Cell-Free Aragonite-Based Scaffold With Bone Marrow Aspirate Concentrate Augmentation for Osteochondral Defects of the Knee

Ron Gilat,* MD, Alexander C. Weissman,* MS, Andrew R. Phillips,* BA, Allen A. Yazdi,* BS, Sarah A. Muth,* BA, and Brian J. Cole,*† MD, MBA
Investigation performed at the Department of Orthopaedic Surgery, Rush University Medical Center, Chicago, Illinois, USA

Background: Damage to the joint surface, which affects articular cartilage and the underlying subchondral bone, is a common cause for significant knee pain and disfunction. The use of CartiHeal Agili-C, a cell-free aragonite-based implant, is an emerging option for patients who may otherwise be a poor candidate for allograft transplantation or within geographic areas where there is a limited availability of donor tissue.

Indications: The CartiHeal Agili-C implant is indicated for patients with an International Cartilage Repair Society grade III or IV lesion with a total treatable area of 1 to 7 cm^2 and without severe osteoarthritis.

Technique Description: Standard parapatellar arthrotomy is performed to reveal an osteochondral defect of the femoral condyle. The cell-free aragonite-based scaffold is then transplanted in 7 steps according to numbered instrumentation in the Agili-C toolset. Surgical pearls of placement include proper alignment of the perpendicular aligner tool with circumferential viewing, assistant confirmation, and arthroscopic verification; avoiding wobbling during the shaping phase of the procedure as this may cause an oblong socket with inadequate fixation; and handling the implant with care and only using a thumb or index finger to insert with light tapping.

Results: A multicenter randomized control trial followed 251 patients and found 88.5% of the implant group had at least 75% lesion fill as seen on postoperative magnetic resonance imaging at a 2-year follow-up. Additionally, patient-reported outcome measures were statistically superior when compared to controls at 24 months.

Conclusion: Transplantation of a cell-free aragonite-based scaffold (Aglili-C; CartiHeal Ltd), augmented with bone marrow aspirate concentrate, provides an efficient, reproducible surgical strategy in the management of osteochondral defects of the femoral condyles.

Patient Consent Disclosure Statement: The author(s) attests that consent has been obtained from any patient(s) appearing in this publication. If the individual may be identifiable, the author(s) has included a statement of release or other written form of approval from the patient(s) with this submission for publication.

Keywords: knee; osteochondral defect; Agili-C; CartiHeal; cell-free aragonite-based scaffold

VIDEO TRANSCRIPT

The following is a video presentation describing our surgical technique for the implantation of a cell-free aragonite-based scaffold (Aglili-C; CartiHeal Ltd), for the management of a focal osteochondral defect of the medial femoral condyle (MFC) of the knee, augmented with bone marrow aspirate concentrate (BMAC).

These are our disclosures, and the authors' full disclosures are available online.

In this video, we will provide a brief overview of osteochondral defects of the knee, indications for the use of cartilage restoration using a cell-free aragonite-based scaffold, discuss a case presentation along with surgical pearls, describe our postoperative management, and review patient-reported outcomes.

BACKGROUND

Damage to the joint surface, which affects articular cartilage and the underlying subchondral bone, is a common cause of significant knee pain and disfunction. Such lesions may be categorized as superficial, affecting only cartilage, or full-thickness, which extends through the cartilage to

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disrupt the osteochondral interface. The Modified International Cartilage Repair Society (ICRS) Classification System for chondral injury categorizes joint surface lesions into 4 grades based on lesion depth.[2,5,7]

Osteochondral allograft is a commonly implemented surgical procedure to treat joint surface lesions and may be indicated during the later stages of cartilage damage, such as ICRS grades 3 and 4.[3,4] The use of a cell-free aragonite-based implant is an emerging option for patients who may otherwise be a poor candidate for allograft transplantation or within geographic areas where there is limited availability of donor tissue.[1,8] Aragonite is a coral-derived crystalline form of calcium carbonate that shares structural characteristics with human bone. The CartiHeal Agili-C implant stimulates revascularization and stromal proliferation, and it received US Food and Drug Administration approval in March 2022. Surgical implantation can be performed in a single-stage procedure as the implant is readily available in the operating room, given its off-the-shelf design. The scaffold has been shown to produce hyaline-like cartilage and does not rely on subchondral bone quality, unlike surface treatments such as matrix-induced autologous chondrocyte implantation (MACI).[6]

