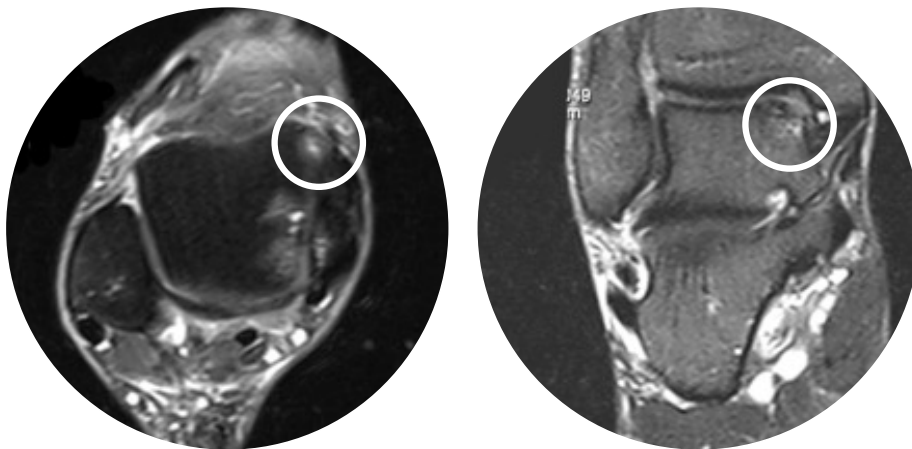


CASE SERIES

Results of Treatment of Chondral Lesions Using CartiMax® FA Viable Cartilage Allograft in Eight Patients

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Pre-operative axial and coronal-view MRI confirming chondral lesion.

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INTRODUCTION

Chondral lesions of the talus cause ankle pain associated with weightbearing, impaired function, limited range of motion, and local swelling. Symptomatic defects often require surgical treatment when conservative management via rest, cast immobilization, and physical therapy have failed. Surgical approaches include excision and curettage combined with drilling or micro-fracture, autogenous bone graft, antegrade or retrograde drilling, and chondral transplantation. Literature for these techniques fluctuate wildly, with success rates varying from 41 to 93%.^{1,2}

The purpose of the current case series is to describe and evaluate the results of treatment of chondral lesions using CartiMax® FA viable cartilage allograft.

TECHNOLOGY OVERVIEW

CartiMax® FA is a viable allograft containing chondrocytes and chondrogenic growth factors with putty-like handling properties, intended for treatment of confined cartilage lesions in the foot and ankle. CartiMax® FA is composed of two components: Viable Cartilage Fibers (VCF) and Cartilage Allograft Matrix (CAM). VCF, which contains cryopreserved native adherent chondrocytes, is combined with CAM,



CartiMax® FA Viable Cartilage Allograft

which contains cartilage extracellular matrix, endogenous growth factors (IGF-1, TGF- β , FGF-2), and other proteins. Together, the two components creates a biologic scaffold that is cohesive and malleable while being capable of repairing focal defects in articular cartilage.³⁻⁵

CartiMax® FA has been proven to:³

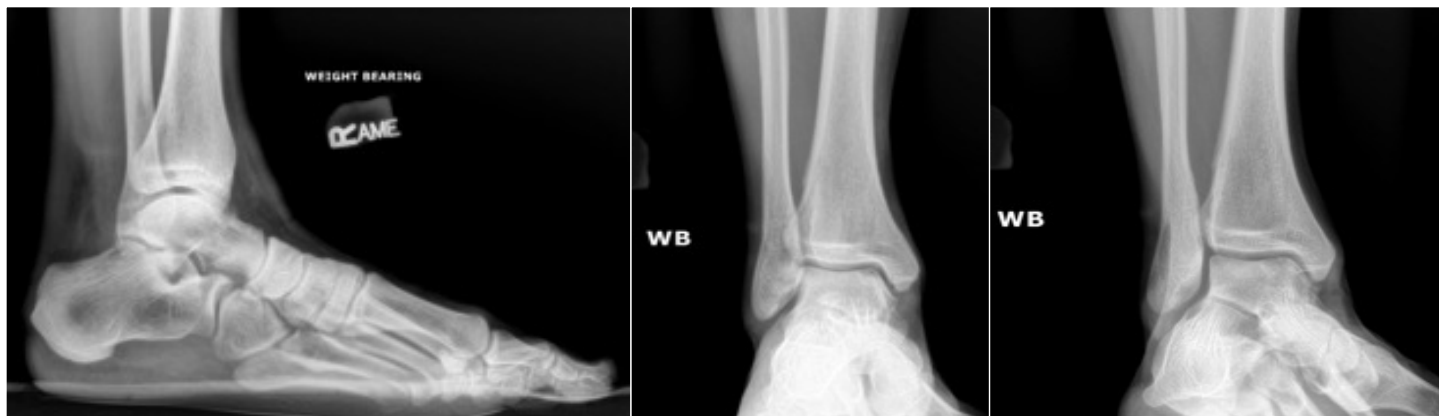
- Safely support cartilage repair and graft remodeling
- Fill contained defects up to 5 cm² and remain in its intended location
- Robustly integrate to edges of native tissue (cartilage edges and subchondral bone)

