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Case Report

Custom megaprosthesis for the management of a failed total ankle replacement with massive cortical osteolysis

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Abstract

Ankle arthritis is a common, debilitating condition. Total ankle replacement (TAR) has become a popular management option for end-stage ankle arthritis. Aseptic loosening is the most common mechanism for implant failure. Third body-mediated inflammatory bone resorption, such as metallosis, is a described mechanism of aseptic loosening. Metallosis can result in massive cortical lysis. Standard revision TAR is not a viable option in the setting of massive cortical osteolysis. The authors present a case of a 67-year-old female,15 years post-primary TAR, presenting with a failed TAR secondary to periprosthetic osteolysis due to metallosis. She was managed with staged revision. The first stage included implant removal, biopsy, debridement, and cement spacer insertion. Histology diagnosed aseptic loosening due to metallosis. Due to massive cortical osteolysis and poor bone stock, the second stage procedure was a custom total ankle megaprosthesis. At the 2-year follow-up, the patient had regained pain-free function, and the AOFAS score improved from 18 to 97. Cortical osteolysis in the setting of a failed TAR makes revision TAR surgery impossible using off-the-shelf revision implants. We describe the successful management of this pathology using a custom-made total ankle megaprosthesis, with good clinical outcomes at two years. Routine clinical and radiographic follow-up is critical following TAR.

Level of evidence V, Case Study

Keywords: Osteolysis; Arthroplasty, Replacement, Ankle; Debridement; Device Removal.

Introduction

Ankle arthritis is a common, debilitating condition with an impact on quality of life similar to end-stage heart failure, renal failure, and hip arthritis[1,2]. Total ankle replacement (TAR) has become a popular treatment option for end-stage arthritis, with theoretical biomechanical advantages over ankle arthrodesis[3]. Modern-day TAR has a reported 10-year survival rate of 77% to 91%[1]. Abdulmhsen et al.[4] demonstrated that TAR had a significantly lower risk of infection and amputation than arthrodesis, but noted unique complications, including subsidence, implant loosening, and periprosthetic cyst formation.

Periprosthetic cysts, defined as lucencies with absent bony trabeculae and sclerotic margins at the bone-implant interface, have been reported to have an incidence as high as 95% at long-term follow-up after TAR[1]. Although the majority of periprosthetic cysts are asymptomatic, they are one of the common causes of aseptic loosening. Aseptic loosening, the most common mechanism of implant failure in TAR, accounts for 28% to 55% of revision TAR cases[1].

Third-body-mediated inflammatory bone resorption is a described mechanism for developing osteolytic cysts. Wear particles identified in periprosthetic tissue include polyethylene, hydroxyapatite, and metal[1]. Metallosis, a complication

Study performed at the Netcare Sunninghill Hospital, Johannesburg, Gauteng, South Africa.

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most often seen in metal-on-metal total hip replacements, is defined as aseptic fibrosis, local necrosis, or device loosening secondary to metal corrosion and the release of wear debris[5,6]. Abnormal metal-on-metal contact leads to metal debris production, which accumulates in surrounding tissues[5]. Metal particulate debris is phagocytosed by macrophages, triggering a local inflammatory response with resultant synovitis and osteolysis, leading to pain, swelling, and ultimately implant loosening[5,7,8].

If the periprosthetic cysts become large enough, the implant becomes unstable and fails, which is commonly managed with either revision TAR or conversion to an arthrodesis (ankle or tibiotalocalcaneal). In severe cases, osteolysis involves cortical bone loss, which, if extensive, makes revision arthroplasty impossible and arthrodesis very complex[1]. In cases of severe metallosis, it is critical to excise all metal debris from the soft tissues, similar to a radical debridement seen in tumor resection, and many of the principles of tumor management may apply in severe metallosis with bone loss[9].

Limb-salvage surgery for orthopedic tumors has advanced significantly since its introduction in the 1970s[10]. Endoprosthetic reconstruction (EPR) for distal tibia tumors is a viable technique over traditional options of amputation, frame-assisted bone transport, or free (vascularized or non-vascularized) fibula autograft with ankle arthrodesis[11]. Performing an EPR does not compromise a below-knee amputation being done at a later time if required[12].

