

# A Prospective Investigation of the Biopro<sup>®</sup> Hemi-Arthroplasty for the First Metatarsophalangeal Joint

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*First metatarsophalangeal joint hemi-implant arthroplasty is commonly used for 1-sided degenerative joint disease. This study examined outcomes in patients that underwent hemi-arthroplasty using the BioPro<sup>®</sup> hemi-implant. Twenty-three of 30 patients completed the 12-month follow-up between October 2001 and June 2003. Repeated measures multivariate analysis of covariance was used to consider the influence of the implant on a number of dependent variables, while controlling for the amount of first metatarsal head cartilage degeneration. The average amount of first metatarsal head cartilage degeneration visualized intra-operatively was  $71.8\% \pm 21.7\%$ . From the preoperative to postoperative periods, the average hallux abductus angle went from  $12.6^\circ \pm 6.5^\circ$  to  $10.2^\circ \pm 5.3^\circ$  ( $P = 0.521$ ), the average first intermetatarsal angle went from  $11.0^\circ \pm 2.3^\circ$  to  $10.5^\circ \pm 2.0^\circ$  ( $P = 0.434$ ), the average first metatarsal declination angle went from  $18.5^\circ \pm 4.1^\circ$  to  $18.3^\circ \pm 4.1^\circ$  ( $P = 0.297$ ), the average ACFAS score went from  $41.2 \pm 11.6$  to  $80.4 \pm 8.8$  ( $P = 0.003$ ), average dorsiflexion went from  $12.6 \pm 12.4$  to  $50.0 \pm 8.7$  ( $P = 0.009$ ), and average plantarflexion went from  $8.0 \pm 8.0$  to  $17.5 \pm 6.7$  ( $P < 0.001$ ). Despite the presence of first metatarsal head cartilage degeneration, the ACFAS outcome score and the range of motion improved following implant arthroplasty, and these findings support the use of this procedure as a useful salvage intervention even in patients with pre-existing double-sided first metatarsophalangeal joint disease. Level of Clinical Evidence: 4 (The Journal of Foot & Ankle Surgery 47(6):505–509, 2008)*

**Key Words:** Biopro<sup>®</sup> hemi-implant, double-sided joint disease, endoprosthesis, first metatarsophalangeal joint, implant arthroplasty, osteoarthritis

The metallic hemi-implant of the first metatarsophalangeal joint (MTPJ) was introduced to address the issues of durability and component failure as seen with total joint replacement implants (1–13). Patients with signifi-

cant degeneration of the first metatarsophalangeal joint (MTPJ) are presented with 2 surgical options: joint destructive and joint salvage procedures (1–11). Total joint replacement or arthrodesis is more commonly chosen rather than joint replacement via a hemi-implant (1–3). In the past, silicone polymer implants were widely used as the hinge and joint replacement of the first MTPJ. The silicone polymer hemi-implant failed and silicone shards would shear off secondary to degenerative changes present within the first metatarsal head (4–11). The total silicone polymer implant was designed as a solution to the degenerated first metatarsal head. However, documented complications with the total implant included late failure secondary to osteolysis, foreign body reactions, fracture and dislocation of components, and potential inguinal granulomatous adenopathy due to silicone dissemination (6–11). The durability of silicone polymer implants was suboptimal due to the structural inability to resist shear, rough uneven surfaces, and tension forces associated with normal gait. Although studies have been performed using the hemi-implant, there have been limited documented studies that have demonstrated the func-

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**TABLE 1** Demographics of enrolled patients in study: date of birth, date of surgery, age ( $56.9 \pm 9.2$  years), sex, and side of surgery

