Case Report

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Failed Hydrogel Synthetic Cartilage Implant With Osteolytic Cyst Formation in the First Metatarsophalangeal Joint

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Introduction

Hydrogel synthetic cartilage implants are US Food and Drug Administration (FDA)–approved devices for the treatment of advanced first metatarsophalangeal joint arthritis. A prospective, randomized, multicenter clinical trial was performed to assess the safety and efficacy of hydrogel implant (Cartiva; Wright Medical, Memphis, TN) compared to first metatarsophalangeal joint (MTPJ) arthrodesis.[3] At 2-year follow-up, clinical outcome scores demonstrated statistically equivalent pain relief, function, and safety between the 2 groups.

Initial results have been promising when compared to prior techniques for first MTPJ arthroplasty, including first- and second-generation silastic implants as well as metal implants. Silastic implants demonstrated mixed results in early testing, but have been associated with foreign body type reactions, significant osteolysis, and implant loosening.[6,10,13] Metal implants though varied in design have been associated with high rates of implant loosening and subsidence.[6,8,10] One of the major difficulties with these stated complications is the increased difficulty to revise these implants to a first MTPJ arthrodesis because of the presence of significant bone loss in the event of implant failure. The current literature does not identify cyst formation and major bone loss in the setting of failed synthetic cartilage implants.[1,2,3] Revision techniques for removal of the synthetic cartilage implant and subsequent first MTPJ arthrodesis have been described in small case series. Fusion rates and patient outcomes are comparable to those of primary arthrodesis.[7,9]

The following case report describes a unique synthetic cartilage implant failure with ballooning osteolytic cyst formation throughout the first metatarsal head. To our knowledge, there are no published reports of ballooning osteolytic cyst formation about these types of first MTPJ implants. We describe the course of treatment, radiographic and histologic findings, and the technique for the successful management of this complication.

Case Report

Preoperative Course

A 49-year-old female with medical history including rheumatoid arthritis (RA) and depression presented to our clinic from an outside practitioner approximately 10 months after undergoing treatment for right first MTPJ arthritis with implantation of a hydrogel implant. Her RA was well controlled with no clinical deformity of her hands or feet and she was only taking anti-inflammatories to manage her symptoms. She had no radiographic changes consistent with RA on her images prior to her Cartiva procedure (Figure 1). She reported that since the time of her index procedure, she had continued to have pain and swelling about the great toe. Imaging at the time of this initial encounter demonstrated a right first MTPJ status post implantation of the hydrogel implant with subsequent joint collapse, implant loosening, and ballooning osteolysis in both the first metatarsal and proximal phalanx (Figure 2). There was no evidence for

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Figure 1. (A) Anteroposterior and (B) lateral of the patient's foot prior to implantation of hydrogel implant.

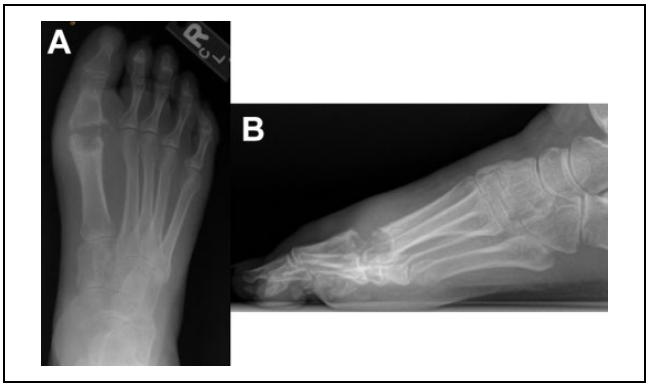

Figure 2. (A) Anteroposterior and (B) lateral radiographs of a right foot status post implantation of a synthetic cartilage implant. Imaging demonstrates ballooning osteolysis about the first MTP joint space. MTP, metatarsophalangeal.

cystic changes on radiographs prior to placement of her hydrogel implant. Because of her clinical appearance and radiographic findings, she was sent for blood work including erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), and complete blood count (CBC) with differentiation, all of which came back with normal values. Additionally, a computed tomography (CT) scan of her right foot was ordered to further define her bone loss.