We present a case of massive cortical osteolysis due to metallosis after TAR. The extent of cortical osteolysis made standard revision arthroplasty impossible, and following thorough discussion with the patient, she was managed with a custom total ankle megaprosthesis.

Case description

We present the case of a 67-year-old female presenting with worsening pain and progressive deformity of her left ankle. She had a TAR performed 15 years prior using the Hintegra prosthesis (Newdeal, Lyon, France; Integra Lifesciences) for primary osteoarthritis.

She presented with a severe valgus deformity of her left ankle with a preserved medial longitudinal arch. There was circumferential swelling around the ankle. She had a severely antalgic gait. There was global tenderness of the ankle joint. The valgus deformity (seemingly from the ankle) was passively correctable to neutral. Ankle range of motion was painful and limited to 5° dorsiflexion and 15° plantarflexion. No sensory or vascular deficit was noted. Her AOFAS score was 18.

Weight-bearing radiographs showed loosening and collapse of the TAR prosthesis into valgus, resulting in metal-on-metal articulation laterally. The talar component had subsided through the talar body onto the calcaneus. The tibial component collapsed into hyperextension with anterior cortical osteolysis. Multiple periprosthetic cysts were noted in both the talus and tibia (Figure 1).

The management plan consisted of a 2-stage surgical treatment. The first stage was to remove the implant, debride the ankle joint and surrounding soft tissue, collect multiple specimens for histology and MC&S, and insert an antibiotic-loaded cement spacer. The second stage would depend on specimen results and remaining bone stock post-debridement.

Stage 1: An anterior approach via the previous TAR incision was used to access the prosthesis. Extensive metal-stained

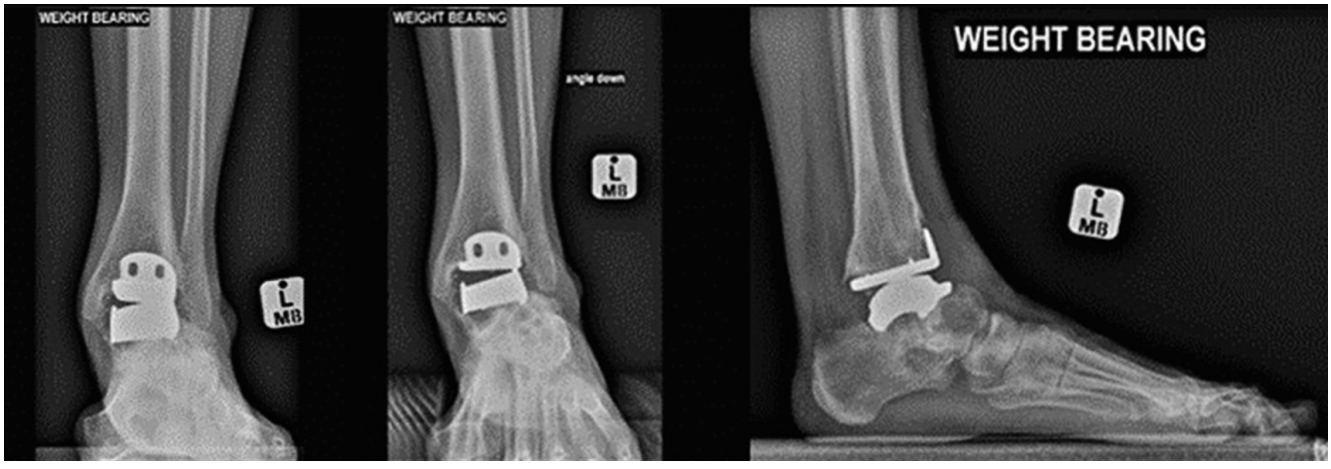

Figure 1. Preoperative radiographs (AP, oblique, and lateral views) demonstrating the failed TAR with implant alignment in valgus and asymmetrical polyethylene wear. Periprosthetic cystic changes are extensive on both sides of the joint, with a very large tibial-sided cyst.

necrotic soft tissue was found, which was extensively debrided, and specimens were sent for histology and MC&S. The prosthesis was loose and easily removed. Large osteolytic cysts in both the tibia and talus were identified and debrided (Figures 2 and 3). Of note, the medial malleolus was significantly compromised by a large osteolytic cyst with cortical osteolysis. The remaining void was filled with a Vancomycin-loaded cement spacer.