Characterization testing of CartiMax® FA verifies the presence of functioning viable chondrocytes and

chondrogenic growth factors while affording maximum handling flexibility with its putty-like consistency.¹ Multiple studies have demonstrated that chondrocytes migrate and proliferate from the cartilage fibers and secrete components found in hyaline cartilage.²⁻⁴ It has the potential to circumvent the morbidity and technical difficulties of currently available restorative procedures such as arthroscopy with marrow stimulation via microfracture or autologous chondrocyte implantation.^{6,7} Usage of CartiMax® FA does not require perpendicular access to the chondral lesion, which eliminates the necessity of the medial malleolar or fibular osteotomy often required with other methods of cartilage repair.^{8,9} In addition, fewer steps are required in its application, as it is moldable and conformable to the defect without need for templating, suturing, or the use of fibrin glue. Finally, due to the cryopreservation process of CartiMax® FA, there is an increased shelf-life with chondrocyte viability up to 2 years post-cryopreservation compared to fresh osteochondral grafts that can maintain viable cells only for very limited periods of time.¹⁰

METHODS

Eight patients with median age of 31 (range 17-48) were included. There



Figures 1, 2, and 3. Pre-operative lateral, AP, and Mortise-view radiographs demonstrating chondral lesion of the medial talar dome.



Figures 4 and 5. Pre-operative axial and coronal-view MRI confirming chondral lesion.

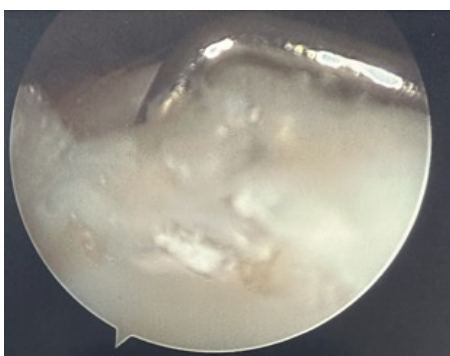


Figure 6. Chondral lesion with damaged cartilage cap

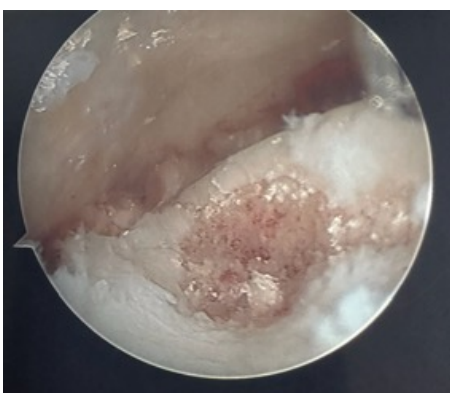


Figure 7. Chondral lesion following debridement

were 4 females and 4 males with a collective 7 medial talar defects and 1 lateral talar defect. The average size of the chondral lesion was 1.62 cm² (range 0.78 cm² to 3.36 cm², standard deviation 0.81 cm). All patients had failed conservative treatment including activity modifications, immobilization, physical therapy, injections and medications. Radiographically, none of the patients had joint space narrowing or arthritic changes.

