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Short-Term Clinical Outcome of Hemiarthroplasty Versus Arthrodesis for End-Stage Hallux Rigidus

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ABSTRACT

Few data are available to compare the outcomes of first metatarsophalangeal joint (MTPJ) hemiarthroplasty and arthrodesis. We included 46 patients who had undergone BioPro[®] first MTPJ hemiarthroplasty and 132 who had undergone arthrodesis, with a minimum follow-up duration of 12 months. The primary outcome was patient satisfaction, which was determined using binominal questions. The Foot and Ankle Outcome Score, Foot Function Index, and Numerical Rating Scale for pain and limitations questionnaires were also used. The secondary outcome was treatment failure. No differences were found in the satisfaction rate (p = .54) after a median period of 38.4 (range 12 to 96) months and 39.8 (range 12 to 96) months in the hemiarthroplasty and arthrodesis patients, respectively. Furthermore, no differences were found in the failure rates (p = .93) or the interval to failure (p = .32). The results of the present study showed no significant differences in the short-term clinical outcomes and failure rates for BioPro[®] first MTPJ hemiarthroplasty and arthrodesis. Prospective comparative studies are required to determine whether BioPro[®] first MTPJ hemiarthroplasty is a good alternative for first MTPJ arthrodesis in the long term.

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Arthrodesis is still considered the reference standard for the treatment of severe hallux rigidus (1–3). However, arthrodesis has been criticized, because it eliminates all first metatarsophalangeal joint (MTPJ) motion and can be complicated by delayed union or nonunion and malposition of the phalanx and could increase stress on the adjacent joints (4). BioPro First MPJ Hemiarthroplasty[®] (BioPro, Port Huron, MI) partially replaces the articular surface of the proximal phalanx and seems to maintain joint function in the earlier postoperative period in contrast to arthrodesis. However, hemiarthroplasty survival is uncertain, and complications such as loosening of the implant, infections, arthrofibrosis, mechanical deformity, and persistent pain have been reported (3,5,6). Published studies have reported ambivalent results for first MTPJ hemiarthroplasty, with a limited number of studies reporting satisfying results (5–8). In contrast, arthrodesis is more predictable in its

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outcome. Only a few short-term comparative studies of first MTPJ hemiarthroplasty and arthrodesis have been published and included only small numbers of patients. None have been conclusive enough to define which procedure is superior (3,4). Therefore the most effective choice for treating end-stage hallux rigidus remains debatable. The aim of the present study was to evaluate and compare the satisfaction rate, failure rate, and other short-term results of patients with end-stage hallux rigidus who had undergone BioPro[®] first MTPJ hemiarthroplasty or first MTPJ arthrodesis.

Patients and Methods

A retrospective comparative cohort study was conducted. Patients with end-stage hallux rigidus who had undergone first MTPJ hemiarthroplasty (BioPro[®]) or first MTPJ arthrodesis from January 2005 to March 2012 were eligible. Patients were included if the follow-up period was >1 year. Deceased patients (n = 6) and patients who had undergone revision arthrodesis (n = 4) were excluded. The medical ethical review board decided that no approval was necessary (METCZWH, no.13-043).

In the present study 178 patients were eligible, including 46 hemiarthroplasty patients and 132 arthrodesis patients. The patients who had undergone bilateral foot surgery were included in the study for both feet, including 4 hemiarthroplasty and 18 arthrodesis patients.

The basic demographic data, information on smoking status, surgery side, preoperative pain, previous minor surgery on the joint, postoperative complications, and







Table 1

Demographic factors in hemiarthroplasty and arthrodesis patients

Variable	$\begin{array}{l} \text{Hemiarthroplasty} \\ (n=46) \end{array}$	$\begin{array}{l} \text{Arthrodesis} \\ (n=132) \end{array}$	p Value (95% CI)
Age (y)	61.9 ± 8.4	59.6 ± 9.5	.18 (-5.42 to 0.68)
Sex			.00
Male	1 (2)	34 (25)	
Female	48 (98)	101 (75)	
Laterality			.62
Right	33 (67)	83 (61)	
Left	16 (33)	48 (39)	
Current smoker	8 (16)	7 (11)	.40
Postoperative time of data extraction (mo)			.96
Median	38.4	41.5	
Range	12 to 94	13 to 98	
Previous operations	9 (21)	21 (17)	.56

Abbreviations: CI, confidence interval; mo = months, y = years.

