

Use of Patient-Specific 3D-Printed Titanium Implants for Complex Foot and Ankle Limb Salvage, Deformity Correction, and Arthrodesis Procedures

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Abstract

Background: The advancement of 3D printing technology has allowed for the use of custom-designed implants for difficult-to-treat foot and ankle pathologies. This study reports on the radiographic and functional outcomes of a case series of patients treated with patient-specific 3D-printed titanium implants.

Methods: Fifteen consecutive patients treated with custom-designed 3D-printed implant cages for severe bone loss, deformity correction, and/or arthrodesis procedures were included in this study. A minimum of 1 year of clinical and radiographic follow-up was required. No patients were lost to follow-up. Patients completed a visual analog scale for pain, the Foot and Ankle Ability Measure Activities of Daily Living score, and the American Orthopaedic Foot and Ankle Score outcomes questionnaires preoperatively and at most recent follow-up. All patients had postoperative radiographs and computed tomography (CT) scans to assess bony incorporation. The mean age was 53.3 years (range, 22-74 years) with a mean follow-up of 22 months (range, 12-48 months) for these 15 patients.

Results: Radiographic fusion verified by CT scan occurred in 13 of 15 patients. There was significant improvement in pain and all functional outcome score measures. All patients who went on to fusion were satisfied with their surgery. There were 2 failures, consisting of 1 infection and 1 nonunion, with an overall clinical success rate of 87%.

Conclusion: These patients demonstrated the successful use of patient-specific 3D-printed titanium implants to treat complex large bony defects, deformities, and arthrodesis procedures. These implants offer surgeons a novel and promising approach to treat both lower extremity pain and deformity that is not always available with current techniques.

Level of Evidence: Level IV, retrospective case series.

Keywords: 3D implants, custom implants, salvage, deformity, arthrodesis

Lower extremity limb salvage in the setting of large bone defects, poor quality bone, or nonunion continues to be a difficult pathology to treat. With regard to lower extremity trauma, traditional options for definitive management of large bone defects include bone transport using the patient's native biology,¹⁰ large allograft struts, osteomyocutaneous flaps of the fibula,¹ and Masquelet staged techniques.⁷ However, these treatment modalities are prone to nonunion, multiple surgical procedures, and potentially prolonged external fixation. In addition to trauma, large defects about the hindfoot and tibia can occur from prior failed procedures (total ankle arthroplasty or failed fusion) or diseases of the bone, including talus avascular necrosis, osteomyelitis, Charcot arthropathy, or neurofibromatosis. Recently, the use of a femoral head allograft for hindfoot and ankle

defects has gained in popularity due to the fact that it can restore normal limb length, offer a conduit for fusion, and is somewhat customizable for intraoperative modifications.⁵ However, because of mixed clinical results (50% fusion rate), along with size and shape limitations, there remains a need for new and advanced surgical techniques to approach these difficult clinical problems.

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The emerging and increasingly popular field of additive manufacturing, also known as 3D printing, has been introduced to the medical community in many forms, including medical models for surgical training¹³ and medical implants.⁹ Recently, a patient-specific 3D-printed titanium implant was used to treat traumatic distal tibia bone loss.⁴ Patient-specific 3D-printed titanium implants have the potential benefits of unlimited geometry, increased size options over allograft or autograft bone, and no donor-site morbidity. Aside from single-patient case reports, there are no reports detailing the use of patient-specific 3D titanium implants. The purpose of this study was to report on the use of patient-specific 3D titanium implants for a variety of tibia, ankle, and hindfoot defects.

Methods

This was a retrospective consecutive series of patients who underwent a tibia, ankle, or hindfoot reconstructive procedure with patient-specific 3D-printed titanium implant at our institution between 2014 and 2016 by a single surgeon. Of note, the first patient to receive a 3D implant at our institution for a lower extremity deformity was included in this study, and no reconstructive procedures with 3D implants occurred prior to this study. A minimum follow-up of 1 year was required to be included in this report. Institutional review board approval was obtained prior to initiation of this study. There were 15 consecutive patients included in this study. The mean follow-up was 22 months (range, 12-48 months). Patient demographics, procedure type, fusion adjuncts used, and results can be found in Table 1.

The primary outcome of this study was successful radiographic fusion demonstrated by computed tomography (CT) scan. Fusion was determined by an independent fellowship-trained radiologist and confirmed by the senior author. Criteria were determined by bridging 3 of 4 cortices, as described in previous studies.^{2,3} Secondary outcomes in this study were the lack of need for further foot and ankle surgery (arthrodesis, revision, or amputation), as well as improvement in functional outcome scores from the preoperative period to most recent follow-up. Preoperative assessment included physical examination, radiographs, CT scan, and administration of patient outcome measures, including a 100-mm visual analog scale for pain, the American Orthopaedic Foot and Ankle Score (AOFAS), and the Foot and Ankle Ability Measure Activities of Daily Living score (FAAM ADL).

