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Case Reports and Series

Treatment of an osteochondral lesions of the talus with a novel patient-specific metallic implant: A case report with 5-year follow-up and review of the literature

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ABSTRACT

Osteochondral lesions of the talus are a relevant cause of pain and disability while their treatment remain challenging. If conservative treatments fail, surgical interventions such as core decompression, microfracturing of the talus or osteochondral treatments can be performed. As already described for the knee joint, there are also novel patient-specific implants for the treatment of focal osteochondral defects. For the first time such implant technology was used in the ankle joint. We report a 33-year-old male patient with persistent pain and reduced range of motion following an ankle sprain. He was referred after initial conservative treatment and an osteochondral autograft transplant. An MRI was performed to identify the location and dimension of the medial talar cystic defect with a length of 15 mm and a width of 7 mm. Using this data, a patient-specific implant and guiding instruments were manufactured for this surgery. Postoperatively, the patient reported reduced pain and improvements in clinical outcomes (range of motion) as well as in subjective scores Foot and Ankle Ability Measure (sports subscale), Foot Function Index, Visual Analogous Scale pain, Foot and Ankle Outcome Score and Healthy score were recorded preoperatively and at follow-ups up to 5 years. The patient returned to his former job as a car mechanic and plays soccer up to three times a week. In the presented case, the first implantation of a novel patient-specific metallic implant for the treatment of focal osteochondral lesion of the talus has been highly successful up to five years after implantation.

Introduction

Osteochondral lesions of the talus (OLT) are an important cause of pain and disability.[1] These osteochondral lesions can be classified into four subtypes: chondral, osteochondral, subchondral, or cystic as well as stable or unstable and displaced and non-displaced.[2] In most cases, the lesions are caused by supination or pronation trauma of the ankle joints.[3,4] Li et al. (2018) reports that cartilage injury occurs in 17-66% of all patients with lateral ligament injuries of the ankle.[5] In 2010, van Dijk reported that the avascularity of the subchondral bone is responsible for the non-healing and persistent deep ankle pain is caused by the nerve endings in the subchondral bone.[6] Traumatic lesions often affect the lateral talus shoulder while the Osteochondrosis Dissecans (OCD) often is localized on the medial shoulder. These OCD lesions often only become symptomatic after a trauma.[7] If conservative treatment does not solve the symptoms, surgery is recommended. Deeper defects often show poor results with conservative treatment[8].

For the treatment of focal osteochondral lesions of the knee joint there are patient-specific metallic mini-implants as a validated procedure with promising clinical results.[9] In this case report, we present the first clinical results and follow-up data of a novel patient-specific metallic implant for the treatment of focal osteochondral lesion of the talus.

Case report

A 33-year-old man (BMI 26.5 kg/m^2) was referred to medial talar surgery in January 2016 for the treatment of an osteochondral lesion. The osteochondral lesion of the medial talar dome originated from a medial ankle sprain in August 2014. After this sprain, he developed an OLT which had already been surgically treated with an osteochondral autograft transplant system (OATS) which was implanted via a medial malleolus osteotomy. At the time of referral, the patient had persisting

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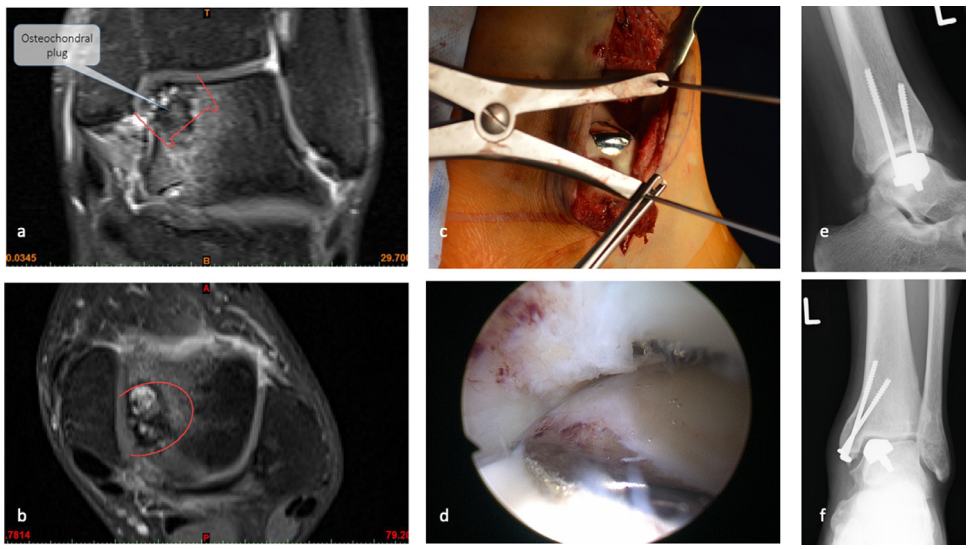

