■ FOOT AND ANKLE

Treatment of osteochondral defects of the talus with a metal resurfacing inlay implant after failed previous surgery

A PROSPECTIVE STUDY

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We have evaluated the clinical effectiveness of a metal resurfacing inlay implant for osteochondral defects of the medial talar dome after failed previous surgical treatment. We prospectively studied 20 consecutive patients with a mean age of 38 years (20 to 60), for a mean of three years (2 to 5) post-surgery. There was statistically significant reduction of pain in each of four situations (i.e., rest, walking, stair climbing and running; $p \leq 0.01$). The median American Orthopaedic Foot and Ankle Society ankle-hindfoot score improved from 62 (interquartile range (IQR) 46 to 72) pre-operatively to 87 (IQR 75 to 95) at final follow-up ($p < 0.001$). The Foot and Ankle Outcome Score improved on all subscales ($p \leq 0.03$). The mean Short-Form 36 physical component scale improved from 36 (23 to 50) pre-operatively to 45 (29 to 55) at final follow-up ($p = 0.001$); 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 a metal implant is a promising treatment for osteochondral defects of the medial talar dome after failed previous surgery.

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Approximately 63% of osteochondral defects (OCDs) of the talus are located on the medial talar dome and are generally deep and cup-shaped.[1,2] An OCD may sometimes heal and stabilise but often progresses to a cystic lesion causing ankle pain on weight-bearing, prolonged swelling, diminished range of movement and synovitis.[3]

Arthroscopic debridement and bone marrow stimulation is the preferred primary treatment.[2] Other treatment options include osteochondral autograft transfer, autogenous bone grafting, and autologous chondrocyte implantation.[2] These treatments can provide satisfactory clinical results but disadvantages include rates of donor site morbidity of up to 50%, talar surface mismatching and limited availability of graft material.[4-7]

In order to treat OCDs of the medial talar dome after failed primary treatment, a metal resurfacing inlay implant (HemiCAP; Arthrosurface Inc., Franklin, Massachusetts) has been developed.[8,9] The implant comprises two components: a cobalt–chromium modular articular component (diameter 15 mm) and a titanium cannulated screw, which are connected together via a taper interlock. The articular component is available in 15 incremental offset sizes, based on the surface geometry of the medial talar dome.[8]

Promising short-term clinical results have been reported with designs of similar implants used in various human joints.[10-14] Two mechanical cadaver studies provided a base line for the use of the talar implant in the ankle joint.[8,9] These studies showed that recessing the implant slightly relative to the level of the adjacent cartilage leads to acceptable contact stresses in the talocrural joint and is beneficial compared with leaving it proud.[8,9]

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

Patients and Methods

This study was approved by the local Medical Ethics Committee. We included patients with an OCD of the medial talar dome, with the largest diameter being between 12 mm and 20 mm as measured on CT scans. We chose these thresholds based on our experience that smaller lesions respond well to arthroscopic debridement and bone marrow stimulation (even if secondary) and larger lesions would probably have insufficient coverage by the implant. For inclusion patients had to have complained persistently for more than a year after previous surgical treatment. Exclusion criteria included an age < 18 years, defect

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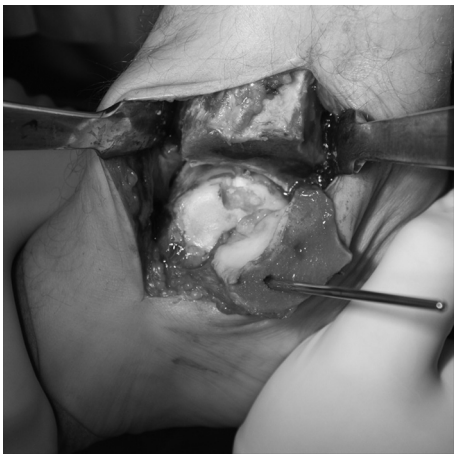
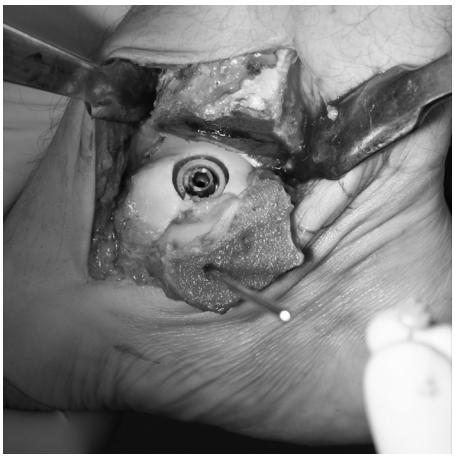


