Surgical repair of osteochondral lesions of the talus using biologic inlay osteochondral reconstruction: Clinical outcomes after treatment using a medial malleolar osteotomy approach compared to an arthroscopically-assisted approach

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\textbf{A B S T R A C T}

\textit{Background:} Surgical treatment of osteochondral lesions of the talus affecting the medial aspect of the talar dome is typically performed using medial malleolar osteotomy to optimize access. This study compares clinical outcomes of lesions repaired using biologic inlay osteochondral reconstruction in patients who did or did not undergo medial malleolar osteotomy, depending on defect dimensions.

\textit{Methods:} Patients treated for osteochondral lesions of the talus through a medial malleolar approach or arthroscopically-assisted approach were prospectively followed. Assessment tools consisted of the visual analogue scale (VAS) and the American Orthopaedic Foot and Ankle Society Ankle-Hindfoot score (AOFAS). The magnetic resonance observation of cartilage repair tissue (MOCART) score was used postoperatively.

\textit{Results:} Data for 24 patients (mean age 34 years, mean follow-up 22 months) was analyzed. Mean preoperative/ final AOFAS and VAS in those who underwent osteotomy were 57.7/81.2 and 5.7/1.9 (p < 0.001), respectively. In those who underwent arthroscopically-assisted reconstruction, mean preoperative/ final AOFAS and VAS were 54.4/84.0 and 7.6/2.0 (p < 0.001), respectively. There was no difference in mean MOCART score (p = 0.662) for those treated with osteotomy (67.3) compared to those without (70.8).

\textit{Conclusions:} Osteochondral lesions of the talar dome can be treated successfully by biological inlay osteochondral reconstruction technique without medial malleolar osteotomy, with good to excellent clinical outcomes expected. MRI demonstrates good integration of the graft into surrounding tissue.

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\section*{1. Introduction}

Osteochondral lesions of the talar dome (OCLT) may result from a variety of pathologies which present with similar clinical symptomatology and macroscopic appearance of osteochondral injury [1]. The majority of these lesions are thought to be associated with a traumatic etiology, with lesions identified in 50–73% of acute ankle injuries [2,3]. Among non-traumatic causes of OCLT, degenerative joint disease, avascular necrosis, peripheral vascular disease, and metabolic or endocrine disorders are important contributors [1].

Talar morphology and physiology are important anatomic considerations when treating osteochondral injury, as more than 60% of the surface is covered by articular cartilage, and limitations of vascular supply contribute to reduced healing potential [4–7]. Healing rates after non-operative treatment have been estimated to be approximately 50% [8]. Commonly employed options for operative treatment of OCLT include bone marrow stimulation (BMS), osteochondral grafting procedures, and cell-based repair techniques. BMS is recommended by many clinicians as a treatment of choice for small and shallow lesions less than 150 mm\textsuperscript{2} in total area, and 15 mm in diameter [9–12]. Management of large or deep OCLT can pose greater therapeutic challenges, given the need to restore both the subchondral bone and the overlying articular cartilage [13]. Osteochondral autologous

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transplantation (OAT) is a proposed method of treatment of such lesions by some authors, despite several disadvantages [13–16]. Advances in cell-based osteochondral repair have led to the development of a two-stage “sandwich” autologous chondrocyte implantation (ACI) procedure to treat OCLT, initially developed by Peterson and applied by Mandelbaum for use in the ankle joint [17]. Further developments in single-stage cell-based osteochondral repair by Sadlik have been used to reconstruct the dual-layer osteochondral unit in both the knee and ankle using biologic inlay osteochondral reconstruction (BIOR), which is a technique capable of restoring the anatomic radius of curvature of the native talus [18,19]. This technique relies on implantation of bone chips in the form of a malleable bone graft inlay, which is covered by a collagen or hyaluronic acid-based matrix, embedded with bone marrow aspirate concentrate (BMAC). This technique is typically performed with malleolar osteotomy in order to provide sufficient perpendicular access to the talar articular surface. Unfortunately, malleolar osteotomy extends the duration of the postoperative recovery period, and may be a contributing factor to the future development of degenerative cartilage injury and osteoarthritis (OA) [20–23].

The aim of this study is to provide a comparative analysis of clinical outcomes of talar osteochondral lesion repair using BIOR in patients who did or did not undergo medial malleolar osteotomy, with specific focus on lesion surface area and volume. It is hypothesized that equally successful clinical outcomes will be demonstrated by this technique in cases where an arthroscopically-assisted approach was used, as opposed to a medial malleolar osteotomy.