A postoperative computed tomography (CT) scan was performed to evaluate bony defects and plan the definitive surgery (Figure 4). The CT confirmed the massive bony defect involving the tibial plafond and talar body, with cortical osteolysis of the medial malleolus and anterior tibia. Multiple large subchondral cysts were also noted in the calcaneus.

Histology confirmed a giant cell reaction to metal particulate with no microbial growth on cultures. These findings supported the diagnosis of metallosis with no histological or microbiological evidence of infection.

Due to extensive tibial cortical osteolysis, the possible management options included: a custom cage interposed tibiocalcaneal fusion, frame-assisted tibiocalcaneal fusion with bone transport, amputation, and custom total ankle megaprosthesis. The patient was extensively counselled regarding these options and involved in the decision-making process. The patient wanted to leave amputation as a final resort and preferred maintaining motion in her ankle, opting for EPR. The novelty, lack of clinical outcomes, and risks associated with EPR were discussed in detail with the patient.

A custom total talus and modular distal tibial replacement prosthesis was designed using CAD software from the CT scan data by LRS Implants (Cape Town, ZA) (Figure 5). A CT scan of the contralateral talus was used for the design of the total talus implant. The undersurface of the talus had a trabecular mesh for bony ingrowth with the calcaneus, with two screws for fixation. The tibial component was designed as a two-part modular tibial prosthesis. The proximal part

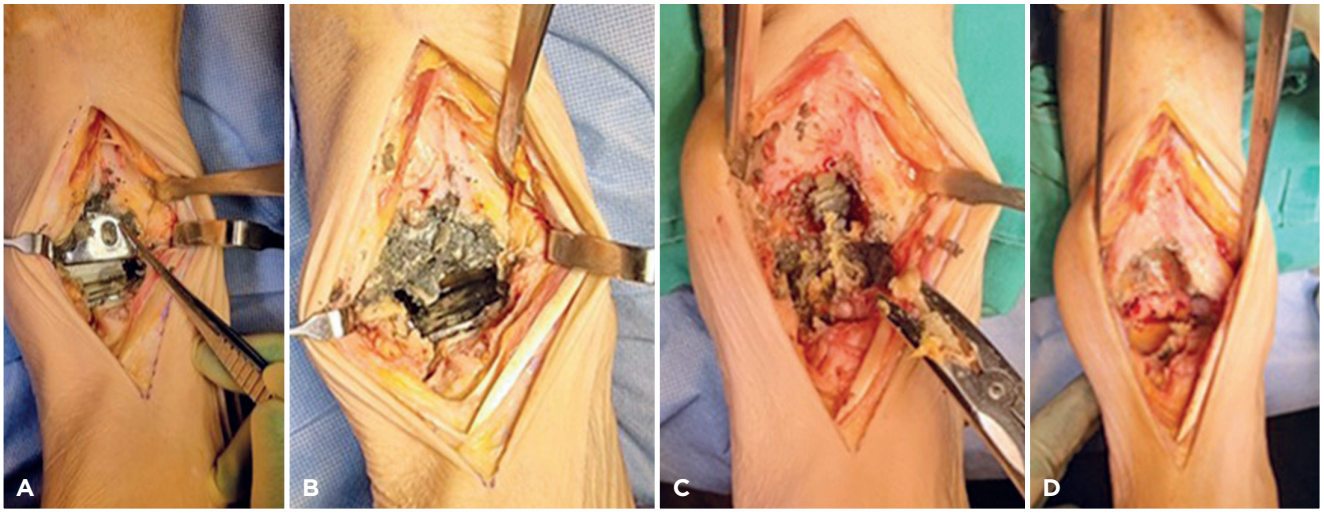

Figure 2. Intraoperative clinical photographs demonstrating extensive metallosis around the implant and within soft tissues (A, B, C) and the large defect following implant removal and thorough debridement (D).

Figure 3. Metallosis noted within the periprosthetic soft tissues (A) and on the implant surfaces (B and C).

consisted of a shaft component with a cemented stem and collar with trabecular mesh-lined extracortical support struts. The distal part was the articular component with a fixed ultra-high-molecular-weight polyethylene insert.

