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Treatment of Severe Avascular Necrosis of the Talus Using a Novel Keystone-Shaped 3D-Printed Titanium Truss Implant

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Abstract

Background: Avascular necrosis (AVN) of the talus most commonly occurs secondary to trauma. Significant bone loss and collapse in severe talar AVN remains an operative challenge. Tibiotalocalcaneal arthrodesis (TTC) using femoral head allograft is at risk of collapse and subsidence. The use of a void-filling titanium truss can mitigate against this. This study describes the use of a novel keystone shaped 3D-printed titanium truss for treatment of severe talar AVN.

Methods: Three patients with end-stage AVN of the talus were included. Each patient underwent a TTC arthrodesis with a custom-made, 3D-printed, keystone-shaped, truss implant in conjunction with a hindfoot intramedullary nail. Modified patient American Orthopaedic Foot & Ankle Society (AOFAS) scores were recorded at the preoperative, 6-month, 12-month, and annual postoperative timepoints.

Results: All patients progressed to satisfactory radiological union by one year. Mean follow up time was 32 months (24-48 months). Mean preoperative modified AOFAS score was 5. There was progressive improvement in AOFAS scores from 6 months postoperatively. Mean modified AOFAS score improved from 28 at 6 months to 37 at 2 years postoperatively.

Conclusion: Custom-made 3D-printed titanium trusses provide promising outcomes for treating severe AVN of the talus. The "keystone" design is advantageous as it allows for bone stock preservation and conforms to the shape of the native calcaneum. All patients showed progressive improvements in outcomes at sequential time intervals postoperatively. The implant provides a strong mechanical structure resisting collapse and subsidence during the arthrodesis process.

Level of Evidence: Level IV, retrospective case series.

Keywords: talus, avascular, necrosis, 3D-printed, truss, custom implants, arthrodesis

Introduction

Avascular necrosis (AVN) of the talus most commonly occurs secondary to a fracture of the talar neck or body. Less frequently, it can also result from long-term corticosteroid therapy, excessive alcohol consumption, hyperlipidemia, post chemotherapy or thrombophilia.[1] The talus is at particular risk of AVN owing to its tenuous blood supply.[14]

AVN of the talus can be classified using a modified Ficat & Arlet classification based on radiologic findings.[8] In advanced stage AVN, there is significant collapse and large bone loss within the body of the talus leading to progressive arthrosis involving the ankle and subtalar joints. The challenges of operative treatment are to address large bone defects and any associated arthrosis, while maintaining alignment of the hindfoot.

When the body of the talus is involved, a favored operative strategy is for hindfoot arthrodesis. Large bone defects, in such cases, have been previously addressed either using structural autograft or femoral head allograft and secured with a hindfoot intramedullary nail, plates, and screws or fine wire

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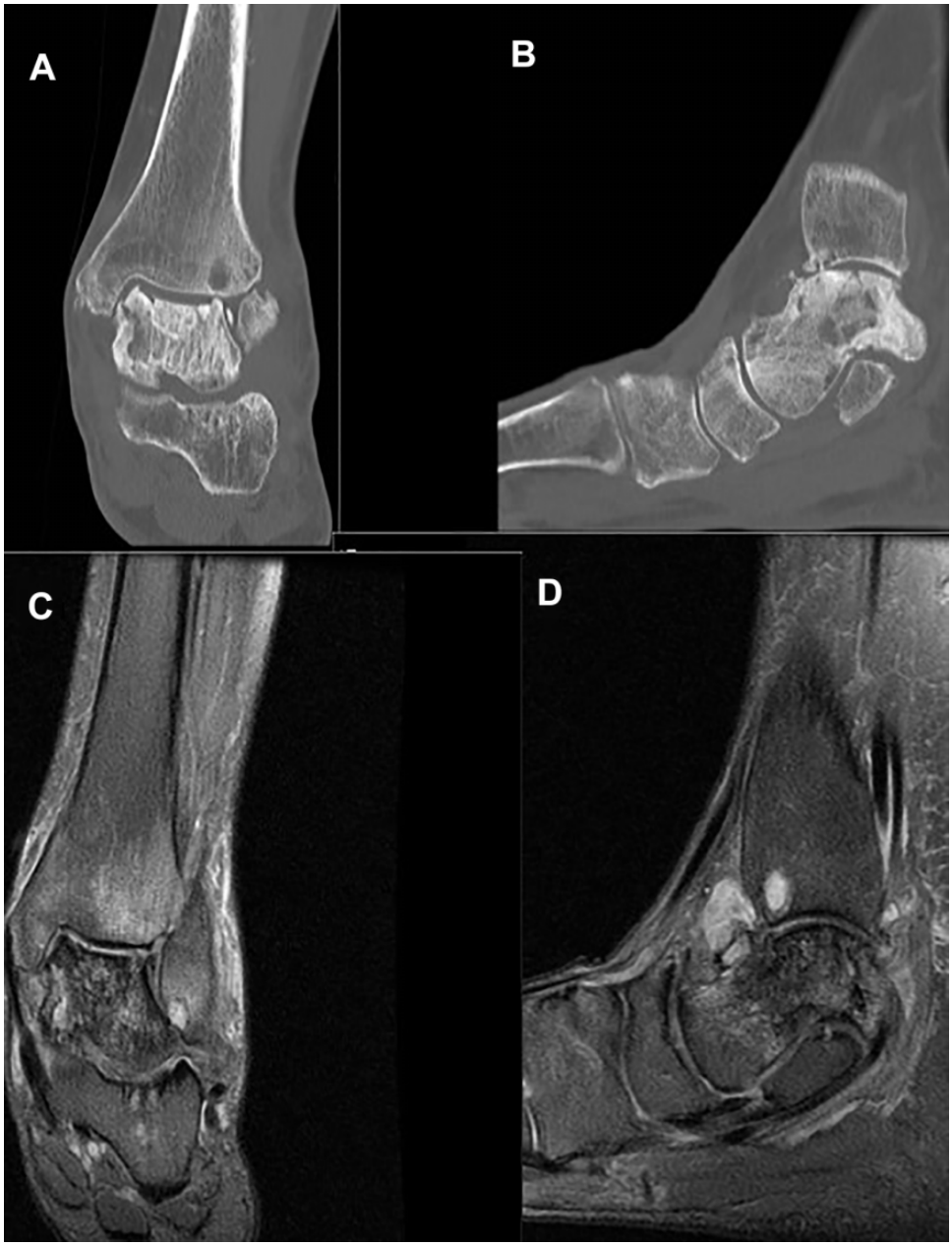

