this association is not known. Our results also showed that surgical implantation of the BioPro hemiprosthesis for the first MTPJ statistically significantly increased dorsiflexion and plantarflexion of the joint, in comparison with the preoperative ranges of motion. Further consideration also showed that the first IMA and first metatarsal elevatus were statistically significantly decreased, although we feel that these small changes were probably not clinically significant. Furthermore, the results of the regression analyses also seemed to us to be intuitive, in that the presence of an antalgic gait and any form of postoperative complication decreased the likelihood of a successful outcome, whereas satisfaction with the postoperative appearance of the toe, normal postoperative joint function, and the ability to wear conventional shoe gear increased the likelihood of a successful outcome. And, most notably, the ability to wear normal shoe gear remained the only statistically significant independent variable that increased the likelihood of a successful outcome, even when all of the other independent variables were included in the multiple logistic regression model. We also feel that this fact attests to the importance that the ability to wear the desired shoe gear has on subjective patient satisfaction in the postoperative phase, a finding that has previously been described with regard to outcomes after bunion and rheumatoid forefoot surgery (9, 10). Finally, interpretation of the Greenland sensitivity analysis shows that our results are resistant to the hypothetical influence of an unmeasured variable, even when the unmeasured variable is strongly associated with the statistically significant independent variables and a successful outcome. For this reason, we consider our results to most likely be valid, even though we did not directly measure every independent variable that experienced surgeons would consider important in regard to first MTPJ hemi-implant arthroplasty.

Our results compare with previous studies that observed good clinical and subjective results after use of the proximal phalangeal resurfacing implant (1, 3, 11–14). Based on our experience with the implant, we feel that it offers a number of advantages, including minimal postoperative debilitation and reliable pain relief, and similar findings have also been previously noted (1, 3). In addition, the procedure is a relatively uncomplicated intervention that entails minimal osseous resection at the proximal phalanx, and we believe that this enables preservation of intrinsic muscular attachments to the phalanx, which in turn aids in maintaining hallux purchase and stability in stance. Although our results did not show a statistically significant association between transfer of the FHL to the proximal margin of the proximal phalangeal plantar cortex and hallux purchase, we recommend that the FHL be transferred whenever the short flexor tendons have been compromised.

In conclusion, we observed the following main effects related to use of the BioPro metallic hemiarthroplasty resurfacing prosthesis for osteoarthritis of the first MTPJ:

1. A successful outcome, stringently defined as a patient experiencing no postoperative pain while subjectively being either

satisfied or highly satisfied with the results of the operation, was observed in 43 (54.43%) of 79 procedures.
2. The mean postoperative ACFAS Universal Evaluation first MTPJ and first ray score was 94.00 (range, 44-100).
3. First MTPJ dorsiflexion and plantarflexion increased, and first IMA and metatarsal elevatus decreased, statistically significantly after first MTPJ hemiarthroplasty, although the changes in the IMA and elevatus are unlikely to be clinically significant.
4. A postoperative antalgic gait and any form of postoperative complication decreased the likelihood of a successful outcome, whereas patient satisfaction with the postoperative appearance of the toe and normal postoperative joint function was statistically significant in association with a successful outcome.
5. The ability to wear normal shoe gear in the postoperative period was the only independent variable that, when all of the other preoperative and postoperative independent variables were taken into consideration, was statistically significant in association with a successful outcome.
6. Active cigarette smoking was statistically significantly more prevalent in the group of patients who experienced a successful outcome.
7. The results of this investigation were resistant to the hypothetical influence of an unmeasured confounding variable.

Based on these findings, we believe that this procedure is a reasonable surgical option for the treatment of symptomatic hallux rigidus or first MTPJ arthrosis associated with hallux valgus.

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