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Ten-Year Follow-Up of Metatarsal Head Resurfacing Implants for Treatment of Hallux Rigidus

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ABSTRACT

Controversy remains regarding the use of arthroplasty versus arthrodesis in the surgical treatment of late-stage hallux rigidus. The purpose of our retrospective study was to report the long-term follow-up results of the metatarsal head resurfacing implant used for hemiarthroplasty. The patient assessments were conducted using the American Orthopaedic Foot and Ankle Society (AOFAS) metatarsophalangeal clinical rating system and a satisfaction questionnaire. A total of 59 consecutive implantations were performed from January 2005 to December 2009 at our institution. Of the 59 patients, 2 had died and 12 were lost to follow-up, for a 76.3% follow-up rate (45 of 59 procedures) at a mean of 117.67 (range 96 to 143) months. The mean overall AOFAS scale score was 90.6 ± 7.6. The AOFAS pain scale score was 37.78 ± 4.71. One implant was removed, and all remaining patients were happy with their outcome and would repeat the procedure on their other foot, if needed. A subset of patients from a previous mid-term study at our institution showed no significant change in the AOFAS scale scores. Of these 32 patients, 30 (93.75%) were available for follow-up examination at a mean of 122.62 (range 96 to 143) months. We were able to obtain long-term results for 32 implants (30 patients), resulting in a 10-year follow-up rate of 93.7%. With the minimal resection required for this implant, salvage arthrodesis remains a viable option if revision is needed. The surgical treatment of late-stage hallux rigidus with metatarsal head resurfacing allows for low-risk and excellent outcomes at long-term follow-up point.

Hallux rigidus describes a painful condition that affects the great toe at the metatarsophalangeal joint (MPJ). This degenerative joint disease results in limited dorsiflexion of the joint, painful range of motion, and proliferative bone formation. The pain is believed to be caused by shearing forces at the arthritic joint (1). The attempted motion at the joint is restricted by periarticular spurring. Hallux rigidus can result in radiographic changes, including osteophyte formation, loose bodies, subchondral sclerosis, flattening of the metatarsal head, and joint space narrowing (1). Reports on the etiology of hallux rigidus have varied, as further described by Coughlin and Sherman (1). Their study found that hallux rigidus was not associated with metatarsus elevatus, first ray hypermobility, metatarsal length, hallux valgus, shoe gear, or occupation. However, they did find that it was associated with hallux valgus interphalangeus, trauma, female gender, a flat-shaped joint on radiographs, and a familial history in bilateral cases (1).

Treatment of hallux rigidus varies depending on disease severity and the age and physical demands of the patient. Several treatment options have been reported. Cheilectomies or corrective osteotomies of the MPJ are effective for early- and intermediate-stage hallux rigidus. Arthrodesis or arthroplasty of the MPJ is generally reserved for more severe arthritis (2).

The area of controversy lies in which of the 2 options, arthroplasty or arthrodesis, will be best for a patient's requirements, activities, and pain levels. Arthrodesis has been long reported as the reference standard treatment because of its reliability and longevity. However, it is not without risks, such as transfer metatarsalgia, shoe wear limitations, malunion, and nonunion (3,4). The constructs for arthroplasty have several permutations. Total arthroplasty, or a bipolar construct, is composed of various materials, including silicone or metal, at both sides of the joint. Another option is hemiarthroplasty, or a unipolar construct, which addresses either the proximal phalanx or the metatarsal head.