INDICATIONS

The CartiHeal Agili-C implant is indicated for patients with an ICRS grade III or IV lesion with a total treatable area of 1 to 7 cm^2 and without severe osteoarthritis. The implant may be utilized by surgeons and patients seeking alternatives to traditional cartilage restoration techniques.

In this case presentation, a 57-year-old man presented with 6 months of right knee pain following an atraumatic event where his right knee twisted awkwardly while ambulating. The patient's primary concern was sharp pain with walking, specifically on uneven surfaces. Conservative treatment, including nonsteroidal anti-inflammatory medications and rest, failed.

On physical examination of the right knee, the patient demonstrated no effusion, full active range of motion (extension to 0° and flexion to 135°), slight varus alignment, medial joint line tenderness, and a positive McMurray's sign. He was ligamentously stable and neurovascularly intact.

Standard knee radiographs showed mild osteoarthritic changes.

Magnetic resonance imaging of the right knee demonstrated a focal osteochondral lesion of the MFC approximately 1 cm^2 in size with accompanying bone marrow edema.

After a thorough discussion of treatment options, the patient opted to move forward with surgical intervention, utilizing transplantation of a cell-free aragonite-based scaffold with BMAC augmentation to address the focal osteochondral defect of the MFC of the knee.

TECHNIQUE DESCRIPTION

In the operating room, the patient was placed in a supine position in a standard fashion, with a lateral post applied. After standard preparation and sterile draping, bone marrow aspirate was harvested from the proximal tibial metaphysis and centrifuged using a commercial kit (Arthrex) to a total volume of 5 cc. The tourniquet was then inflated to 300 mm Hg.

Next, a diagnostic knee arthroscopy was performed via standard lateral and medial infrapatellar portals. Inspection of the cartilaginous surface of the MFC revealed a 0.8-cm^2 grade 4, osteochondral defect. The defect was probed and then debrided to obtain a stable rim with vertical walls. The medial meniscus and medial tibial plateau were found intact. Next, a standard medial parapatellar arthrotomy of 4 cm in length was performed. After opening the retinaculum, 2 Z-retractors were placed, and the osteochondral defect in the MFC was revealed. The cell-free aragonite-based scaffold transplantation procedure has 7 steps, which are marked in numbers on the corresponding instrument in the Agili-C toolset. The perpendicular aligner (tool 1) is positioned over the center of the defect. Care must be taken to verify the aligner is perpendicular and in full contact with the entire surface of the articular defect. A K-wire is then drilled until the laser mark on the K-wire reaches the proximal end of the perpendicular aligner. The perpendicular aligner is then removed, and the drill sleeve (tool 2) is introduced over the K-wire. While holding the drill sleeve firmly over the defect, a drill bit (tool 3) is used to drill to a firm stop. Following removal of the drill sleeve and drill bit, the reamer (tool 4) is inserted over the K-wire and then manually rotated clockwise until the indicator line is no longer visible to ensure

†Address correspondence to Brian J. Cole, MD, MBA, Department of Orthopaedic Surgery, Rush University Medical Center, 1611 West Harrison Street, Chicago, IL 60607, USA (email: cole.research@rushortho.com).

*Department of Orthopaedic Surgery, Rush University Medical Center, Chicago, Illinois, USA.