Data presented as mean \pm standard deviation for continuous numeric data and n (%) for categorical data.

Current smoker included 78 of 132 arthrodesis patients.

Previous operations on the same foot included joint salvage operations, hallux valgus correction, bunionectomy, and combinations of several joint operations.

repeat operations were collected from the patients' medical records (Table 1). For 57 arthrodesis patients, the smoking status was not available.

The hallux rigidus grade, presence of a hallux valgus, and postoperative consolidation were evaluated from the radiographs. To grade hallux rigidus, the radiographic grading system of Giza et al (8), which was based on the clinical and radiographic system of Coughlin and Shurnas (9), was used. A radiographic examination was performed preoperatively to grade the hallux rigidus and 3 months postoperatively for the consolidation stage.

The patients were asked to participate in the study and complete the questionnaires. The participating patients received the questionnaires at their home. The patients who did not return the questionnaires within 6 weeks after sending were telephoned and request again to complete the questionnaires.

Outcome Measures

The primary outcome measure was patient satisfaction. Satisfaction was measured using 2 binominal anchor questions and repetitive choice for the received treatment. The secondary outcomes were treatment failure and the results of the patient-completed questionnaires. Treatment failure for the hemiarthroplasty patients was defined as removal of the prosthesis, which could be followed by reimplantation of a new implant or arthrodesis, and as revision arthrodesis for the arthrodesis patients. The questionnaires included the Foot and Ankle Outcome Score (FAOS) (10), Foot Function Index (FFI) (11), and Numerical Rating Scale (NRS) for pain and limitations. To the best of our knowledge, no validated questionnaires for arthrodesis patients are available.

Surgical Techniques

For hemiarthroplasty, the first MTPI was exposed through a dorsomedial incision. A limited cheilectomy of the metatarsal head was performed, and the articular surface of the proximal phalanx was resected. The appropriate implant size was chosen by measuring the phalangeal surface. A central hole was made, and test prosthesis was inserted, after which the range of motion and overstuffing was checked. After positioning the final prosthesis, the joint range of motion was again tested, followed by closure of the wound in layers. In all operations, a BioPro® hemiarthroplasty device was used. All operations were performed by or under the direct supervision of 1 orthopedic surgeon (R.v.d.F.) in the Medical Center Haaglanden (The Hague, The Netherlands). Postoperatively, the patients were not allowed to bear weight on the operated foot for 2 weeks, followed by 4 weeks of protected mobilization. For arthrodesis, the first MTPJ was exposed through a dorsomedial incision. After exposing the articular surface, the osteophytes were removed. The articular surfaces of the metatarsal and proximal phalanx were then resected to created flat bone ends and aligned into proper position. The proper position consisted of 10° of dorsiflexion in relation to the ground surface and 15° to 20° of valgus and neutral rotation. Fixation with a Hallufix plate (Newdeal, Integra, Plainsboro, NJ) was then performed, and, if necessary, a positioning screw was placed. Eventually, all layers were closed. All arthrodesis operations were performed by or under the direct supervision of 1 orthopedic surgeon (F.W.M.F.) in the HAGA Hospital (The Hague, The Netherlands). The arthrodesis patients were immobilized by a cast postoperatively, with the first 2 weeks non-weightbearing followed by 4 weeks of protected weightbearing.

Statistical Analysis

The data were tested for normality using the Kolmogorov-Smirnoff test. When the data were not normally distributed, the median and range are presented, and, when normally distributed, the mean, standard deviation, and 95% confidence intervals are presented. The primary outcome, patient satisfaction, was determined using a chi-square test. The secondary outcome, treatment failure, was determined for both groups using a chi-square test, and a Kaplan-Meier curve was generated. To determine the correlations, the Spearman correlation test was used. The postoperative FAOS, FFI, and NRS scores were compared between the hemiarthroplasty and arthrodesis groups using the Mann-Whitney *U* test. Statistical significance was set at the 5% level (p < .05). The data were analyzed using SPSS, version 20.0, for Windows (SPSS, Chicago, IL).