Figure 1. Preoperative MRI scans (A) CT coronal, (B) CT sagittal, (C) T2-weighted fat-suppressed coronal, and (D) T2-weighted fat-suppressed sagittal. The scans demonstrate end-stage avascular necrosis of the body of the talus with arthrosis of the ankle and subtalar joints.

external fixation with a frame.[4,6,7,11,12,19] Such grafts require incorporation and bony union but are at risk of collapse and subsidence.[11] Void-filling titanium truss implants packed with autograft and allograft can mitigate against this risk during incorporation of the graft with the host bone.[15]

Tibiotalocalcaneal (TTC) arthrodesis using a custom-made, 3D-printed, titanium truss implant is a novel technique with few reports in the literature. Such implants have been used to treat large bone defects in conjunction with a hindfoot nail for failed ankle replacement, failed hindfoot arthrodesis, deformity correction, and trauma.[2,5,10,15,16,19] There are also a few reported cases of the technique being used to treat advanced-stage AVN of the talus.[2,5,12]

This study reports on the use of a more anatomic, keystone-shaped, custom-made, 3D-printed titanium truss implant (4WEB Medical, Frisco, TX, USA) in conjunction

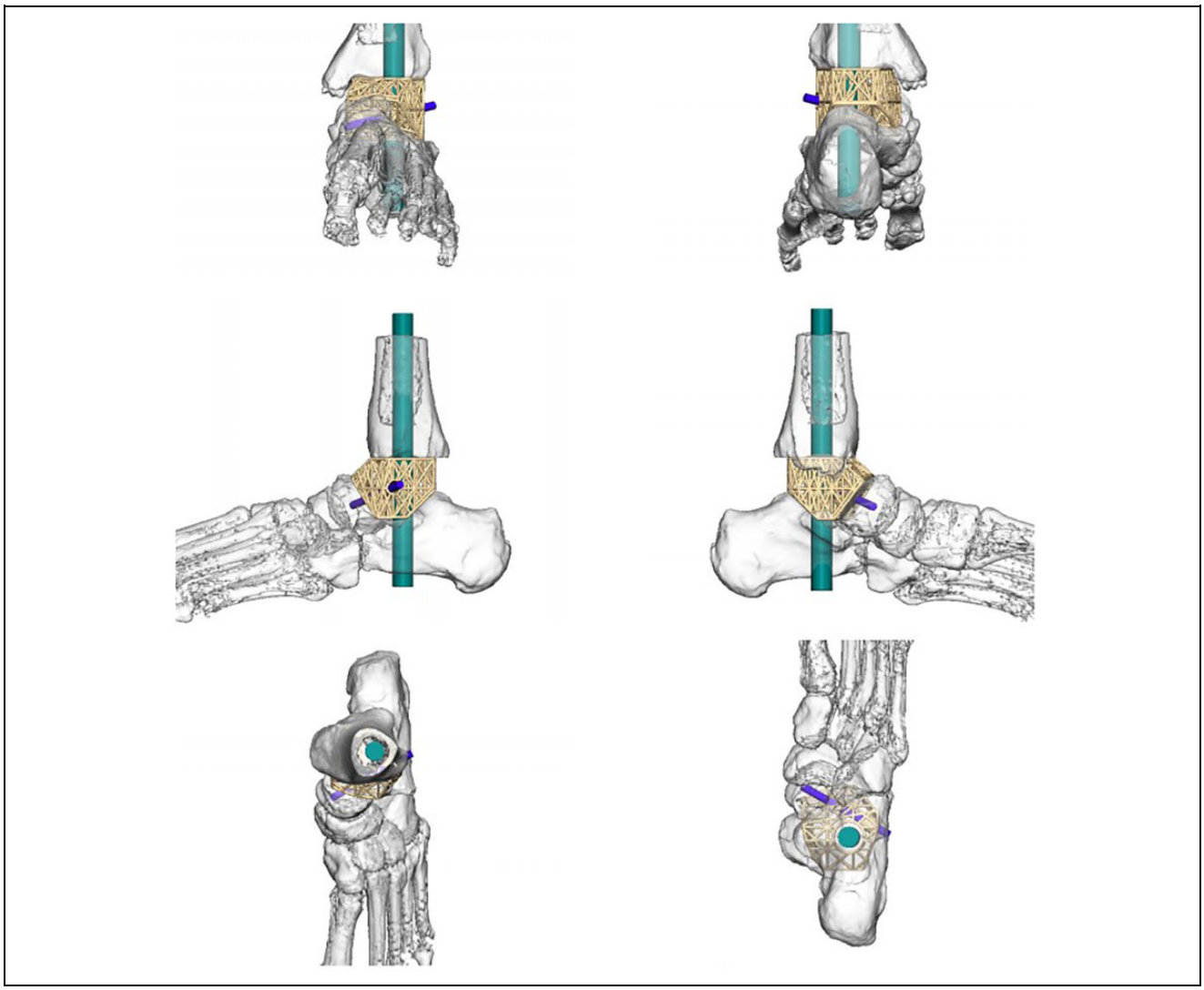

Figure 2. Custom-made design proposal of the "keystone" truss implant in the coronal, sagittal, and axial planes. The truss allows for the passage of a hindfoot nail and screw through the truss into the remaining head of the talus.

with an Oxbridge hindfoot intramedullary nail (OrthoSolutions, UK) for the treatment of advanced-stage AVN of the talar body.

Methods

Three patients with end-stage avascular necrosis of the talus were included in this study. Each patient underwent a TTC arthrodesis with a custom-made, 3D-printed, keystone-shaped, truss implant within a 2-year period (2016-2018).

One patient had developed post-traumatic AVN to the body of the talus secondary to a Hawkins III talar neck fracture that had undergone open reduction and internal fixation (ORIF) 3 years prior to presenting for further treatment. Another patient had developed talar body AVN secondary to long-term corticosteroid use for Sjogren syndrome and had presented with a 1-year history of increasing pain in the ankle and could only walk a few steps. The final patient had idiopathic talar body AVN and reported of intractable pain and a reduced ability to walk. Of the 3 patients, none were smokers nor suffered from diabetes.

In each case, computed tomography (CT) and magnetic resonance imaging (MRI) showed extensive AVN and collapse throughout the body of the talus with arthrosis affecting both the ankle and subtalar joints (Figure 1). Given the significant degree of bone loss affecting the body of the talus and previous poor experiences with the use of bulk allograft as well as with each patient not wishing to undergo fine-wire frame distraction osteogenesis, it was decided to proceed with TTC arthrodesis using a custom-made titanium truss implant to replace the affected anatomic volume.

One-millimeter-slice CT images of each patient were sent to the manufacturer, and a web-based planning process was used to design the truss implant. The premise for the