Fig. 1. Preoperative MRI images in the frontal (a) and horizontal (b) plane with the suggested implant position indicated. An Episealer ® talus implant has been inserted into the medial corner of the Talus after performing an osteotomy of the medial malleolus (c). Distraction is maintained by means of a bone spreader. Arthroscopic view (d) of the talus implant after 8 months in the course of the removal of the screws *for the fixation of the medial osteotomy*. X-ray 8 month after Episealer implantation in the lateral (e) and anterior-posterior (f) view.

pain at the left ankle and was severely limited in his physical and daily activities as well as increasing problems in managing his job as a car mechanic. On physical examination, the patient showed a limited dorsoflexion with swelling of the ankle. Medial and lateral ankle stability was not affected. The MRI showed a medial talar defect with a length of 15 mm and a width of 7 mm. Beneath the cartilage damage the MRI showed and subchondral cyst (Fig. 1**a** + **b**). Thereupon, the diagnosis was made at: secondary medial OLT.

Surgical intervention

After ample consideration and decision with the patient on possible treatment options it was decided to implant a patient-specific metal implant (Episealer® Talus Implant, Episurf Medical, Stockholm, Sweden). Based on the MRI, a patient-specific virtual 3D model of the focal osteochondral lesion was created digitally and used to design an individualized metal implant and corresponding instruments before the surgery. In the course of the damage mapping (Damage Marking Report), the cartilage and bone structure of the entire joint was assessed, in particular also the tissue opposite the defect. The assessment confirmed a localized isolated cartilage damage without an opposing cartilage defect or other comorbidities, so a 3D model of the joint was created (Fig. 2 a +b). The implant was designed to cover the entire defect of cartilage and underlying bone. After this procedure the implant was approved for production by the surgeon.

The metal implant was made of cobalt-chrome alloy covered with titanium (undercoating) and hydroxyapatite (outer coating). Both joint facing layers had a thickness of approximately 60 µm and in the center the implant, there is one or two centered pins to ensure immediate fixation. The Episealer® in this patient was performed on a custom-made basis, meaning that the company had obtained a regulatory exemption to produce this implant before approval.

Eight weeks after the modeling, the surgery was performed in January 2016. In order to access the medial talus dome an osteotomy of the medial malleolus was performed. The surgery was conducted in a supine position. A tourniquet was used, the surgery was performed in general anesthesia. After the osteotomy and posterior capsular release, the medial malleolus was displaced. The patient specific drill guide (Epiguide®) was placed and secured with 2 K-wires on the bone surrounding the defect (Fig. 2 **c**+**d**). The guide was also planned on the basis of the 3D model.

The guide was produced in a 3D printer and made of polyamide. Furthermore, the implant is delivered with a dummy (Epidummy). This simulates the implant to ensure that the drilling is deep enough and that the Episealer is not protruding and finally implanted at the "save zone" 0.4 mm below the native cartilage surface. A patient specific guide ensures the correct position of the osteotomy (Fig. 2 c + d).

Through the Epiguide® the defect was drilled. The drill has a deep stop to prevent over reaming and can be adjusted by 0.2mm steps. The correct depth is checked by placement of a dummy. If the resection is deep enough the implant can be inserted. It is important to implant the component 0.4 – 0.5 mm under the adjacent cartilage border to avoid damage on the opposite tibial cartilage.[10] The tibia-oriented surface of the implant (diameter 15 mm) is designed to exactly mimic the original curvature of the talus (Fig. 1 f). After implantation the osteotomized tibia was reduced and fixed with two screws. The capsular and subcutaneous tissue as well as the skin was closed after a lavage.

