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Chapter 10

Treatment of secondary osteochondral defects of the talus with a metal resurfacing inlay implant: a prospective study

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Abstract

The aim of this study was to evaluate the clinical effectiveness of a metal resurfacing inlay implant for osteochondral defects of the medial talar dome after failed prior surgical treatment. Twenty consecutive patients, aged 20 to 60 years (mean, 38 years), were prospectively studied for 2 to 5 years (mean, 3 years). There was statistically significant reduction of pain in each of four situations (i.e., rest, walking, stair climbing, and running; p ≤0.01). The median American Orthopaedic Foot and Ankle Society ankle-hindfoot score improved from 62 (interquartile range, 46 – 72) preoperatively to 87 (interquartile range, 75 – 95) at final follow-up (p <0.01). The Foot and Ankle Outcome Score improved on all subscales (p ≤0.03). The Foot and Ankle Outcome Score improved on all subscales (p ≤0.03). The mean Short Form-36 physical component scale improved from 36 (range, 23 – 50) preoperatively to 45 (range, 29 – 55) at final follow-up (p <0.01); the mental component scale did not change significantly. On radiographs, progressive degenerative changes of the opposing tibial plafond were observed in two patients. One patient required additional surgery for the osteochondral defect. This study shows that the metal implantation technique is a promising treatment for osteochondral defects of the medial talar dome after failed previous treatment.

Introduction

Approximately 63% of osteochondral defects (OCDs) of the talus are located on the medial talar dome.322,458 These medial defects are generally deep and cup-shaped.322 An OCD may sometimes heal and stabilize, but often progresses to a cystic lesion causing deep ankle pain on weight bearing, prolonged swelling, diminished range of motion, and synovitis.434

Arthroscopic debridement and bone marrow stimulation is considered the primary treatment.458 Current secondary treatment options include osteochondral autograft transfer, autogenous bone graft, and autologous chondrocyte implantation.458 However, these techniques are associated with donor site morbidity and limited availability or involve two-stage surgery.39,312,407

In order to treat OCDs of the medial talar dome after failed primary treatment, a metal resurfacing inlay implant (HemiCAP®, Arthrosurface Inc., Franklin, MA, USA) has been developed.17,411 The implant comprises two components: a cobalt-chromium modular articular component, with a diameter of 15 mm, and a titanium cannulated screw, which are connected together via a taper interlock. Fifteen incremental offset sizes of the articular component are available, based on the surface geometry of the medial talar dome.411

Promising short-term clinical results have been reported of other designs of the implant for the treatment of various human joints.95,148,404,437 Two biomechanical cadaveric studies provided foundations for use of the talus implant in the ankle joint.17,411 These studies showed that recessing the implant slightly relative to the adjacent cartilage level leads to acceptable contact stresses in the talocrural joint and is beneficial compared to leaving it proud.17,411

The aim of this study was to evaluate the clinical effectiveness of the metal implantation technique for OCDs of the medial talar dome after failed previous surgery.

Methods

This prospective case series was approved by the local Medical Ethics Committee. We included
patients with an OCD of the medial talar dome, with the largest diameter between 12 and 20 mm on computed tomography, and persistent complaints >1 year after prior surgical treatment. Exclusion criteria were: age <18 years, defect size >20 mm, ankle osteoarthritis grade III, concomitant ankle pathology (tibial osteochondral defect, ankle instability, or ankle fracture), advanced osteoporosis, infection, a known allergy to implant material, and diabetes mellitus (because diabetes is associated with increased risk of infection as well as softer and more permeable talar cartilage). All patients provided informed consent.

Computed tomography scans were obtained preoperatively to measure the size in three directions and grade the defect according to the modified Berndt and Harty classification. In addition, the defects were graded intraoperatively with use of a macroscopic classification system.

**Operative technique**

The senior author performed all surgical procedures using a standard technique (Figure 1). An oblique medial malleolar osteotomy was created to expose the talus. The osteotomy was aimed at the intersection between the medial malleolus and the tibial plafond, which was identified with use of an aiming probe, and directed 30° relative to the long tibial axis.