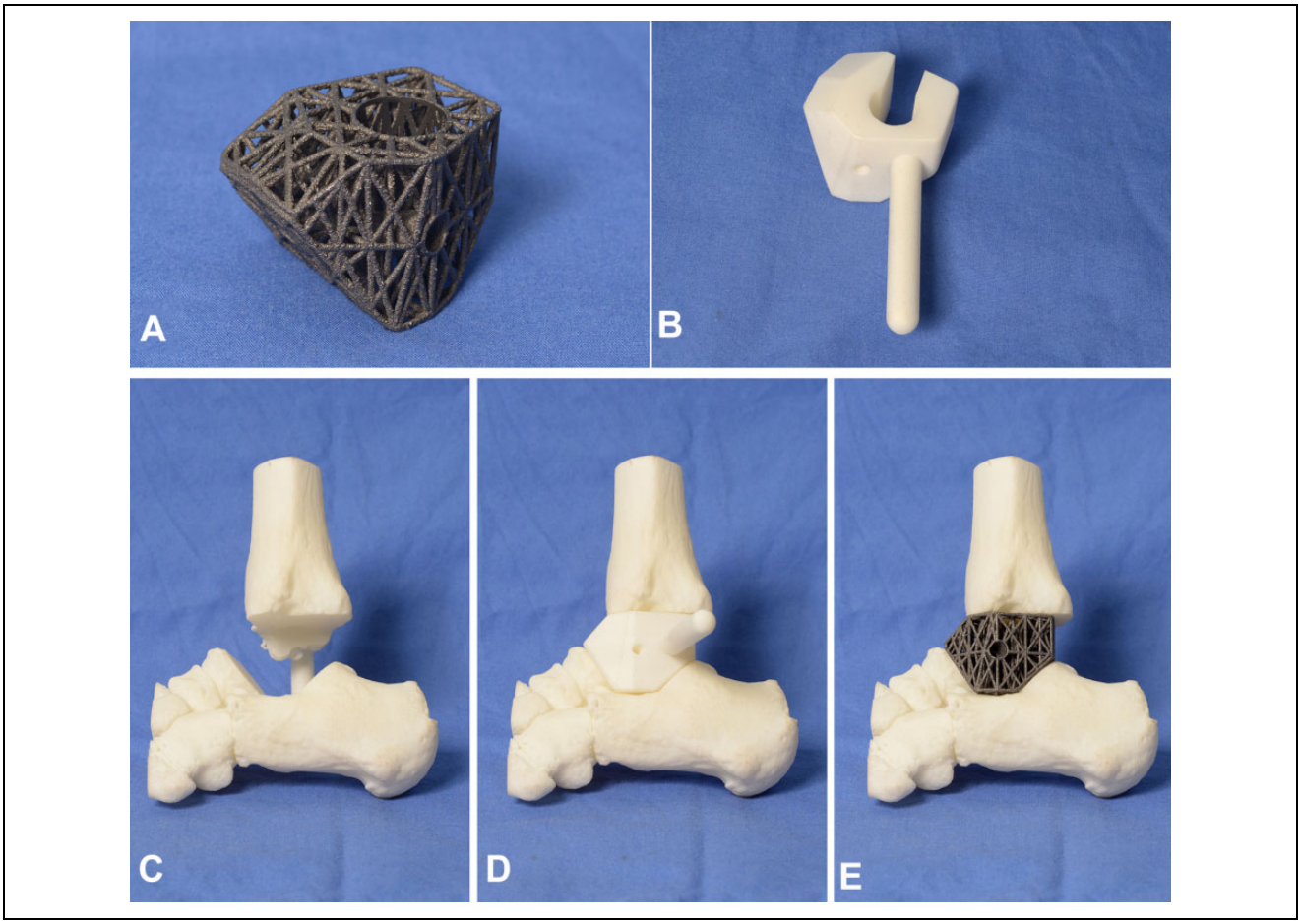

Figure 3. (A) The custom 3D-printed titanium truss is shown. The keystone shape conforms to the superior surface of the calcaneum. The central hole for the passage of the hindfoot nail and the hole for the screw into the remaining talar head is clearly demonstrated. (B) An example of the plastic trial implant is shown. It is mounted onto a handle, which allows for ease of insertion. (C) An example of the 3D-printed custom-made plastic model demonstrating the defect with the planned talar resection, (D) with the trial inserted, (E) with the titanium truss inserted.

keystone-shaped implant was to minimize resection of healthy bone from the calcaneus and to replicate the shape of the inferior surface on the talus as it mates with the strongest bone located at the Gissane angle on the calcaneus. Cannulations can be designed into the truss allowing fixation of the implant. A large cannulation allows a straight hindfoot nail to pass through the truss for tibial and calcaneal integration whereas an oblique, smaller cannulation permits lagging of the remaining head of the talus onto the anterior surface of the truss (Figures 2 and 3). Three different truss implants were manufactured based on the CT measurements. Given that, in each case, the body of the talus had lost superior to inferior height, a smaller implant was made with 2 mm less height in this plane and a corresponding one was made 2 mm larger in this plane. Additionally, 3 trials were manufactured corresponding to the implant sizes.

Each patient underwent surgery in the lateral position with a thigh tourniquet inflated. A lateral approach was performed via a longitudinal hockey stick incision. A sagittal fibula osteotomy was made, and the deep surface of the fibula removed to create a fascio-osseous flap reflected posteriorly on a hinge. The deep surface of the osteotomized fibula was morselized in a bone mill and used for bone graft. Using a sterile plastic model for reference, a guide wire was passed across the talar neck and the neck then osteotomized. The remaining avascular talar body was resected piecemeal. Further use of the model guided flat cuts to the tibial plafond. The posterior facet of the calcaneum was then denuded of cartilage and prepared to accommodate the truss implant.

