Case Report

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Salvage of Severe Foot and Ankle Trauma With a 3D Printed Scaffold

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Level of Evidence: Level V, expert opinion.

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Introduction

Treatment of segmental tibial bone loss in the setting of high-energy trauma remains a clinical challenge despite advances in modern orthopaedic traumatology. In the acute setting, options to span large bony defects are limited by devitalized soft tissue and contamination in the case of open injuries. Delayed reconstruction of these injuries has been described through a variety of methods including autograft bone transport utilizing an external fixator,[16] massive cancellous bone grafting with and without tissue transfer,[6] vascularized fibular transfer,[5] osteomyocutaneous flaps, and 2-stage reconstructions including the Masquelet technique.[12]

In cases of large segmental defects, bone transport utilizing an external fixator has traditionally been selected over other techniques because of surgeon familiarity and the desire to employ the patient's intrinsic healing biology. While bone transport has historically proven beneficial, it is not a panacea and has its own complications, including nonunion, stress or refracture at the docking site, pin tract infection, extended period of non-weightbearing, and prolonged external fixator placement.[22] From a patient perspective, this represents a long-term investment that will be a severe hindrance to daily function, and thus compliance can be a limiting factor despite a technically proficient procedure. From a societal perspective, the lost days of work productivity and investment in the patient's recuperation are significant. In fact, Paley et al[17] reported that 1 cm of regenerated bone takes 1 month to consolidate and distal (docking) consolidation is obtained after 6 months of stable contact between the distal and transported fragments, leaving some authors to recommend maintenance of the external fixator for 1 year until significant hypertrophy is demonstrated.[21]

Additive manufacturing—commonly referred to as "3D printing"—is the process of creating a predefined object via precise deposition of materials in a layer-by-layer fashion.[14] 3D printing can create a myriad of structures with a variety of materials, including metals, plastics, and even living cells.[14] The customizability of 3D printing with regard to shape and biocompatible materials make it an attractive potential alternative for the treatment of segmental bone loss in the foot and ankle.

This report describes successful limb salvage through the use of a patient-specific custom 3D printed titanium scaffold to replace intra-articular distal tibia segmental bone loss with concomitant comminuted talus fracture and multiple additional foot fractures.

Case Report

The patient was a 46-year-old woman who was involved in a rollover motor vehicle collision and sustained a left open distal intra-articular tibia fracture with substantial distal tibia bone loss at the scene of the injury (Figure 1). The wound was laterally based and minimally contaminated. Additional injuries included a comminuted fibula fracture, comminuted talar body fracture, depression fracture of the posterior facet of the calcaneus, second through fifth metatarsal fractures, and cuboid fracture. She presented with palpable dorsalis pedis and posterior tibial pulses along with intact sensation in all major nerve distributions to the foot. The patient initially underwent irrigation and debridement of the open wound, external fixator placement for stabilization, insertion of an antibiotic impregnated polymethylmethacrylate spacer,

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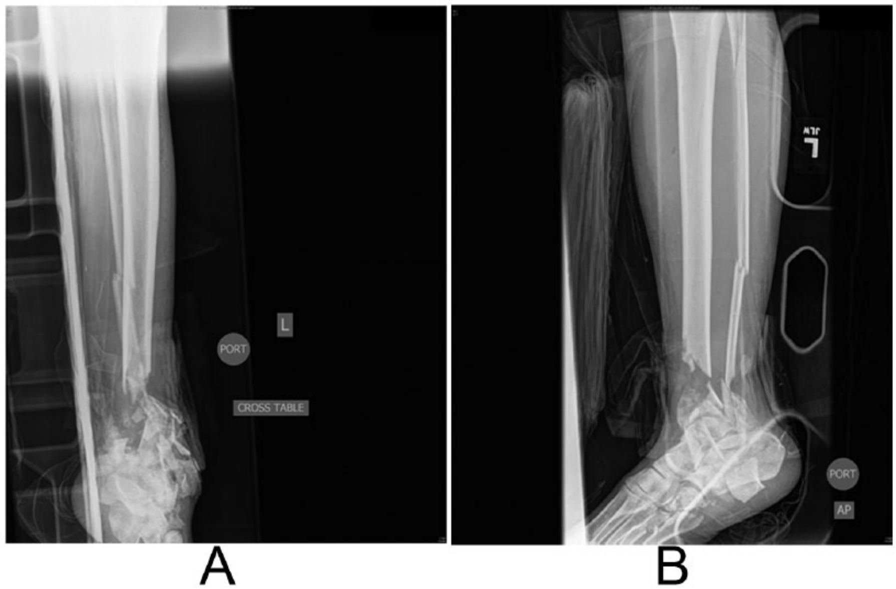