The OCD was debrided until a healthy cartilage rim remained. A guide pin was placed into the center of the defect, perpendicular to the curvature of the medial talar dome, with use of a drill guide. The cannulated screw was pre-drilled and inserted. A contact probe was used to determine the radius of curvature in the sagittal and coronal planes to allow for a precise fit of the articular component to the existing articular surface. A matching reamer prepared the site for placement of the articular component. A sizing trial cap with corresponding offsets allowed for final verification of proper fit. The selected articular component was impacted on the screw, thereby engaging the taper interlock. Sufficient recession of the implant was determined by visual inspection. The osteotomy was reduced and fixed with two lag screws in predrilled holes.

The postoperative management was initiated with a plaster cast for 2 weeks, followed by a detachable plaster cast or brace (Walker, Össur, Son en Breugel, the Netherlands) for 4 weeks. During this period, non—weight-bearing sagittal range-of-motion exercises were prescribed. Radiographs were obtained at 6 weeks after surgery to confirm consolidation of the malleolar osteotomy. Physical therapy was then prescribed to assist in functional recovery and progress to full weight bearing in approximately 1 month.

**Outcome assessment**

The patients were assessed preoperatively and at 2 weeks, 6 weeks, 3 months, 6 months, and annually postoperatively. Authors not involved in the surgical procedures assessed the patients and completed specially designed case report forms.

The primary outcome measure was the numeric rating scale (NRS) of pain. The NRS consists of an 11-point scale, which represents the spectrum of no pain (0 points) to the worst pain imaginable (10 points). Four numeric rating scales were taken, i.e., pain at rest, during walking, during stair climbing, and during running. NRS during running was not assessed in patients that could not or did not run at any time point.

Secondary outcome measures were assessed preoperatively and at each follow-up visit starting 6 months postoperatively, and included the American Orthopaedic Foot and Ankle Society (AOFAS) ankle-hindfoot score, Foot and Ankle Outcome Score (FAOS),
Figure 1. Intraoperative photographs of a right ankle. A medial malleolar osteotomy was performed to expose the medial talar dome (A). The osteochondral defect was debrided (B). The screw was inserted in the center of the defect (C). A trial articular component was placed on the screw (D). The definitive articular component was engaged on the screw (E).
Metal implant for secondary OCDs

and Short Form-36 (SF-36). The AOFAS is a 100-point score, with a subjective and an objective component, which devotes 40 points to pain, 50 points to function, and 10 points to alignment.217 It is frequently used in the assessment of foot and ankle therapy, and the subjective component has been validated.192 The FAOS is a validated subjective questionnaire consisting of five subscales: pain, other symptoms (e.g., swelling, locking, mobility), function (activities of daily living), sport and recreational activities, and foot- and ankle-related quality of life.336 Each subscale’s highest possible score is 100. The SF-36 is a validated outcome measure to assess general quality of life.7 The normative value of the Dutch population is 49.2 for the physical component scale and 50.7 for the mental component scale.7

Complications were assessed at each follow-up visit by a patient interview and physical examination. Furthermore, the time needed to resume work and sports was recorded. Patients indicated the sport level as follows: I, high competitive sportsperson; II, well-trained and frequently sporting; III, sometimes sporting; or IV, not sporting. The use of analgesics was also recorded. At 2 years of follow-up and annually thereafter, patients indicated whether they would undergo the procedure again, and whether they would recommend the procedure to friends and family.

Radiography

Weight-bearing radiographs (anteroposterior mortise and lateral views) were obtained at all follow-up visits as of 6 weeks postoperatively. The radiographs were reviewed for evidence of implant loosening (periprosthetic osteolysis, subsidence, migration, and disengagement), for malunion or nonunion of the malleolar osteotomy, and for degenerative changes of the opposite distal tibia (subchondral sclerosis, cyst formation, and joint space narrowing).