Stage 2: An extensive medial approach was used to expose the distal tibia and ankle. The cement spacer and residual talus were removed, exposing the calcaneus. The tibial resection margin was planned off the CT scan relative to a fixed anatomical bony landmark, giving a precise length for the tibial component. The calcaneus was denuded of all remaining cartilage down to bleeding subchondral bone. Large calcaneal cysts were debrided and grafted with autogenous bone. The cemented tibial stem with collar was implanted using a third-generation cementation technique. The total talus replacement was inserted and fixed to the calcaneus with 2 x 7mm cannulated screws. The tibial articular component with an 8mm polyethylene liner was fitted and locked in place. The ankle was tested for range of motion and stability. Despite being medial malleolus and deltoid-deficient, the ankle was found to be stable. A layered closure was performed. The patient was immobilized in a neutral dorsiflexion plaster cast for six weeks, with strict elevation for the first two weeks.

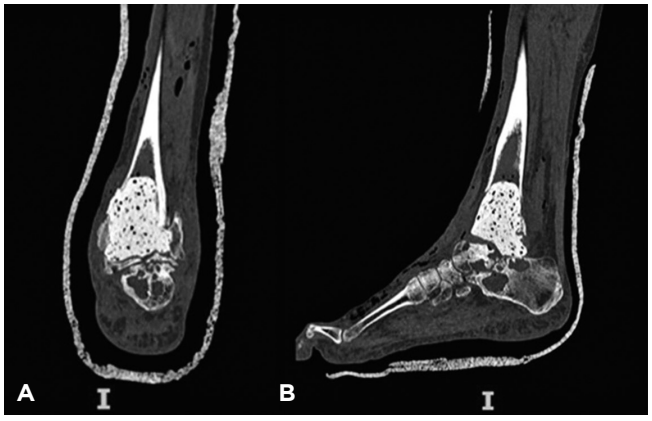

Figure 4. Computed tomography scans (A = Coronal and B = Sagittal) following the initial procedure demonstrating the cement spacer with large cysts in the residual talus and calcaneus, and the bony defect of the distal tibia.

The postoperative period was largely uneventful, with the wound healing well. The patient remained non-weight-bearing for six weeks. The patient was then allowed to progress to full weight-bearing as tolerated with extensive physiotherapy rehabilitation. She was able to walk without assistance at 12 weeks post-surgery. She regained normal daily function with no pain or instability at six months follow-up. The 1-year follow-up showed complete soft-tissue recovery, with no residual swelling and normal ankle alignment. Her gait had normalized with an ankle range of motion from 5° dorsiflexion to 30° plantar flexion (Figure 6). At the 2-year follow-up, her AOFAS improved from 18 to 97. Weight-bearing radiographs