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correct depth. The reamer is removed while the K-wire remains in place. Thorough irrigation with saline is performed. The shaper (tool 5) is then inserted over the K-wire and advanced manually in a clockwise fashion until the indicator line is no longer visible and the shaper is rotating smoothly. Rotate the shaper gently, without wobbling, at least 3 times, to ensure smooth rotation in the hole. The K-wire is removed and irrigation is repeated. Using the cartilage cutter (tool 6), the peripheral cartilaginous edges of the hole are trimmed to ensure smooth edges and to prevent invagination during transplantation. A scalpel or a rongeur may also assist in smoothing the cartilaginous edges. A 7.5-mm cell-free aragonite-based scaffold is then soaked with approximately 1 cc of the patient's BMAC on the back table. The implant is then introduced into the hole and firmly pushed using the thumb until 2 mm deeper than the surrounding cartilage. A tamper (tool 7) may be used to gently push the implant to the correct depth but was not needed in this case. Care should be taken to perform gentle movements and avoid the use of a mallet when handling the implant, as the implant is brittle. A final image of the implant in place is taken with a scope. The tourniquet is then deflated, with hemostasis obtained. Closure is performed in a standard layered fashion with final subcuticular Monocryl (Ethicon, Inc.) and BandGrip (BandGrip) for skin closure.

The authors recommend 3 technical pearls to ensure efficient completion of the procedure.

1. The perpendicular aligner (tool 1) must be perpendicularly aligned when drilling in the K-wire. To do this, one should look circumferentially, ask for assistance to confirm, and also use the arthroscope to verify.
2. Ensure the shaper (tool 5) is rotating smooth and freely within the socket using a very gentle, steady hand. Avoid wobbling as this may create an oblong socket and subsequent inadequate fixation.
3. The implant should be handled with care and inserted with your thumb or index finger and only lightly tapped. The implant is brittle, and cracks or debris may lead to synovitis.

POSTOPERATIVE MANAGEMENT

Postoperatively, patients may use a soft immobilizer, hinged brace, or no brace, which is worn for comfort and discontinued as soon as tolerated, typically in 1 week. Passive range of motion is initiated immediately, along with closed-chain activities and stabilization exercises. Weightbearing is heel touch only during the first 3 to 6 weeks, progressing to 25% body weight by week 8 and full weightbearing after 8 weeks. Active-assisted range of motion exercises are commenced typically at 3 to 4 weeks postoperatively. Full active range of motion is typically achieved by 8 weeks. Strengthening exercises are initiated at approximately 4 to 6 weeks with full return to activities at 6 to 8 months postoperatively.

RESULTS

At 6 weeks postoperatively, our patient reported subjective improvement in pain. On examination of the right knee, his incision was well healed, and his knee demonstrated active extension to 0° and flexion to 120°. Two-view radiographs of the right knee demonstrate expected postoperative findings, with the Agili-C implant well positioned in the MFC. Three-month postoperative patient-reported outcome measures demonstrated significant improvement with statistically superior Knee injury and Osteoarthritis Outcome Score and Western Ontario and McMaster Universities Osteoarthritis Index scores compared to preoperatively.

DISCUSSION/CONCLUSION

In patients with joint surface lesions of the knee, an aragonite-based osteochondral implant has been shown to confer superior clinical outcomes and superior defect fill when compared to arthroscopic debridement or microfractures. In a multicenter randomized control trial published in 2023 that followed 251 patients across 26 medical centers, 88.5% of the implant group had at least 75% lesion fill, as seen on postoperative magnetic resonance imaging at a 2-year follow-up.[1] Moreover, patient-reported outcome measures were statistically superior when compared to controls at 24 months. Further research is necessary to determine the additional clinical benefits of augmentation with orthobiologic agents, such as BMAC.

In conclusion, transplantation of a cell-free aragonite-based scaffold (Aglili-C; CartiHeal Ltd), augmented with BMAC, provides an efficient, reproducible surgical strategy in the management of osteochondral defects of the femoral condyles.

ORCID iDs

Ron Gilat https://orcid.org/0000-0002-9283-1439
Allen A. Yazdi https://orcid.org/0000-0002-4536-7346
Sarah A. Muth https://orcid.org/0009-0003-0819-5981
Brian J. Cole https://orcid.org/0000-0002-4006-2113

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