Studies have attempted to compare arthrodesis and arthroplasty. Many of the higher quality studies have included a proximal phalanx

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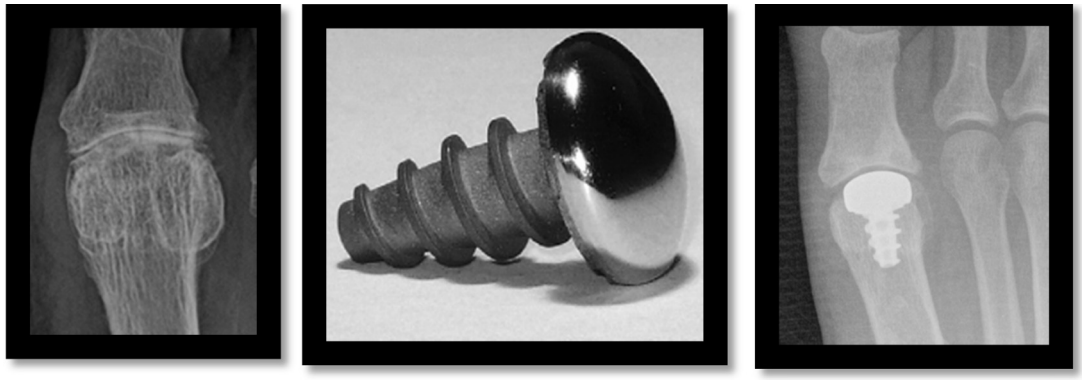

Fig. 1. Metatarsal head implant.

implant for hemiarthroplasty rather than a metatarsal implant. Raikin et al (5) compared arthrodesis and proximal phalanx implant arthroplasty with a 79-month follow-up period. They noted a failure rate of 24% in the arthroplasty group and concluded that arthrodesis at the 30-month follow-up mark was more predictable in alleviating symptoms (5). Erdil et al (6) compared total joint arthroplasty, arthrodesis, and MPJ resurfacing arthroplasty, noting that all 3 procedures showed improvements in the American Orthopaedic Foot and Ankle Surgery (AOFAS) metatarsophalangeal clinical rating system scores and visual analog scale (VAS) scores. The AOFAS scale scores were lower in the arthrodesis group owing to lack of motion; however, that group also had a significant increase in the VAS scores (6).

Arthrodesis for the treatment of hallux rigidus has been advocated as the reference standard; however, challenges remain regarding patient satisfaction. Managing patient expectations are imperative in the treatment of hallux rigidus. The disadvantages of arthrodesis include shoe wear limitations, activity modifications, malunion or nonunion of the fusion site, metatarsalgia, and painful hardware. The loss of motion at the joint can be an issue for those with occupations requiring kneeling or squatting, runners, and adult females attempting to wear high heels. Biomechanical changes such as altered gait, decreased step length, and loss of ankle plantarflexion can also occur with MPJ arthrodesis (7).

Table 1
Possible points for American Orthopaedic Foot and Ankle Society metatarsophalangeal joint-interphalangeal joint scale score

Item	Points
Pain	40 Possible
None	40
Mild, occasional	30
Moderate, daily	20
Severe, almost always	0
Function	45 Possible
Activity limitations	
None	10
Limited recreational activities	7
Limited recreational and daily activities	4
Severe limitation, walker, brace	0
Footwear requirements	
Conventional shoes, no inserts needed	10
Comfort footwear, with shoe insert	5
Modified shoe or brace	0
Big toe joint motion (extension plus flexion)	
Normal or mild (≥75°)	10
Moderate (30° to 74°)	5
Severe restriction (<30°)	0
Interphalangeal joint motion (flexion)	
No restriction	5
Severe restriction (<30°)	0
Stability of joint in all directions	
Stable	5
Unstable, able to dislocate	0
Callous formation	
No callous, no symptoms	5
Callous, symptomatic	0
Alignment	15 Possible
Good, big toe well aligned	15
Fair, some degree of malalignment	8
Poor, symptomatic malalignment	0
Total	100

The HemiCAP® system (Arthrosurface, Franklin, MA) is an implant used for hemiarthroplasty of the metatarsal head (Fig. 1). It functions by resurfacing the metatarsal head through insertion of a 2-part implant composed of a cobalt-chromium articular component and a titanium morse taper post. The implant allows for minimal bone resection of the joint and does not interfere with the intrinsic muscle insertions at the proximal phalanx. The system also allows for decompression of the joint and a stable screw-like fixation of the implant. This construct allows for minimal bone loss, although this still leaves the arthrodesis without a bone graft as a viable salvage option. Several studies during the previous 10 years have investigated hemiarthroplasty with the HemiCAP® implant (Arthrosurface) as an effective treatment of severe hallux rigidus. These investigations studied the short- and medium-term clinical results and reported favorable outcomes (6,8–11).

