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Original Research

Surgical Treatment of Hallux Rigidus Using a Metatarsal Head Resurfacing Implant: Mid-term Follow-up

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ABSTRACT

The treatment of advanced hallux rigidus remains controversial, with many authors discussing arthrodesis versus arthroplasty. The purpose of this study is to report mid-term outcomes after implantation of a motion-preserving metatarsal head–resurfacing prosthetic and to present our technical considerations and modifications to the published technique to further enhance the clinical benefit of the procedure. Thirty-two implantations were performed in 30 patients. Twenty-three patients were women, 9 men. The average age was 62.8 years (range, 39-86 years). Patients were graded at baseline according to Hattrup and Johnson and completed the American Orthopaedic Foot & Ankle Surgery metatarsophalangeal clinical rating system preoperatively and postoperatively and a patient satisfaction question at final follow-up. Seventy-two percent of implantations were grade III hallux rigidus and 28% were grade II. The average follow-up was 27.3 months (range, 12-43 months). The mean change score for the overall American Orthopaedic Foot & Ankle Surgery scale was 236.8% (SD = 146.62, confidence interval [CI] = 186-287.6). A similar result was achieved between grade II (250.9%, SD = 240.3, CI = 93.9-407.9) and grade III (231.3%, SD = 95.83, CI = 195.14-270.46). No implants were revised or removed, and all patients stated that they were happy with their outcome and would repeat the procedure again if needed. In conclusion, metatarsal head resurfacing in combination with joint decompression, soft tissue mobilization, and debridement can achieve excellent results in grade II and III hallux rigidus. Salvage arthrodesis remains an option if future revisions are indicated.

Hallux rigidus is a degenerative and progressive arthritic disease involving the first metatarsophalangeal joint (MPJ), which results in limited dorsiflexion, painful range of motion (ROM), and osteophyte proliferation. Hallux rigidus was first described by Davies-Colley in 1887 (1), and later the term was coined by Cotterill (2).

Hallux rigidus is believed to be caused by any form of micro and macro trauma to the cartilage of the first MPJ resulting in damage and erosion of the joint surfaces (mostly dorso-lateral) and dorsal osteophyte production (3–5). Pain generation is believed to be secondary to increased shear forces at damaged articular cartilage joint surfaces and jamming of dorsal osteophytes upon dorsiflexion. Associated pain levels can range from mild to severe, can limit activity, and can be ongoing and debilitating.

Several treatment options for hallux rigidus have been reported in the literature (3–15). However, management of advanced stage II and III remains controversial, with many authors reporting on arthroplasty or joint fusion (3, 7–15).

The typical age for surgical intervention in patients with hallux rigidus is between 50 and 60 years, with a slightly higher proportion for female patients (3, 5, 6–12, 14). Before any intervention, every patient's age, activity level, expectations, and previous treatments should be considered, along with a radiographic and clinical grading and probable future treatment requirements to provide an appropriate treatment plan.

Hasselman and Shields (14) noted in their article published in 2008 that a metallic implant to resurface the metatarsal head with minimal bone resection and without altering the sesamoid articulation or interfering with the normal balance of the flexor extensors, plantar plate, or adductor-abductor mechanisms was needed. The HemiCAP System (Arthrosurface Inc, Franklin, MA, USA) (Figure 1) seems to fill that need. It can be used to resurface damaged articular surfaces and restore the patient's own unique joint geometry with minimal bone

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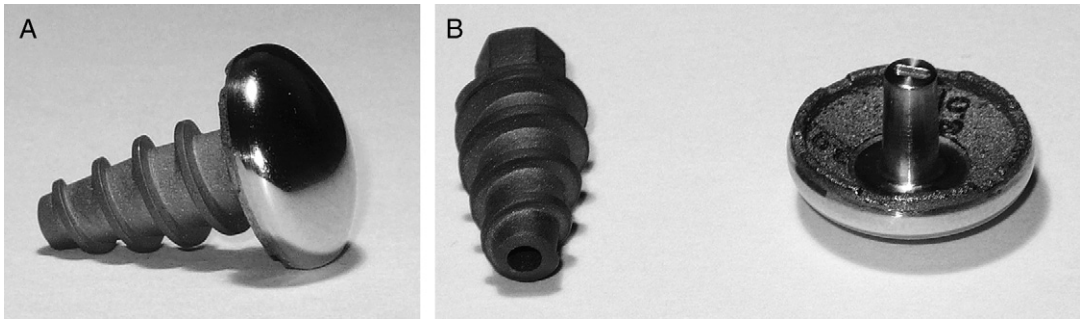