Implant design, selection, and rationale of procedure occurred as discussed by Hamid et al.⁴ Briefly, after an extensive discussion detailing all available options, all patients elected to proceed with limb salvage or arthrodesis procedures in a shared decision-making process with the senior surgeon (SBA). In all cases, a CT scan of the operative extremity was obtained and sent to 4WEB Medical

(Frisco, TX) for processing, along with a prescription for the device. The CT scan data were uploaded to a software program that allowed for 3D manipulation of bones, joints, and/or fracture fragments. The surgeon and company engineers were present on a video conference call to design the implant. The final implant design was approved by the senior surgeon. Individual implants, sterilizable models, and patient-specific cutting guides were 3D printed and shipped to our institution. All implants consisted of Ti₆Al₄V with a patented truss structure (4WEB Medical).

These implants met the definition of a custom device per the US Food and Drug Administration Federal Food, Drug, and Cosmetic Act. They were not generally available in the United States and were custom created on a case-by-case basis to accommodate the specific patient need. The extent of bony resection prior to implantation of the 3D construct was determined both clinically and radiographically. Radiographically, a plan of resection was made to adequately correct any deformity, as well as to remove any sclerotic or avascular bone. Clinically, all tissue was debrided and removed to a healthy and bleeding bed of tissue felt to maximize the ability of the construct to heal. Allograft bone and/or biologic additives were packed at the end of the cages that would contact the patients' bone as detailed in Table 1. After device implantation, patients were kept nonweightbearing on the operative extremity for 6 weeks, followed by 6 weeks of progressive weightbearing in a controlled ankle motion boot. The patients were followed clinically and radiographically with weightbearing radiographs and CT scans. Due to the novelty of the procedure, the senior author verified fusion status at 1 year with CT scans. The early procedures had CT scans at 3 months and at variable times thereafter to monitor fusion status; however, as the procedure frequency increased, the senior author switched to the 1-year time point for continued monitoring of the fusion status with CT. Adjuncts of stem cell allograft (Map3 allograft; RTI, Alachua, FL) and bone marrow aspirate were used on selected cases both in and around the 3D implant due to their efficacy in foot and ankle procedures.² Statistical analysis was performed on pre- and postoperative outcome measures using a paired t test. Statistical significance was set at $P < .05$.

Results

Patient-specific 3D-printed titanium implants were successful in 13 of 15 patients (87%), with average time to fusion of 5 months (range, 2.6-8.2 months) based on CT scan. There were no additional procedures in these 13 patients. Examples of the types of patient-specific implants and radiographic outcomes are illustrated in Figures 1 and 2.

There were 2 failures. One failure occurred secondary to an early deep infection occurring 2 weeks after cage

Table 1. Details and Procedures Regarding the 15 Cases.

Patient	LOF, mo	Laterality	BMI	Sex	Age	Procedure Performed	Etiology	Adjunct	CT Fusion	Failure	Reason for Failure
1	42	L	21.8	F	49	TTC	Open tibia fracture and talus fracture with bone loss	Cellular bone graft/CBMA	Yes	No	
2	28	L	29.1	F	73	TTC	Nonunion of TTC	Cellular bone graft/DBM	Yes	No	
3	24	L	32.7	F	68	TTC	Nonunion of ankle fusion	Cellular bone graft	Yes	No	
4	23	L	18.1	M	35	TTC	Talus AVN and collapse		Yes	No	
5	31	L	29.6	F	49	TTC	TTC nonunion		Yes	No	
6	41	R	30.0	M	74	TTC	Talus AVN and collapse		Yes	No	
7	20	L	27.0	M	64	TTC	Failed TAR	Cellular bone graft	Yes	No	
8	19	R	26.8	M	22	Spanned tibia defect	Tibia nonunion	Cellular bone graft	Yes	No	
9	17	L	32.5	F	33	TTC	Tibia nonunion	Cellular bone graft	Yes	No	
10	16	L	35.0	F	29	TTC	Talus AVN and collapse	Cellular bone graft	Yes	No	
11	13	R	46.4	F	64	Tibia osteotomy	Hindfoot valgus deformity	Cellular bone graft	Yes	No	
12	15	L	35.0	F	69	Tibia osteotomy	Hindfoot valgus deformity	Cellular bone graft	Yes	No	
13	12	L	34.5	M	67	TTC	Failed TAR	Cellular bone graft	Yes	No	
14	2	L	35.0	F	49	Ankle fusion	Talus AVN and collapse	Cellular bone graft	NA	Yes	Infection
15	12	R	22.5	M	54	TTC	TTC nonunion	Cellular bone graft	No	Yes	Nonunion