Results

The cohort consisted of 178 patients, 46 hemiarthroplasty and 132 arthrodesis patients. The median follow-up duration was 38.4 (range 12 to 94) months for the hemiarthroplasty patients and 41.5 (range 13 to 98) months for the arthrodesis patients (p = .96). The baseline data are presented in Table 1; gender was the only factor with a statistically significant difference (p < .001) between the 2 groups.

Satisfaction

Satisfaction questionnaires were available for the hemiarthroplasty group at a median follow-up time of 38.4 (range 12 to 96) months and for the arthrodesis group at a median follow-up time of 39.8 (range 12 to 96) months. The satisfaction rate was not significantly different statistically (p = .54) between the 2 groups. All satisfied hemiarthroplasty patients (81.6%) would have chosen the same treatment again. Seven hemiarthroplasty patients (19.4%) were not satisfied; however, 2 patients would still have chosen to undergo the operation again. Fifty-two arthrodesis patients (64%) were satisfied with the outcome and would choose arthrodesis again. Also, 8 patients (13.3%) were not satisfied but would have chosen the same procedure again. However, 12 arthrodesis patients (16.0%) would not choose the arthrodesis operation again, although 4 were truly satisfied (Table 2). Dissatisfaction in the arthrodesis patients did not correlate with removal of the implant ($r_s = -0.021$, p = .88).

Treatment Failure

Two hemiarthroplasties (4.1%) failed at a median time of 42 (range 12 to 72) months. These were converted to arthrodesis because of persistent pain (not included in the arthrodesis group, in accordance with the intention to treat principle). In the arthrodesis group, 5 patients (3.7%) underwent revision arthrodesis at a median time of 19.5 (range 13 to 84) months. The reason for revision was nonunion in all 5 patients. The results showed no statistically significant difference for treatment failure (p = .93) or the interval to failure (p = .32) between the 2 groups. Apart from a second operation because of failure, 15 arthrodesis patients (11.1%) required a second operation to remove the implant because of pain complaints or infection.

Questionnaires

Of the patients, 78% of the hemiarthroplasty patients and 60% of the arthrodesis patients returned the questionnaires. The postoperative questionnaires were completed after a median period of 37.5 (range 12 to 96) months for the hemiarthroplasty patients and 39.5 (range 12 to 96) months for the arthrodesis patients; the difference was not statistically significant (p = .91). The postoperative FAOS, FFI, and NRS pain and limitation scores are listed in Table 2. No statistically significant differences were found between the hemiarthroplasty and arthrodesis groups in the FAOS (p = .74), total FFI score (p = .73), or NRS score for pain (p = .14) and limitation (p = .42). Also, the subscales of the FAOS and FFI showed no statistically

Table	2		
FAOS,	FFI,	NRS	scores

	Hemiarthroplasty (n	Hemiarthroplasty ($n = 46$)		Arthrodesis ($n = 132$)	
	Patients* (n)	Score	Patients* (n)	Score	
FAOS					
Symptoms	36	64.3 (32.1 to 100)	69	67.9 (35.7 to 100)	0.15
Pain	36	84.7 (36.1 to 100)	69	91.7 (19.4 to 100)	0.44
ADL	36	95.6 (27.9 to 100)	69	97.1 (16.2 to 100)	0.33
Sport	36	80.0 (0.0 to 100)	69	80.0 (0.0 to 100)	0.65
QoL	36	71.8 (18.8 to 100)	69	75.0 (0.0 to 100)	0.56
Total	36	79.2 (28.8 to 98.3)	69	80.2 (18.1 to 100)	0.74
FFI					
Pain	27	25.0 (0.0 to 72.2)	69	11.1 (0.0 to 100)	0.21
Disability	29	11.1 (0.0 to 80.6)	70	16.7 (0.0 to 100.0)	0.84
Activity restrictions	27	15.0 (0.0 to 65.0)	68	0.0 (0.0 to 100)	0.07
Total	29	17.9 (0.0 to 62.0)	70	13.8 (0.0 to 81.0)	0.73
NRS					
Pain total	29	3 (0 to 7)	63	1 (0 to 10)	0.14
Limitation	29	3 (0 to 8)	63	2 (0 to 10)	0.42

Abbreviations: ADL, activities of daily living; FAOS, Foot and Ankle Outcome Score; FFI, Foot Function Index; NRS, Numerical Rating Scale; QoL, quality of life.