Postoperative care included six weeks of non-weightbaring with crutches until the osteotomy was consolidated. Eight months after

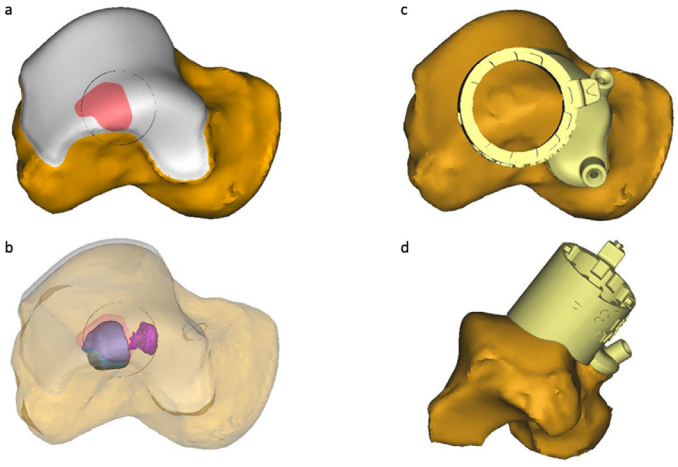

Fig. 2. (a-d) Final design showing the guide from posterior and from mediosuperior view. The anterior lip was designed to fit the anterior facet of the talo-malleolar joint. Two pins secured the positioning of the guide during the operation. The "slots" inside the upper circumference allows an adjustment ring to be incrementally lowered by 0.2 mm/step in order fine-tune the drill depth.

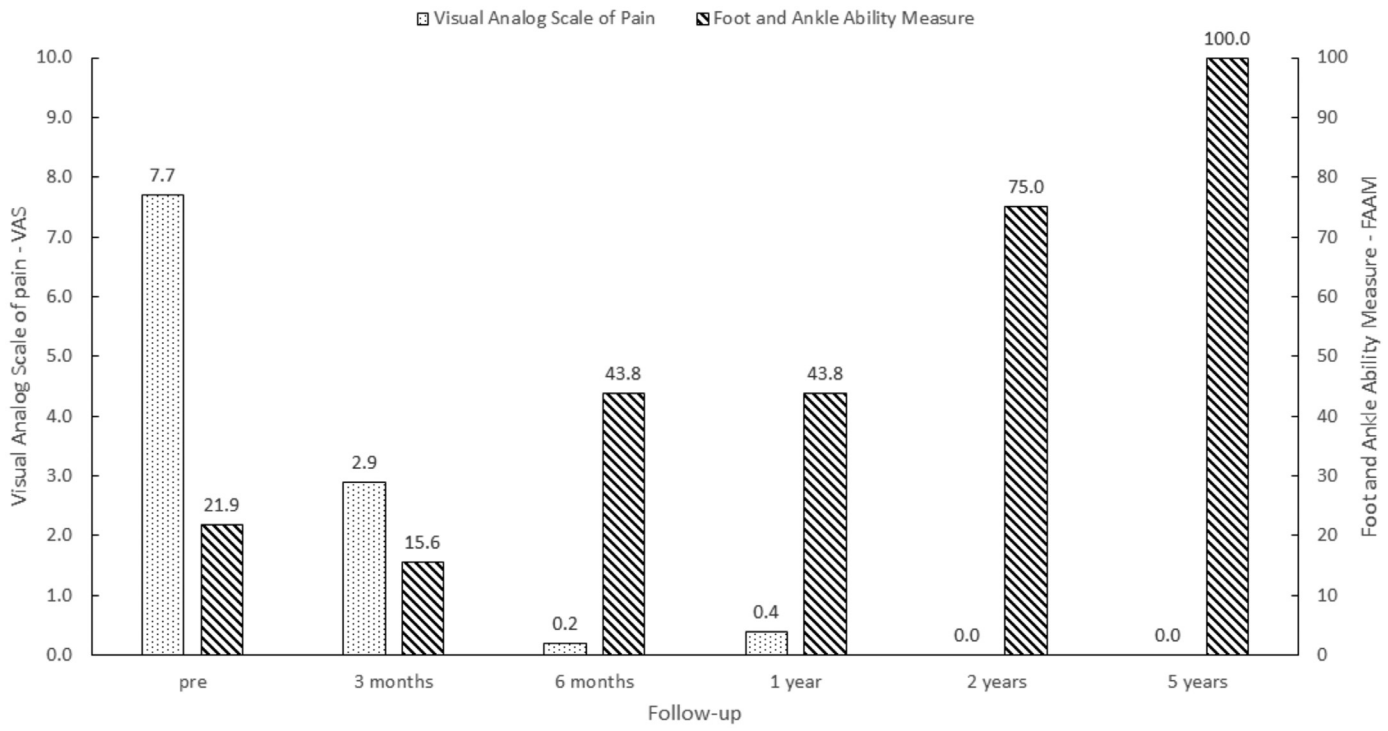

Fig. 3. Visual analog scale of pain and foot and ankle ability measure scores preoperatively and up to 5 years follow-up.