Abbreviations: AVN, avascular necrosis; BMI, bod mass index; CBMA, concentrated bone marrow aspirate; CT, computed tomography; DBM, demineralized bone matrix; F, female; L, left; LOF, length of follow-up; M, male; R, right; TAR, total ankle arthroplasty; TTC, tibiotalocalcaneal.

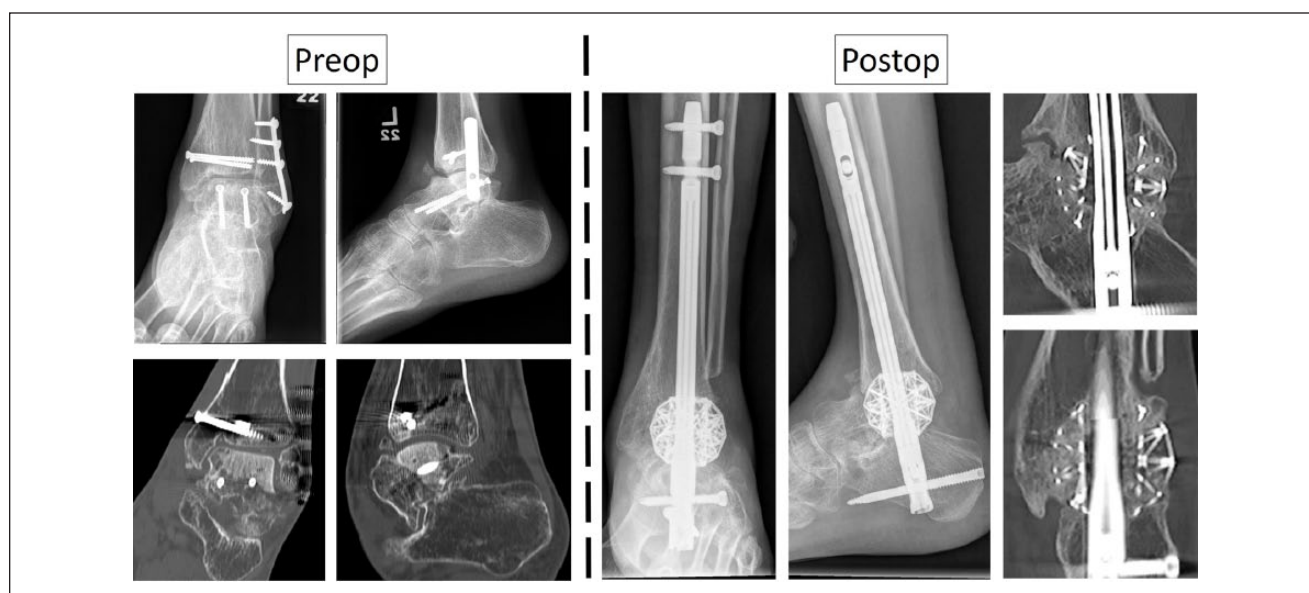


Figure 1. The patient is a 35-year-old man with previous talus and ankle fractures who developed talus avascular necrosis, subtalar arthritis, and varus hindfoot deformity. A tibiototal ankle arthrodesis (TTC) arthrodesis was performed with a spherical patient-specific 3D printed titanium cage, similar to a femoral head allograft. Two-year follow-up demonstrates excellent alignment and computed tomography (CT) confirmation of a stable implant. Preoperative images are to the left of the vertical black bar, and postoperative images are to the right of the bar.