To date, no studies have examined the long-term results of patients who have undergone hemiarthroplasty of the metatarsal with a resurfacing implant. Because previous studies have shown promising short- and mid-term follow-up results, we hypothesized that this procedure would also yield favorable long-term results. The primary purpose of our retrospective study was to investigate the long-term outcomes of patients who had undergone hemiarthroplasty with the HemiCAP® implant (Arthrosurface). We also wished to investigate the outcomes of the subset of patients included in the prospective study by Carpenter et al (9) at the same institution that had examined the mid-term follow-up data for this procedure.

Patients and Methods

We used the AOFAS clinical rating system for the hallux to measure the outcomes of our patients. The AOFAS system is used to evaluate the condition of the first metatarsophalangeal and interphalangeal joints (12,13). This score is used to assess pain, function, and alignment (Table 1). Secondary questions were asked in addition to the AOFAS clinical rating system (Table 2). These additional questions were created by us and were used to further evaluate patient satisfaction and pain medication requirements and

Table 2
Secondary questionnaire

Question	Possible Response
Based on your experience and current condition of the toe, would you undergo the procedure to the contralateral foot?	Yes, no
Do you currently take pain medication for your toe?	Daily, occasionally, never
Have you undergone or been recommended to undergo another surgery to the same toe?	Yes, no

to determine whether the patient had required any further surgical intervention to the toe. In investigating the patients who had undergone this specific procedure with the implant, we believed these additional questions would provide specific data not covered by the AOFAS scale, such as patients who subsequently required arthrodesis of the joint and those who would undergo the same procedure to the contralateral limb.

The selection criteria for our study were a consecutive series of patients who had undergone MPJ hemiarthroplasty with the HemiCAP® implant (Arthrosurface) from February 2005 to January 2009. This range was selected to target an average follow-up period of 10 years since the date of surgery. All patients had presented to the clinics of the senior authors (B.C., A.G., T.M.). The inclusion criterion was grade 2 (moderate osteophytes with joint space narrowing and subchondral sclerosis) or grade 3 (marked osteophytes, loss of joint space, and possible subchondral cysts) hallux rigidus using the Hattrup and Johnson classification system (14).

All surgical procedures were performed by 1 of the 3 senior authors (B.C., A.G., T.M.). The institutional review board at John Peter Smith Hospital approved the present retrospective study. All patient information was obtained using medical record review by the primary author (H.H.). The final follow-up evaluation was conducted via telephone by the primary author (H.H.) or attending surgeon. The data were collected by

Hallux Metatarsophalangeal-Interphalangeal Scale (100 Points Total)

1. Pain (40 points) /
"Do you have any pain?"

- None.....40
- Mild, occasional.....30
- Moderate, daily.....20
- Severe, almost always present.....0

2. Function (45 points)
Activity limitations

- No limitations, no support.....10
- No limitation of daily activities, limitation of recreational activities.....7
- Limited daily and recreational activities, cane.....4
- Severe limitation of daily and recreational activities, walker, crutches, brace.....0

Footwear requirements

- Fashionable, conventional shoes, no insert required.....10
- Comfort footwear, with a shoe insert.....5
- Modified shoes or brace.....0

Big Toe joint motion (extension plus flexion)

- Normal or mild restriction (75 degrees or more).....10
- Moderate restriction (30-74 degrees)..... 5
- Severe restriction (less than 30)..... 0

Interphalangeal joint motion (flexion)