Statistical analysis

A power analysis, performed before the start of the study, indicated that a sample size of 20 patients would detect a clinically important mean pain change of 1 point on the NRS, based on a standard deviation of 1.5, with $\alpha = 0.05$ and a power of 80%.339

Statistical analyses were performed with use of SPSS software (version 19.0; Chicago, IL, USA). Categorical data are presented as frequencies. Continuous data are presented as means with ranges or as medians with interquartile ranges (IQR), depending on their distribution. One-way repeated-measures analyses of variance (ANOVA) were performed to determine differences in mean scores at different time points for the outcomes with a normal distribution (NRS-rest, NRS-walking, NRS-stair climbing, FAOS, and SF-36). In case of significance ($p <0.05$), post-hoc pairwise comparisons were performed using a Bonferroni correction. The assumptions of normality and sphericity were checked with use of the Shapiro-Wilk test and Mauchly’s test, respectively. Due to the skewed distribution of the NRS-running and AOFAS, these scores were analyzed using the Friedman’s two-way analysis of variance by ranks. Post-hoc pairwise comparisons of these outcome measures were performed with use of Wilcoxon signed-rank tests with Bonferroni correction to adjust for multiple comparisons. The SF-36 scales were compared with the normative data for the Dutch population with use of the Student’s $t$-test.

Results

Twenty-four patients received the implant between October 2007 and November 2010. Four were excluded from the study because they had no previous surgery for the OCD
(two patients), had a combined procedure (one patient), or had diabetes mellitus (one patient). Twenty patients were included in the study. The mean duration of follow-up was 3 years (range, 2 – 5 years). No patients were lost to follow-up. There were 13 female and seven male patients, with a mean age of 38 years (range, 20 – 60 years). The left ankle was affected in 13 patients. The median body mass index was 26.1 kg/m² (IQR, 24.2 – 27.0 kg/m²).

Eight patients had one, nine patients had two, and three patients had three prior operations. These included one to three procedures of arthroscopic or open debridement and bone marrow stimulation in all cases; cancellous bone grafting in four cases; and osteochondral screw fixation in one case. Five patients received additional hyaluronic acid injections. The mean time between the last procedure and the metal implantation was 2 years (IQR, 2 – 6 years).

The mean defect size was 15 mm (range, 11 – 20 mm) in the anteroposterior direction, 10 mm (range, 8 – 14 mm) in the mediolateral direction, and 9 mm (range, 4 – 16 mm) in the craniocaudal direction. On radiographs, one defect was classified as stage III (complete avulsion of a fragment), one as stage IV (displaced fragment), and 18 as stage V (cystic lesion). Intraoperatively, two defects were macroscopically classified as grade II (softening or fibrillation of the cartilage), five as grade III (fraying of the cartilage), 10 as grade IV (detached fragment), and three as grade V (displaced fragment). Sixteen defects were located on the centromedial talar dome and four on the posteromedial talar dome.

Outcomes

The NRS-pain improved significantly in all four situations (Table 1 and Figure 2). For example, repeated-measures ANOVA determined that the mean NRS-walking differed significantly between time points ($F_{(4, 76)} = 16.0$, $p < 0.01$). Post-hoc pairwise comparisons using Bonferroni correction revealed that the NRS-walking was significantly decreased at all postoperative time points compared to the preoperative situation ($p < 0.01$ to $p = 0.05$).

The median AOFAS improved from 62 (IQR, 46 – 72) preoperatively to 75 (IQR, 68 – 87) at 6 months, 87 (IQR, 76 – 94) at 1 year, and 87 (IQR, 75 – 95) at the final follow-up ($p < 0.01$). Post-hoc tests revealed significant differences at 1 year and at the final follow-up compared to preoperatively ($p < 0.01$).

Table 1. Numeric rating scale pain

<table>
<thead>
<tr>
<th>Situation</th>
<th>Rest $F_{(4, 76)} = 6.1$; $p &lt; 0.01^{**}$</th>
<th>Walking $F_{(4, 76)} = 16.0$; $p &lt; 0.01^{**}$</th>
<th>Stair climbing $F_{(4, 72)} = 17.6$; $p &lt; 0.01^{**}$</th>
<th>Running $p = 0.01^{****}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative</td>
<td>3.6 (0 - 8)</td>
<td>6.7 (4 - 9)</td>
<td>6.6 (4 - 10)</td>
<td>10.0 (9 - 10)</td>
</tr>
<tr>
<td>3 months</td>
<td>2.4 (0 - 8)</td>
<td>1.00</td>
<td>4.4 (1 - 8)</td>
<td>0.05</td>
</tr>
<tr>
<td>6 months</td>
<td>1.7 (0 - 6)</td>
<td>0.09</td>
<td>3.3 (0 - 9)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>1 year</td>
<td>1.3 (0 - 7)</td>
<td>0.01</td>
<td>3.0 (0 - 7)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Final</td>
<td>1.1 (0 - 5)</td>
<td>0.01</td>
<td>2.8 (0 - 7)</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

The values are given as the mean, with the range in parentheses (rest, walking, stair climbing) or as the median, with the interquartile range in parentheses (running).