Fig. 1. The HemiCAP metatarsal head resurfacing implant. Titanium alloy fixation component connected via Morse taper to the cobalt chromium alloy articular contoured component. (A) Attached components. (B) Individual components.

resection. Hasselman and Shields (14) also noted that a longer-term study was needed to assess the implant in this population.

Therefore, the purpose of this prospective, single center clinical investigation was to evaluate the mid-term results of HemiCAP metatarsal head resurfacing and to present our technical considerations.

Patients and Methods

The primary outcome of this study is the change in the American Orthopaedic Foot & Ankle Society (AOFAS) metatarsophalangeal clinical rating system (16) from baseline (preoperative) to final follow-up postoperative at a minimum of 1 year. The AOFAS was developed by the American Foot and Ankle Society and is used to assess pain, function, and alignment. A score of 100 indicates that the patient is pain free, has full ROM, no instability, and good alignment with no activity limitation. Forty points are allotted for pain, 45 for function, and 15 for alignment.

The secondary outcomes analyzed are patient satisfaction measured by a single question asked at final follow-up, complications, and the separate domains of the AOFAS score.

Population

Consecutive patients who presented to our clinic between August 2002 and May 2008, who were considered for metatarsal implantation and who signed a consent form, were included in the study. All surgical procedures were performed by the three senior authors. Patients were assessed by a resident in clinic before the procedure and completed the AOFAS score (16). They were then graded according to the Hattrup and Johnson radiographic grading system (5), which was developed to grade hallux rigidus radiographically based on increasing osteophyte production, joint space narrowing, and subchondral sclerosis. Only patients with grade II (moderate osteophytes with joint space narrowing and subchondral sclerosis) and grade III (marked osteophytes, loss of joint space, and possible subchondral cysts) preoperative radiographic review were considered for the study.

Final follow-up evaluation included repeat AOFAS score and a patient satisfaction question conducted through phone interview by a resident. Only patients with a follow-up of more than 1 year were included in the analysis. The patient satisfaction question asked at final follow-up was: "Are you satisfied with the outcome of your surgery and would you repeat the procedure if needed in the future?" The patients were asked to give an answer regarding ROM and alignment portions of the AOFAS questionnaire as best they could answer. If they felt any reduction in their ROM, they were graded accordingly. They were also asked to consider the alignment of their foot. Any indication of a malalignment, in their opinion, was graded accordingly.

Statistical analysis was performed with Microsoft Excel Analysis Toolpak 2007 (Microsoft, Redmond, WA). Paired 2-tailed t tests were used to compare means of preoperative and postoperative AOFAS scores. The significance level was set a priori at < 0.05. The study was reviewed and approved by the local institutional review board.

Operative Technique

The HemiCAP Metatarsal Head Resurfacing System consists of a 2-component prosthetic: an articular and a fixation component. The articular component is a contoured, cap-like inlay implant made from cobalt chrome (CoCr) alloy on the articulating surface and titanium plasma spray on its underside. The fixation component is a cannulated, tapered titanium (Ti) screw that allows for solid primary fixation in the metatarsal head.