Fig. 1a



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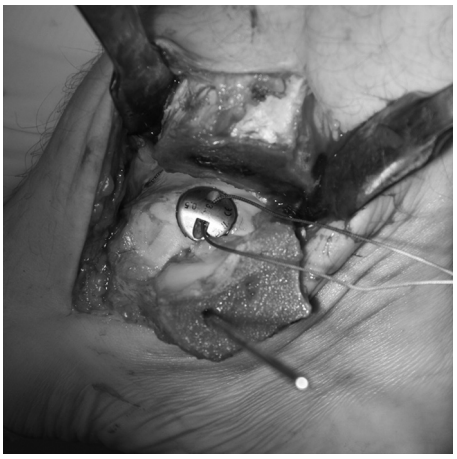

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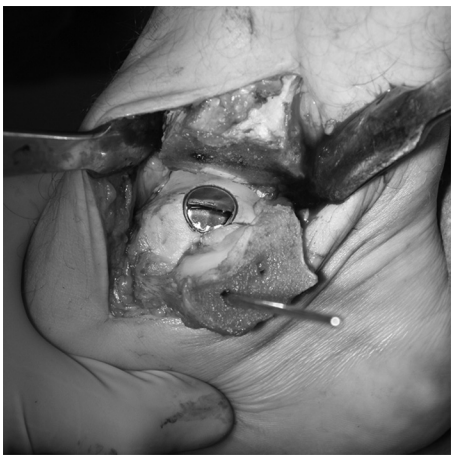

Fig. 1d

Intra-operative photographs of a right ankle showing a) the osteochondral defect debrided following a medial malleolar osteotomy, b) the screw inserted in the centre of the defect, c) a trial articular component in place on the screw and d) the definitive articular component engaged on the screw.

size > 20 mm, ankle osteoarthritis grade III,[15] and other ankle pathology (including tibial osteochondral defect, ankle instability or ankle fracture). We also excluded patients with advanced osteoporosis, infection, known allergy to implant material and diabetes mellitus; the latter because diabetes is associated with increased risk of infection as well as softer and more permeable talar cartilage.[16] All patients provided informed consent.

CTs were obtained pre-operatively to measure the three-dimensional size and grade the defect according to the modified Berndt and Harty classification by one of three authors (CJAvB, ICMvE, MLR).[17,18]

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

Operative technique. All operations were undertaken by the senior author (CNvD) using a previously described technique (Fig. 1).[19] In brief, 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.[20,21]

The OCD was debrided until a healthy cartilage rim remained. A guide pin was placed into the centre of the defect, perpendicular to the curvature of the medial talar dome, with use of a drill guide. Following drilling a cannulated screw was 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 against the existing articular surface and a matching

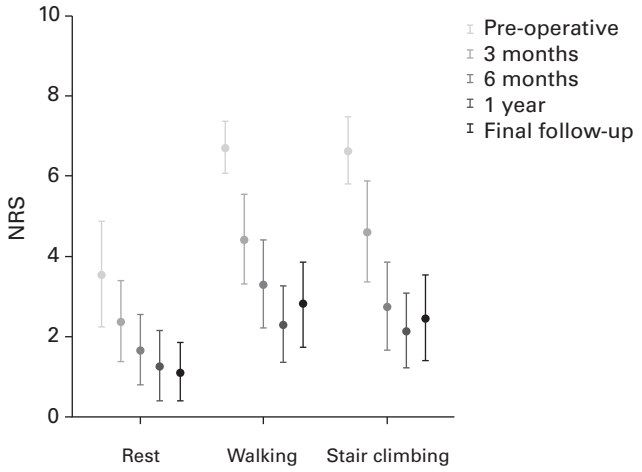

Fig. 2

Graph showing the mean numeric rating scale (NRS) for pain in rest, walking and stair-climbing situations across the follow-up (data regarding NRS-running are not presented due to skewed distribution). P-values for comparisons across time-points are given in Table I. The error bars denote the 95% confidence intervals.

reamer prepared the site for placement of the articular component. A trial cap with corresponding offsets provided final verification of fit. The final articular component was impacted on the screw, thereby engaging the taper interlock. Sufficient recession of the implant was determined by direct inspection. The malleolar osteotomy was reduced and held with two lag screws via pre-drilled holes.