Figure 1. Anteroposterior (A) and lateral (B) radiographs of the left leg performed at the time of presentation. Comminuted distal tibia and fibula fractures with partial loss of the distal tibia can be seen. Additional foot fractures can also be seen.

and percutaneous Kirschner wire fixation of the talus (Figure 2). The traumatic wound was primarily closed, leading to the classification of this injury as a Gustilo and Anderson type III open fracture.[8]

After the damage control phase of care, amputation and multiple limb salvage options were discussed in detail with the patient via the shared decision-making process. She elected to proceed with limb salvage in the form of arthrodesis of the tibia to the hindfoot. The use of a novel custom 3D printed titanium scaffold (FDA approved for custom use) was discussed with the patient. A CT scan of the left leg was obtained and sent to 4WEB Medical (Frisco, TX) for processing and implant creation. The data were loaded into a software program that allowed for 3D manipulation of the bones and fracture fragments. A video conference was performed between the surgeon and company engineers to refine the design for the custom implant.

The rationale for the implant design (Figure 3) was as follows. The distal tibia and talus were to be replaced by the implant, totaling 8.5 cm of bone loss. The decision to replace the talus was made because of the comminution and likely development of avascular necrosis of the body, potentially leading to a nonunion of the distal arthrodesis site. Orthogonal cuts were to be planned in the remaining tibia and talar neck to provide technically feasible saw cuts and stable distal and proximal interfaces for the implant. The distal surface of the implant was designed to match the exact shape of the dorsal calcaneus. A 12-mm cannulation was placed through the implant to accommodate a tibiotalocalcaneal arthrodesis nail. The 3D truss structure was then designed to fit this implant geometry. The total volume of the implant was 30.7 cm^3. The implant, sterilizable resin models, and cutting guides were produced. The implant was made of Ti_6Al_4V with patented truss structure (4WEB Medical) and roughened texture of the cross members to facilitate osteointegration.

The decision was made to treat the patient's foot fractures non-operatively for 4 months to allow for consolidation and a stable base for the implant. This was especially important for her calcaneus fracture to be able to support the arthrodesis nail. The patient was taken back to the operating room and the external fixator was removed. A lateral approach to the ankle and hindfoot was performed incorporating her previous wound. The distal fibula, antibiotic spacer, and distal tibia fragments were removed. The distal tibia and fibula were morcelized for bone graft. The talar dome was highly sclerotic and without evidence of infection at the time of talar excision. The distal aspect of the remaining tibia and the talar neck were cut using the supplied patient-specific cutting guides. The posterior and middle facets of the calcaneus were identified and denuded of cartilage until bleeding subchondral bone was encountered.

The model of the implant was inserted into the wound to ensure proper fit. The foot was held in appropriate neutral position and the guidewire for the arthrodesis nail was placed. Subsequent reaming for the nail was performed with the cannulated trial in place as opposed to the manufactured implant to avoid abrasion or destruction of the implant. The trial was placed in the defect and the guidewire was inserted through the heel under fluoroscopic guidance. Although the