The joint is accessed through a dorsal medial incision, leaving the extensor tendon laterally. A McGlamry elevator is introduced to mobilize any adhesions in the sesamoidal space. The size of the metatarsal head is examined and confirmed with a sizing trial. A guide wire is introduced into the center of the metatarsal head with 1 to 2 mm plantar to the center in the sagittal plane. Proper position is verified under fluoroscopy, identifying the guide wire in 2 planes. The fixation component is predrilled, tapped, and implanted, and the appropriate insertion depth is confirmed. A centering shaft is introduced into the head of the fixation screw to allow for reaming. Because of the advanced degeneration of the patients in this study, we chose to select the implant with the largest curvature in the superior/inferior plane, thereby assisting with increased postoperative ROM and improved joint space configuration in the dorsal aspect of the joint. In addition to this modification from the recommended technique guide, we decompress all joints during the reaming and tapping stages of the fixation screw preparation and by advancing the screw by 1 to 3 mm, depending on the tightness of the joint and the length of the first metatarsal. After reaming of the first metatarsal head, a sizing trial is introduced, assisting in the final stages of reshaping the metatarsal head to conform to the resurfacing implant (Figure 2). Dorsal osteophytes and periprosthetic joint remnants are debrided, recreating a smooth and unobstructed metatarsal head. The plantar aspect of the first metatarsal head and sesamoid crista are contoured to ensure a smooth articulation of the sesamoids over the implant during ROM. Patients with advanced degeneration of the sesamoids undergo distal sesamoid debridement and sesamoidal contouring to avoid impingement during MPJ dorsiflexion. The base of the phalangeal joint is carefully debrided of all osteophytes as needed. The final HemiCAP resurfacing implant is placed into the implant bed and slightly impacted (Figure 3). Decompression, debridement, removal of loose bodies, release of all periarticular adhesions, and implantation of a new surface restores ROM and necessary joint space.

Any patient with metatarsus elevatus, a large amount of hypermobility, metatarsus varus, or hallux varus also underwent adjunct procedures before the time of surgery to correct structural deformities.

Postoperatively, patients who did not have adjunct procedures were weight bearing in a surgical boot or shoe as tolerated. Once the incision was healed, sutures were removed and patients returned to normal shoe gear as tolerated. Passive ROM was begun at the first postoperative visit, and aggressive ROM was initiated when the integument was healed. Once patients returned to normal shoe gear, activities could be resumed as tolerated.

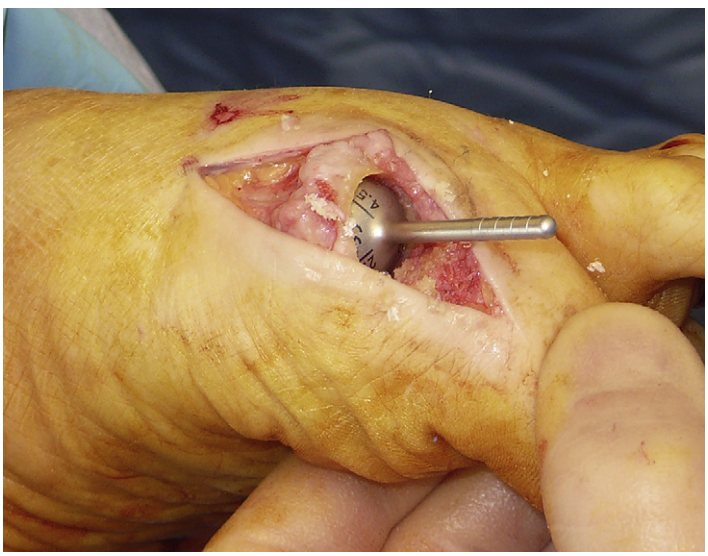

Fig. 2. Sizing trial in the metatarsal head. Placement of the sizing trial before insertion of the final articular component.

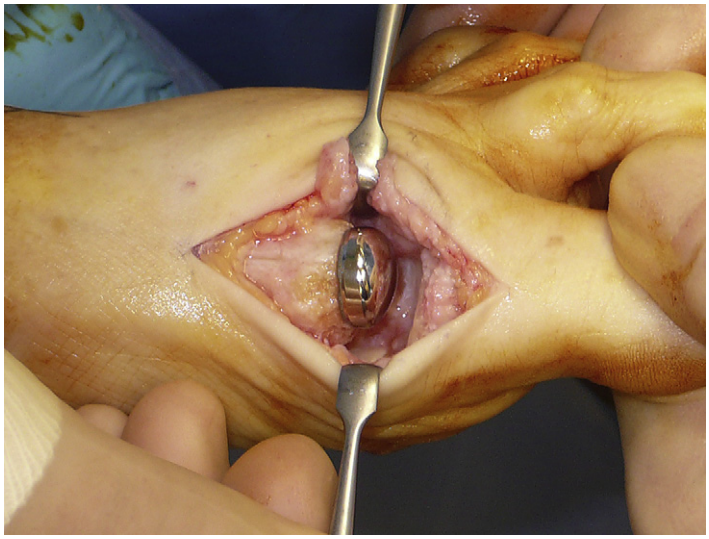

Fig. 3. Dorsal view of the first metatarsal head with final implant placement. Final placement of the HemiCAP implant on the metatarsal head.