Data presented as median (range), unless otherwise noted. * Number of patients who completed the questionnaire.

significant differences. In the hemiarthroplasty and arthrodesis groups, more patients had no or slight pain than had severe pain

Discussion

(Table 2).

The present study compared the results of BioPro[®] hemiarthroplasty first MTPJ with arthrodesis of the first MTPJ in patients with end-stage hallux rigidus. We found no statistically significant differences between the 2 groups in satisfaction, failure, or outcome measures. Compared with previous studies, our study included a large number of patients, with a short follow-up period. However, not all of our results were equivalent to those from previous studies (3,4).

The hemiarthroplasty patients in our study had a high satisfaction rate (81.6%) and a low failure rate (5.6%). Few comparisons in the published data with the BioPro[®] first MTPJ hemiarthroplasty have been made. Salonga et al (5) described 79 BioPro[®] first MTPJ hemiarthroplasties after a mean follow-up of 2.91 years, with 86% of the patients satisfied with the outcome. The mean American College of Foot and Ankle Surgeons scaling score was 94 (range 44 to 100); however, 14% still had an antalgic gait. That study did not report other patient-specific outcomes. The complication rate was low (10.1%), with only a 2.5% revision rate after almost 3 years. Our revision rate and rate of persistent pain were greater than the results reported by Salonga et al (5). However, their findings were not based on patientreported outcome measures and the use of the American College of Foot and Ankle Surgeons score is not possible for arthrodesis patients because they have impaired hallux mobility (5).

Giza et al (8) reported 2 failures in 22 elective BioPro[®] first MTPJ hemiarthroplasties (9%) after a 2-year follow-up period. They reported a satisfying outcome for 90% and stated that hemiarthroplasty was a viable alternative to arthrodesis for end-stage hallux rigidus.

Kissel et al (12) reported on 30 patients after a 12-month follow-up period. First MTPJ function dramatically improved after surgery; however, they reported the outcomes using the American College of Foot and Ankle Surgeons score, which combines objective and subjective parameters. Thus, a true comparison was not possible, although all scores improved after surgery.

In our study, 77.4% of the arthrodesis patients were satisfied, with a failure rate of 11% (16 patients). Compared with other studies, these results are less impressive. Goucher and Coughlin (13) reported the results of 54 arthrodesis patients in their prospective study, with a

minimum 1-year follow-up period. They reported a revision rate of 4% and a patient satisfaction rate of 98% (13). Neither result is in line with ours, although the median follow-up period in our study was manifestly longer. The satisfaction rate for the arthrodesis patients in our study could also be explained by the preoperative expectations of the outcome. Despite the preoperative explanation of the procedure, in which the elimination of all first MTPJ motion is highlighted, patients cannot foresee the consequences of the impaired mobility.

The satisfaction rate was similar for both groups. If satisfaction results from pain relief and first MTPJ motion, the satisfaction rate in the arthrodesis patient will actually be greater because satisfaction will not result from first MTPJ motion, but from pain relief. Therefore, if the satisfaction rate was similar in both groups, the arthrodesis patients might have realized a greater degree of pain relief. Additional research should focus on patient satisfaction in these 2 groups to make hemiarthroplasty and arthrodesis even more comparable.

We found no statistically significant differences in the failure rate. For the purpose of the present investigation, treatment failure in the hemiarthroplasty group was defined as removing the hemiarthroplasty device and in the arthrodesis group as requiring revision arthrodesis. Although the failure rate was not different between the 2 groups, 15 arthrodesis patients (10.5%) underwent a second operation for implant removal, which was not included in the failure definition. Most of the failures in the arthrodesis group were due to nonunion or malunion and occurred within the first postoperative year. However, all patients had persistent postoperative pain complaints. Complications such as loosening of the implant and wear for the hemiarthroplasty patients will generally occur after years. However, long-term follow-up studies for this implant are lacking.