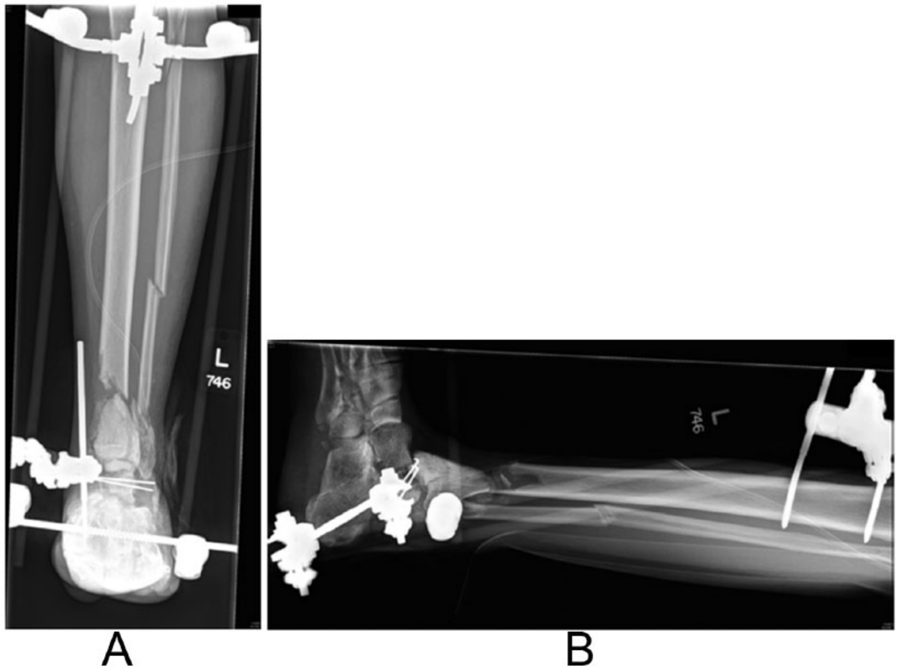

Figure 2. Anteroposterior (A) and lateral (B) radiographs demonstrating external fixation of the left leg. The antibiotic spacer can be seen replacing the anterior distal tibia.

trial was mostly radiolucent, the cannulation could be seen. The guidewire was positioned in the approximate center of the trial implant. The cannulation in both the trial and real implants was oversized compared to the nail diameter so the guidewire did not have to be in the exact center. The model was removed and the wound was copiously irrigated. The implant was packed with morcelized bone that had been soaked in iliac crest bone marrow aspirate concentrate (BMAC, Harvest Technologies Corporation, Lakewood, CO) (Figure 4). Allograft bone containing viable stem cells (rti surgical Map3, Alachua, FL) was also implanted for additional osteoinductive, osteoconductive, osteogenic, and angiogenic potential. The implant was placed in the wound and a 10 mm diameter by 240 mm long tibiotalocalcaneal arthrodesis nail (Biomet, Warsaw, IN) was placed for internal fixation. Two proximal and 2 distal interlocking screws were placed in standard fashion. A well-padded splint was applied for postoperative immobilization. Frozen sections revealed no acute inflammation and intraoperative cultures were negative.

Postoperatively, the patient remained non-weightbearing for 6 weeks followed by 6 weeks of limited weightbearing in a cast. She then transitioned to full weightbearing in a boot brace over the following 6 weeks. Weightbearing was allowed prior to full radiographic union as the intramedullary device spanned the defect and provided load-sharing. By 6 months, the patient had returned to teaching without ambulatory aids and with regular shoe wear as tolerated. The authors feel that the sports and activities for this implant should be consistent with the treating surgeon's standard recommendations for tibiotalocalcaneal arthrodesis. This patient was limited to routine activities of daily living and unlimited walking for exercise. She is a school teacher and is allowed to be on her feet all day. At 13 months after surgery, she complained of only heel pain at the nail insertion site and by 15 months this pain had resolved in its entirety, leaving her pain-free with a visual analog score of 0 of 10 for pain.

She was followed closely with routine plain radiographs and CT scans. Most recent clinical and radiographic follow-up was at 13 months. Plain radiographs and CT scan demonstrated successful bone incorporation of the talus, calcaneus, and 3 of 4 cortices of the tibia (Figure 5). On CT scan there was a focal area of no radiographically identifiable bony bridge at the proximal anterior junction of the residual tibia and the custom implant. Stress shielding likely contributed to this scenario but in the face of no clinical pain at the partial union site, the authors and patient have jointly elected to continue with radiographic monitoring.

Discussion

Treatment of segmental bone loss in the lower leg has proven problematic for bone and joint surgeons. Several