Patient Number	Date of Birth	Date of Surgery	Age	Sex	Side
1	05/22/46	11/26/01	55	F	L
2	10/14/46	11/26/01	55	F	L
3	07/26/41	01/28/02	60	F	L
4	05/01/47	01/21/02	54	F	L
5	06/09/41	02/04/02	60	M	R
6	11/04/44	02/16/02	57	F	R
7	08/06/25	04/22/02	76	M	L
8	02/21/44	05/13/02	58	F	R
9	03/01/30	10/07/02	72	F	R
10	02/21/44	10/14/02	58	F	L
11	05/07/41	10/14/02	61	F	R
12	08/08/52	10/21/02	50	M	L
13	08/08/52	10/21/02	50	M	R
14	06/19/57	11/18/02	45	F	L
15	05/30/48	01/23/03	54	F	R
16	09/08/47	01/27/03	55	F	L
17	10/24/44	04/21/03	58	M	L
18	06/09/57	05/05/03	45	M	R
19	05/16/60	05/05/03	42	M	R
20	10/10/46	05/19/03	56	F	L
21	02/26/23	06/09/03	80	F	L
22	10/10/43	06/16/03	59	F	R
23	12/03/54	06/16/03	48	F	L
<b>Mean Average</b>			<b>56.9</b>		
<b>SD</b>			<b>9.2</b>		

M, male; F, female; R, right; L, left; SD, standard deviation.

tional improvement and patient outcome in a first MTPJ with significant cartilage loss on both sides of the joint (2).

The BioPro<sup>®</sup> cobalt-chromium hemi-implant (Biopro Corporation, Port Huron, MI) has demonstrated approximately 95% good to excellent results in 279 MTPJs over 33 years of follow-up (1, 2). The indications for the procedure are hallux limitus/rigidus, rheumatoid arthritis, and degenerative changes due to hallux valgus deformity (1, 2).

The purpose of this study was to provide prospective data on the hemi-implant arthroplasty procedure in the presence of double-sided first MTPJ disease. This study attempts to correlate the degree of articular cartilage degeneration present on both sides of the first MTPJ and how the cobalt chromium hemi-implant effects joint function, pain, and range of motion (ROM).

## Methods and Materials

Between October 2001 and June 2003, 30 patients were enrolled in a prospective clinical study designed to evaluate the viability and outcome of the cobalt-chromium hemi-implant through the senior author's (C.G.K.) private office. The first 30 consecutive patients with hallux limitus/rigidus pain resistant to conservative treat-

ment options were enrolled. The minimum age for enrollment was 40 years. To be enrolled, the first intermetatarsal angle had to be less than or equal to  $14^\circ$ . The senior author performed all the clinical evaluations. Patients enrolled in the study completed the ACFAS Universal Foot and Ankle Scoring System for first metatarsophalangeal joint and first ray preoperatively (12). Dorsiflexion and plantarflexion of the first MTPJ were measured with the forefoot loaded. The same author (M.A.S.) measured all the first intermetatarsal, first metatarsal declination, and hallux abductus angles. Articular cartilage degeneration was defined as complete absence of cartilage. If a portion of cartilage was yellow or soft, it was not included in the measurement for degeneration. Complete loss of articular cartilage was measured by dividing the first metatarsal head into 4 quadrants representing 25% of the head. The senior surgeon would quantify the amount of cartilage loss by extrapolating from the quadrant grid. Quantification was estimated intraoperatively only.

The hemi-implant was surgically inserted as recommended by the manufacturer. Intraoperative fluoroscopy was used to confirm proper implant positioning. The articular cartilage of the first metatarsal head was not addressed during the surgical procedure. No subchondral drilling or fenestration was performed. However, a cheilectomy was performed when indicated with a rongeur. All patients were allowed to bear weight immediately in a surgical shoe and were started in a continuous passive ROM device at 3 days postoperatively for 6 weeks. Patients were permitted to advance to regular shoe gear 2 weeks postoperatively if tolerated. Follow-up evaluations were at 1 week, 1 month, 6 months, and 12 months. At the final follow-up, patients completed the ACFAS Universal Scoring System questionnaire postoperatively and had final radiographic evaluation. The senior author, who was not supplied with the intraoperative data during the clinical examination, performed all postoperative clinical evaluations.