Results

Metatarsal head resurfacing was performed on 30 patients. Two patients underwent bilateral procedures for a total of 32 cases. The demographics of the patient population can be seen in Table 1. The mean patient age was 62.8 years (range, 39-86 years), with most patients being between 50 and 70 years of age (24/32). One implantation was performed in a patient less than 50 years of age, 11 in patients between 50 and 60 years of age, 13 in patients between 60 and 70 years of age, and 5 in patients more than 70 years of age. The preoperative radiographic staging according to Hattrup and Johnson classified 72% of all cases as grade III hallux rigidus and 28% as grade II. The average follow-up was 27.3 months (range, 12-43 months). No patient was lost to follow-up. The mean % change score for the overall AOFAS scale was 236.8 (SD = 146.62, 95% confidence interval [CI] = 186-287.6). The same result was achieved for the secondary outcomes: grade II (250.9%, SD = 240.3, CI = 93.9-407.9) and grade III (231.3%, SD = 95.82, CI = 192.14-270.46). The results of the change score for the separate domains of the AOFAS can also be seen in Table 2. The mean absolute AOFAS score significantly improved by 58.5 points. The preoperative mean was 30.84 (range, 10-54), and the postoperative mean was 89.31 (range 70-100) ($P < .001$,) Ninety-four percent (30/32) of all cases achieved a final AOFAS score between 80 and 100 points. The absolute raw scores for the separate domains of the AOFAS can be seen in Table 3. In addition to the implant, all patients received joint decompression, capsular release, soft tissue mobilization, and debridement of periarticular osteophytes. One patient who received a Weil osteotomy is outlined below.

When asked if they were satisfied with their outcome, 100% of the patients said they were and all patients indicated they would undergo the procedure again if necessary.

Complications

No intraoperative or postoperative complications were encountered. All patients were free of delayed wound healing or infection. No implant failure, musculoskeletal deformities, or neurological complications were noted. All patients' postoperative care was similar and uneventful without any implant revisions or removals.

Of note is one patient who was previously treated with a Lapidus bunionectomy and excisional second toe proximal interphalangeal joint arthroplasty. After 4 months, the patient continued to have limited, painful dorsiflexion of the first MPJ, as well as plantar second MPJ pain. The patient was then scheduled for metatarsal head resurfacing and Weil osteotomy of the second metatarsal. At 2 months, the patient returned to work as a custodian. At 5 months, ROM and ambulation were normal and pain free (Figure 4). At the last follow-up at 18 months, the AOFAS score had improved 86.5% (from 52 to 97/100). The patient stated that she would recommend the procedure to family and friends and would undergo the procedure again.

Discussion

Results in this investigation demonstrated significant improvement in pain relief and change from baseline to final follow-up and all AOFAS domain scores, with no complications reported. When compared with previous studies, the mean postoperative AOFAS score of 89.31 is equivalent to reported scores on arthrodesis (Raikin [11] :83.8) and higher than the scores reported for other arthroplasty solutions (Fuhrmann [17]: 74.0, Raikin [11]: 71.8). The patients in our study were still able to have movement at the MPJ. Because the goal of any arthrodesis is to have no motion at the MPJ joint, the ROM score would be reduced by at least 10 points. Pain relief and total AOFAS scores in this study demonstrated no deterioration with increasing follow-up of this patient population.

Hallux rigidus is a common finding affecting up to 10% of adults (18, 19) and can be a debilitating cause of pain and functional limitations during low and high impact activities of daily living. Patients with advanced stages of hallux rigidus are typically between 50 and 60 years of age and most often desire to maintain MPJ joint motion for professional and personal reasons. Therefore, the treatment goal is dictated by the patient's disease stage, patient expectations, and a procedure that suits immediate and long-term requirements. Primary patient expectations are focused on pain relief and functional improvement, yet the professional impact of postoperative recovery and associated activity restrictions have to be considered when choosing an individual treatment plan.