- No Restriction.....5
- Severe restriction (less than 30 degrees).....0

Stability of the joint in all directions

- Stable 5
- Unstable, able to dislocate 0

Callous formation

- No callus or one that is asymptomatic 5
- Callous, symptomatic.....0

3. Alignment (15 points)

- Good, big toe is well aligned.....15
- Fair, some degree of malalignment, no symptoms.....8
- Poor, symptomatic malalignment.....0

Secondary Questions

- Based on your experience and current condition of the toe, would you undergo this procedure again to the contralateral foot?
- Have you undergone or been recommended to undergo another surgery to the same toe?
- Do you currently take pain medication for the toe you had surgery on?

Fig. 2. Questionnaire.

creating a questionnaire that had components of the AOFAS hallux metatarsophalangeal scale and our secondary questions. The questionnaire is shown in Fig. 2. The AOFAS scale score and patient satisfaction question score were calculated. With our inclusion criteria encompassing a larger surgical window for the present study, we were also able to interview the same patients included in the previous study by Carpenter et al (9), which had reported AOFAS scale scores in the mid-term and included their preoperative scores.

Operative Technique

An ankle tourniquet was used for hemostasis. After a standard preparing and draping technique, the joint was approached through a dorsomedial incision of the first MPJ extending from the interphalangeal joint to approximately 3 cm proximal to the MPJ. Neurovascular structures were avoided and retracted safely. The extensor tendon was retracted laterally. A linear capsulotomy was performed, and a McGlamry elevator was used to free any adhesions between the sesamoids and metatarsal head. The guide pin was placed in the central aspect of the metatarsal head, 1 to 2 mm plantarly to the center in the sagittal plane. After the proper position of the guide pin was verified by fluoroscopy, a step drill was used and advanced flush with the articular surface. This was drilled at full speed before contact with the metatarsal to avoid any shattering of the bone or articular surface. The drill hole was then tapped manually. No cement was used. The taper post was advanced over the guidewire. All joints were decompressed 1 to 3 mm by advancing the post. The amount of advancement depended on the tightness of the joint and the length of the metatarsal parabola. After reaming of the metatarsal head, the sizing trial was fit into the post. We elected to use the implant with the largest curvature in the superoinferior plane. With the trial in place, periarticular osteophytes were debrided. After ensuring smooth dorsiflexion of the joint to 90° of dorsiflexion to the metatarsal shaft with the trial implant, the articular component was tapped into place. Closure was performed in layer by layer fashion.

The patients did not undergo any other procedures at implantation that would have required non-weightbearing. Protected weightbearing in a surgical shoe was encouraged immediately postoperatively. Passive range of motion exercises were started at the first visit within 5 days postoperatively. Weightbearing and a normal gait were encouraged without a shoe at home beginning 48 hours after the procedure if tolerated. After the incision had healed, active range of motion exercises were immediately started, and the patients were allowed to wear normal shoe gear. The patients were permitted normal activity once they had returned to wearing shoes without pain.

Statistical Analysis

A test of binomial proportions were used to determine for a difference in the outcome responses (yes versus no). Statistical significance was set at $p \leq .05$.

Table 3
Descriptive analysis of 10-year follow-up study of metatarsal head resurfacing surgery (N = 45 implants in 42 patients)

Variable	Value
Age (y)	65.48 ± 13.21
Gender	
Female	29 (64.29)
Male	16 (35.71)
Follow-up duration (mo)	117.67 ± 14.33
Pain (40)	37.78 ± 4.71
Function (45)	38.60 ± 4.70
Activity (10)	9.27 ± 1.30
Footwear (10)	7.67 ± 2.52
Toe motion (10)	7.11 ± 2.72
Interphalangeal motion (5)	4.56 ± 1.44
Stability (5)	5.00 ± 0.00
Callous (5)	5.00 ± 0.00
Alignment (15)	14.22 ± 2.22
Would do it again	
Yes	44 (97.78)
No	1 (2.22)
Underwent further surgery	
Yes	2 (4.44)
No	43 (95.56)
Pain medication	
Very occasionally (over the counter)	5 (11.63)
No	38 (88.37)

Data presented as mean ± standard deviation or n (%); data in parentheses in left column denote total possible score.

