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Role of Demineralized Allograft Subchondral Bone in the Treatment of Shoulder Lesions of the Talus: Clinical Results With Two-Year Follow-Up

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ABSTRACT

Cystic osteochondral lesions of the talus present a considerable challenge for foot and ankle surgeons. The purpose of the present study was to evaluate the effect of a medial malleolar osteotomy and implantation of demineralized allograft subchondral bone on pain and function 2 years after surgery. For inclusion, patients demonstrated radiographic evidence of a medial cystic full-thickness osteochondral defect of the talus and previously failed microfracture (N = 12). We hypothesized that improvements in pain and disability would be maintained across time. Compared with the preoperative values, 2 years after surgery, pain and disability had significantly reduced ($p < .001$). Significant reductions had occurred in postoperative pain from 6 months to 1 year ($p = .001$) and from 6 months to 2 years ($p = .005$). Similarly, significant reductions had occurred in postoperative disability from 6 months to 1 year ($p = .008$) and from 6 months to 2 years ($p = .03$). The reductions in postoperative pain and disability were maintained from 1 year to 2 years ($p \geq .79$). Multiple regression analyses identified depression as a predictor of 2-year postoperative pain ($R^2 = 0.36$, $p = .04$). No variables were identified as significant predictors of postoperative disability at 2 years. Other than 1 previously reported peroneal deep venous thrombosis, no additional complications occurred. With successful graft incorporation, no inflammatory response, and no additional complications, the allograft subchondral plug appears to successfully treat osteochondral lesions of the talus and maintain improvements in pain and disability at intermediate follow-up.

Osteochondral lesions of the talus (OLTs) are often associated with pain and disability. The size of these cartilaginous deformities varies, and, when left untreated, subchondral cystic changes can develop (1). However, the exact etiology and pathogenesis of these challenging lesions are not fully understood (2), making their management increasingly complex.

Among foot and ankle surgeons, debate continues regarding the proper surgical management of OLTs. Although ankle arthroscopy with microfracture remains a mainstay in the surgeon's repertoire (3), the success rates of standard marrow stimulation have proved unacceptable for larger lesions (4). Consequently, new surgical innovations have been developed. Advancements in allograft preparation and bone substitutes have promoted cartilage restoration without the undesirable donor site morbidity and limited graft availability associated with autograft transplantation (5–13).

Full-thickness OLTs are particularly challenging defects; even more so, when cystic changes are present. Treatment of type V OLTs is intensely exigent (14–16). Healthy bone has been architecturally altered to a degraded cystic mass. Therefore, this area must be completely cored and reinstated with mechanically sound bone. Reconstituting a healthy os base using a subchondral plug allows fibrocartilage to surface and has been theorized to thwart additional degeneration (17,18).

Preliminary reports examining the use of allograft bone to treat OLTs have demonstrated promising, provisional results (17,18). Although retrospectively conducted and limited to small patient populations, these studies have shown significant improvements in pain and activity after operative intervention at 6 months and 1 year,

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Conflict of Interest: Stephen A. Brigido serves on the surgery advisory board for Alliqua and Bacterin International and as a consultant for Stryker; Alliqua, Bacterin International, and Stryker had no knowledge or influence in the study design, protocol, or data collection.

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with no evidence of graft rejection (17,18). The first case series reported no major perioperative or postoperative complications (17); however, the latter study reported a single deep venous thrombosis that was successfully treated without embolism (18). Considering these results collectively, the allograft subchondral plug appears to successful treat OLTs without a resultant inflammatory response.

According to the manufacturer's guidelines, the OsteoSponge® SC (Bacterin International, Belgrade, MT) is an allograft composed of 100% human, demineralized, cancellous bone. It was designed to treat bony defects in the subchondral region of articulating joints. The demineralization process creates an elastic, compressible graft that is easy to handle intraoperatively. Given its cylindrical shape, it can be press-fit into osseous voids. The graft retains the natural architecture of the subchondral cancellous bone as well as its osteoconductive and osteoinductive properties. In an effort to reduce patient morbidity, our preferred surgical cartilage restoration technique for OLTs has involved a single-stage, single-incision application of the demineralized subchondral allograft (OsteoSponge® SC, Bacterin International, Belgrade, MT). Intraoperatively, a vertical plug, including the cyst, is reamed, and an allograft of the same size is chosen and tamped into the osseous void. This maintains the contour of the talar dome while reconstructing the subchondral plate. In the present study, we examined the clinical outcomes 2 years after treatment of cystic OLTs with medial malleolar osteotomy and implantation of an allograft subchondral bone plug.

