The Journal of Foot & Ankle Surgery 56 (2017) 788–792

Contents lists available at ScienceDirect

The Journal of Foot & Ankle Surgery

journal homepage: www.jfas.org

Results of HemiCAP® Implantation as a Salvage Procedure for Osteochondral Lesions of the Talus

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ARTICLE INFO

Level of Clinical Evidence: 4

Keywords:
ankle
cartilage
metal resurfacing implant
osteochondral defect
subchondral bone
talus

ABSTRACT

Osteochondral defects (OCDs) of the talus remain a surgical challenge, especially after failed primary treatment. The aim of the present study was to examine the clinical outcomes after HemiCAP® implantation for OCDs of the medial talar dome after failed previous surgery. Our retrospective study included 11 patients, who had undergone surgery from June 2009 to September 2012 for an OCD of the medial talar dome and received a HemiCAP® on the talus after failed previous surgery for OCD. The data were acquired using patients' medical records and standardized questionnaires, including the Foot and Ankle Outcome Score (FAOS), University of California at Los Angeles (UCLA) activity score, EQ-5D, numerical rating scale (NRS), and Short-Form 36-item Health Survey (SF-36). Using these scores, the possibility of returning to work and sports was determined. Any complications and the need for revision surgery were recorded. One patient refused to participate in the study, leaving 10 patients for evaluation. The mean age was 47.64 ± 10.97 years. The mean follow-up period was 43.5 ± 35.51 months. The FAOS and SF-36 subscale scores and the EQ-5D and UCLA activity scores did not improve significantly ($p < .05$). The mean postoperative pain score on the NRS improved significantly from 6.6 ± 1.77 preoperatively to 5.1 ± 2.02 postoperatively ($p < .05$). A greater body mass index led to worse postoperative outcomes with higher scores on the pain-NRS and less satisfaction ($p < .05$). Ten revisions for ongoing pain were performed in 7 patients (70.0%) within a mean of 28.4 ± 13.35 months of the initial procedure, and 6 patients (60%) indicated they would undergo surgery again. The results of the present study have shown that implantation of the HemiCAP® as a salvage procedure for OCDs of the talus is challenging and does not consistently lead to good clinical results. Also, overweight patients appear to have an increased risk of postoperative dissatisfaction and persistent ankle pain.

Most osteochondral defects (OCDs) of the talus appear on the medial dome. They affect the articular cartilage with the underlying subchondral bone (1,2). Clinically, OCDs lead to load-dependent pain of the ankle, combined with swelling, restricted range of motion, and synovitis (3). In many cases, OCDs do not regenerate, depending on parameters such as localization, depth, size, and patient age, and surgery becomes necessary (4,5).

OCDs can be treated using a variety of techniques. In many centers, arthroscopic bone marrow stimulation techniques are standard primary treatment (6). Overall, in 85% of surgically treated OCDs, arthroscopic bone marrow stimulation and debridement will be successful (7). However, some patients still experience persistent deep ankle pain after primary treatment. Different surgical techniques have been described for their treatment, including autologous matrix-induced chondrogenesis, matrix-induced autologous chondrocyte implantation, autologous chondrocyte implantation, osteochondral autologous transplantation, axis correction, and/or even arthrodesis (6,8,9).

van Dijk et al (3) reported that it is not the cartilage, but the subchondral bone, that causes the deep ankle pain in OCDs owing to insufficient healing in failed OCD treatment. To address this insufficient bone stock, a metallic resurfacing implant (HemiCAP®; Arthrosurface Inc., Franklin, MA) was developed to treat patients with failed primary surgery by a joint-preserving method (10–12). The

Financial Disclosure: None reported.
Conflict of Interest: None reported.

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http://dx.doi.org/10.1053/j.jfas.2017.04.001

HemiCAP® implant has been tested previously in mechanical cadaver studies, which led to promising results regarding the biomechanical properties in ankles with large OCDs (10–12). Despite the promising results when used in other joints and the relevance of OCDs of the ankle, only limited data are available on the clinical results with this metal resurfacing implant (12,13). The purpose of the present study was to analyze the mid-term results after implantation of a HemiCAP® after failed previous surgery for OCD of the talus.

Patients and Methods

In the present retrospective study, 11 consecutive patients were included, who had undergone surgery from June 2009 to September 2012 for an OCD of the medial talar dome and had received a HemiCAP® implant. The responsible ethics committee of the Medical School Hannover approved the study (approval no. 2469-2014). All the patients gave informed consent to have their information used in the present study. The indications for HemiCAP® implantation were an OCD of the medial talar dome and persistent pain present for ≥9 months after previous surgery, including ankle arthroscopy with cartilage therapy (Table 1). The contraindications included additional pathologic features of the ankle, such as ligamentous instability, advanced ankle osteoarthritis (Kellgren and Lawrence grade >I), tibial osteochondral defect, relevant misalignment, diabetes mellitus, and peripheral arterial occlusive disease.

All the patients underwent surgery under general anesthesia and in the supine position by a senior foot and ankle surgeon (H.W.). HemiCAP® implantation was performed according to the manufacturer's instructions. A standard medial malleolar osteotomy was used to gain access to the lesion of the talar dome. The OCD was debrided and a Kirschner wire was placed into the center of the defect. The size of the defect was measured, and the implant site was prepared using a mortising machine to fit the implant. A trial component was used, and the size was checked for optimal fit. Next, the original components were inserted cementless, aiming for a position of the implant just below the border of the surrounding cartilage. The medial malleolus was repositioned and fixed with 2 lag screws.