2. Materials and methods

All patients treated at our institution between January, 2011, and December, 2015, for OCLT with the technique of BIOR who met the inclusion and exclusion criteria were prospectively followed for a minimum duration of 12 months. Procedures were performed by a single orthopaedic surgeon experienced with the technique (BS). Inclusion criteria consisted of functionally limiting symptomatic OCLT of post-traumatic or spontaneous etiology that were associated with subchondral pathology to a depth of greater than 2 mm. Exclusion criteria consisted of a diagnosis of rheumatoid arthritis, concomitant knee, hip or spine disorder, and previous intra-articular ankle joint injection of hyaluronan or bone marrow aspirate preparations.

Clinical assessment tools consisted of the visual analogue scale (VAS) and the American Orthopaedic Foot and Ankle Society Ankle–Hindfoot score (AOFAS), which were recorded preoperatively and at final follow-up [24]. Radiological evaluation was performed by an independent radiologist using high field MRI (Phillips Ingenia 3.0T) in standardized sagittal and coronal planes with proton density and T2 weighted sequencing. The magnetic resonance observation of cartilage repair tissue (MOCART) was used 12 months postoperatively to examine the quality of cartilage repair tissue and the integration into surrounding structures [25].

2.1. Surgical technique

Localization and dimensions of the osteochondral lesion were used to determine the appropriate surgical approach for each lesion, without randomization, in order to ensure adequate access. Plain X-ray sagittal imaging with the ankle in maximum plantarflexion was used preoperatively to visualize the proportion of talar dome exposure anterior to the articulating tibiotalar surface. MRI was used to characterize the size, shape, location, depth, volume, and shape of the lesion, and also to identify any cystic changes. For consideration of an arthroscopically-assisted approach, the lesion was required to be localized to the frontal or central part of the talar dome (zones 1–6 as described by Elias) [26]. Lesion depth was less than 10 mm for those cases treated arthroscopically to ensure sufficient access to the lesion base for abrasion and preparation of sclerotic bone. In cases where part of the lesion was located posteriorly, behind zones 3–6, or where the lesion shape or presence of cystic changes were such that direct access was expected to be insufficient for arthroscopic repair, a malleolar osteotomy was the chosen approach.

2.1.1. Biologic inlay osteochondral reconstruction: medial malleolar osteotomy approach

A medial malleolar chevron osteotomy was performed, using preoperative MRI or CT imaging in the coronal plane to assist with determination of the ideal direction of osteotomy to optimize lesion access. The tibialis posterior tendon and adjacent neurovascular structures were appropriately protected at the time of osteotomy. A non-abrasive sterile material was packed into the joint to prevent soft tissue displacement into the working space, which improves visualization during lesion debridement. Loose chondral fragments were excised and the lesion was prepared by creating vertical walls of healthy articular cartilage about the periphery, perpendicular to the subchondral plate. To develop consistently vertical walls of cartilage surrounding the lesion, a number 11 blade, a curette, and a small rounded chisel were used [27]. The base of the defect was abrased using a burr in order to stimulate bleeding from superficial vessels within the subchondral bone. Areas of sclerotic bone were drilled using a 1.6 mm K-wire. Autologous cancellous bone was harvested from the ipsilateral tibia via a cortical window. Harvested bone chips were pressed into the box compartment of the bone inlay applicator (Bone Inlay Applicator, ATMED, Katowice, Rafalski, Fig. 1). Bone marrow aspirate was harvested from the iliac crest and concentrated using the MarrowStim system (Biomet, Warsaw, Indiana) to obtain an isolate with concentrated mesenchymal stem cells. One cc of bone marrow aspirate concentrate was then applied to the bone graft in the box compartment of the applicator. An initial portion of the bone inlay was then compacted into the base of the lesion. A second portion of bone graft and BMAC was then combined with several drops of fibrin glue (Tissueel, Baxter, Deerfield, IL, USA) to create a more malleable bone graft inlay. The malleable bone graft inlay was then applied to the defect, reconstituting the remaining subchondral bone deficit, and molded to recreate the anatomic radius of curvature of the articular surface at the talar dome. A type
I/III collagen (Chondro-gide, Geistlich, Wolhusen, Switzerland) or hyaluronic acid-based scaffold (Hyalofast, Anika Therapeutics, Srl, Abano Terme, Italy) was size matched to the defect and combined with BMAC. The scaffold embedded with BMAC was then implanted into the defect, overlying the reconstituted and anatomically contoured subchondral bone graft inlay. Fibrin glue was used about the periphery of the implant to stabilize the graft in cases of lesions greater than 1.5 cm² in area. The medial malleolus was then realigned and the osteotomy site was stabilized by two parallel 4.5 mm lag screws. Screws were removed from the medial malleolus 12 months postoperatively in all patients prior to MRI examination. A schematic representation of the surgical procedure is presented in Fig. 2.