Using the 3 trials, the adequacy of bone resection was gauged, and the defect size was assessed for selection of the best-fit implant (Figure 3). With the trial in place the plantar aspect of the heel was approached to establish the entry point for retrograde nailing. A guide wire was passed through the calcaneus, through the cannulation within the trial, and into the tibia. Reaming was then performed through the trial implant up to the desired diameter for the nail. The selected truss implant was then packed with bone-milled graft from the fibula and then inserted into the defect. The hindfoot nail was then inserted and locked using 2 tibial locking screws

Table 1. AOFAS Scores of Patients Involved.

AOFAS Score	Patient A	Patient B	Patient C	Mean
Preoperation	0	6	9	5
6 mo postoperation	24	26	34	28
12 mo postoperation	27	28	39	31.3
24 mo postoperation	30	31	50	37
3 y postoperation			60	
4 y postoperation			60	

Abbreviation: AOFAS, American Orthopaedic Foot & Ankle Society.

and a posterior screw into the calcaneum. A supplementary 4-mm titanium screw was then passed through the truss implant to lag the remaining talar head.

Fluoroscopy was used throughout, and final images were taken prior to closure to ensure adequate position of the implant and screw lengths. Each patient was initially placed into a nonweightbearing plaster for 6 weeks and the wound reviewed at 2 weeks postoperatively. Patients could weightbear in a walker boot 6 weeks postoperatively after satisfactory radiographs were obtained.

Patients underwent follow-up with regular clinical and radiographic assessment. Modified patient-reported American Orthopaedic Foot & Ankle Society (AOFAS) scores were recorded for each patient at: preoperative, 6-month, 12-month, and annual postoperative time points (Table 1). The original AOFAS score (out of 100) combines subjective scores by the patient with objective scores from the surgeon based on clinical examination.[9] We wished to evaluate patient-reported outcomes only and hence modified the scale to exclude surgeon reporting. Scores pertaining to surgeon assessment of the patient—gait (8 points), sagittal motion (8 points), hindfoot motion (6 points), ankle-hindfoot stability (8 points), and alignment (10 points)—were excluded from the study. Hence our maximum possible score was 60 (range 0-60).

Results

There were no reported early postoperative complications. Each patient was successfully placed into a walker boot at 6 weeks and gradually weaned out of this into their normal footwear at 3 months.

Mean follow up time was 32 months (range 24-48 months). Mean modified preoperative AOFAS score was 5. There was progressive improvement in AOFAS scores at each time point postoperatively. The greatest improvement was seen in the first 6 months postoperatively (Figure 4). The mean patient-reported AOFAS score improved from 28 at 6 months to 37 at 2 years postoperatively. One patient, who has been followed up for 4 years postsurgery, showed a progression in AOFAS score from 9 preoperatively to 60 by 36 months. Paired t test revealed a significant improvement in all scores at 2 years postoperatively compared with before surgery ($P = .021$).

Two patients are currently back at work working full-time in manual occupations. One is able to comfortably walk 10 miles a day. The third patient can ambulate short distances without pain and drive independently, having been only able to walk a few steps owing to constant pain prior to surgery.

Postoperative radiographs showed signs of truss dynamization and stabilization from 6 months (Figure 5). Two patients had breakage of the calcaneal posterior to anterior locking bolt and movement of the proximal tibial locking bolts within the slotted hole of the nail at this stage. We propose that this happened during settling of the implant into the bone. Secondary to this, bone was then able to ingrow and the implant start to incorporate.

Each patient progressed to satisfactory union with bridging trabeculae and incorporation of bone into the truss structure by 1 year. All individual arthrodesis sites united. Serial radiographs were performed for each patient in the postoperative period. Routine postoperative CT scan was not performed if patients were progressing well clinically and radiologically. One patient had pain at 11 months postoperatively; hence, a CT scan was performed in this case (Figure 6). This reassuringly showed a stable ingrowth of bone into the implant and a stable hindfoot arthrodesis. The source of the pain was determined to be the lag screw perforating the talonavicular joint. This screw subsequently broke and was removed at the mobile end, with the remainder left in the navicular with improved levels of comfort.

Discussion

Dealing with bone loss and achieving tibiotalocalcaneal arthrodesis is an operative challenge. Rates of nonunion following arthrodesis with femoral head allograft have been shown to be as high as 50%.[11] However, a recent study has suggested an arthrodesis rate of 89% and positive patient outcomes using femoral head allograft.[4] The bone loss could be ignored and the patient treated by excising the talus and performing a tibiocalcaneal fusion; however, this route results in a limb length discrepancy unless combined with distraction osteogenesis techniques of the proximal tibia.