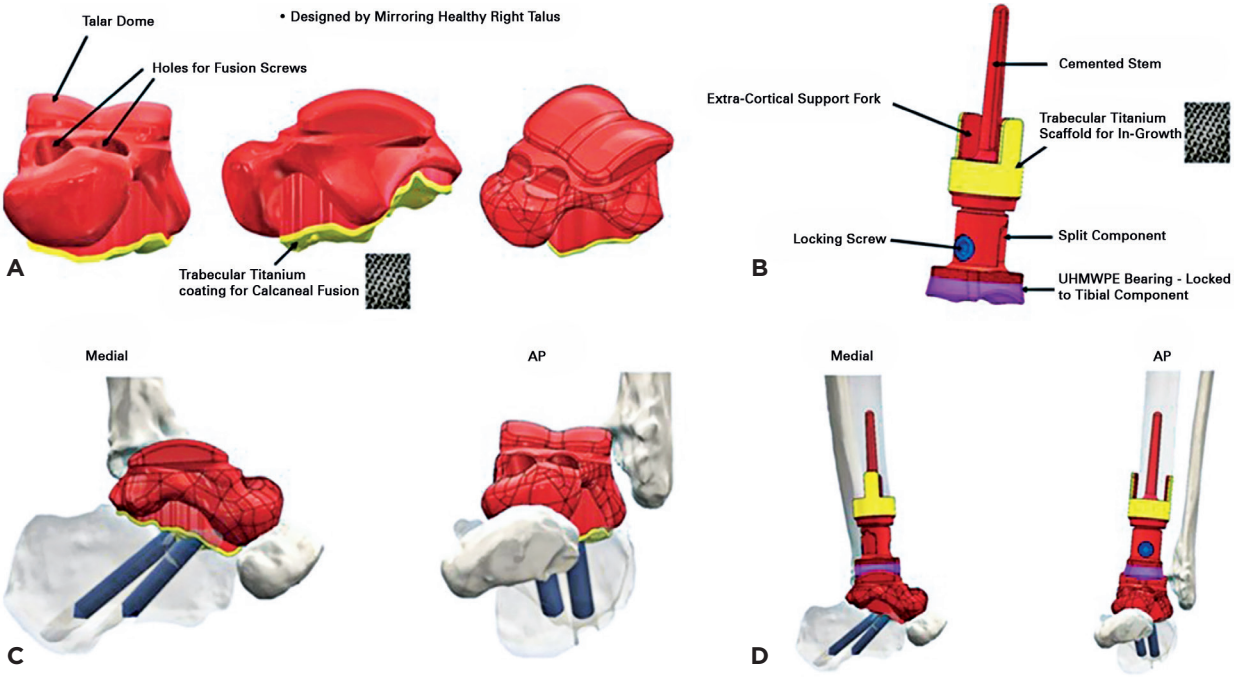

Figure 5. Implant design with specifications. A) Design of total talus component with two screw holes for 7mm screws to anchor into calcaneus and trabeculated metal B) Modular tibia component C) Designed fit of talus of talus component onto calcaneus D) Planned prosthesis fit.

showed a well-aligned, stable implant with no evidence of loosening or subsidence (Figure 7).

Discussion

Total ankle replacement has become a popular treatment option for end-stage ankle arthritis. A common cause for implant failure is the formation of periprosthetic cysts and osteolysis. The cause of osteolysis is often a foreign-body-mediated inflammatory response, as seen in metallosis. Although most commonly observed in metal-on-metal hip arthroplasty, metallosis has also been reported in non-metal-on-metal hip, shoulder, wrist, and knee arthroplasties. Abnormal metal-on-metal wear can occur following complete

