



Early results of HemiCAP® resurfacing implant

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Objective: Metallic implants in the first metatarsophalangeal (MTP) joint have been used for many years in the treatment of hallux rigidus (HR). The HemiCAP® prosthesis is the first implant used for resurfacing the metatarsal head in HR treatment. The aim of our study was to evaluate the early results of the HemiCAP® prosthesis for the treatment of HR.

Methods: A total of 27 toes of 25 patients with MTP arthritis of the great toe were treated with an ArthroSurface® HemiCAP® resurfacing implant. The average follow-up time was 37.6 (range: 30 to 43) months. All patients were evaluated clinically and radiographically. Postoperative satisfaction and function were scored according to the American Orthopaedic Foot and Ankle Society (AOFAS) score. Pain was assessed with the use of a visual analogue scale (VAS) ranging from 0 to 10, with 0 indicating the absence of pain and 10 describing the worst pain imaginable.

Results: Mean preoperative AOFAS score improved from 40.94 (range: 25 to 63) to 85.1 (range: 54 to 98) at the final follow-up ($p < 0.0001$). Preoperative average VAS pain scores improved from 8.30 preoperatively to 2.05 at the final follow-up ($p < 0.0001$). The average MTP joint range of motion (ROM) improved from 14.36 degrees preoperatively to 54.38 degrees at the final follow-up. No radiologic loosening or osteolysis was observed in patients with HemiCAP® implant.

Conclusion: The early results of the HemiCAP® implant on the metatarsal head are promising. However, studies over a longer period involving more patients would be beneficial in terms of defining and reviewing the stability of the implant and any innovations in the treatment strategy for HR.

Key words: ArthroSurface®; hallux rigidus; HemiCAP®; metatarsal head resurfacing.

Hallux rigidus (HR) is the osteoarthritis of the first metatarsophalangeal (MTP) joint, characterized by pain, restricted dorsiflexion of the great toe and dorsal osteophyte formation.^[1-3] HR has many causes, including osteoarthritis, rheumatoid arthritis, gout, neuromuscular disorders, congenital defects, and failed joint operations.^[4]

Surgical management options for HR include cheilectomy, osteotomy, resection arthroplasty, soft tissue interpositional arthroplasty, arthrodesis, hemiarthroplasty, and total joint replacement.^[1,5-9]

Although arthrodesis of the MTP joint is a reliable and reproducible means of treating advanced stages of HR, in young patients, it can limit shoe wearing and functional and sportive activities. Complications of arthrodesis include non-union, implant failure and the development of arthritis at the interphalangeal and tarsometatarsal joints.^[1,9,10]

The treatment of advanced HR remains controversial, with many authors discussing arthrodesis versus arthroplasty.^[2,11] MTP joint arthroplasty was introduced in the 1950s as an alternative solution in patients for

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Submitted: February 1, 2011 **Accepted:** August 25, 2011

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Available online at
www.aott.org.tr
doi:10.3944/AOTT.2012.2610
QR (Quick Response) Code:



whom arthrodesis, metatarsal osteotomy and excisional type arthroplasty were not ideal choices.^[12] Metallic implant for metatarsal head resurfacing should not change sesamoid articulation and should be applied together with bone resection. Implants should also not interfere with the normal flexor-extensor balance, plantar plate and the abductor-adductor mechanism.^[13]

The HemiCAP[®] resurfacing implant (Arthrosurface Inc., Franklin, MA, USA) was first introduced by Hasselman and Shields in 2008.^[13] In this study, we aimed to evaluate the early results of this new treatment modality for the metatarsal head in HR.

Patients and methods

A total of 27 toes of 25 patients (6 male, 19 female) with HR were treated with HemiCAP[®] resurfacing implant (Arthrosurface Inc., Franklin, MA, USA) between March 2007 and April 2008. The average age of the patients was 58 (range: 40-71) years. The average follow-up time was 37.6 (range: 30 to 43) months.