Results

Metatarsal head resurfacing was performed on 56 patients from January 2005 to December 2009. Three patients underwent bilateral first ray MPJ hemiarthroplasty, for a total of 59 procedures. At the last follow-up point, 2 patients had died of unrelated causes and 12 patients could not be interviewed. Including the bilateral cases, we were able to obtain long-term results for 45 implants in 42 patients, for a 10-year follow-up incidence of 76.3%; 16 implantations (35.56%) were in males and 29 (64.44%) were in females. The average patient age at surgery was 57.4 (range 33 to 86) years. The average final follow-up period was 117.67 (range 96 to 143) months. No intraoperative or immediate postoperative complications, including wound healing or infection, were encountered. The mean overall AOFAS scale score at the 10-year follow-up point was 90.6 ± 7.6. The pain component of the AOFAS scale score was 37.78 of 40 (94.5%).

The most common deduction in the AOFAS scale scores was attributed to the decreased range of motion. This might have been improved compared with the patient's baseline score; however, we could not determine this owing to the lack of preoperative data but was not significant. Of the 45 MPJ hemiarthroplasties, 44 remained implanted. All the patients, with the exception of 1 patient (2.22%), were satisfied with the procedure and stated they would undergo the procedure again to their other foot, if needed. The p values were all $< .05$ for the 3 outcome measures.

Two patients underwent repeat surgery to the MPJ. One patient (2.22%), with a history of chronic pain, underwent elective implant removal and concurrent in situ MPJ arthrodesis without the need for grafting. A second hardware removal of the arthrodesis fixation because of continued pain was also performed. One other patient (2.22%) underwent cheilectomy for dorsal spurring without removal of the implant and was very satisfied after the procedure. The overall statistical results are summarized in Table 3 and Fig. 3.

The patients in the present study also included the cohort described by Carpenter et al (9) in 2010 from our institution. In their study, 32 patients had undergone the same procedure and their preoperative and mid-term AOFAS scores had been reported (9). Of these 32 patients, 30 were available for follow-up at a mean of 122.62 (range 96 to 143) months. Including the bilateral cases, we were able to obtain long-term results for 32 implants in 30 patients, for a 10-year follow-up incidence of 93.7%. The mean overall AOFAS scale score in this subset at the final follow-up point was 89.97 ± 8.13. Using a t test of the mean values from the present study versus the study in 2010, the p value was $> .05$, showing no significant change in the AOFAS scale scores from the mid-term follow-up evaluation. These results are summarized in Table 4.

Discussion

The long-term results from the present investigation support hemiarthroplasty of the metatarsal head with the HemiCAP® implant

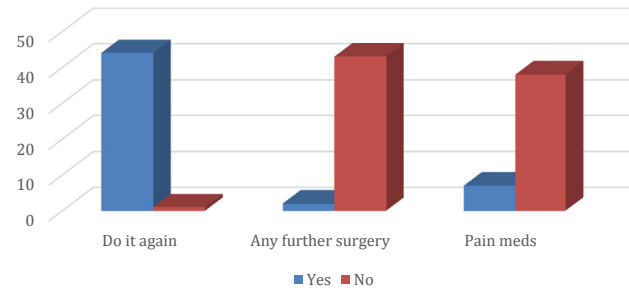

Fig. 3. Frequency of outcome measures.

Table 4
Mid- and long-term comparison (N = 42 patients)

	Preoperative, 2010	Mid-Term, 2010	Long-Term, 2016
AOFAS scale score	36.62 ± 11.96	89.16 ± 7.50	90.60 ± 7.63
p Value	< .0001		NA
	NA	.3856	
	< .0001 (preoperative versus long-term)		

Abbreviations: AOFAS, American Orthopaedic Foot and Ankle Society; NA, not applicable.