2.1.2. Biologic inlay osteochondral reconstruction: arthroscopically-assisted approach

A 3 cm skin longitudinal incision was made anterior to the lesion, followed by an arthroscopy. Arthroscopy was performed to confirm the lesion location and suitability for reconstruction without malleolar osteotomy. Full plantar flexion and eversion was used to assist with complete visualization and access to the lesion. Arthroscopic osteochondral lesion preparation proceeded with removal of unstable chondral fragments and preparation of vertical cartilage walls about the periphery using Chondrectomes (Chondrectome Set, ATMED, Katowice, Rafalski, Fig. 3B). Preparation of the lesion base and subsequent reconstruction by method of biologic inlay osteochondral reconstruction proceeded as described for those cases performed using the malleolar osteotomy approach (Fig. 3).

2.2. Postoperative care

The operative lower extremity was immobilized during the first postoperative week using a short-leg, non-weight bearing cast, which was then substituted for a removable cast-boot. The patients were non-weight bearing for 4 weeks postoperatively, and then progressed to full weight-bearing, typically by 6 weeks. During the 6th postoperative week, MRI and clinical evaluation were performed to ensure appropriate rehabilitation progression. Propriotype training, lower extremity muscular conditioning and stabilization therapy, and light sporting activity (swimming and cycling) were allowed after the 6th week. Patients underwent follow-up at 12 weeks for clinical and radiographic examination, which included routine weight bearing anteroposterior and lateral radiographs. Return to competitive sports was allowed after 5–6 months postoperatively. Clinical evaluation and MRI examination were routinely performed 12 and 24 months after surgery.

2.3. Statistical methods

Data analysis was performed using SPSS software (version 22.0, IBM, Armonk, NY). The normal distribution of each parameter was tested with the Shapiro–Wilk test and quantile-quantile plots. All continuous variables are presented as the mean ± standard deviation. The Student’s paired t-test was performed to test hypotheses about continuous data differences between preoperative and postoperative scores. The Mann–Whitney U test was used to test hypotheses about continuous data between treatment groups and the chi-square test was used to test frequency distribution. Spearman’s rank correlation analysis was performed to analyze the association between lesion size and improvement in clinical outcome scores. Statistical significance was set at p < 0.05.

3. Results

Twenty-four patients (14 male/10 female) were treated for OCLT using BIOR and prospectively followed. Eleven patients underwent medial malleolar osteotomy as part of the surgical...
approach, and 13 were treated without osteotomy using the arthroscopically-assisted technique through an anteromedial approach. Mean age for those treated with osteotomy was 35.3 ± 13.3 years, and for those treated without osteotomy was 32.9 ± 14.0 years. Mean body mass index (BMI) for those treated with and without osteotomy was 26.2 ± 3.8 kg/m² and 24.0 ± 3.2 kg/m², respectively. The mean lesion area and volume in those treated with osteotomy were 130.6 ± 56.4 mm² and 988.6 ± 995.1 mm³, respectively, and for those who did not undergo osteotomy, mean area and volume were 120.5 ± 35.4 mm² and 768.2 ± 516.8 mm³, respectively. There were no statistically significant differences between treatment groups with respect to age (p = 0.523), BMI (p = 0.213), lesion area (p = 0.977), or lesion volume (p = 0.417). Patient characteristics and clinical outcome scores are summarized in Table 1.

To reconstruct the osteochondral defect, Chondrogide matrix was used in 13 cases, and Hyalofast matrix was used in 11 cases. The mean duration of follow-up was 22 months (range 12–30 months), and there was no difference in follow-up duration for those patients who did or did not undergo osteotomy (p = 0.366). There were 14 right and 10 left ankle joints treated. The largest treated lesion area/volume in those patients who did and did not undergo osteotomy was 280 mm²/3920 mm³ and 187 mm²/1870 mm³, respectively.