Degeneration of the first MTP joint was assessed according to the Coughlin and Shurnas classification.^[14] The severity of HR was Stage 3 in 18 patients and Stage 4 in 7 patients. The range of motion (ROM) in the first MTP joint as defined by the angle between the proximal phalanx and the first metatarsal shaft with the foot and ankle in the plantigrade position was noted both preoperatively and postoperatively at the final follow-up. All ROM measurements were performed with the same goniometer and by the same observer.

Radiographic evaluation was performed preoperatively and at the postoperative 1st, 3rd, and 6th months, and 1st and 2nd years.

Routine anticoagulant and antibiotic prophylaxis was preoperatively administered to all patients.

On the first postoperative day, all patients were allowed weightbearing with crutches and ROM exercises were started. After the 15th postoperative day, patients were allowed to wear shoes if they could tolerate the pain.

Preoperative and postoperative evaluations were performed according to the American Orthopaedic Foot and Ankle Society (AOFAS) score. Pain was assessed using a visual analogue scale (VAS) pain score ranging from 0 to 10, with 0 indicating the absence of pain and 10 describing the worst pain imaginable.

All preoperative and postoperative values were evaluated with MedCalc[®] v10.1.6.0 (MedCalc Software, Ghent, Belgium) statistical software. Since all groups had normal distribution, the paired samples t-test was used. The p values below 0.05 were considered significant.

A dorsal skin incision through the center of the MTP joint was used, as a dorsal approach allows easy insertion of the implant and access to medial, dorsal and lateral osteophytes.^[3] The capsule was opened longitudinally 2 to 3 mm medial to the extensor hallucis tendon and detached from the bone (Fig. 1). After the metatarsal head was exposed, a guide wire was placed from the center of the metatarsal head towards the shaft in mediolateral and dorsoplantar directions under fluoroscopy (Fig. 2). Following drilling and tapping of the head, the tapered post was implanted into the bone. According to the mediolateral and inferosuperior measures of the implant that were taken, reaming of the metatarsal head to this size were carried out and the implant was placed onto the tapered post (Fig. 3). A 15-mm articular component was used in 20 toes and a 12-mm articular component was used in 7 toes (Fig. 4).

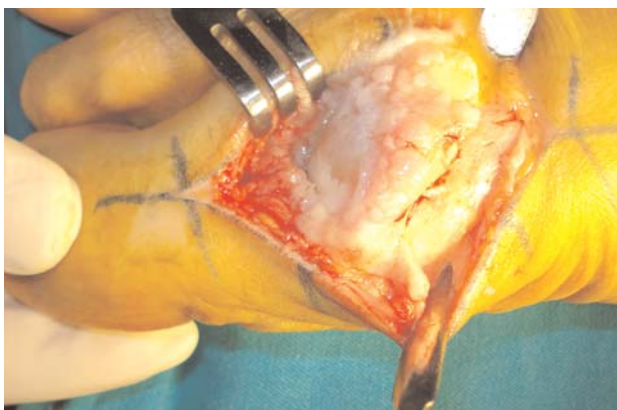


Fig. 1. Grade 4 lesion, following metatarsophalangeal capsulotomy. [Color figure can be viewed in the online issue, which is available at www.aott.org.tr]



Fig. 2. Guide wire placement through the center of the metatarsal head. [Color figure can be viewed in the online issue, which is available at www.aott.org.tr]

Results

Statistically significant differences were found in all preoperative and postoperative values ($p < 0.0001$).

The preoperative average AOFAS score improved from 40.94 (range: 25 to 63) preoperatively to 85.1 (range: 54 to 98) at the final follow-up ($p < 0.0001$). Preoperative average VAS pain score improved from 8.30 preoperatively to 2.05 at the final follow-up ($p < 0.0001$).

The preoperative average plantarflexion of the patients improved from 4.42 degrees preoperatively to 13.68 degrees at the final follow-up ($p < 0.0001$). Average dorsiflexion of the patients improved from 9.68 degrees preoperatively to 39.10 degrees at the final follow-up ($p < 0.0001$). Average ROM of each joint improved from 14.36 degrees preoperatively to 54.38 degrees at the final follow-up ($p < 0.0001$).