She returned to the clinic the following week after sustaining a ground-level fall that resulted in pain about her second metatarsal. She was placed into a short controlled ankle movement (CAM) boot for comfort and asked to follow through with her previously ordered CT scan. Her CT scan further defined the ballooning osteolysis present throughout her effective first MTPJ space involving both the metatarsal head and proximal phalanx (Figure 3). It also demonstrated a minimally displaced right second metatarsal fracture. Conservative treatment was continued in a short CAM boot.

One month later, she returned for reevaluation. She was continuing to have pain and swelling about her great toe. After a discussion of the risks and benefits of surgery, we proceeded with right first MTPJ removal of implant and fusion with cancellous autograft 3 weeks later.

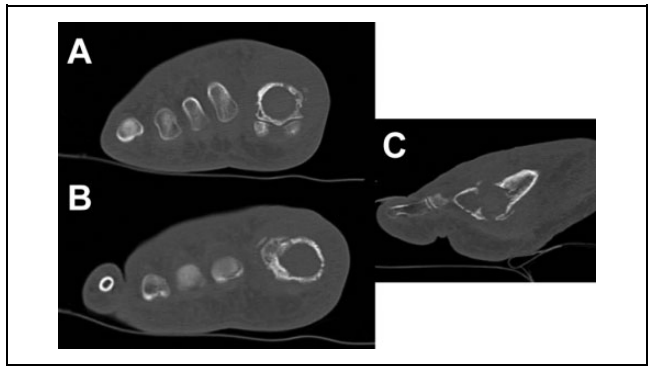

Figure 3. Computed tomographic (CT) scans of right foot. (A) Coronal plane CT at the level of the distal first metatarsal demonstrating a large cyst formation about the synthetic cartilage implant. (B) Coronal plane CT at the level of the proximal first toe proximal phalanx demonstrating a large cyst formation. (C) Sagittal plane CT at the level of the first MTPJ demonstrating large cyst formation throughout the effective joint space. MTPJ, metatarsophalangeal joint.

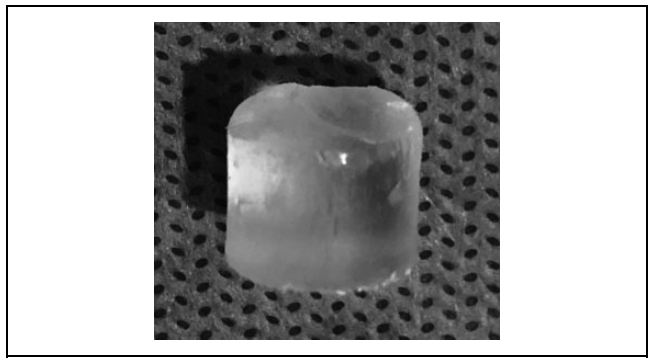

Figure 4. Photograph of the removed synthetic cartilage implant demonstrating pitting and wear.

Operative Technique

A dorsal approach was made over the first MTPJ following the previous operative incision. There was a large degree of reactive tissue around the hydrogel implant. The implant was grossly loose, and it was removed without difficulty. The implant demonstrated pitting and wear (Figure 4). A curette was then used to excavate the cyst present within the metatarsal and phalanx (Figure 5). Cystic tissue was sent for culture and pathology.

Because of the large volume of bone loss, an incision was made over the tibial tubercle on the lateral side. A window was made into the lateral aspect of the proximal tibia, and a curette was used to obtain approximately 4-5 mL of autologous cancellous bone graft.