(Arthrosurface). The patients in our study had high mean AOFAS scale scores at the long-term follow-up evaluation and had excellent overall pain relief. The data also showed high patient satisfaction, a very low reoperation rate, and no serious complications.

Hemiarthroplasty has been further developed as an answer to the challenges of arthrodesis. The disadvantages of arthrodesis include malunion, nonunion, metatarsalgia, interphalangeal joint arthritis, and an extended postoperative recovery time (15). A study by Beertema et al (15) reviewed the long-term results (mean of 7 years) of arthrodesis versus Keller arthroplasty and noted increased satisfaction for patients with grade 3 hallux rigidus who had undergone arthrodesis, reporting an AOFAS scale score of 73. However, the reoperation rate in the arthrodesis group because of nonunion or malunion was 9% (15).

Problems with proximal phalanx implants have included documented stiffness, continued pain, and prosthetic loosening. It is possible that the shear stress of the proximal phalanx on the pathologic metatarsal head with repeated dorsiflexion contributes to loosening. The proximal phalanx implants also require resection of the bone where the intrinsic musculature attaches, which can lead to loss of stability. The HemiCAP® resurfacing system (Arthrosurface) focuses treatment on the metatarsal side of the joint, where most of the pathologic features of hallux rigidus are believed to be present.

Several studies have investigated this hemiarthroplasty system and demonstrated promising results. In 2008, Hasselman and Shields (8) noted success in 25 patients with an AOFAS scale score of 82 after 1.7 years. These outcomes were achieved across patients with various occupations, including carpenters, physicians, homemakers, and manual laborers. Carpenter et al (9) reported their experience with 32 patients and a mean follow-up period of 27.3 months, noting successful AOFAS scale scores and no revisions or removals during their mid-term follow-up period. Aslan et al (16) performed the procedure on 27 patients with average follow-up period of 37 months. They reported a decrease in the VAS score from 8.3 to 2.05 and no evidence of loosening (16). Hasselman and Shields (8) reported their findings for 100 patients with average follow-up period of 30 months. The revision rate was 2%, with high patient satisfaction rates and good functional outcomes and no reports of loosening or osteolysis of the implant at the last follow-up point (8). Kline and Hasselman (10) studied the follow-up data at 27 and 60 months for 30 patients, 4 of whom had required revision at 3 years.

Just as for most surgeries, no procedure is without some form of risk. Arthrodesis would be considered one bailout option in the event of an arthroplasty complication. One benefit of the HemiCAP® system (Arthrosurface) is the minimal bone resection, which can allow for adequate bone stock if the joint required revision to arthrodesis. Hopson et al (17) reported success using the osteochondral autograft transfer system from the lateral femoral condyle for a failed HemiCAP® implant (Arthrosurface). The HemiCAP® implant (Arthrosurface) in that case had been used as a partial articular prosthesis rather than a total metatarsal head prosthesis such as was done in our study. Stone et al (18) reported a case of a patient who had developed hematogenous infection of the joint 7 months postoperatively after developing an upper respiratory infection. The most common consequence with HemiCAP® (Arthrosurface) hemiarthroplasty is a relative reduction in dorsiflexion postoperatively compared with the intraoperative motion. It is therefore important to target 90° of dorsiflexion during surgery, which, in turn, will allow patients to achieve a postoperative range of motion allowing normal ambulation (19). According to the study by Hasselman and Shields (8) in 2008, this decrease in range of motion was adequate for patients and did not limit their activities. In their series of 100 patients, they did report 2 failures, 1 from infection and 1 from metallosis secondary to metal anchor loosening in close proximity to the implant (8). In a recent retrospective case series, Gheorghiu et al (20) reported on 11 patients (12 feet) with a 47-month follow-up period. Five patients reported they would not undergo the same operation again, and another requested revision to MPJ fusion. Their results are in contrast to our long-term results. In our experience, it is important to consider the