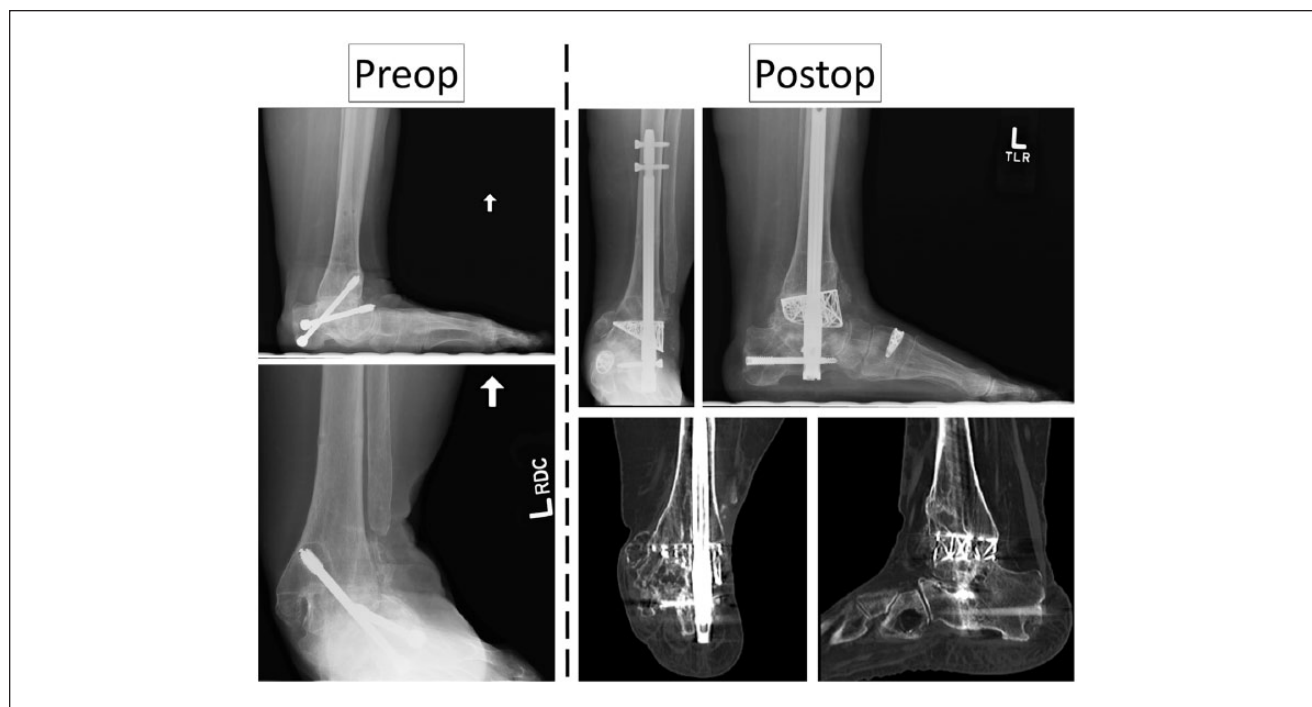


Figure 2. The patient is a 69-year-old woman with severe hindfoot valgus deformity and nonunion of prior tibiototalcalcaneal (TTC) arthrodesis. A biplanar wedge graft was inserted. One-year follow-up demonstrates substantial correction of her alignment and computed tomography (CT) confirmation of a stable implant. Preoperative images are to the left of the vertical black bar, and postoperative images are to the right of the bar.



Figure 3. The patient is a 54-year-old man with hindfoot deformity and nonunion of a previous tibiototalcalcaneal (TTC) arthrodesis attempt. A biplanar wedge was created that corrected his deformity. However, there was never bone incorporation into the implant. The patient experienced continued pain and elected to have a below-knee amputation.

implantation. This patient previously sustained a pilon fracture and had multiple prior surgeries for attempted reconstruction. She suffered from chronic pain and elected to have an amputation rather than continued attempts at limb salvage. The second failure was in a patient who had a nonunion of a prior attempt at ankle arthrodesis. After cage implantation, the patient continued to have pain. Serial CT scans demonstrated no bony incorporation into the cage at 2 years, and there was continued sclerotic tibia bone (Figure 3). A subsequent bone biopsy demonstrated no infection, but the patient elected to have an amputation rather than revision surgery. There were no cases of hardware failure.

Patients were given the AOFAS, FAAM ADL, and 100-mm VAS questionnaires preoperatively and at most recent follow-up. In addition, patients were asked to rate subjective satisfaction with their surgical outcome and to report their willingness to undergo the same operation if they were faced with the same situation. All functional outcome scores demonstrated significant ($P < .05$) improvement. The mean FAAM ADL score improved from 23.5 (range, 4-44) prior to surgery to 62.8 (range, 48-78) at most recent follow-up. Similarly, the AOFAS improved from 28.4 (range, 15-50) prior to surgery to 64.8 (range, 47-87) at most recent follow-up. Finally, the 100-mm VAS scores significantly decreased, showing improvement from 89.0 (range, 65-100) prior to surgery to 23.9 (range, 0-56) at most recent follow-up. All patients besides the 2 failures stated they would undergo the same procedure again in an attempt at salvage of their extremity.