Alternatively, titanium truss implants packed with autograft or allograft can fill a void and provide a solid structure, thus reducing the risk of collapse and subsidence during the period of graft incorporation with the host bone.[15] Studies have considered the use of an off-the-shelf tantalum trabecular metal spacer to address bone loss during TTC fusion.[17,20] These have been used primarily to perform TTC fusion in the context of failed ankle replacement surgery with variable success. Furthermore, these spacers are limited because they do not fill the unique pathoanatomic defect and they cannot be used for incorporating fixation other than a predetermined cannulation to accommodate a hindfoot nail.[15] In contrast, patient-specific, custom-made, 3D-printed titanium truss implants can be designed to fill an anatomic void incorporating a variety of methods of fixation. They also allow for a strong but lightweight structure

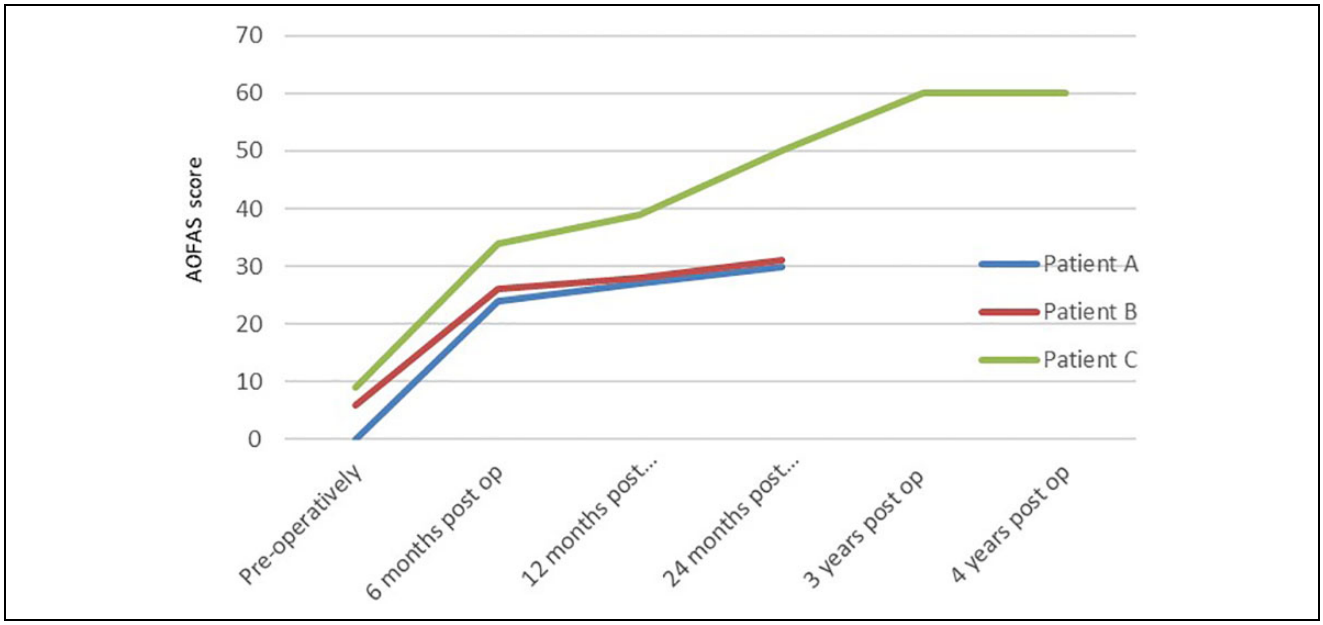

Figure 4. Line graph demonstrating progression in modified AOFAS scores for each patient.

that can withstand the forces through the foot and ankle and allow packing of bone graft through its truss architecture.[21] These custom-made, 3D-printed truss implants achieved a superior rate of union compared to femoral head allograft (75% vs 43%) in patients with talar bone loss with no evidence of graft resorption.[19] Other studies have reported a fusion rate between 85% and 87% using the 3D-printed truss implants, with a mean time to union of 9.8 months.[2,5] Nonunion using 3D-printed truss implants would be best managed nonoperatively if found to be asymptomatic. Symptomatic nonunion or secondary to infection presents an operative challenge. We might question the futility of revising a large reconstructive procedure in such instances, and transtibial amputation may be the most appropriate treatment option.