Post-operative management consisted of immobilisation in a plaster cast for two weeks, followed by a removable plaster cast or brace (Walker; Össur, Son en Breugel, the Netherlands) for four weeks. During this latter period, plantar and dorsiflexion exercises were encouraged. Patients were kept non-weight-bearing for the initial six weeks. Radiographs were obtained at six weeks after surgery to confirm consolidation of the malleolar osteotomy. Physiotherapy was subsequently prescribed to assist in functional recovery with progression to full weight-bearing over approximately one month.

Outcome assessment. The patients were assessed pre-operatively and at two and six weeks, three and six months, and annually post-operatively. Authors not involved in the surgical procedures (CJAvB, ICMvE, MLR) assessed the patients and completed specially designed case report forms.

The primary outcome measure was the numeric rating scale (NRS) of pain. The NRS comprises an 11-point scale, which represents the spectrum of no pain (0 points) to the worst pain imaginable (10 points).[22] Four NRSs were used; 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.

Secondary outcome measures were assessed pre-operatively and at each follow-up visit starting six months post-operatively, and included the American Orthopaedic Foot and Ankle Society (AOFAS) ankle-hindfoot score,[23,24] Foot and Ankle Outcome Score (FAOS),[25] and Short-Form 36 (SF-36).[26] 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. It is frequently used in the assessment of foot and ankle therapy, and the subjective component has been validated.[24] 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. Each subscale's highest possible score is 100. The SF-36 is a validated outcome measure to assess general quality of life. The normative SF-36 value of the Dutch population is 49.2 for the physical component scale and 50.7 for the mental component scale.[26]

Complications were assessed at each follow-up visit through a patient interview and physical examination. The time taken to resume work and sports was recorded. Patients indicated their sport level as follows: I, highly competitive athlete; II, well-trained and frequently active in sport; III, sometimes active in sport; or IV, not active in sport.

The use of analgesics was also recorded. At two 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.

Radiology. Weight-bearing radiographs (anteroposterior (AP) mortise and lateral views) were obtained at all follow-up visits including and after six weeks post-surgery. The radiographs were reviewed by one of three authors (CJAvB, ICMvE, MLR) for evidence of implant loosening (peri-prosthetic osteolysis, subsidence, migration and disengagement), for malunion or nonunion of the malleolar osteotomy, and for degenerative changes of the opposing distal tibia.

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 one point on the NRS, based on a standard deviation (SD) of 1.5, with $\alpha = 0.05$ and a power of 80%.[22]

Statistical analyses were performed with use of SPSS software v19.0 (SPSS Inc., Chicago, Illinois). Categorical data are presented as frequencies. Continuous data are presented as means with ranges or as medians with IQRs, 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). A p-value < 0.05 was used to define significance. When this was found, *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 analysed using the Friedman's two-way

Table I. Numeric rating scale (NRS) for pain (IQR, interquartile range)

	Mean (range)						Median (IQR)	
Time point	**NRS-rest**	**p-value***	**NRS-walking**	**p-value***	**NRS-stair climbing**	**p-value***	**NRS-running**	**p-value†**
Pre-operative	3.6 (0 to 8)		6.7 (4 to 9)		6.6 (4 to 10)		10.0 (9 to 10)	
Three months	2.4 (0 to 8)	1.00	4.4 (1 to 8)	0.05	4.6 (0 to 8)	0.24	7.0 (5 to 10)	0.10
Six months	1.7 (0 to 6)	0.09	3.3 (0 to 9)	0.001	2.8 (0 to 7)	0.001	6.0 (3 to 10)	0.03
One year	1.3 (0 to 7)	0.01	2.3 (0 to 7)	< 0.001	2.2 (0 to 6)	< 0.001	3.0 (1 to 6)	0.005
Final	1.1 (0 to 5)	0.01	2.8 (0 to 7)	< 0.001	2.5 (0 to 7)	< 0.001	4.5 (1 to 7)	0.001
p-value	$F_{(4, 76)} = 6.1$; $p < 0.001$‡		$F_{(4, 76)} = 16.0$; $p < 0.001$‡		$F_{(4, 72)} = 17.6$; $p < 0.001$‡		$p = 0.01$§	