Only a limited number of studies are available that have compared hemiarthroplasty and arthrodesis (3,14,15). These studies were all short term and contained a small number of patients. We have reported similar long-term satisfaction rates and failure rates in both groups. Others have reported different results. Raikin et al (3) retrospectively compared the outcome of arthrodesis and BioPro[®] in 48 patients. They reported a 24% failure rate in the BioPro[®] patients and a good or excellent outcome in only 57%. The arthrodesis group had a far better outcome, with a 100% union rate, no revisions, 2 cases of hardware removal, and 81% with a good or excellent outcome. They favored treatment of end-stage hallux rigidus with arthrodesis. However, Raikin et al (3) did not report the outcomes using a

validated patient-reported outcome measure questionnaire, and the mean follow-up time of the arthrodesis patients was 2.5 times shorter. Thus, the published data on the outcomes of BioPro[®] first MTPJ hemiarthroplasty are scarce and very ambivalent.

Reports of other metallic first MTPJ hemiarthroplasty devices, such as the HemiCAP[®] (Arthrosurface[®], Franklin, MA) or the Toe-Fit-Plus system (Plus Orthopedics AG, Rotkreuz, Switzerland) have also had varying results. Kline and Hasselman (16) reported on 30 implants after a follow-up period of 60 months. They reported an 87% survival rate at 5 years, with 4 prostheses (13.3%) revised at 3 years. The AOFAS and Medical Outcomes Study short-form questionnaire outcomes were excellent. These results are in line with our outcomes using the BioPro[®] first MTPJ hemiarthroplasty device.

Bartak et al (17) reported on the Toe-Fit-Plus system used in 28 patients. Their revision rate was 21.4% because of persistent pain and loosening. The latter is more in line with the more pessimistic report (3) of prosthetic arthroplasty of the first MTPJ.

The questionnaires showed no significant differences in the FAOS, FFI, and NRS scores. These results might have been underrated for arthrodesis patients, because some questions relate to the mobility of the first MTPJ, and arthrodesis patients will have a stiff first MTPJ, previously reported by Erdil et al (4). However, no validated questionnaires for arthrodesis patients are available.

The limitations of the present study were first that it was a retrospective study; thus, not all the data were reported, and the study was not randomised or blinded. Second, 57 arthrodesis patients had no information about their smoking status. This could have been a confounder, because smoking is a known risk factor for impaired bone healing (19). However, excluding these patients would have introduced a selection bias. Considering the demographic data of these specific patients further, no significant differences were found in the remaining demographic factors between these 57 patients and the other arthrodesis patients. Another limitation was that we did not take radiographs at 1 year postoperatively after successful hemiarthroplasty and arthrodesis; radiographs were only taken in the case of complications or complaints. In future research, the bone quality and vitamin D status should be reported, because this could be risk factors for implant or arthrodesis failure. The strengths of the present study were the number of patients and the outcome measurement of satisfaction.

Considering the results of both hemiarthroplasty and arthrodesis in the present study and in published studies, a definitive answer to the question of which treatment is best cannot be given. Hemiarthroplasty can be considered a possible alternative to arthrodesis, with the advantage of maintaining (some) first MTPJ motion. The latter could be a vital advantage for more active patients. In the case of failure of hemiarthroplasty owing to loosening or continuing pain, revision to arthrodesis (with the use of some type of bone graft) will be possible, with predictable results, as reported by Garras et al (18).

In conclusion, our observational study has shown that the shortterm results for BioPro[®] first MTPJ hemiarthroplasty and arthrodesis are similar; however, the median follow-up period was only 38.4 (range 12 to 94) months for the hemiarthroplasty patients and 41.5 (range 13 to 98) months for the arthrodesis patients. Additional research is required to determine whether BioPro[®] first MTPJ hemiarthroplasty can be a complete alternative to first MTPJ arthrodesis in the long term, in particular, because failure in arthrodesis patients will usually occur earlier (nonunion within the first postoperative year) than failure in prosthesis patients.

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