* Bonferroni-adjusted $p$-value of pairwise comparison with the preoperative NRS

** Repeated-measures ANOVA

*** Wilcoxon signed-rank test

**** Friedman’s two-way analysis of variance by ranks

130
The FAOS improved significantly on all subscales (Figure 3). Post-hoc pairwise Bonferroni-adjusted comparisons revealed statistically significant differences between preoperative scores and most postoperative scores (Table 2).

The mean SF-36 physical component improved from 36.2 (range, 22.8 – 50.3) preoperatively to 42.2 (range, 21.0 – 52.3) at 6 months (p = 0.05), 44.0 (range, 28.5 – 57.4) at 1 year (p = 0.01), and 45.0 (range, 28.6 – 54.6) at final follow-up (F(3, 51) = 6.4; p <0.01). The SF-36 mental component did not change significantly; the mean score was 53.0 (range, 21.9 – 67.9) preoperatively, 50.6 (range, 34.7 – 62.1) at 6 months, 52.8 (range, 39.8 – 60.3) at 1 year, and 54.3 (range, 24.9 – 66.5) at final follow-up (F(3, 51) = 2.5; p = 0.07). Neither the final physical nor the mental component differed significantly from the population norm.7

Preoperatively, 16 patients worked. All 16 patients resumed their work during follow-up. The median time to return to work was 8 weeks (IQR, 4 – 23 weeks).

Twelve patients used to play sports before their ankle symptoms had started. Only three were able to play sports preoperatively. Eleven of these 12 patients resumed sports during follow-up. The level of sports decreased in five patients, was equal in four, and improved in...
Figure 3. Graph showing the mean and 95% confidence interval for each component of the Foot and Ankle Outcome Score (FAOS) from preoperatively to the final follow-up. The improvement of each subscale was statistically significant (p ≤0.05).

two, as compared to the presymptoms level. Two additional patients, who did not play sports before the symptoms, started playing sports during follow-up. The median time to resumption of sports was 17 weeks (IQR, 8 – 27 weeks).

Seven patients used analgesics preoperatively. During follow-up, analgesics were used by none of the patients at 6 weeks and 3 months, by one at 6 months, by three at 1 year, and by none at the final follow-up.

At the final follow-up, 18 patients (90%) indicated that they would undergo the procedure again and that they would recommend the procedure to friends and family.

Radiography

There were no signs of implant loosening (Figure 4). The medial malleolar osteotomy healed in all cases by 6 weeks. One patient showed subchondral sclerosis of the opposing tibial plafond at final follow-up. Another patient had a progressive subchondral cyst of the opposite tibial plafond.

Complications and reoperations

Some patients had a temporary area of numbness about the scar, which resolved within months. One patient had a superficial wound infection,
Metal implant for secondary OCDs

Table 2. Foot and ankle outcome score

<table>
<thead>
<tr>
<th>Subscale</th>
<th>Pain p*</th>
<th>Symptoms p*</th>
<th>Function (ADL) p*</th>
<th>Sport p*</th>
<th>Quality of life p*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>F(3, 54) = 13.5; p &lt;0.01**</td>
<td>F(3, 54) = 3.2; p = 0.03**</td>
<td>F(3, 54) = 19.2; p &lt;0.01**</td>
<td>F(3, 54) = 11.5; p &lt;0.01**</td>
<td>F(3, 54) = 21.6; p &lt;0.01**</td>
</tr>
</tbody>
</table>

Preoperative  50.5 (14 - 78)  52.0 (11 - 96)  58.6 (15 - 85)  25.4 (0 - 70)  15.2 (0 - 44)
6 months  74.1 (56 - 100) <0.01  54.9 (21 - 89)  1.00  82.5 (43 - 100) <0.01  37.2 (0 - 75)  0.20  34.8 (0 - 63) <0.01
1 year  73.1 (39 - 100) <0.01  57.1 (25 - 91)  1.00  81.5 (54 - 100) <0.01  48.0 (10 - 100) <0.01  45.1 (13 - 88) <0.01
Final  76.6 (25 - 100) <0.01  66.4 (21 - 96)  0.07  83.7 (46 - 100) <0.01  58.3 (5 - 100) <0.01  52.7 (6 - 100) <0.01

The values are given as the mean, with the range in parentheses.
* Bonferroni-adjusted p-value of pairwise comparison with the preoperative score
** Repeated-measures ANOVA
ADL = activities of daily living.