Postoperative care consisted of non-weightbearing for 6 weeks using a walker to allow for secure healing. Physiotherapy was allowed with mobilization of the ankle from immediately postoperatively. Immediate postoperative and 6-week postoperative radiographs of the ankle were obtained. After consolidation of the malleolus medialis, patients started increasing load until full weightbearing during the next 6 weeks in a walker boot (VACO®ped; OPED GmbH, Oberlaindern, Germany). After 12 weeks, normal footwear was allowed.

The data were acquired using the patient medical records and standardized questionnaires, including the Foot and Ankle Outcome Score (FAOS) (14), University of California at Los Angeles (UCLA) activity score (15), EQ-5D (16,17), numerical rating scale (NRS) (18), and Short-Form 36-item Health Survey (SF-36) (19). The outcome scores and medical record information were abstracted by 2 of us (S.E., L.C.). In addition to these scores, the following data were collected: age, sex, anatomic side, body mass index (BMI), duration of pain, use of analgesics, ability to return to work and sports, hindfoot alignment (defined as the tibiocalcaneal angle), medial distal tibia angle (MDTA) (20), and complications related to surgery. To evaluate the sports activity level, all patients were divided into 4 groups (highly active, well trained, moderately trained, and not active) according to van Dijk et al (13). The incidence of complications and revision surgery were also recorded. The following conditions were considered complications: implant misalignment, wound infection, and pseudarthrosis of the medial malleolus. All data were evaluated with the implants in situ.

Six patients (54.5%) had full clinical follow-up data available, and 4 patients (36.4%) could only be interviewed by telephone, 3 (27.3%) because of non–foot-related disease (1 [9.1%], apoplexy; 2 [18.2%], mental illness) and 1 (9.1%) refused to complete the whole questionnaire. One patient (9.1%) refused to participate in the study at all. The telephone interviews were conducted by 1 of us (S.E.) and included pre- and postoperative pain using the NRS (0, no pain to 10, the worst pain), satisfaction with the operation (score, 1 to 6; 1, very good; 2, good; 3, satisfied; 4, sufficient; 5, inadequate; and 6, unsatisfactory), and whether the patient would undergo the surgery again, given the same circumstances.

Preoperatively, all patients had their painful ankle evaluated using magnetic resonance imaging scans and weightbearing radiographs (ankle anteroposterior, weightbearing lateral foot, and hindfoot alignment views (21)). Directly postoperatively and at all follow-up visits, anteroposterior ankle and lateral foot radiographs were obtained, with the patients weightbearing when possible (Fig. 1). Two of us (S.E., C.P.) examined all postoperative radiographs, focusing on implant loosening, progression of ankle osteoarthritis using the Kellgren and Lawrence classification (22), nonunion of the malleolar osteotomy, and examination of the MDTA (20) and hindfoot alignment.

All the data were collected using Excel® (Microsoft Corporation, Redmond, WA). Prism, version 6.0 (GraphPad, San Diego, CA), was used to conduct the statistical analyses. A paired Student's *t* test was performed to analyze the data for statistically significant differences, and Pearson's correlation was used to analyze associations between exposures and outcomes. The outcome measurements, postoperative

Table 1
Clinical and radiologic data

Pt. No.	Sex	Age (y)	BMI (kg/m²)	Previous Surgery	Clinical Follow-Up (mo)	Additional Surgery	Pain-NRS Score (0 to 10)		Satisfaction Score (1 to 6)	Return to Work (mo)	Return to Sports (mo)	Progression of Degenerative Changes	Hindfoot Alignment (°)	Implant Loosening	Pseudarthrosis of Medial Malleolus	MDTA (°)
							Preoperative	Postoperative								
1	Female	35	28.37	BMS	57	Arthroscopy	4	4	3	10	18	I → I	172.5	No	No	89.4
2	Male	33	28.39	BMS, ACI, AMIC	57	None	4	3	4	12	12	0 → 0	182	No	No	88.7
3	Female	54	35.86	BMS	48	Calcaneal osteotomy	6	5	3	20	20	I → II	172.1	No	No	88.1
4	Male	47	27.43	BMS, OATS	33	Arthroscopy, screw removal	7	7	5	6	16,5	I → II	173	No	No	87.1
5	Female	47	29.30	BMS, OATS	39	Screw removal, arthroscopy	10	7	4	12	Inactive	I → II	181	No	No	84.8
6	Female	68	27.96	BMS	69	None	7	2	2	10	16	I → I	182	No	No	84.7
7	Female	49	25.53	BMS	20	Arthroscopy	6	4	3			I → II	175.5	No	No	86.9
8	Female	48	36.64	AMIC	46	Arthroscopy, ankle arthrodesis	7	7	5			I → II	169.9	No	No	85.1
9	Female	37	44.12	AMIC	57	Arthroscopy, screw removal, ankle arthrodesis	8	8	6			I → III	182	No	No	83.2
10	Male	63	23.55	BMS	9	None	7	4	3			I → I	182	No	No	82.6

Abbreviations: ACI, autologous chondrocyte implantation; AMIC, autologous matrix-induced chondrogenesis; BMI, body mass index; BMS, bone marrow stimulation; MDTA, medial distal tibial angle; NRS, numerical rating scale; OATS, osteochondral autologous transplantation.