Moreover, 3D-printed titanium truss implants have other theoretical advantages over femoral head allograft. These include superior mechanical properties, and implant surface finishes that promote bone ingrowth and could prevent infection.[19] Roughened titanium on the surface of the implant used in this study acts as an adhesion site for osteoblasts. Subsequent release of bone morphogenic proteins that help promote ingrowth of bone into and around the implant has been proposed.[10] The truss design acts as an "open lattice" structure that can regularly be filled with 75% of its entire volume with bone graft and in certain instances can approach 90%.[18] The authors' preference is to fill the truss with autograft rather than allograft for its greater osteogenic potential.[16]

Previous studies have all reported the use of custom-made spherical-shaped titanium trusses for treating AVN of the talus.[2,5,12,16,19] There are 6 cases in total. Each underwent a TTC arthrodesis using a spherical-shaped truss packed with allograft in combination with a retrograde nail. Spherical shapes allow the foot to be rotated around the sphere to achieve the desired amount of varus/valgus and dorsiflexion/plantarflexion relative to the tibia. This helps greatly when dealing with any significant deformity correction; however, it does involve reaming resection of healthy calcaneal bone at key condensations of strong trabecular bone. The principal advantage of the "keystone" design is that the keystone shape allows conformity of the inferior surface of the truss to the superior surface of the calcaneum. Not only does this negate the need for resecting healthy bone from an unaffected bone but studies have shown that the highest trabecular thickness and bone volume ratio lies in the superior portion of the calcaneus just underneath the angle of Gissane.[3,13] This region is where the compressive trabeculae converge and thus provides a firm and supportive platform for the truss implant.[13]

Despite the promising use of this technology, cost remains a concern. The average cost of each implant in our study was $13 000. Customized 3D truss implants have been reported to cost up to $20 000.[5] However, as 3D printing technology develops and becomes more accessible, it is likely that the cost of such implants will continue to fall over time. Evidence has shown limb reconstruction/salvage to be more cost effective compared to amputation over the lifetime of a patient.[5] Hence, despite the initial upfront expense, positive patient outcomes with 3D-printed implants may prove cost-effective in the long run.

Total talus replacement is an evolving treatment option for severe AVN of the talus. Most talar replacements are unconstrained, re-creating the native talar anatomy with