Patients and Methods

Aims

The primary aim of the present study was to review the clinical outcomes of patients with an OLT in whom microfracture had previously failed and who had been treated with medial malleolar osteotomy and an allograft subchondral bone plug. We hypothesized that patients with a large, cystic, OLT would experience improvements in pain and disability after talar subchondral allograft reconstruction and that these improvements would be maintained 2 years after surgery.

Our subsequent aims were to assess the relationship between lesion size and the outcome variables of pain and disability and to determine whether patient demographics and lesion size could predict the pain and disability experienced 2 years postoperatively. Finally, we were interested in reporting the postoperative complications associated with this procedure.

Assessors

As detailed in the 1-year report (18), the medical records with the Common Procedural Terminology code for medial malleolar osteotomy (code 27705) were identified by way of database analytics (19) and manually reviewed by 2 coauthors (S.A.B., S.T.B.). When the inclusion and exclusion criteria were met, the endpoints, contributory patient demographics, and comorbidity data were recorded (18). The statistical analyses were performed by a coauthor (N.M.P.), who also serves as a research associate at our institution.

Study Population

The inclusion and exclusion criteria were consistent with those reported in our 1-year study (18), with 1 exception. Patients lacking follow-up data at 2 years were excluded. Patients with magnetic resonance imaging evidence of a full-thickness, medial OLT with subchondral cysts (Fig. 1) were included in the present study. Full-thickness OLTs were defined as deep articular cartilage defects that extended into the subchondral bone of the talus (20). Consecutive

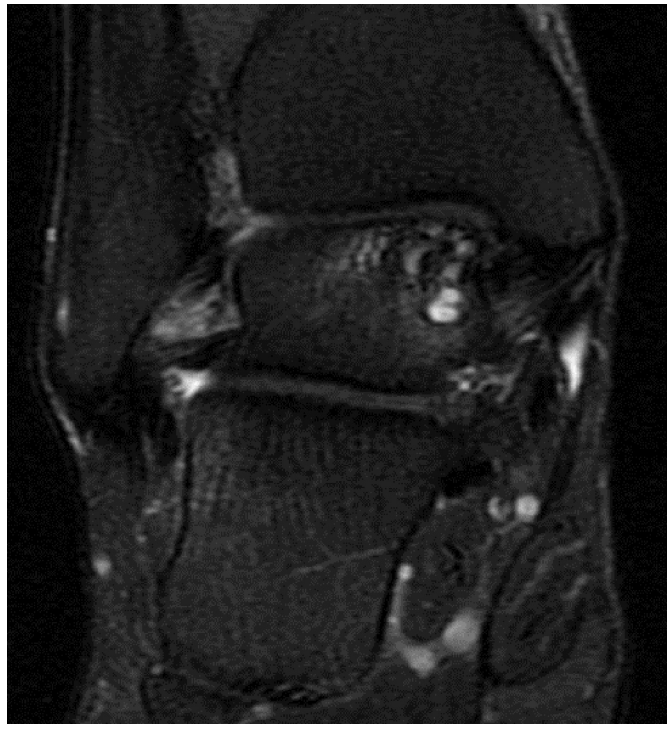

Fig. 1. Full-thickness cystic osteochondral lesion of the talus. Magnetic resonance image demonstrating a type V medial osteochondral lesion with gross talar cystic alterations.

patients who had elected to undergo medial malleolar osteotomy with allograft reconstruction from January 1, 2009 to January 1, 2011 were included. All operative procedures were performed by the senior surgeon (S.A.B.), and the same surgical technique was routinely used. The data were recorded in a password-protected, secure database. The confidentiality and privacy of the patients was ensured and maintained. The Coordinated Health institutional review board approved the study.

Intervention

The surgical technique and postoperative protocol were unchanged from the 1-year report (18). A transmalleolar approach was used, the medial OLT was identified, the damaged cartilage was extruded by curettage down to the healthy, bleeding subchondral bone, the periphery of the subchondral lesion was reamed, and the presized allograft (OsteoSponge® SC, Bacterin International) was inserted (18). After a layered closure, a compressive, below-the-knee, posterior splint was applied (18). The patients remained nonweightbearing for 6 weeks and were then transitioned to partial weightbearing and physical therapy was initiated (18).

Endpoints

The medical records were examined for the primary outcomes (pain and disability), which had been recorded during the preoperative and the 6-month, 1-year, and 2-year postoperative visits. Pain and disability were measured using a visual analog scale with a numeric rating scale. The pain scale ranged from 0 to 10, with 0 representing no pain and 10 representing excruciating pain. The patients were asked to report the pain experienced with their first step in the morning, during walking, and at the end of the day. Using these 3 measures, the average pain score was computed for each time point. The disability scale also ranged from 0 to 10, with 0 representing no disability and 10