No complication was observed, with the exception of a superficial infection in one patient in the early postoperative period. Infection in this patient was treated with oral antibiotics.

Discussion

There are many treatment alternatives in the treatment of HR. Cheilectomy is preferred to reduce pain and increase ROM in the early phases of the disease.^[5,6] In advanced phases, other alternative surgical methods should be planned.

Due to the safety and efficiency of autogenous soft tissue interpositional arthroplasty, it has been accredited as an alternative method to arthrodesis and other forms of arthroplasty for the treatment of end-stage HR. However, prospective studies with long-term follow-up are required.^[15]

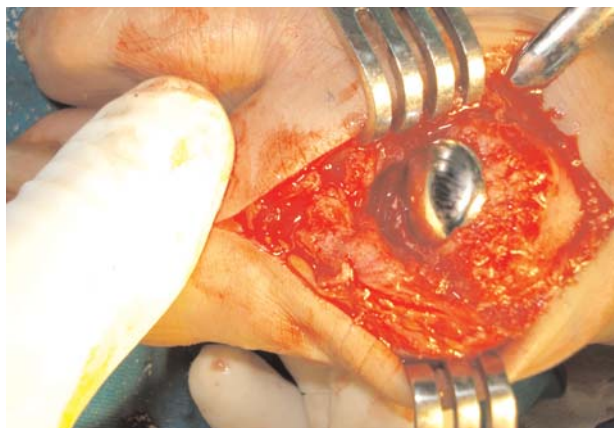


Fig. 3. The HemiCAP® implant inserted in the taper post. [Color figure can be viewed in the online issue, which is available at www.aott.org.tr]

Arthrodesis is a successful treatment method for serious and end-stage degenerations in the MTP joint, with long-term results that vary from good to perfect.^[1,3,9] However, to avoid dissatisfaction based on unrealistic expectations, patients should be informed in advance regarding post-surgery activity limitation and special shoe requirement.^[1]

Arthroplasty of the MTP joint was a logical consequence following the development of implants for other joints. The primary advantage of MTP arthroplasty is the restoration of functional joint motion. The ideal implant should relieve pain, improve function and maintain stability.^[8,16,17] Numerous implant systems have been developed over the years. Commonly used implants are silicone, metal (cobalt chrome and titanium) and ceramic.^[10,18] Silastic implants have been used in the past, although complications, such as synovitis, granulomato-



Fig. 4. Bilateral implantation in the same session. **(a)** Preoperative anteroposterior radiograph of the patient. **(b)** Anteroposterior radiograph of the patient 32 months after HemiCAP® resurfacing arthroplasty.

sis reaction, lymphadenopathy, and metatarsalgia have been observed with these implants.^[8,10,19]

A press-fit ceramic Moje implant was first used in the United Kingdom in 1999. The bioceramic-covered structure of the implant stimulates bone ingrowth. Other advantages, such as the prevention of pain, preservation of joint motion, good biocompatibility, and easy usage and application without cement have been reported.^[18,20] Satisfying results with the Moje prosthesis were noted in 33 of 40 patients (82.5%) in a 24-month follow-up period.^[18] However, Nixon et al.^[20] detected a high rate of loosening and revision during a 3-year follow-up of 21 Moje prostheses implanted in 14 patients. It has been stated that radiological follow-up at certain intervals is required because of the difficulty in clinical detection of loosening in the prosthesis.

Despite the successful results and increasing interest in replacement arthroplasty, the overall results are inconsistent and few comparative studies evaluating other treatment methods exist. In a comparative study of 21 hemiarthroplasties and 27 arthrodeses, a 24% rate of unsuccessful results was noted in the hemiarthroplasty group, while bony fusion was achieved in all patients in the arthrodesis group and there was only one unsuccessful result.^[21] In a randomized controlled trial, Gibson and Thomson evaluated clinical outcomes after first MTP arthrodeses and replacement arthroplasties.^[22] Significantly greater pain improvement was determined in the arthrodesis group than in the arthroplasty group at 24 months. In the arthrodesis group, bony fusion occurred in all patients, while in the arthroplasty group 15% had to be removed due to phalangeal component loosening.