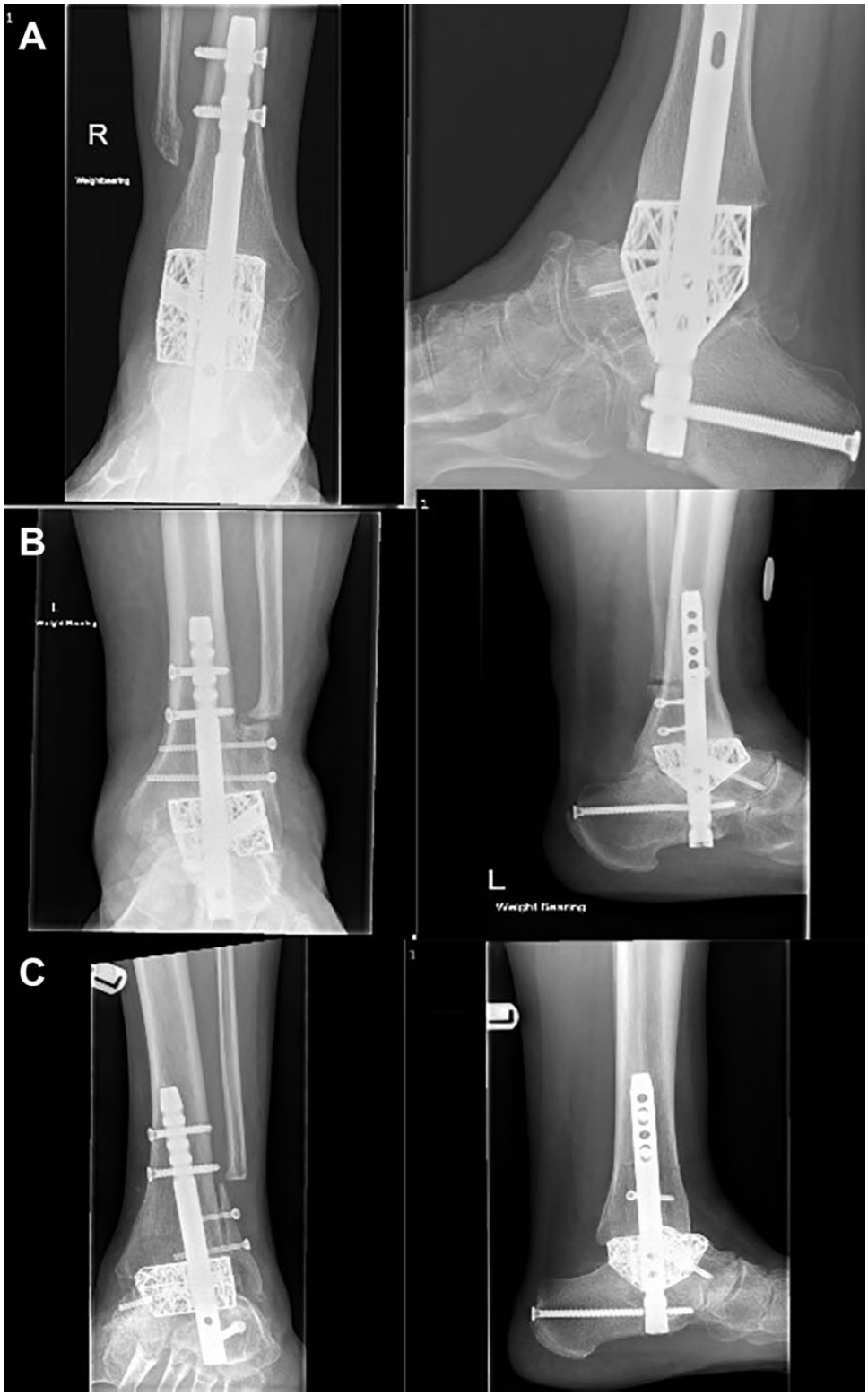

Figure 5. Six-month postoperative radiographs of all 3 patients. (1a, 1b) Patient A. (2a and 2b) Patient B. (3a and 3b) Patient C. Breakage of the calcaneal locking screws can be seen secondary to dynamization of the intramedullary nail (2b and 3b).

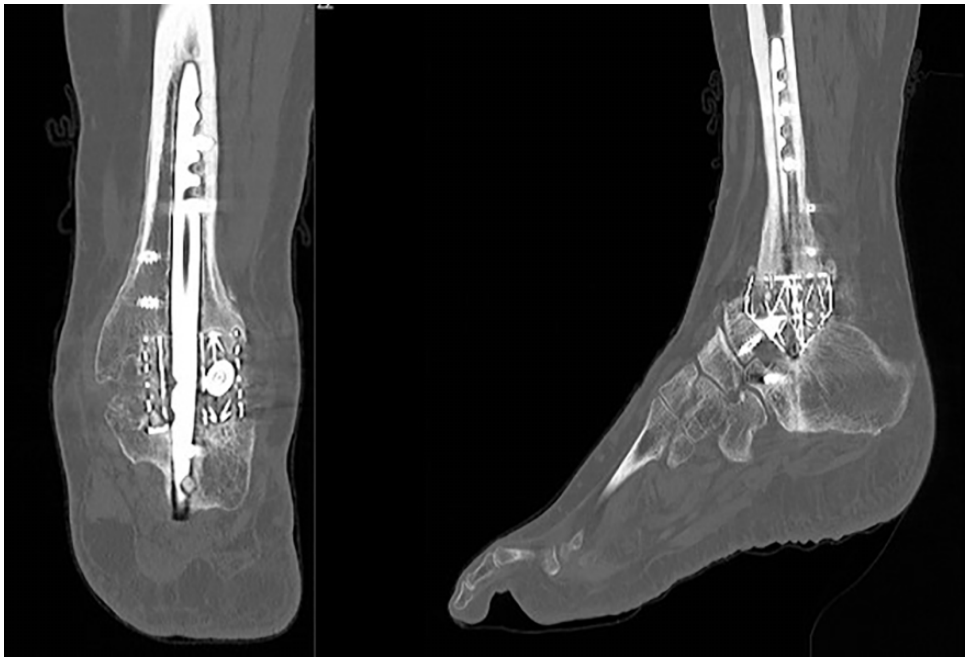

Figure 6. Coronal and sagittal CT shows ingrowth of bone into the truss and a stable hindfoot arthrodesis.

articulations at both the ankle and subtalar joints. Implants have been used in isolation but also as part of an ankle replacement to address concomitant arthrosis at the ankle joint.[22] All patients in our study had severe talus AVN in conjunction with arthrosis at both the ankle and subtalar joints. Each patient also had a pre-existing hindfoot deformity that needed addressing. Hence, a corrective hindfoot arthrodesis using a 3D-printed truss was used rather than considering a talus replacement.

In conclusion, this study has provided promising clinical and patient-reported outcomes with the use of a novel keystone-shaped truss implant to treat severe AVN of the body of the talus. All 3 patients progressed to satisfactory arthrodesis with incorporation of the truss implant. All our patients showed progressive improvements in AOFAS scores at sequential time intervals postoperatively. These results appear to support the current evidence that 3D-printed titanium truss implants can be used to treat AVN of the talus with bone loss. It is a patient-specific implant that acts to facilitate bone ingrowth, providing a strong mechanical structure to resist collapse and subsidence during the arthrodesis process. The "keystone" design is particularly advantageous as it allows for bone stock preservation and conforms to the shape of the native calcaneum.

Ethics Statement

Ethical approval was not sought for the present study as this was a retrospective case series containing no more than 3 patients. All patients consented to their inclusion in the study.

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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