The metatarsophalangeal joint was irrigated with normal saline. A drill pin was used to make multiple holes into the metatarsal and phalanx fusion sites. Bone graft was placed into the phalanx and the metatarsal cyst areas, as well as in the gap between the bones. The first MTPJ was provisionally reduced

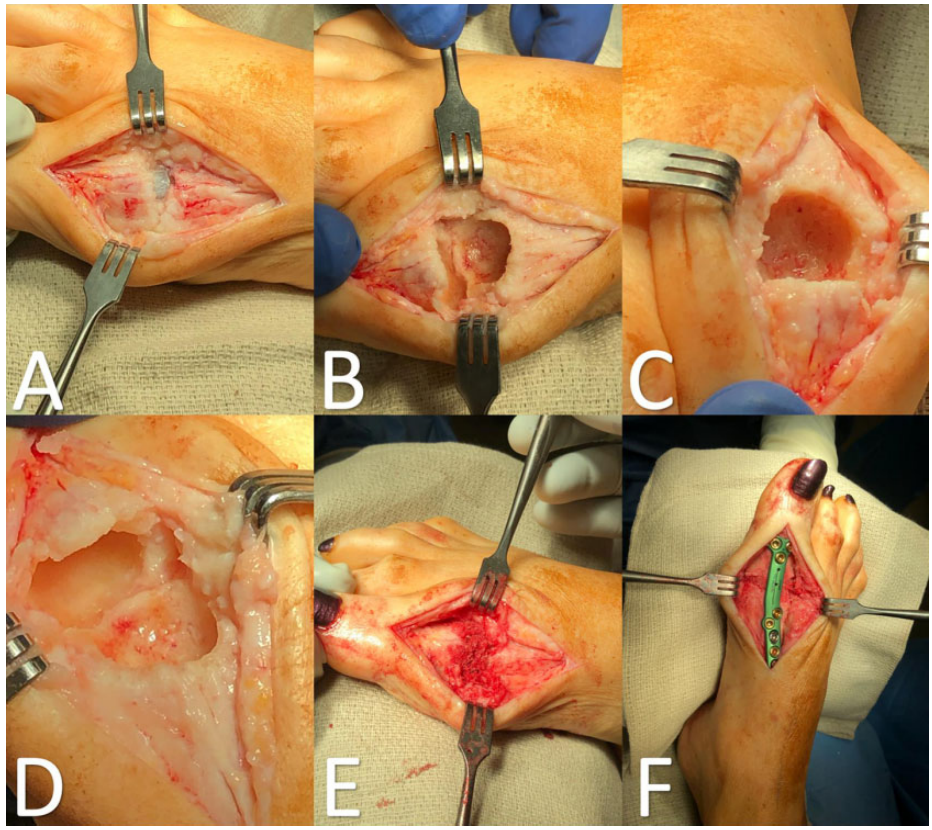

Figure 5. Intraoperative photographs. (A) First MTPJ after joint capsule has been opened and extensor hallucis longus tendon retracted laterally. Implant visible. (B) First MTPJ after removal of implant and debridement of cyst (right = proximal). (C) First metatarsal cavitary defect. (D) First proximal phalanx cavitary defect. (E) First MTPJ prepped for fusion with placement of proximal tibial bone graft. (F) First MTPJ final operative construct with dorsal first MTPJ fusion plate applied spanning the defect reaching good quality bone. MTPJ, metatarsophalangeal joint.

and pinned in a position of approximately 5 to 10 degrees of dorsiflexion, neutral supination and pronation, and slight valgus. A revision first MTPJ fusion plate was placed with 3 locking screws into the phalanx, and a nonlocking and 3 locking screws were placed on the metatarsal side (Figure 5). Fluoroscopic imaging demonstrated satisfactory position of internal fixation and alignment of the toe. The wounds were irrigated and closed in a layered fashion with 3-0 Vicryl and 3-0 nylon.

Postoperative Course

The patient was allowed to bear weight through her heel in a hard-sole postoperative sandal immediately postoperatively. At week 2 after surgery, the incisions were well healed with no signs of infection. Radiographs were obtained that demonstrated maintenance of alignment of her first MTPJ fusion site without evidence of hardware failure or loosening.

Her intraoperative cultures were negative for any bacterial growth. The histologic analysis of the cystic tissue revealed perivascular deposition of hyperchromatic granules, foreign body material located within the vessel walls, and mild lymphocytic response. Plasma cells, neutrophils, macrophages, and multinucleated giant cells, which are usually seen with silicone or crystal deposition disease, were absent. Instead the patient's cystic tissue revealed a more perivascular response in the form of endothelial lining irritation and lymphocytic inflammation (Figure 6).