Figure 4. Mortise view and lateral weight-bearing radiographs of a left ankle 3 years postoperatively. Sufficient recession of the implant was confirmed intraoperatively.

which was effectively treated with oral antibiotics. The medial malleolar osteotomy entered the posterior tibial plafond in one patient, but healing of the osteotomy was uneventful.

There were a total of seven additional surgical procedures in six patients. One patient required a lateral displacement calcaneal osteotomy after 26 months because of persistent deep ankle pain and subtle varus malalignment. One patient underwent arthroscopic treatment of anterior ankle impingement. In five patients the malleolar screws were removed after a mean of 15 months (range, 8 – 26 months) due to a prominent screw and/or tenderness on
Chapter 10

palpation. These patients had NRS scores similar to the complete study group (mean final NRS-rest, walking, stair climbing, and running of 1.2, 2.8, 3.2, and 4.3, respectively).

Discussion

Treatment of OCDs by focal metal resurfacing implants is relatively new. This prospective study describes the results of a metal implant designed for the talus. The presented outcomes show that patients generally benefit from the procedure. This was evidenced by the statistically significant improvement in almost all outcome measures and high rates of work and sport resumption. Progressive degenerative changes were present on radiographs of two patients. One patient required a lateral displacement calcaneal osteotomy because of persistent pain. Ninety percent of the patients indicated that they would undergo the procedure again.

We theorize that the effectiveness of the resurfacing implant is simply based on the mechanism of filling and coverage of the defect. Increased fluid pressure from the joint into the subchondral bone has been described as the cause of pain and of progressive subchondral cysts in untreated defects. This process possibly is stopped by filling and covering the defect.

The study population represents a therapeutic challenge. The OCDs were cystic, relatively large, and had failed prior surgical treatment. Alternative treatment methods for these cases include osteochondral autograft transfer and cancellous bone grafting. Both can lead to satisfactory clinical results, but disadvantages include donor site morbidity in up to 50%, talar surface mismatching, and limited availability. Furthermore, recurrent lesions, cartilage degeneration, and discontinuity of the subchondral bone plate have been observed after osteochondral autograft transfer, as well as inferior results in the treatment of secondary OCDs. Autologous chondrocyte implantation is another alternative but involves two surgical procedures and is more suitable for superficial cartilage defects than for cystic lesions.

Massive, refractory OCDs can be treated with an allograft, ankle arthrodesis, or total ankle prosthesis. Allografts are not recommended for focal defects, because of the loss of viability and stability in approximately one-third of the grafts. Ankle arthrodesis or prosthesis are more definite solutions for a recurrent OCD but are rather not used in these relatively young patients because of sacrifice of ankle motion and limited durability, respectively. If the metal implant should fail in the long term, it can be removed and the ankle joint can still be fused or replaced.

Strengths of this study are the prospective methodology, completeness of follow-up, and the use of various validated outcome measures. Limitations include the relatively small series, absence of a control group, and lack of long-term follow-up. A limitation of the implant is the fixed diameter of 15 mm. This size is based on the finding that primary arthroscopic treatment is generally successful for defects up to 15 mm in diameter. If the secondary OCD is smaller than 15 mm, some healthy cartilage is sacrificed for implantation of the metal device. In contrast, if the defect is larger, a part of it cannot be covered by the implant. In the latter situation, we expect the remainder of the OCD to be filled by fibrocartilaginous tissue.

In conclusion, the metal implantation technique is a promising treatment for OCDs of the medial talar dome after failed previous treatment. Although the results of this study are encouraging, more patients, longer follow-up, and preferably a control group may determine the place of the implant in the treatment of osteochondral talar defects.