Data were analyzed using SPSS 15.0 for Windows (SPSS Inc, Chicago, IL). To compare pre- and postoperative clinical and radiographic nonparametric variables (dorsiflexion and plantarflexion of first metatarsophalangeal joint, hallux abductus angle, first metatarsal declination angle, and ACFAS scores), nonparametric analysis using Wilcoxon matched-pairs signed-ranks test (2-tailed) was performed on these independent, continuous numeric variables. In addition, a repeated measures multivariate analysis of covariance (MANCOVA) was used examining the effects of treatment on the various dependent measures while controlling for the effects of cartilage degeneration. Preoperative values were compared against postoperative values on the following parameters: hallux abductus angle, first metatarsal declination angle, dorsiflexion and plantarflexion of the first MTPJ, and the

**TABLE 2 Radiographic measurements of the data collected pre- and postoperatively on the 23 of 30 patients completing the study**

Patient Number	Hallux Abductus Angle		First Intermetatarsal Angle		1st Metatarsal Declination		1st MPJ Dorsiflexion		1st MPJ Plantarflexion		Total 1st MPJ ROM		Cartilage Degeneration
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	
1	10	5	8	8	18	16	25	52	0	14	25	66	60
2	10	9	10	10	25	26	20	61	0	12	20	73	100
3	8	11	10	10	18	18	20	62	30	34	50	96	90
4	17	8	14	9	17	16	5	48	5	12	10	60	100
5	15	4	8	8	16	16	8	51	8	14	16	65	96
6	16	9	12	9	18	17	15	38	2	16	17	54	40
7	9	6	10	9	16	16	25	54	6	14	31	68	50
8	40	32	18	16	28	27	52	63	18	20	70	83	100
9	11	10	11	12	17	16	0	56	0	10	0	66	75
10	13	13	12	11	16	16	2	60	0	12	2	72	75
11	12	8	8	8	14	14	5	52	5	14	10	66	55
12	8	8	10	10	16	16	10	48	4	18	14	66	60
13	8	10	12	12	18	19	5	52	5	12	10	64	100
14	10	8	12	14	16	16	8	50	5	10	13	60	100
15	11	9	9	10	16	16	30	48	25	34	55	82	60
16	11	10	11	10	25	25	0	25	10	25	10	50	50
17	14	12	12	12	26	26	24	56	5	22	29	78	50
18	12	12	11	10	16	16	0	54	5	20	5	74	100
19	10	9	12	12	25	25	5	49	5	16	10	65	65
20	8	10	8	9	17	16	10	44	5	18	15	62	65
21	14	11	14	10	16	16	5	45	10	14	15	59	45
22	12	12	10	10	16	17	5	38	10	18	15	56	70
23	10	8	12	12	16	16	10	45	20	24	30	69	45
<b>Average</b>	<b>12.6</b>	<b>10.2</b>	<b>11.0</b>	<b>10.5</b>	<b>18.5</b>	<b>18.3</b>	<b>12.6</b>	<b>50.0</b>	<b>8.0</b>	<b>17.5</b>	<b>20.5</b>	<b>67.6</b>	<b>71.8</b>
<b>SD</b>	<b>6.5</b>	<b>5.3</b>	<b>2.3</b>	<b>2.0</b>	<b>4.1</b>	<b>4.1</b>	<b>12.4</b>	<b>8.7</b>	<b>8.0</b>	<b>6.7</b>	<b>17.3</b>	<b>10.3</b>	<b>21.7</b>
<b>P-value</b>	<b>0.5210</b>		<b>0.4340</b>		<b>0.2970</b>		<b>0.0090</b>		<b>&lt;0.0001</b>		<b>0.0010</b>		

MPJ, metatarsophalangeal joint; ROM, range of motion; SD, standard deviation.

Statistical significance based on repeated measures multivariate analysis of covariance (MANCOVA) effects of treatment on the various dependent measures while controlling for cartilage degeneration. Statistical significance noted for hallux abductus angle and ROM of the first metatarsophalangeal joint (dorsiflexion, plantarflexion, and total).

ACFAS outcome scores. Statistical significance was defined at the 5% ( $P \leq .05$ ) level.