At her 6-week postoperative evaluation, she demonstrated excellent alignment of her right great toe without tenderness to palpation. Radiographs demonstrated anticipated alignment and early consolidation of her fusion mass. She was allowed to progress to full weightbearing in the hard-sole sandal.

Three months following the procedure, she reported 0 out of 10 pain in the right great toe. Radiographs demonstrated maintenance of alignment of her right great toe with interval consolidation at the fusion site (Figure 7). The patient had transitioned to regular shoes.

Discussion

We describe a unique case of a patient with a failed hydrogel synthetic cartilage implant who presented with ballooning osteolysis about the metatarsal head and proximal phalanx. Previous reports of failures have not described extensive

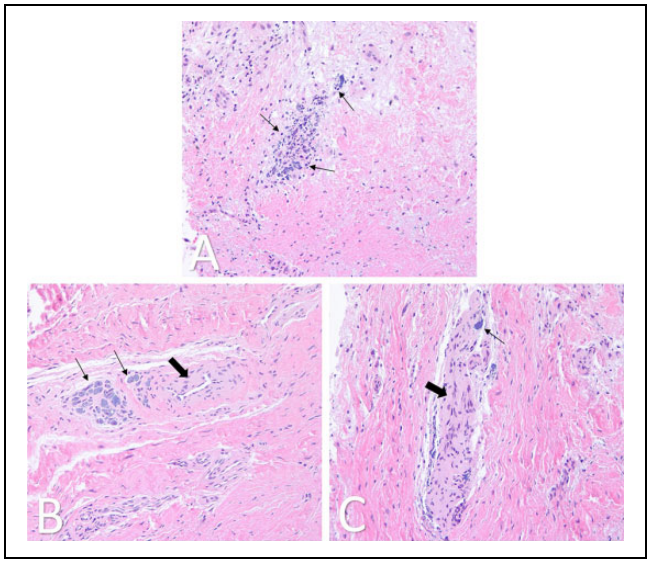

Figure 6. Photographs of intraoperative pathology specimens at 400× magnification. The tissue was stained with a standard hematoxylin and eosin protocol. (A) Granular foreign material with admixed small lymphocytes (highlighted by the arrows). There are many more lymphocytes in the upper left-hand portion of the image. (B and C) Perivascular deposition of hyperchromatic granules. Wide arrow: blood vessel; thin arrows: foreign material.

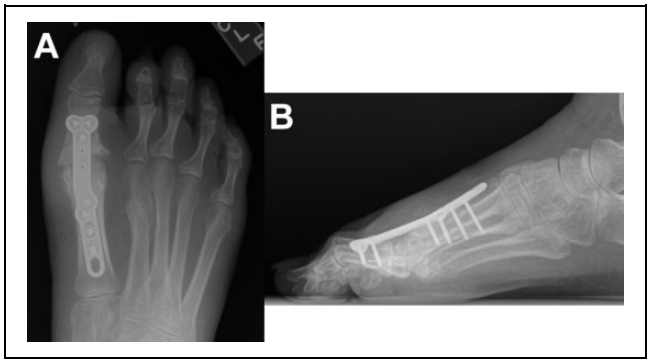

Figure 7. (A) Anteroposterior and (B) lateral radiographs of the right foot taken 3 months postoperatively demonstrating maintenance of alignment, intact hardware, and consolidation of the first MTPJ fusion site. MTPJ, metatarsophalangeal joint.

cystic bone loss in the periarticular space. Although our patient had RA, she appeared to be well controlled and not taking any antirheumatic medications and had no physical manifestations.