surgical treatment, the screws inserted to fix the osteotomy were removed. Fig. 1 g + i shows the x-ray before the removal. During the course of this surgery, a second-look arthroscopy of the ankle was performed (Fig. 1c). The implant showed a very good integration. Adjacent cartilage showed a slight overgrowth over the implant as described by Beyzadeoglu et al. as a "Biological Response" to the implant.[11]

Follow-up and outcomes

The patient was consequently followed up 3, 6, 12, 24, 36, 48 and 60 months using standard subjective outcome measures: VAS pain score, Foot and Ankle Outcome Score (FAOS), and the 8-item sports subscale of the Foot and Ankle Ability Measure (FAAM). There was immediate pain relief, and a fast rehabilitation was achieved. Six weeks postoperatively, the patient stopped immobilizing the leg and returned to work. There have not been any limitations in activities of daily living or work-related activities until today. Preoperative pain was VAS 7.4 which decreased postoperatively after three months to 2.9 and after six months to 0.2 and remained close to VAS 0 till today (Fig. 3 and Table 1). The FAOS improved in all subgroups continuously (Table 1). For the sports subscale of the Foot and Ankle Ability Measure (FAAM) there was an initial decrease 3 month after implantation which improved subsequently from the second postoperative year to 75 and 5 years postoperatively to 100 (Table 1).

Discussion

This is the first report of a successful implantation of a patient-specific mini metal implant for secondary medial OLT with a 5-year follow up. The most important finding was a clinical and subjective improvement including a full return to severe physical work and sports. The VAS pain score decreased 6 months after surgery and remained at VAS 0 up to five years after surgery.

Various procedures are available for the treatment of OLT, they are similar to those used for the treatment of osteochondral defects in the knee joint. Hence, microfracturing has been tried with an average of 84-86% of good/excellent results in lesions up to 10 mm. For larger defects it becomes less predictable. Matrix associated chondrogenesis is available for larger defects. Here, the defect is covered with a membrane.[12,13] Osteochondral autograft transfer (OATS) procedures may be viable but donor site availability and morbidity, as well as incomplete ingrowth or the formation of cysts remain a problem, especially in the complex shape of the talus borders.[4] Finally, autologous chondrocyte cell transplantation (ACI) has been discussed with reasonable success rate, especially in the young patients. The level of evidence is, however, low.[14] Treatment of an OLT with a small metallic implant has been tested in recent years. Results have been promising by some reports[12] while a higher revision rate was reported by others.[15] The reason for concern is the difficulty to predict a defect for the "of the shelf" implant. This is probably due to the limited numbers of implant sizes which are available, but the main reason is the lack of anatomic landmarks during the surgery to guide the implantation. Any mismatch

Table 1
Outcome scores before and after the implantation of the patient-specific talus implant.

	pre	3 months	6 months	1 year	2 years	3 years	4 years	5 years
VAS	7.7	2.9	0.2	0.4	0.0	0.0	0.0	0.0
Health	75.0	80.0	80.0	85.0	92.0	97.7	100.0	100.0
FAOS	38.1	70.2	78.0	78.6	96.4	98.8	99.4	100.0
*** Sym**	57.1	82.1	78.6	85.7	89.3	100.0	100.0	100.0
*** Pain**	33.3	72.2	80.6	83.3	100.0	100.0	100.0	100.0
*** ADL**	45.6	79.4	89.7	86.8	100.0	100.0	100.0	100.0
*** Sport**	20.0	45.0	60.0	55.0	95.0	100.0	100.0	100.0
*** QOL**	6.3	37.5	43.8	50.0	87.5	87.5	93.8	100.0
FAAM	21.9	15.6	43.8	43.8	75.0	*NA*	*NA*	100.0
FFI	39.2	24.2	21.7	22.5	3.9	*NA*	*NA*	0.0

VAS = Visual Analog Scale of Pain (0 is the best score); Health = general health (100 is the best score), FAOS = Foot and Ankle Outcome Score (100 is the best score), *FAOS Subscales are Sym (other Symptoms), Pain, ADL (Function in daily living), Sport (Function in Sport and Recreation) and QoL (Quality of Life); FAAM = Foot and Ankle Ability Measure (100 is the best score); FFI = Foot Function Index (0 is the best score); NA = these data were not collected in the system at these times.

during the surgery will lead to failure especially when the implant is placed protruding. Patient specific implantation guides and implants can avoid these disadvantages.