## Results

Complete data were collected from 23 of the 30 patients originally enrolled in the study at the final 12-month follow-up visit. Seven patients failed to make their final 12-month clinical evaluation. Tables 1 to 3 list the collected raw data. Of the patients enrolled, 23 completed the full follow-up with an overall average age of  $56.9 \pm 9.2$  years (7 males:  $54.4 \pm 11.5$  years, 16 females:  $57.9 \pm 8.3$  years). Side of surgery was noted to be 10 on the right and 13 on the left. The average hallux abductus angle preoperatively was  $12.6 \pm 6.5^\circ$  and  $10.2 \pm 5.3^\circ$  postoperatively. The average first intermetatarsal angle preoperatively was  $11.0 \pm 2.3^\circ$  and  $10.5 \pm 2.0^\circ$  postoperatively. The average first metatarsal declination angle preoperatively was  $18.5 \pm 4.1^\circ$  and  $18.3 \pm 4.1^\circ$  postoperatively. The average ACFAS Universal

Foot and Ankle Score preoperatively was  $41.2 \pm 1.6$  and  $80.4 \pm 8.8$  postoperatively. The average amount of dorsiflexion preoperatively was  $12.6 \pm 12.4^\circ$  and  $50.0 \pm 8.7^\circ$  postoperatively. The average amount of plantarflexion preoperatively was  $8.0 \pm 8.0^\circ$  and  $17.5 \pm 6.7^\circ$  postoperatively. The average amount of articular cartilage degeneration noted intraoperatively was  $71.8\% \pm 21.7\%$ . Scatter plots were created to correlate the amount of cartilage degeneration to the total joint ROM (Figure 1) and ACFAS scores (Figure 2) postoperatively.

The nonparametric analysis using Wilcoxon matched-pairs signed-ranks test (2-tailed) was performed on the measured parameters. The results showed statistical significance for hallux abductus angle ( $P = .006$ ), first MTPJ dorsiflexion ( $P < .0001$ ), first MTPJ plantarflexion ( $P < .0001$ ), total first MTPJ ROM ( $P < .0001$ ), and ACFAS outcome scores ( $P < .0001$ ). The multivariate effect of treatment is highly significant ( $F = 6.5$ ,  $df = 6.16$ ,  $P < .001$ ). Subsequent examination of the individual dependent

**TABLE 3** The ACFAS pre- and postoperative scores

Patient Number	ACFAS Score	
	Pre	Post
1	64	79
2	42	78
3	60	100
4	21	71
5	55	92
6	45	60
7	51	92
8	46	70
9	28	80
10	28	82
11	48	89
12	34	84
13	31	81
14	31	81
15	48	92
16	49	81
17	39	75
18	31	78
19	26	70
20	51	74
21	31	79
22	41	84
23	47	78
<b>Average</b>	<b>41.2</b>	<b>80.4</b>
<b>SD</b>	<b>11.6</b>	<b>8.8</b>
<b>P-value</b>	<b>0.0030</b>	

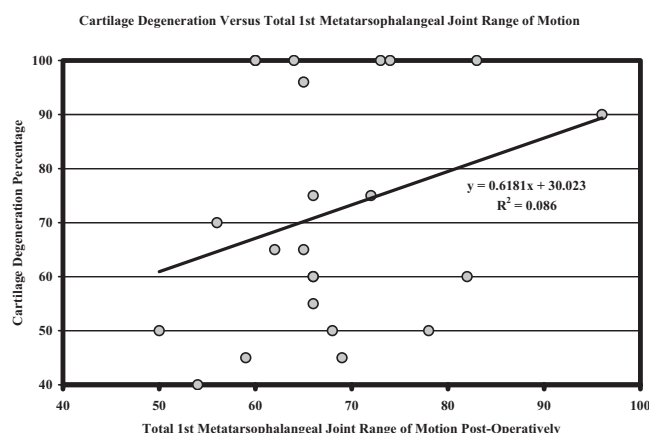
SD, standard deviation.