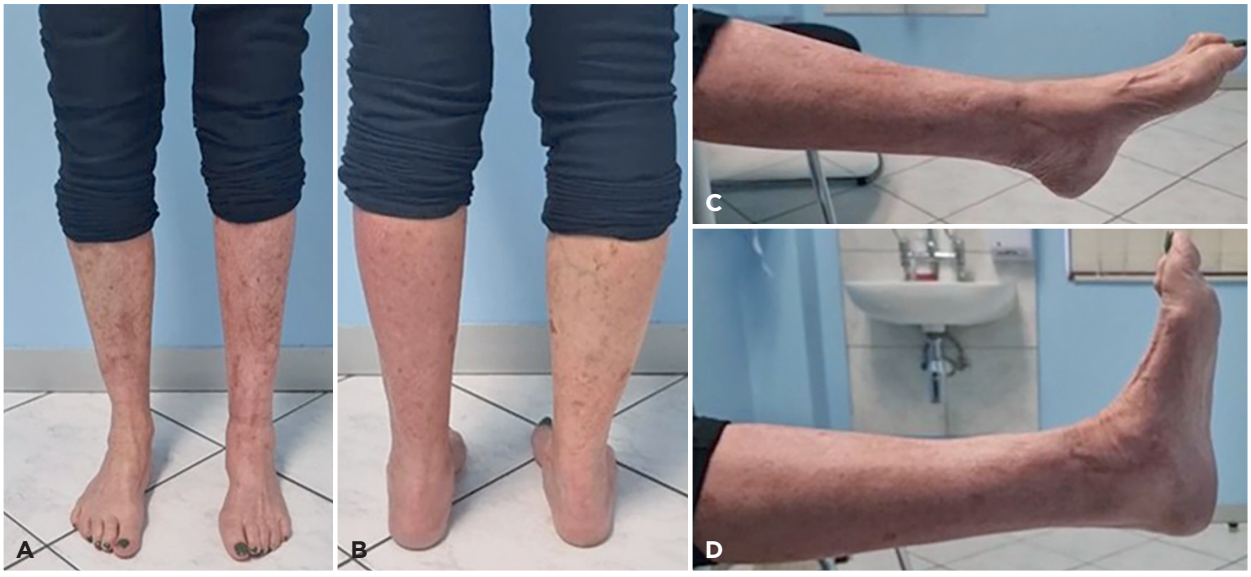

Figure 6. Clinical pictures at 1-year follow-up (Coronal plane front (A) and back (B), plantarflexion(C) and dorsiflexion(D)) showing well-healed surgical incisions, good mechanical alignment with maintained ankle plantar- and dorsi-flexion.

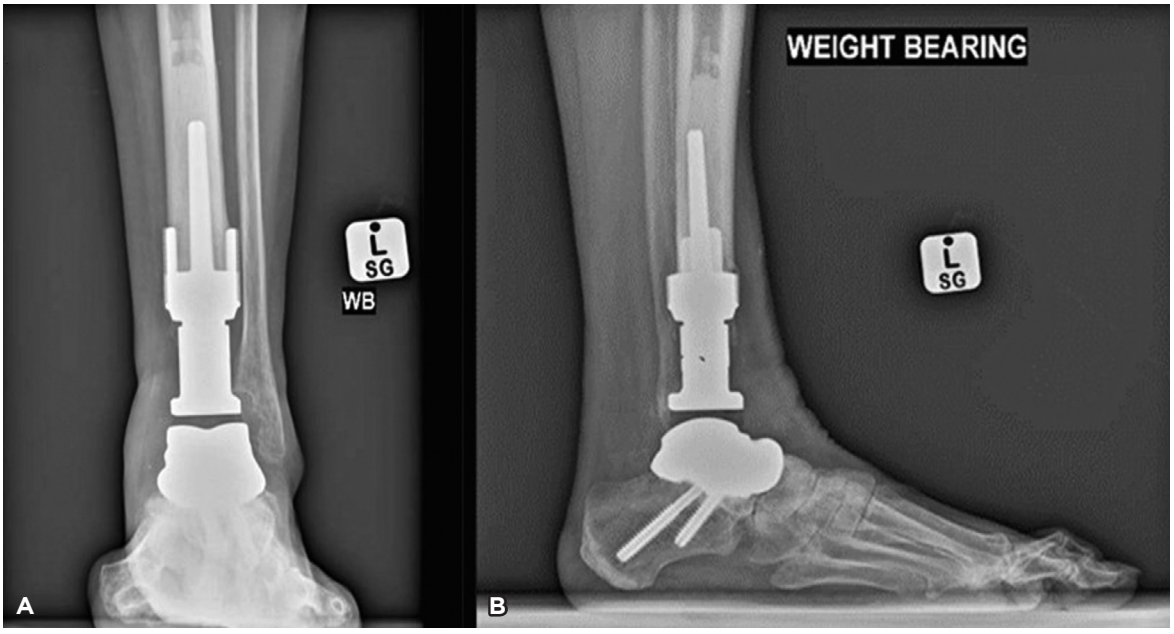

Figure 7. Postoperative radiographs (A = Anteroposterior and B = Lateral) showing the custom total talus and cemented distal tibia replacement with good alignment and fixation.

wear, dislocation, or trauma to the polyethylene liner[13]. Edge loading, a topic extensively described in hip and knee arthroplasty, results from abnormal, locally increased contact pressure between implant surfaces, leading to failure of the pressure-film lubrication, increased mechanical wear, and the formation of metal debris[8]. Our patient presented with collapse of the Hintegra TAR into valgus and destruction of the polyethylene liner, leading to metal edge loading on the lateral side. The ensuing metal debris and histologically confirmed metallosis resulted in extensive soft-tissue and bony destruction, with large periprosthetic cyst formation. To the authors' best knowledge, only a single case report of revision TAR for implant loosening due to metallosis is documented in the literature. Kasai et al.[7] described metallosis in a case of a ceramic TNK-TAR (Kyocera Medical, Kyoto, Japan). The TNK implant uses initial fixation of the tibia component via screw fixation. Loosening of this screw and subsequent abrasion identified at revision was reported as the source of metallosis. A successful revision using a new tibia component and a custom-made total talar prosthesis was performed[7].