Early management of hallux rigidus consists of conservative measures including icing, anti-inflammatory medication, intra-articular corticosteroid injections, physical therapy, and shoe modifications with a stiff sole, enlarged toe box, and a rocker bottom to

Table 1
Patient demographics (N = 32 implants in 30 patients)

	Age (years) (mean ± SD)	Gender	Affected side	Follow-up (months)
Total N = 32	62.8 ± 9.7 (range, 39-86)	9 M, 23 F	13 L, 19 R	27.3 ± 9.1 (range, 12-43)
Grade II,* n = 9	60.2 ± 5.8 (range, 51-66)	1 M, 8F	3L, 6R	23.0 ± 7.7 (range, 12-38)
Grade III,* n = 23	63.85 ± 10.7 (range, 39-86)	8 M, 15F	10 L, 13R	28.96 ± 9.19 (range, 15-43)

* First metatarsophalangeal joint graded according to Hattrup and Johnson (Hattrup SJ, Johnson KA. Subjective results of hallux rigidus following treatment with cheilectomy. Clin Orthop Relat Res 226:182191, 1988), wherein grade 2 = moderate osteophytes with joint space narrowing and subchondral sclerosis, and grade 3 = marked osteophytes, loss of joint space, and possible subchondral cysts.

Table 2
Change scores for the American Orthopaedic Foot & Ankle Society (N = 32 implants in 30 patients)

	Overall (N = 32)	Grade II* (n = 9)	Grade III* (n = 23)
Total score			
% Change ± SD	236.8 ± 146.62	250.9 ± 240.3	231.3 ± 95.82
Confidence interval	186, 287.6	93.9, 407.9	192.14, 270.46
Pain			
% Change ± SD	88.54 ± 22.18	81.48 ± 28.19	91.3 ± 19.38
Confidence interval	80.86, 96.22	63.06, 99.9	83.38, 99.22
Function			
% Change ± SD	123.36 ± 135.6	107.85 ± 70.1	129.43 ± 154.9
Confidence interval	76.38, 170.34	62.05, 153.65	66.12, 192.74
Alignment			
% Change ± SD	231.64 ± 507.26	406.64 ± 527.4	214.68 ± 510.3
Confidence interval	55.75, 407.53	62.07, 751.21	6.13, 423.23

* First metatarsophalangeal joint graded according to Hattrup and Johnson (Hattrup SJ, Johnson KA. Subjective results of hallux rigidus following treatment with cheilectomy. Clin Orthop Relat Res 226:182191, 1988), wherein grade 2 = moderate osteophytes with joint space narrowing and subchondral sclerosis, and grade 3 = marked osteophytes, loss of joint space, and possible subchondral cysts.

decrease demands in dorsiflexion and to allow adequate room for swelling (20). When conservative treatment options have failed, a wide variety of surgical procedures have been described for treatment of hallux rigidus (3–14). Cheilectomy or excision of osteophytes has been used to treat lower grades of the deformity in which joint space and cartilage are preserved, but dorsiflexion is limited by the presence of osteophytes (3, 5).

The treatment of advanced stages of hallux rigidus is challenging because of the chronicity of the disease process. Osteophyte formation, loss of joint space, and restriction of ROM gradually increase over time, leaving peri-articular soft tissues in a contracted state (1). This provides challenges for motion-preserving treatment options. As an alternative, MTP arthrodesis has been advocated by many authors (7, 8, 11, 13). Implant arthroplasty and joint fusion have demonstrated successful outcomes; however, both have been subject to great debate.

In comparative studies, MPJ arthrodesis has been shown to provide higher patient satisfaction rates when compared with arthroplasty solutions (8, 11), yet the procedure is not without controversy based on reports of nonunion, progressive interphalangeal degeneration, malalignment in 3 possible planes, transfer metatarsalgia, shoe wear restriction, and protected postoperative recovery until union is confirmed (9, 21–23). Many patients who are possible candidates for MPJ implant procedures require a Lapidus procedure. Arthrodesis of both joints in the first ray would cause intolerable results.

With the availability of modern implant designs, we believe joint fusion in hallux rigidus should be limited to end-stage salvage procedures, as commonly accepted for other musculoskeletal joints (24–29).