Multivariate analysis of covariance testing revealed statistical significance ( $P = .0030$ ).

measures reveal a significant effect of treatment on first MTPJ dorsiflexion ( $P = .009$ ), first MTPJ plantarflexion ( $P = .0001$ ), the ACFAS outcome scores ( $P = .003$ ), and the first MTPJ total range of motion (ROM) ( $P = .0010$ ). The hallux abductus ( $P = .521$ ), first metatarsal declination ( $P = .297$ ), and first intermetatarsal angles ( $P = .434$ ) were not significantly affected by the treatment while controlling for cartilage degeneration.

## Discussion

The literature favors the use of arthrodesis or a total joint implant in the presence of significant amount of double-sided joint disease of the first MTPJ (1–13). The outcome results of the metallic hemi-implant studies have been positive, but there were no correlations between first metatarsal head cartilage degeneration and the clinical outcomes (2, 7, 8). The improved pain and ROM parallel these previous studies. In this study, pre- and postoperative ROM values were obtained to determine if the amount of articular cartilage defect to the first metatarsal head would have any impact on motion in the first MTPJ. With the increase in

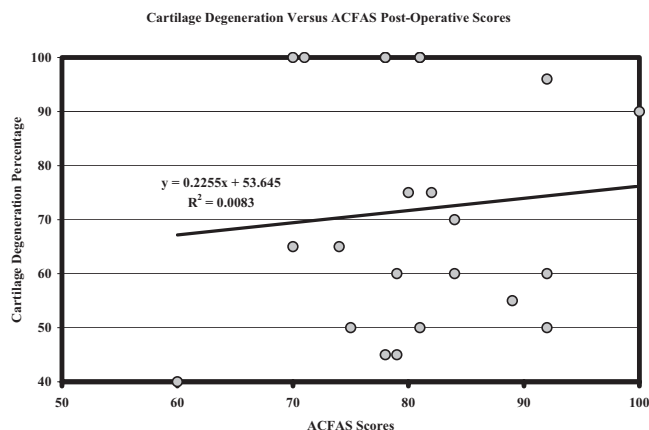


**FIGURE 1** Scatter plot of total first metatarsophalangeal joint range of motion postoperative and amount of cartilage degeneration shows no linear correlation ( $R^2 = 0.086$ ). This finding indicates that despite the degree of double-sided joint disease, the total joint range of motion is not limited following the hemi-implant procedure.

ROM and decrease in pain following placement of the hemi-implant, articular cartilage defects of the first metatarsal head would appear to have minimal bearing on outcome results. The scatter plots generated from the collected data show no correlation or pattern when assessing outcome results with the amount of cartilage degeneration. Clinical outcome results of joint salvage procedures with double-sided joint disease of the first MTPJ has not been a focus of any studies encountered. Although this study has an extremely small sample size, the authors attempted to use this study as a pilot study to investigate the role of the hemi-implant arthroplasty in addressing various amounts of double-sided joint disease of the first MTPJ.

Limitations noted with this study include a small study size and lack of a control group or another group to compare against. Durability is not addressed within this study. However, the durability of the cobalt-chromium hemi-implant has been well documented to function for more than 38 years (1, 2). Larger patient pools, longer follow-up times, and a more objective and accurate way to measure the cartilage degeneration would be recommendations for future studies. The authors plan to expand this method of evaluation pre- and postoperatively to other hallux limitus/rigidus procedures for direct comparison of the outcome results. Potential complications will also be tracked such as metatarsalgia, loss of ROM, and second metatarsal stress fracture.

In conclusion, the hemi-implant arthroplasty procedure has not been investigated in double-sided joint disease of the first metatarsophalangeal joint. Twenty-three patients underwent the procedure and were followed for 12 months postoperatively. Final joint ROM and ACFAS outcome scores revealed statistically significant improvement, and



**FIGURE 2** Scatter plot of ACFAS postoperative scores and amount of cartilage degeneration shows no linear correlation ( $R^2 = 0.0083$ ). This finding indicates that despite the degree of double-sided joint disease, the hemi-implant procedure yields favorable clinical outcomes.

despite the amount of double-sided joint disease, the outcomes were dramatically improved.

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