* Bonferroni-adjusted p-value of pairwise comparison with pre-operative NRS
† Wilcoxon signed-rank test
‡ repeated-measures analysis of variance
§ Friedman's two-way analysis of variance by ranks

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

The mean duration of follow-up was three years (2 to 5). No patients were lost to follow-up.

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 median time between the last procedure and the metal implantation was two years (IQR 2 to 6).

The mean defect size was 15 mm (11 to 20) in the AP direction, 10 mm (8 to 14) in the mediolateral direction, and 9 mm (4 to 16) in depth. Radiologically, one defect was classified according to the modified Berndt and Harty classification as stage III (complete avulsion of a fragment), one as stage IV (displaced fragment), and 18 as stage V (cystic lesion). Sixteen defects were located on the centromedial talar dome and four on the posteromedial talar dome.

The NRS-pain improved significantly in all four situations (Table I and Fig. 2). Repeated-measures ANOVA determined that the mean NRS-walking differed significantly between time points ($F_{(4, 76)} = 16.0$, $p < 0.001$). *Post-hoc* pairwise comparisons using Bonferroni correction revealed that the NRS-walking was significantly decreased at all post-operative time points compared with the pre-operative situation ($p < 0.001$ to $p = 0.05$).

The median AOFAS improved from 62 (IQR 46 to 72) pre-operatively to 75 (IQR 68 to 87) at six months, 87 (IQR 76 to 94) at one year and 87 (IQR 75 to 95) at final follow-up ($p < 0.001$; Friedman's two-way analysis of variance by ranks). *Post-hoc* tests revealed significant differences at one year ($p < 0.001$) and at the final follow-up ($p = 0.001$) compared with pre-operatively.

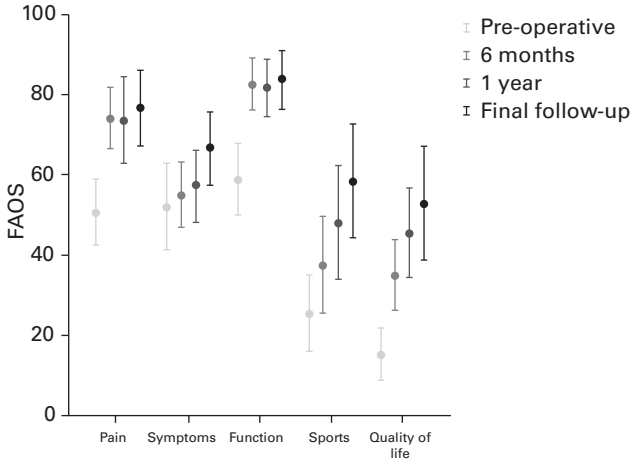

Fig. 3

Graph showing the mean Foot and Ankle Outcome Score (FAOS) by subscore across the follow-up. P-values for comparisons across time-points are given in Table II. The error bars denote the 95% confidence intervals.

The FAOS improved significantly on all subscales (Fig. 3). *Post-hoc* pairwise Bonferroni-adjusted comparisons revealed statistically significant differences between pre-operative scores and most post-operative scores (Table II).