Hemiarthroplasties that resurface the proximal phalangeal base have shown promise as well, but stiffness, continued pain and prosthetic loosening are still limiting factors.^[13,17] Konkeland Menger^[23] reviewed 10 patients who underwent titanium hemiarthroplasty with an average follow-up of 30 months. All titanium prostheses had subsided to varying degrees with lucencies around the implant.

The HemiCAP[®] Metatarsal Head Resurfacing System consists of two components; a fixation component and an articular component, that mate together via a taper interlock to provide stable and immobile fixation of the implant and stress bearing contact at the bone/prosthetic interface. The fixation component is a modified titanium cancellous screw with a tapering distal tip. The articular component is a contoured, cap like

inlay implant made from cobalt-chromium-molybdenum alloy with titanium plasma spray coverage on the underside for bone ingrowth.^[2,13,24] The HemiCAP[®] implant is available in 12- and 15-mm diameter sizes to accommodate metatarsal head dimensions.^[13]

The HemiCAP[®] prosthesis was the first implant used for resurfacing the metatarsal head in the treatment of HR. Bone stock in patients is preserved, as minimal bone resection is performed. By resurfacing the metatarsal head at the joint level, tendon attachments at the base of the toe are preserved and a potential fusion option for the future is preserved. Additionally, a press-fit implant allows early weight-bearing. As a result of early motion, the risk of stiffness decreases.^[13,25] Impaction of the proximal phalanx on the metatarsal head is seen as the major etiologic factor in the development of HR. Therefore, resurfacing the metatarsal head explains the postoperative improvement.^[13]

We observed that all patients experienced pain relief in the postoperative period, though two of our patients experienced mild pain and one reported medium pain. Strikingly, we found that at the final follow-up, the difficulty in wearing shoes was eliminated postoperatively in all of the 25 patients who had presented with this complaint.

Postoperative average AOFAS scores of our patients were compatible with other studies in the literature.^[2,13] The average increase in the ROM of our patients in the postoperative period was 40 degrees, and this corresponds with the results of Hasselman and Shields.^[13] According to Hasselman and Shields, the good postoperative ROM and decrease in pain are most likely due to the resurfacing of the damaged cartilage, creating a new smooth and compatible joint surface, as the main pathology and cartilage loss in HR are in the metatarsal head.^[13]

According to the comprehensive review of hemiarthroplasty and other forms of operative treatment for HR, hemiarthroplasty has been considered to have a high rate of satisfactory outcomes regardless of grading. It is a good alternative to fusion for maintaining functional ROM for severe HR. However, there is still a need for long-time follow-up studies.^[26]

Loosening of implants in phalangeal arthroplasties affects results. Arbuthnot et al.^[18] detected radiological loosening in 4 of 42 toes (40 patients) with ceramic-covered endoprostheses, and Nixon and Taylor^[20] detected loosening in 9 patients with Moje ceramic press-fit

arthroplasty. No radiologic loosening, change in the position of the implants or osteolysis was observed in our study with the HemiCAP® implant in an average of 37.6 months of follow-up. Kissel et al. did not find any correlation between the articular cartilage defect ratio in the first metatarsal head and the increase in postoperative ROM and decrease in pain in the patients they treated with BioPro® (BioPro Inc., Port Huron, MI, USA) hemiarthroplasty.^[25] Based on the same logic, we think that a separate study should be carried out to determine whether the cartilage destruction ratio on the phalangeal joint surface has an impact on postoperative clinical and functional results in patients with HemiCAP® resurfacing arthroplasty.

In conclusion, we believe that early results for the use of the HemiCAP® implant on the metatarsal head in the treatment of HR are promising. However, studies with a longer follow-up period involving more patients would be beneficial in terms of defining and reviewing the stability of the implant and any innovations in the treatment strategy of HR.

Conflicts of Interest: No conflicts declared.

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