Discussion

This study demonstrated the successful use of patient-specific 3D-printed titanium implants for complex foot and ankle limb salvage, deformity correction, and arthrodesis procedures at early follow-up. 3D printing could help revolutionize medical care and has entered modern medicine in several forms, including medical modeling for education, customized prostheses, and, as described in this report, patient-specific customized implants.¹² This small case series demonstrates that patient-specific 3D-printed implants give the surgeon another tool to attempt to address limitations surrounding autograft and allograft reconstruction, as well as bone transport in complex lower extremity cases. Benefits of their use include no donor-site morbidity as encountered with autograft and no limitations in size or shape as seen with autograft and allograft. In addition, 3D-printed implants allow for a quicker recovery than current bone transport techniques as they can acutely span large bony defects. This small case series demonstrated these benefits by showing early promising results for the use of 3D-printed patient-specific implants as bone scaffolds in an attempt to address difficult segmental lower

extremity defects. We demonstrated a high rate of bony incorporation and fusion, significant improvements in functional outcome scores, and a high overall rate of patient satisfaction.

However, there are still limitations to the use of this promising technology. Cost is a major concern. The analysis of value-based care is required when considering implementing any new technology. Customized 3D implants can cost in excess of \$20 000 for the implant alone.⁴ The mean cost of the implants in this study was \$11 700. Although this is a large upfront cost, the positive clinical results of this implant may make it cost-effective in the long term. Moreover, as 3D printing technology becomes more prevalent and efficient, it is not unreasonable to consider that the cost of these implants will continue to decrease. The senior author has already seen a decrease in cost of these implants in his practice over time.

In addition, other salvage options and amputation are not as cost-effective as they may seem upon initial comparison. A closer look into amputation versus limb salvage has shown that over the lifetime of the patient, prosthetic costs are more cost-prohibitive than once thought.¹ MacKenzie et al⁶ demonstrated that lifetime costs associated with amputation versus reconstruction/salvage are significantly different, with the mean cost of amputation exceeding \$500 000 versus the mean cost of limb salvage totaling around \$160 000.

Other concerns include bony incorporation, stress shielding, and mechanical strength. There are many aspects of 3D implant design that contribute to its ability to promote bony incorporation and provide strength. Implants can be made from a variety of materials that promote bone in-growth and, as a result, long-term success.⁸ Prior case reports have documented successful outcomes with titanium alloy implants,⁴ which have mechanical properties similar to those of native bone.⁸ In our early follow-up series, we saw what appears to be bone incorporation in 13 of 15 patients and no evidence of stress shielding or implant failure. However, longer-term follow-up is necessary to adequately monitor and address these concerns.

Finally, infection is a concern. We included active infection as a strict contraindication to the use of these implants and uncontrolled diabetic patients and smokers as relative contraindications due to the concern for infection. These are similar to the contraindications of a tibiototalcalcaneal fusion with an intramedullary implant.¹¹ Furthermore, as these implants are made of titanium, there is a risk of infection with the development of biofilm and the potential difficulty of removal if there is good incorporation. In this series, we had 1 infection with implant removal and amputation. The infection was early in the postoperative period, and there was no bone incorporation.

As detailed above, this is a short-term study, and longer-term follow-up is needed to fully understand the longevity

and complications of these implants. In addition, outcome questionnaires were not completed at every visit, and as such, we are unable to report a trend in scores over time. To this end, our protocol has now been changed to obtain functional outcome scores at each visit after reconstructive surgery with custom 3D-printed implants. Finally, the 2 failures in this study did result in amputation. However, it must be noted that these amputations were elective and that failure with this implant does not automatically necessitate amputation. Other options, including an alternative custom implant, can be offered to patients if failure is secondary to nonunion.

Conclusion

The use of patient-specific 3D-printed titanium implants offers a new technology that can be used to address a variety of complex bone defects and lower extremity deformities more effectively and with less morbidity than current autograft, allograft, and bone transport techniques. The flexibility and ease of customizable implants allow for patient-specific needs to be met and planned for preoperatively. Although there is a high upfront cost associated with the implant, our preliminary results demonstrating fusion are promising, and our hope is that the benefits of successful limb salvage, improved long-term function, and increased patient satisfaction will outweigh these higher upfront costs. Larger, long-term studies are required to monitor long-term outcomes and delayed complications (infection, stress shielding, implant failure, etc) in order to determine the true value of the implant.

Declaration of Conflicting Interests

The authors declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Samuel B. Adams, Jr, MD, reports personal fees from 4web outside the submitted work. ICMJE forms for all authors are available online.

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