Revision TAR can be performed for cases with large contained cysts, an unstable or malaligned TAR, and adequate bone stock[1]. Other important prerequisites include adequate soft-tissue coverage, efficient range of motion, and a compliant patient[14]. Treatment strategies have been described for the management of unstable implants due to osteolysis. Hintermann published a treatment algorithm for revision of the Hintegra prosthesis based on the amount of bone loss. On the talar side, bone loss of < 18 mm can be managed with primary components, 19 to 24 mm with revision components, and > 25 mm with a custom talar component. On the tibial side, if bone loss is < 10mm, primary components can be used; > 10mm bone loss requires revision components[15].

In cases with extensive cortical osteolysis, standard revision TAA is contraindicated. In cases with inadequate bone stock and significant talar bone loss, arthrodesis is more suitable[1]. Arthrodesis will require the use of a structural tricortical autograft, a femoral head allograft, or a custom titanium cage to manage the bone loss[1,16]. Rates of nonunion in the literature after conversion of a failed TAR to arthrodesis vary from 11% to 42%[1]. Furthermore, Rahm et al.[17] demonstrated that arthrodesis following TAR led to impaired quality of life, reduced function, and significantly higher pain than in primary ankle arthrodesis.

The amount of cortical bone loss observed in our case cannot be managed solely using the algorithm proposed by Hintermann above. The previously described defects in this case made restoring leg length, correcting alignment, and attaining stability while maintaining function very challenging. Various options were discussed with the patient, including ankle fusion using a 3D printed titanium cage with autogenous bone graft, bone transport using an external fixator, revision to an articulating total ankle megaprosthesis, and a below-knee amputation.

The combination of a custom total talus and a distal tibial megaprosthesis was chosen as the optimal strategy to manage the defect, restore leg length, and provide a stable articulating surface limiting stress at the bone-implant interfaces. EPR has been used in the lower limb for the management of destructive bone tumors. Aggressive distal tibia malignancies have conventionally been treated with amputation due to the osseous anatomy being subcutaneous, causing difficulty with soft tissue cover, close proximity to neurovascular structures, and complex biomechanics[11]. Due to improved chemotherapy and surgical techniques, limb-salvage strategies have been developed, including free vascularized or non-vascularized fibula autograft with arthrodesis, osteo-articular allograft, and EPR[11].

Shekkaris et al. (2009)[10] looked at six patients who underwent EPR for distal tibia malignancies. Two patients required below-knee amputations for persistent infection, and the remaining four (mean follow-up of 9.6 years) were pain-free and could perform all activities of daily living. Yang et al. (2017)[11] reported on eight patients who underwent EPR for aggressive distal tibia malignancies. Of the four patients who survived the disease, no patients required revision surgery and had good functional outcomes at a median follow-up of 77 months.

Our main concern with performing the EPR in this patient was the absence of the medial malleolus and deltoid. After discussion with an orthopedic tumor specialist and reviewing similar medially deficient cases utilizing an EPR post-tumor resection, the risk was deemed sufficiently low to proceed. At the 2-year follow-up, the patient had a well-aligned, stable ankle with no sense of instability.

The staged approach to this case included soft-tissue cultures, dead-space, and antibiotic management with a cement spacer, and further advanced imaging for definitive surgical planning. This case study offers a potential treatment option in the management of difficult failed TAR cases with extensive cortical bone loss, which is a viable alternative to amputation. In this short-term follow-up, we demonstrated good clinical and radiographic outcomes, with the patient returning to normal daily activities and improving the AOFAS score from 18 to 97 at 2 years.

The paucity of literature on the management of failed TAR with extensive cortical osteolysis limits our understanding of management options and long-term outcomes for this complex problem. We found the use of a custom total ankle megaprosthesis for the management of this failed TAR with extensive cortical lysis to be a management option for this challenging pathology. We recommend careful, consistent clinical and radiographic follow-up of TAR patients. Regular surveillance and early interventions can limit damage and ensure more revision strategies are available before extensive destruction of bone and soft tissues.

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