The mean SF-36 physical component improved from 36.2 (22.8 to 50.3) pre-operatively to 42.2 (21.0 to 52.3) at six months ($p = 0.05$), 44.0 (28.5 to 57.4) at one year ($p = 0.01$), and 45.0 (28.6 to 54.6) at final follow-up ($p = 0.004$) ($F_{(3, 51)} = 6.4$, $p = 0.001$; one-way repeated-measures ANOVA). The SF-36 mental component did not change significantly; the mean score was 53.0 (21.9 to 67.9) pre-operatively, 50.6 (34.7 to 62.1) at six months, 52.8 (39.8 to 60.3) at one year, and 54.3 (24.9 to 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.[26]

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

Table II. Foot and Ankle Outcome Score (FAOS) (ADL, activities of daily living)

	Mean FAOS subscore (range)									
Time point	**Pain**	**p-value***	**Symptoms**	**p-value***	**Function (ADL)**	**p-value***	**Sport**	**p-value***	**Quality of life**	**p-value***
Pre-operative	50.5 (14 to 78)		52.0 (11 to 96)		58.6 (15 to 85)		25.4 (0 to 70)		15.2 (0 to 44)	
Six months	74.1 (56 to 100)	0.001	54.9 (21 to 89)	1.00	82.5 (43 to 100)	0.001	37.2 (0 to 75)	0.20	34.8 (0 to 63)	0.001
One year	73.1 (39 to 100)	< 0.001	57.1 (25 to 91)	1.00	81.5 (54 to 100)	< 0.001	48.0 (10 to 100)	0.002	45.1 (13 to 88)	< 0.001
Final	76.6 (25 to 100)	< 0.001	66.4 (21 to 96)	0.07	83.7 (46 to 100)	< 0.001	58.3 (5 to 100)	< 0.001	52.7 (6 to 100)	< 0.001
p-value	$F_{(3, 54)} = 13.5$; $p < 0.001$†		$F_{(3, 54)} = 3.2$; $p = 0.03$†		$F_{(3, 54)} = 19.2$; $p < 0.001$†		$F_{(3, 54)} = 11.5$; $p < 0.001$†		$F_{(3, 54)} = 21.6$; $p < 0.001$†	

* Bonferroni-adjusted p-value of pairwise comparison with pre-operative score
† repeated-measures analysis of variance

In total, 12 patients used to play sports before their ankle symptoms had started. Only three were able to play sports pre-operatively. Of these 12 patients, 11 resumed sports during follow-up. The level of sports decreased in five patients, was equal in four, and improved in two compared with their level prior to developing symptoms. 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 to 27).

Analgesics were used pre-operatively by seven patients. During follow-up, analgesics were used by none of the patients at six weeks and three months, by one at six months, by three at one year, and by none at the final follow-up.

At the final follow-up (mean three years (2 to 5)), 18 patients indicated that they would undergo the procedure again and that they would recommend the procedure to friends and family. There were no signs of implant loosening. The medial malleolar osteotomy healed in all cases by six weeks. One patient showed subchondral sclerosis of the opposing tibial plafond at final follow-up. Another patient had a progressive subchondral cyst on the opposite tibial plafond.

Some patients had a temporary area of numbness about the scar, which resolved within three months. One patient had a superficial wound infection, 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 varus malalignment. One patient underwent arthroscopic treatment for anterior ankle impingement. In five patients the malleolar screws were removed after a mean of 15 months (8 to 26 months) due to a prominent screw and/or tenderness on palpation. These patients had NRS scores similar to the complete study group.

Discussion

Treatment of OCDs using focal metal resurfacing implants is relatively new.[10-14] This prospective study shows that patients with talar OCDs generally benefit from the procedure. The study population represents a therapeutic challenge as the OCDs were cystic, relatively large, and had failed prior surgical treatment. Almost all the outcomes demonstrated statistically significant improvements and high rates of resumption of work and sports. Progressive degenerative changes were present on radiographs of two patients and one patient required a lateral displacement calcaneal osteotomy because of persistent pain. Satisfaction was high, with 18 patients indicating that they would undergo the procedure again.

We believe 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.[3,27] We might speculate that this process is possibly stopped by filling and covering the defect.

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.[28] Ankle arthrodesis or replacement are more definite solutions for a recurrent OCD but are best avoided in our relatively young and active patients. If the metal implant should fail in the long term, its removal would not compromise ankle fusion or joint replacement.

Strengths of this study include 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.[29] If the OCD is smaller than 15 mm, some healthy cartilage is sacrificed for implantation of the metal device. In contrast, if the defect is larger, incomplete coverage is provided by the implant. We have no evidence but would hope in the latter situation that the remainder of the OCD might fill with fibrocartilaginous tissue.

In conclusion, this 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 this implant in the treatment of these defects.

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