In the group of patients who underwent malleolar osteotomy, mean AOFAS increased from 57.7 ± 13.0 preoperatively to 81.2 ± 12.3 at final follow-up (p < 0.001), and mean VAS decreased from 5.7 ± 1.0 preoperatively to 1.9 ± 1.0 (p < 0.001). In those who did not undergo osteotomy, mean AOFAS increased from 54.4 ± 12.4 preoperatively to 84.0 ± 14.6 at final follow-up (p < 0.001), and mean VAS decreased from 7.6 ± 1.7 preoperatively to 2.0 ± 1.4 (p < 0.001). The distribution of scores for each instrument is depicted in Fig. 4. The change in mean score from preoperative assessment to final follow-up was not significantly different for the VAS (p = 0.067) or AOFAS (p = 0.213) scores between treatment groups. The mean MOCART score of 70.8 ± 16.6 in the group treated without osteotomy was not significantly different than the mean score of 67.3 ± 17.5 in the group that did undergo osteotomy (p = 0.662). MRI evaluation is depicted in Fig. 5.

There were no significant correlations identified between lesion area/volume and improvements in mean scores of VAS (r_s = 0.083, p = 0.699/r_s = −0.205, p = 0.336) or AOFAS (r_s = −0.377, p = 0.070/ r_s = −0.150, p = 0.484) scores. Comparing outcomes between cases using the different types of matrices (type I/III collagen or hyaluronic acid-based), there was no significant difference in improvements of VAS (p = 0.328) or AOFAS (p = 0.480) scores at final follow-up.

Twenty-two cases (92%) had a satisfactory result, with full return to previous levels of recreational and sporting activity. One patient from the osteotomy group and 1 patient from the arthroscopically-assisted group presented with persistent ankle pain and were considered to have failed the procedure. Radiological follow-up using MRI examination did not identify any cases of complication such as bony cyst formation. No early or late
postoperative complications were identified in either treatment group, and all medial malleolar osteotomy sites healed.

4. Discussion

This study assessed clinical and radiological outcomes after repair of talar dome osteochondral lesions using the BIOR technique, and compared outcomes between those patients who were treated with an arthroscopically-assisted approach, and those treated with medial malleolar osteotomy. Successful clinical outcomes were achieved, irrespective of surgical approach used.

Given the poor outcomes expected after non-operative treatment of osteochondral lesions affecting the talar dome and
the likelihood of lesion progression in untreated cases, surgical management is often the treatment of choice for many clinicians [8,28]. In case of lesions smaller than 150 mm², bone marrow stimulation techniques such as microfracture, nanoafracture, ostechondral drilling, and abrasion arthroplasty are commonly used surgical procedures [9–12]. It has been demonstrated that these marrow stimulation techniques are more commonly associated with the development of fibrous cartilage repair tissue, composed of high type I collagen content that has poor wear characteristics, as opposed to hyaline-like repair tissue consisting of greater type II collagen content [29]. The presence of cartilage repair tissue that lacks durability is consistent with clinical research that has estimated the failure rate of bone marrow stimulation treatment of OCLT is 30% after 5 years [30]. Moreover, poor quality of cartilage repair tissue and progressive arthrosis after marrow stimulation treatment of OCLT has been observed on postoperative MRI and second look arthroscopy [31,32]. Subchondral cysts have also been described as a complication of bone marrow stimulation, and are more likely in the case of techniques that lead to greater diameter of bone penetration, such as 2 mm microfracture or 1.25 mm K-wire drilling, compared to 1 mm nanoafracture [33–36]. Recent reports from animal studies have described improved repair tissue in cases of bone marrow stimulation treatment supplemented with bone marrow aspirate concentrate, compared to bone marrow stimulation alone [37].

Currently, the most commonly used method of reconstructing large OCLT is ostechondral autograft transfer (OAT) with ipsilateral knee graft [38–40]. Importantly, this is a surgical method designed to replace the injured ostechondral tissue, as opposed to repairing the ostechondral unit [41]. Furthermore, transferring an ostechondral autograft from the knee to the talus dome does not reconstitute the native anatomic radius of curvature, and restoration of joint congruence is difficult to achieve [38,41]. According to recent histological reports, the layered structure of talus articular cartilage is notably different from the layered structure of cartilage in the femoral condyle, although the clinical implications of these differences requires further evaluation [42]. From the authors’ perspective, the primary concerns of OAT treatment of OCLT are incomplete integration of the graft with native ostechondral tissue, donor site morbidity, and subchondral cyst formation [3,38,43–47,39,48]. Despite the disadvantages associated with OAT, this technique remains an effective method to treat OCLT, as demonstrated by several retrospective studies. In a recent systematic review, 87% of patients treated with OAT were classified as having good to excellent outcomes at final follow-up [16]. In a cohort of professional athletes treated with the OAT technique, 63–95% returned to previous sporting activities, which demonstrates greater success than would be expected in cases of BMS, and comparable outcomes to cell-based techniques such as ACI [11–13,49].