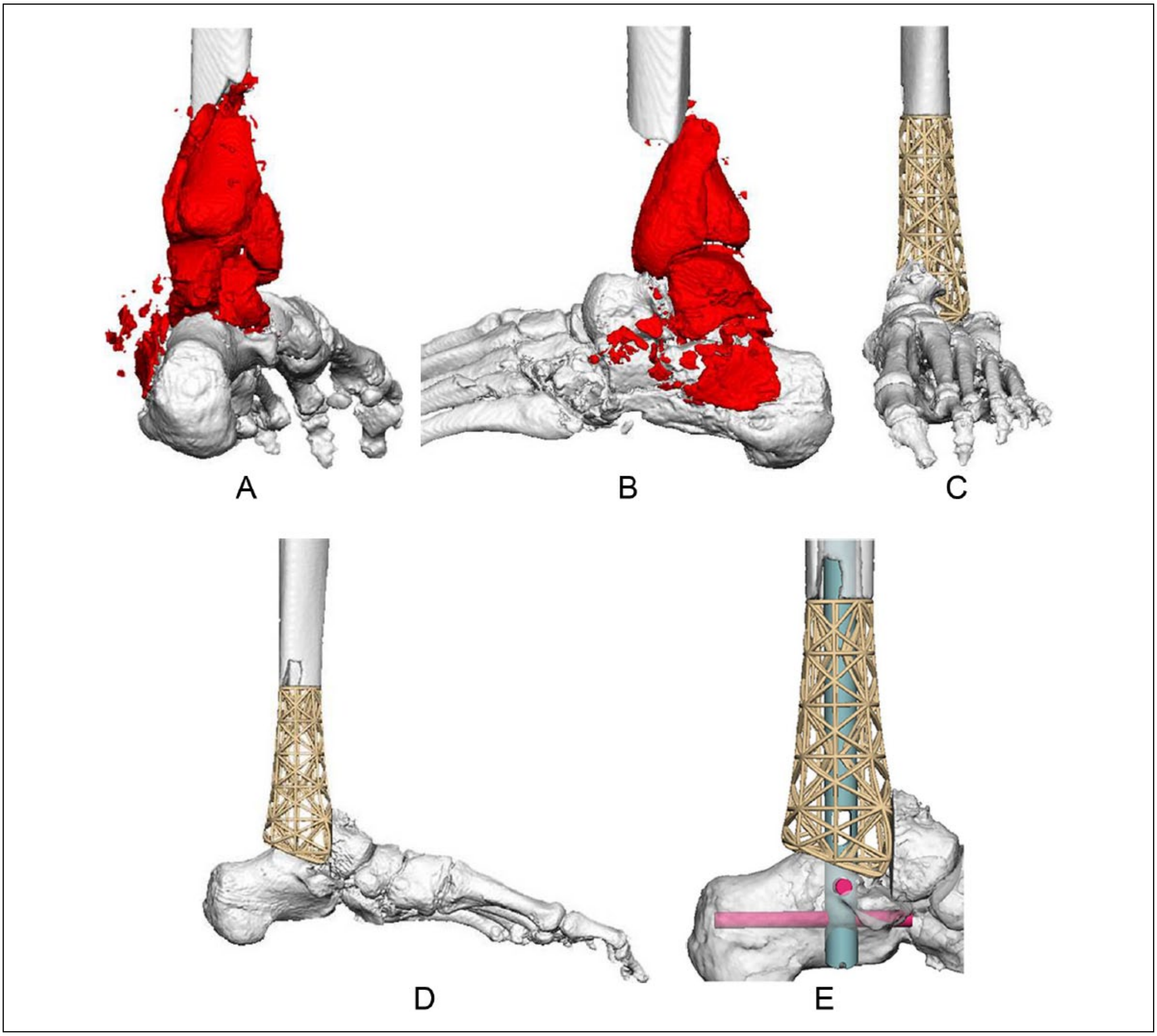

Figure 3. Posterior (A) and lateral (B) 3D reconstructions of the distal leg. Dark gray indicates bone (and distal anterior antibiotic spacer) that was deemed unsalvageable and removed for the 3D scaffold. Additional flat cuts on the distal tibia and talus were incorporated into the design and performed in the operating room for ease of implantation. Anterior (C) and medial (D) 3D reconstructions of the leg with the truss structure design in place. The final design (E) is cannulated to accept an intramedullary rod.

methods of reconstruction using autograft or allograft have been described with variable amounts of success and an unspecified maximum distance of reconstruction.[5,6,16,17,22] Autograft has the considerable disadvantages of donor site morbidity and limited quantity.[2,10] Allografts are also potentially limited in size and are less osteogenic with higher rates of nonunion. Allografts additionally carry the theoretical risk of disease transmission.[3,13] Moreover, both have been known to undergo late collapse leading to structural failure and can be limited by the ability to truly achieve the correct shape for reconstruction based on limitations in human osseous anatomy from which the graft is obtained.[3,7] Emerging technology, in the form of custom 3D printing, could solve many of the problems of both autograft and allograft. This report describes successful limb salvage with the use of a custom 3D printed titanium implant for segmental bone loss of the foot and ankle. The patient-specific implant discussed in this case report followed the FDA's custom device guidelines and was custom made for this application.