In 2016, a hydrogel synthetic cartilage implant was proposed over arthrodesis for treatment of advanced first MTPJ arthritis because of reliable pain relief, function, and safety through a prospective, randomized clinical trial. The implant group demonstrated a 6.2-degree improvement in active dorsiflexion of the first MTPJ that was maintained at 2-year follow-up. Fourteen (9.2%) of the 152 patients who underwent treatment with the implant required removal and subsequent first MTPJ fusion secondary to continued or recurrent pain. This occurred at an average of 390 days from the index procedure.[3] Midterm results with 5-year follow-up of the same patient population demonstrated maintenance of pain control and clinical improvement over their preoperative state. From 2 to 5 years following implantation, 8 of the 119 patients available for evaluation underwent removal of implant and first MTPJ fusion for persistent or recurrent pain. One patient underwent removal of implant and MTPJ fusion for infection. Total implant survivorship at an average of 5.8 years was 84.9%, and the authors do not report any instances of implant loosening.[2]

Early biocompatibility testing of the polyvinyl alcohol used in the hydrogel implant has demonstrated low immunologic reactivity compared with other commonly used materials such as ultrahigh-molecular-weight polyethylene.[4,11] Though long-term results are not yet available, there appear to be advantages over prior attempts at first MTPJ arthroplasty. Earlier metal and silastic implants were associated with implant loosening, subsidence, and bone loss that made salvage procedures difficult, with histologic findings consistent with a foreign body reaction with giant cells and particulate matter.[6,8,10,12,13] The currently available literature suggests low rates of synthetic cartilage implant loosening and osteolysis.[2,3]

In 2019, Cassinelli et al[5] performed a retrospective review of 60 patients who underwent 64 synthetic cartilage implants by a single surgeon. At an average of 18.5 months' follow-up, 42% of patients were satisfied with the procedure. PROMIS scores demonstrated mild pain and mild physical dysfunction. There was a 20% reoperation rate, and 8% of the implants required conversion to first MTPJ arthrodesis. One of their reported failures resulted from implant subsidence. At the time of the revision surgery, implant wear was noted. Pathology demonstrated foreign body giant cell reaction and neovascularization. On a follow-up MRI study, the group described subsidence and increased diameter surrounding the implant of approximately 1 mm in 18 patients.[1] In addition, edema was present in both the metatarsal head and proximal phalanx. They did not describe ballooning osteolysis in their population of failed implants.

Our patient's clinical outcome was not unusual relative to the published synthetic cartilage implant failure rate, reported at 10% within a year.[3] Our patient sought a revision 10 months after her index procedure. What is unique to our patient's outcome that has not been published previously is the implant loosening and ballooning osteolytic cystic changes surrounding the hydrogel prosthesis. There was no radiographic evidence of cystic bone loss before the index procedure (Figure 1).

The original randomized study investigating the hydrogel implants excluded patients with any form of inflammatory arthritis; however, rheumatoid arthritis is not listed among the manufacturer's contraindications for the synthetic cartilage implant. The intraoperative pathology is not consistent with rheumatoid disease as the cause for the observed bone

cysts. Histologic findings of rheumatoid arthritis would include granulomas with central fibrin deposition and necrobiosis and peripheral palisading histiocytes would usually be present. None of these findings were present.

Our patient's unique outcome with ballooning osteolysis suggests individual patient responses to the hydrogel implant may not be clearly understood. On gross inspection, our patient had obvious surface wear on the articulating surface with the phalanx. Histologic review of the patient's cyst presented signs of lymphocytic inflammation and perivascular response to the implant in the form of endothelial lining irritation and deposition of hyperchromatic granules in the vessel walls. It is important to note the absence of plasma cells or multinucleated giant cells, which are often seen in the more robust cellular responses to other previously used silicone or metal implants.

Conclusion

Introducing new operative implants has the potential to improve patients' lives. Materials used as bearing surfaces require diligent observation as wear debris is guaranteed and the host reaction may have significant ramifications. Although hydrogel implants are an alternative to arthrodesis, there remain unknown factors that influence outcomes. Our manuscript presents a case where this implant was associated with adverse symptoms and ballooning osteolytic cyst formation. In order to alleviate the patient's symptoms, she underwent removal of the hydrogel implant and reactive tissue, autologous cancellous bone grafting of the phalanx and metatarsal cysts, and fusion of the first MTPJ. Further analysis and longer follow-up are needed to understand the complications associated with hydrogel synthetic cartilage implants in treating first MTPJ arthritis.

Ethics Approval

Ethical approval was not sought for the present study because this was a retrospective review of a single case history with no intention of determining treatment outcomes or recommendations.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article. ICMJE forms for all authors are available online.

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