Recently, Cook et al reported on their meta-analysis of first MPJ arthroplasty (15). Based on their study of 47 peer-reviewed publications on 3049 implant procedures, patient satisfaction ranged from 85.7% to 94.5%, with a mean follow-up of 61.48 months. The investigators excluded any studies before 1990 due to the evolution of implant designs and indications. Despite these promising results, several authors reported on implant radiolucencies (8, 17, 30–32), subsidence (30–32), or prosthetic failure (30, 33).

Furthermore, Cook et al presented a historical generation review of implant arthroplasty and proposed the following classification based on implant material and fixation (15):

- First generation: material—silicone; design—hemi and total
- Second generation: material—improved silicone; design—hemi and total implants with grommets
- Third generation: material—metallic; design—hemi and total implants that are press fit
- Fourth generation: material—metallic; design—hemi and total implants that have a threaded stem

In their study on hemiarthroplasty compared with arthrodesis, Raikin et al concluded that most failures occur within the first 2 years after implant arthroplasty (11). With the current average follow-up in our patient population of 27 months (range, 12-43 months), we provide promising results of the metatarsal head resurfacing implant with no failures.

HemiCAP metatarsal head resurfacing is a fourth generation implant design that involves replacement of the damaged articular surface with

Table 3
Absolute preoperative and postoperative American Orthopaedic Foot & Ankle Society scores (N = 32 implants in 30 patients)

	Overall (N = 32)		Grade II* (n = 9)		Grade III* (n = 23)	
	Mean	SD	Mean	SD	Mean	SD
Total score						
Preop	30.84	11.64	32.4	15.03	30.21	10.36
Postop	89.31	7.9	83.89	7.66	91.43	7.05
P value	< .001		< .001		< .001	
Pain						
Preop	4.38	8.4	6.6	10	3.48	7.75
Postop	36.25	5.54	32.2	6.67	37.8	4.21
Function						
Preop	19.56	5.5	19.56	6.27	19.57	5.29
Postop	38.28	4.4	37.44	5.25	38.6	4.16
Alignment						
Preop	11.13	5.64	10.11	6.45	11.52	5.14
Postop	14.78	1.24	14.2	2.3	15.0	0.0

* First metatarsophalangeal joint graded according to Hattrup and Johnson (Hattrup SJ, Johnson KA. Subjective results of hallux rigidus following treatment with cheilectomy. Clin Orthop Relat Res 226:182191, 1988), wherein grade 2 = moderate osteophytes with joint space narrowing and subchondral sclerosis, and grade 3 = marked osteophytes, loss of joint space, and possible subchondral cysts.

Fig. 4. Preoperative and postoperative radiographs of hallux valgus deformity case. (A) Preoperative anteroposterior radiograph with hallux valgus deformity. (B) Postoperative anteroposterior radiograph status post-lapidus bunionectomy, second toe excisonal phalangeal-interphalangeal arthroplasty, Weil osteotomy, and metatarsal head resurfacing.

a patient-specific implant that requires minimal cartilage and bone removal if indicated. The reason for its success may include preserving normal metatarsal bone and cartilage, which allows for easier and better salvage procedures, if revision surgery may become necessary in the future. Other benefits include no loss of intrinsic muscle function, no change in the contour of the joint surfaces, the ability to decompress the MTP joint if necessary, and a stable screw fixation.

One of the limitations of this study was the lack of a comparative treatment group. Based on intraoperative joint assessment of this patient population, early treatment options such as cheilectomy were not indicated because of advanced degeneration. We believe that joint arthrodesis should be limited to those patients requiring an end-stage salvage procedure; for that reason, we did not feel that a randomized clinical trial was possible.

Another weakness of the study was the lack of a consistent follow-up interval of more 2 years. The telephone interview at final follow-up was also not ideal. We found it difficult to schedule patients to come in to the clinic but were able to reach each patient by telephone and therefore did not have any dropouts to the study. We continue to observe this patient population and will report further long-term results in the future.

In conclusion, after conservative treatment has failed in moderate to severe hallux rigidus, metatarsal head resurfacing provides key benefits and excellent outcomes after mid-term follow-up.

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