Table 5
Treatment recommendations

Variable	Description
Preoperative	
Patient expectations	Establish treatment goals: pain relief versus motion and how important motion is to patient
Absolute contraindications	Significant bone demineralization, inadequate bone stock, neuropathic changes, metal sensitivity, or history of osteomyelitis or persistent infection
Intraoperative	
Hemostasis	Reduces postoperative swelling and lowers risk of early loss of motion
Joint decompression	Reset metatarsal joint line 1 to 3 mm proximally, followed by aggressive periprosthetic debridement Reduces pain, improves dorsal roll-off, can lower risk of phalangeal remodeling
Soft tissue release	Aggressive release, including collateral ligaments, sesamoid sleeve, and fibrotic flexor brevis tendon insertion onto proximal phalangeal base (18)
Screw height placement	If screw advancement needed, ensure repeat reaming to avoid poor component adhesion Avoid retracting screw after joint reaming, which could compromise implant–bone interface One full turn changes screw height by 4 mm but implant bed remains unchanged
Range of motion	Aim for 90° of dorsiflexion using joint decompression and metatarsophalangeal joint soft tissue releases
Implant choice	Highest curvature in superoinferior plane supports range of motion, dorsal roll off, and improved joint space configuration (8)
Angular deformities	Avoid concomitant osteotomies because they compromise early rehabilitation and motion Can use concomitant suspensory fixation devices for metatarsal corrections
Postoperative	
Aggressive rehabilitation (16,18)	Passive and active dorsiflexion and plantarflexion of joint encouraged immediately postoperative Immediate full weightbearing without a shoe at home encouraged to prevent joint stiffness Emphasize heel to toe stride to force hallux motion At 2 weeks, formal physical therapy prescribed for range of motion and strengthening exercises Running, impact exercises, and high-heeled shoes allowed at 6 weeks postoperatively

joint as a whole rather than reducing the procedure to an implant and reporting the related results. Gheorghiu et al (20) did not report any details regarding soft tissue and sesamoid release, joint decompression, or early rehabilitation. They also omitted reporting on the use of concomitant osteotomies that might relegate patients to deferred active rehabilitation until bone healing is complete or a high curvature implant selection to improve roll-off. Combined, all these considerations have made this procedure a success in our experience (Table 5).

One of the limitations of our study was the lack of a comparative treatment group. In our practice, we prefer to reserve arthrodesis as an end-stage salvage procedure; therefore, we did not believe a randomized clinical trial was feasible. Another limitation of our study was that we were only able to contact 76% of the patients who had undergone the procedure during our selected study period. Every effort was made to obtain the correct address or contact information for our patients; however, with the longer follow-up duration comes the increased difficulties in communication. We were also somewhat limited in that our final follow-up evaluation was conducted by telephone. This was another limitation to our study in that our questionnaire was not tested for reliability; however, we believe it did produce valid information about this procedure. Because most patients were doing very well, it was difficult to request that they come to the clinic for evaluation. Therefore, the criteria of the AOFAS scale score such as joint motion could be somewhat subjective.

Future studies of metatarsal head arthroplasty could consider the long-term data with newer implant designs. The second-generation HemiCAP® implant (Arthrosurface) is nearly identical but has a dorsal curvature to improve hallux role-off and prevent osteophyte regrowth. All implants used in our study were first-generation implants that did not include a dorsal flange. We believe this feature might have helped with our patient who required repeat surgery for dorsal spurring and increased range of motion. Further research could also study bipolar implants that address both sides of the joint.

In conclusion, the surgical treatment of late-stage hallux rigidus using metatarsal head resurfacing combined with important procedural considerations allows for low risk and excellent outcomes after long-term follow-up.

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