SURGICAL INTERVENTION

The average chondral lesion size was 1.62 cm² (ange 0.78 cm² to 3.36 cm², standard deviation 0.81 cm). There were 7 medial and 1 lateral defects. Reconstruction was necessary due to ankle instability, and CartiMax[®] FA allograft matrix was found to be strong enough to sustain the impact forces of the hindfoot and malleable enough to fill the defect in its entirety. Operations began with standard ankle arthroscopy to inspect the talar articular surface and visualize the talar defect. Initially, a generalized synovectomy was performed.



Figure 8. Anteromedial arthrotomy as extension of anteromedial portal, providing excellent exposure of chondral lesion.



Figure 9. Status-post chondral lesion debridement and curettage, demonstrating full size of defect in medial talar bone.



Figure 10. CartiMax[®] FA insertion, demonstrative of product's malleability, moldability, and ease of application.

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After the chondral lesion was identified, it was prepared for CartiMax® FA implantation by excision of the loose chondral flap and creation of a stable border with a curette and arthroscopic shaver. The subchondral bone was then debrided to stimulate bleeding bone. No microfracture was performed. If present, any talar and tibial exostoses were excised with an arthroscopic shaver or burr.

After preparation of the chondral lesion arthroscopically, an anteromedial or anterolateral arthrotomy was performed as an extension of the respective arthroscopic portal, depending on the location of the chondral lesion. In addition, if necessary for visualization, a tibial plafondplasty was performed. The foot was then plantarflexed to expose the chondral lesion. The base of the lesion was dried, and the CartiMax® FA cartilage allograft was packed into the chondral lesion. Care was taken to ensure the allograft was slightly recessed to the native talar cartilage to prevent prominence in cases of graft hypertrophy. Finally, the ankle was passively dorsiflexed and plantarflexed to ensure graft stability and optimize contour. The wound was closed in standard fashion.

FOLLOW-UP

Patients were placed in a posterior splint immediately following the procedure. They remained nonweight bearing for 6 weeks post-operation. However, early active range of motion was initiated at 2 weeks postop. Weightbearing in a CAM boot and formal physical therapy was initiated at 6 weeks

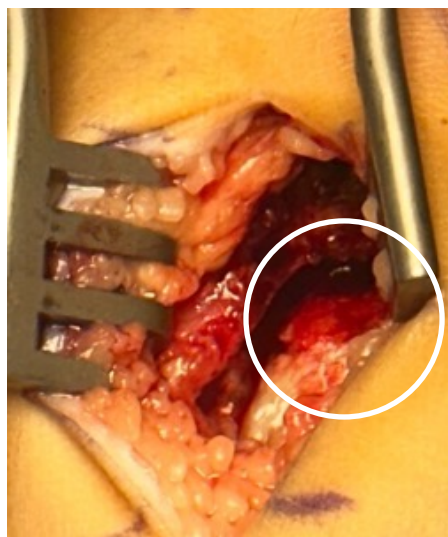


Figure 11. Chondral lesion following CartiMax® FA application.

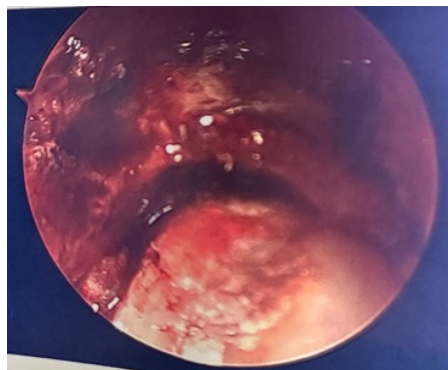


Figure 12. Status-post CartiMax® FA application.

postoperatively. Impact activity was restricted until 4 months postop. Median follow-up time was 3.8 months (range 94 days), with excellent early clinical results. Patients reported decreased pain scores, improved range-of-motion, and improved function at an average of 3 months (range 7 days) postoperatively.

CONCLUSION

Eight patients underwent successful chondral lesion repair utilizing CartiMax® FA viable cartilage allograft. Throughout each procedure, we achieved a stable and reliable repair without need for microfracture or osteotomy, thereby minimizing morbidity. All patients had improved pain and function at 3-months postoperatively. Chondral lesion treatment is safe and effective with CartiMax® FA.

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