The concept of patient-specific implants has previously been introduced in the arthroplasty literature for creation of

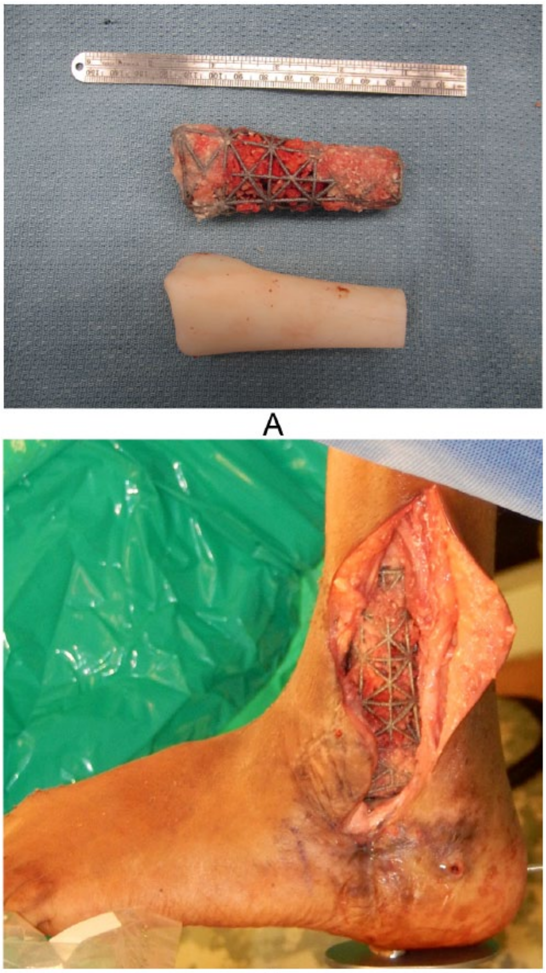

Figure 4. The actual implant (top) has been packed with bone graft. The sterilizable model is seen below the actual implant (A). The implant is seen after placement in the body (B).

cutting guide instrumentation in total knee replacements[15,20] and recently the development of custom-made total knee implants.[23] Foot and ankle surgeons have utilized patient-specific technology in prior attempts to create customized talar implants for patients with talar avascular necrosis using a template based on the mirror image of the contralateral talus.[1] The advent of 3D printing ushers in an era of even more customizable patient-specific implants with seemingly limitless size, shape, and material options, thus opening a new frontier for reconstructive efforts in patients previously relegated to complex limb salvage or amputation. The advantages of 3D printed implants are numerous from a technical and mechanical perspective but it has its potential strengths in cost effectiveness as well. Limb salvage literature has demonstrated that amputation costs over a lifetime care cycle are much more cost-prohibitive than previously thought owing to prosthetic costs.[4] Costs of limb salvage in the form of Ilizarov bone transport are less than amputation but still considerable.[11] Though still expensed as a new technology (approximately $20 000 for the implant and patient-specific instrumentation), the future may have promise for 3D printing in value-based healthcare as costs decrease.[9]

The use of metallic devices to span short bone defects about the foot and ankle have been described. Sagherian and Claridge[19] reported on the use of porous tantalum to perform ankle arthrodesis after failed ankle replacement in 3 patients. The maximum height of these implants was 30 mm. All 3 patients reported improvement in pain and functional outcome questionnaires and proceeded to fusion at a mean of 3 months. Papadelis et al[18] reported on a series of 18 patients who underwent subtalar bone block arthrodesis with porous tantalum implants. They reported a 100% fusion rate at a mean final follow-up of nearly 18 months with significant improvement in pain and the AOFAS hindfoot score.