The use of metallic mini-implants in the knee joint has become a standard procedure with very satisfactory results.[9] When reviewing the literature, we found only a few articles using metallic mini-implants in osteochondral defects of the talus. van Bergen et al. (2013) and Ettinger et al. (2017) report on the use of prefabricated implants (HemiCAP® – Arthrosurface, Franklin MA, USA). All studies reported a significant improvement in postoperative pain and high return to work (100%) and return to sports rates (83.3% and 92.7%). Furthermore, van Bergen et al. (2013) showed significant improvement in almost all collected scores (FAOS, pain-NRS, American Orthopaedic Foot and Ankle Society Score and SF-36). Van Bergen et al. (2013) reported that 30% of patients needed revision surgery, while Ettinger et al. (2017) reported a rate of 70%, including two ankle arthrodesis (20%). The prospective study by van Bergen et al. (2013) included 20 patients with a mean age of 38 years compared to the retrospective study by Ettinger et al. (2017) including 11 patients with a mean age of 48 years.[9,15] In our case, the patient was 33 years old at the time of surgery. As shown by Ettinger et al. (2017) the use of metal mini-implants seem to be less promising in overweight patients. In these patients, revision with arthrodesis of the ankle joint was necessary. Unsatisfactory results in overweight patients may also be expected in patients after Episealer® implantation. Therefore, metallic mini-implant may be considered as a promising treatment option in normal-weight younger adults.

Recently, Ebskov et al. (2020) presented mid-term results of 31 patients who have also received a HemiCAP® implant.[16] All patients experienced improvement in outcomes (American Orthopaedic Foot and Ankle Society Score, FAOS and NRS) and high return to work rates. The FAOS sport subscore improved by 148%. In 41.9% of the cases additional surgeries were necessary. Ebskov et al. (2020) also include the hardware removals after osteotomy among these.[16]

In our case, the patient was able to return to his athletic level and has started playing soccer again. The FAOS and FAAMS sport subscore increased by more than 400%. This may be due to the fact that our patient was an athletic, active 33 years old patient at the time of surgery. The mean age of the patients of Ebskov et al. is 42.8 (22-70 years). Alternatively, the use of a patient-specific implant that perfectly imitates the articular surface could be advantageous over prefabricated implants. There is no need to compromise on implant size and shape. For example, Anderson et al. (2010) underlined the importance of proper implant placement. In a biomechanical study, they were able to show that metallic implants could restore normal joint mechanics. Slight deviations from correct placement, however, result in significantly altered contact stresses.[17] Revision rates of up to 50% have been described when using prefabricated implants. After the initial implant of this first patient the company applied for CE approval which was recently obtained in January 2020. Since then, 10 more Episealer® were implanted without any complication failures or revisions. The Episealer® in this patient was performed on a custom-made basis, meaning that the company had obtained a regulatory exemption to produce an implant before approval.

In conclusion, the first implantation of a patient-specific metallic implant for the treatment of focal osteochondral lesions of the talus has been found to be very promising up five years after surgery. A larger number of patients need to be treated with this technique in order to better understand the long-term impact this individualized treatment option for OLT.

Patient perspective: "Before the surgery, I had extremely limited mobility after a previous failed ankle surgery. I was in severe pain every day and had little quality of life when it came to sports activities or even walking. As a passionate soccer player, this was a disaster. In addition, I had just become a father and wanted to finally be free of pain so that I could later actively care for my daughter. The treatment and surgery were successful. The recovery was without complications and I was very quickly free of pain. Today I can play soccer again, romp around with my daughter and go for long walks without any pain. I have regained a tremendous amount of quality of life and I am very grateful for that to this day."

Declaration of competing interest

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Patient Informed Consent Statement

Complete informed consent was obtained from the patient for the publication of this study and accompanying images.

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