While clinical outcomes of ACI in the treatment of OCLT are expected to be good, there are several limitations of this procedure that limit widespread use. Firstly, this procedure is performed in
two stages, requiring the patient to assume the risks associated with multiple procedures. Harvested chondrocytes are incubated ex vivo in order to expand the chondrocyte cell lines, which is costly and requires significant off-site resources. These cells are then combined with any of a number of matrix types to create a graft for implantation at the second surgery [6,50,51].

There are further alternative techniques that have been used to treat OCLT, such as autologous matrix-induced chondrogenesis (AMIC). In contrast to ACI, AMIC is a single-stage procedure, which has been described by Behrens and adapted for use in the ankle joint by Valeddarrabano [52]. This technique relies on the regenerative capabilities of released marrow elements after marrow stimulation, which are contained within the defect by applying a matrix such as type I/III collagen or hyaluronic acid-based scaffold. Medium-term results for AMIC have demonstrated statistically relevant AOFAS score increases postoperatively, and normal or near-normal signal intensity of the repair tissue on MRI examination [52,53]. The technique of AMIC, however, does not have the potential to treat deeper osteochondral lesions that require both cartilage repair and reconstruction of subchondral bone. Successful restoration of the contour of the native talar dome is necessary to recreate joint congruence, and this can only be accomplished by appropriately addressing both the subchondral and chondral injury at the time of surgery.

For OCLT that require restoration of subchondral bony deficits, the BIOR technique employs a method to reconstitute the bone by creating a malleable bone inlay using autologous bone chips, BMAC, and fibrin glue. This inlay has excellent physical properties that allow the surgeon to reconstruct areas of bone loss, while enabling exact recreation of the articular surface contour, which is challenging in cases of lesions affecting the talar dome. Initially, medial malleolar osteotomy was used routinely for joint access to treat OCLT with BIOR. Unfortunately, there is concern that this osteotomy may increase postoperative risk for developing osteoarthritis and prolongs patient convalescence [20–23]. The capability to treat OCTL with the BIOR technique in an arthroscopically-assisted fashion, without performing osteotomy, has obvious advantages. This study has demonstrated that for lesions of area/volume that are smaller than 187 mm²/1870 mm³, and which are positioned at the front or central area of the talar dome (zones 1–6), osteotomy is not required to perform OCLT reconstruction by BIOR technique. Additionally, arthroscopically-assisted implantation of the repair graft has the potential to be performed with greater precision and accuracy, given the visualization and magnification provided by the arthroscope to improve the quality of both lesion preparation and reconstruction.

There are several limitations of this study to address. The duration of follow-up for several of the study participants was greater than 1 year but less than 2 years, and so increased duration of patient assessment is necessary to examine the durability of improved clinical outcomes, and to identify late cases of complication and failure. Furthermore, there is currently limited data available to allow direct comparison of the BIOR technique with well-established OCTL treatment methods such as OAT. Additionally, it has been shown that MOCART scores may be less reliable in predicting outcome success when used to examine treatment of ankle disorders [42]. While randomized of surgical approach was considered for the participants, it was determined that localization and characterization of the lesions should be the primary determinant of surgical approach, given the need to ensure adequate access to the osteochondral lesions in all cases. Recent advancements in cell-based cartilage restoration using biocompatible scaffolds embedded with bone marrow aspirate concentrate have great potential to provide durable cartilage repair tissue [54–56]. Combining scaffold-cell composites with a malleable bone graft inlay, as in the case of biologic inlay osteochondral reconstruction, provides impressive versatility for this technique to be used in a wide variety of osteochondral injury sizes and types, particularly in the ankle joint where reconstruction of native talar osteochondral anatomy with current methods of repair can be technically challenging.

5. Conclusions

Osteochondral lesions of the talar dome can be treated successfully by biological inlay osteochondral reconstruction technique without medial malleolar osteotomy, in cases where lesion location and dimensions are amenable to a minimally-invasive approach. Good to excellent clinical outcomes of reconstruction are expected in patients who undergo either a medial malleolar osteotomy approach or arthroscopically-assisted approach, depending on defect dimensions. Due to technique limitations related to adequate exposure, it is recommended to perform a medial malleolar osteotomy for lesions larger than 187 mm² in area and 1870 mm³ in volume. Postoperative MRI examination demonstrates that recreation of the anatomic radius of curvature of the talon dome and good integration of the graft into surrounding tissue is expected after biologic inlay osteochondral reconstruction, irrespective of using a medial malleolar osteotomy or arthroscopically-assisted approach.

Conflict of interest

The authors declare no conflict of interest with respect to the research, authorship, or publication of this article.

References