Several aspects of this case portended a successful outcome. First, the presence of the posterior distal tibia allowed for anatomic limb length reconstruction. Additionally, despite severe trauma, the limb was sensate and well perfused. The authors do not recommend performing this type of reconstruction in the neurovascularly compromised limb. Third, the patient was well informed about the risks of the procedure and was extremely compliant with the postoperative protocol. The usage of generous osteoinductive and osteoconductive adjuncts undoubtedly assisted in the robust bony union demonstrated on plain films and CT, though the portion of healing attributable to them is uncertain. Future well-designed research will likely be required to justify the usage of these costly adjuncts in the future. On CT scan, there is a focal area of no radiographically identifiable bony bridge at the proximal anterior junction of the residual tibia and the custom implant. Stress shielding has likely contributed to this scenario but in the face of no clinical pain at the partial union site, the authors and patient have jointly elected to continue with radiographic monitoring. The patient currently has no functional limitations and is satisfied with her procedure.

Conclusion

The use of a custom 3D printed titanium truss structure contributed to successful limb salvage in the setting of substantial distal tibial bone loss, unreconstructable talus fracture, and multiple additional foot fractures. 3D printed implants can avoid the complications and limitations of autografts and allografts in foot and ankle surgery. Furthermore, value-driven models of care may favor the adoption of 3D technology as it becomes more accessible. Longer-term studies are needed to monitor delayed complications such as stress shielding and implant failure.

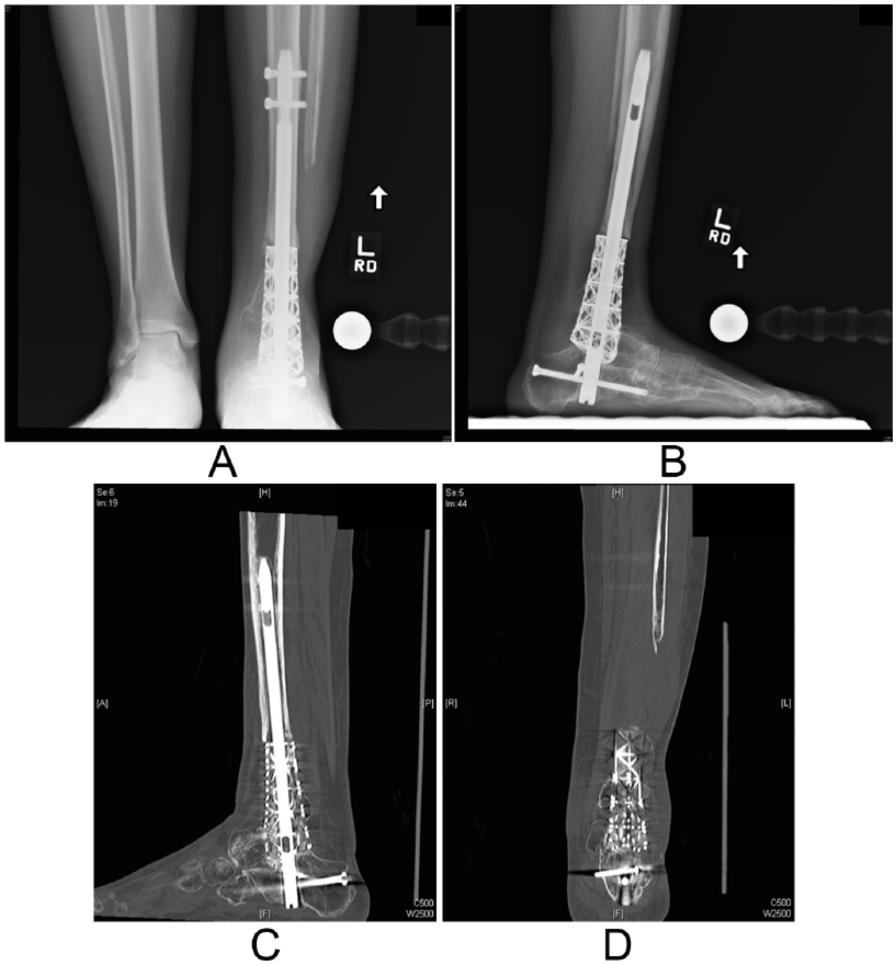

Figure 5. Anteroposterior (A) radiograph of both lower extremities. Bone formation can be seen around the tibial-implant interface. Bone can be seen medially as well. Lateral (B) shows limited bone growth around the anterior tibial-implant interface. Sagittal CT scan image (C) demonstrating union of the talus and calcaneus to the bone within the implant. No bone integration at the anterior proximal junction. Coronal CT scan image (D) demonstrating union of the calcaneus to bone within the implant. Note that there appears to be bone throughout the implant. All images were taken at 15 months after surgery.

Declaration of Conflicting Interests

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