〈 Technology (Column) 〉

From Patient to Procedure

The Process of Creating a Custom 3D-Printed Medical Device for Foot and Ankle Pathology

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Abstract: *Three-dimensional (3D) printing technology has advanced greatly over the past decade and is being used extensively throughout the field of medicine. Several orthopaedic surgery specialties have demonstrated that 3D printing technology can improve patient care and physician education. Foot and ankle pathology can be complex as the 3D anatomy can be challenging to appreciate. Deformity can occur in several planes simultaneously and bone defects either from previous surgery or trauma can further complicate surgical correction. Three-dimensional printing technology provides an avenue to tackle the challenges associated with complex foot and ankle pathology. A basic understanding of how these implants are designed and made is important for surgeons as this technology is becoming more widespread and the clinical applications continue to grow within foot and ankle surgery.*

Levels of Evidence: *Level V*

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Three-dimensional (3D) printing technology, also referred to as additive manufacturing, has revolutionized the design and manufacturing process. First commercially available in 1988, 3D printing has since transformed how we translate ideas into tactile creations. As technology advanced and accessibility to 3D printers increased, 3D printing has become more prevalent in many industries, including medicine. The burgeoning popularity of 3D printing is in part fueled by its ability to create highly customized products in an efficient and accurate manner. This is in contrast to traditional manufacturing methods, which are often impractical and costly to implement for geometrically complex and custom "one-off" designs. Three-dimensional printing technology has even made it possible to print on-demand, providing ample opportunity for rapid prototyping for an improved final product or fast turnaround time production runs.

The use of 3D printing technology in the medical field has evolved from anatomic models, to surgical cutting guides, and now customized patient-matched implants. In 2017, the Food and Drug Administration (FDA) released a guidance document for industry on Technical Consideration for Additive Manufacturing of Medical Devices, which outlines additional considerations for testing safety and efficacy for 3D-printed implants.[1] Since then, the use of 3D printing in orthopaedics has grown immensely across many different

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subspecialties. Surgeons can utilize 3D-printed anatomic models for preoperative planning as the models provide an accurate and tactile representation of the underlying anatomy. It becomes possible to see and feel what will be encountered in the operating room, which aids in hardware selection and allows prebending of hardware to optimize fit.[2] For example, in the treatment of clavicle fractures, these 3D printed models can be used to fit the plate to the patient's individual anatomy and facilitate a more accurate reduction.[3] Within hip and knee arthroplasty, this technology has introduced several new implant types. Three-dimensional printed acetabular cups are thinner and less expensive than traditionally manufactured cups and have resulted in satisfactory patient outcomes.[4,5]

Foot and ankle pathology can be challenging to treat due to the inherent complexity of the 3D anatomy, involving multiple bones and articulations. The utilization of 3D-printed anatomic models preoperatively has provided an opportunity to plan hardware placement and osteotomies, while 3D-printed patient-specific cutting guides ensure precision and accuracy during deformity correction. Several studies have reported that patient specific instrumentation is both accurate and reproducible when used for total ankle arthroplasty.[6,7] Customized patient specific 3D-printed implants have become a desirable alternative to structural bone grafts since they are able to provide superior mechanical stability while optimizing fit to the patient's native anatomy. Three-dimensional printed titanium implants have been successfully implemented for the management of bone loss in the setting of failed foot and ankle surgery and following severe trauma to the foot and ankle.[8,9] Dekker et al[10] reported on a cohort of 15 patients who underwent complex lower extremity reconstruction and arthrodesis with custom 3D-printed titanium cases in the setting of deformity and bone loss. They achieved radiographic union in thirteen of the fifteen patients with two complications.[10] The clinical applications of 3D printing technology within foot and ankle surgery are immense and can provide solutions to even the most complex pathology.

Here we will describe the step-by-step process of creating a 3D-printed patient-specific implant and the rationale behind each step. While the example is for the replacement of a foot bone from ballistic trauma, the process and principles are generalizable throughout the foot and ankle.

Case Presentation to Demonstrate Step-by-Step Process of Patient Identification and Implant Creation

The authors present the case of a 42-year-old man who sustained a ballistic navicular fracture. Figure 1 represents his injury radiographs and computed tomography (CT) scan. Imaging revealed a highly comminuted navicular fracture with significant joint surface destruction. Furthermore, there was also some ballistic trauma to the articular surface of the talar head. Standard open reduction and internal fixation would be difficult given the degree of comminution, and the patient is likely to develop post traumatic arthritis to the talonavicular (TN) and/or naviculocunieform (NC) joints given the irreversible damage to the articular surfaces evident on imaging. The decision was made to proceed with arthrodesis of the TN and NC joints. To properly restore the patient's native alignment, it is imperative to maintain medial column length in this case and arthrodesis would likely require the use of structural autograft versus allograft in order to be successful. Iliac crest autograft was considered but was not chosen secondary to the potential risk of donor site morbidity as a large graft was required. Structural allograft was also considered but deemed suboptimal due to the lack of vascularized biology need to support successful fusion. It was expected either option could lead to graft subsidence and/or nonunion.

Therefore, a custom 3D-printed navicular cage was created to fill this critical-sized bony defect. There are many potential benefits of using a 3D-printed cage. First, the cage has the potential to provide the mechanical stability needed to maintain medial column length. Second, the implant is porous, which would enhance bony ingrowth, while also allowing for the placement of bone graft and provide adequate bony ingrowth surfaces for osseointegration. Third, customized instrumentation can also be 3D printed to ensure precise anatomic fit of the implant. Finally, the fixation options with a custom 3D implant are myriad and matched to the patient's anatomy. All options were discussed with the patient. The patient opted to have a custom 3D implant. Here we will discuss the process of creating the 3D-printed implant.

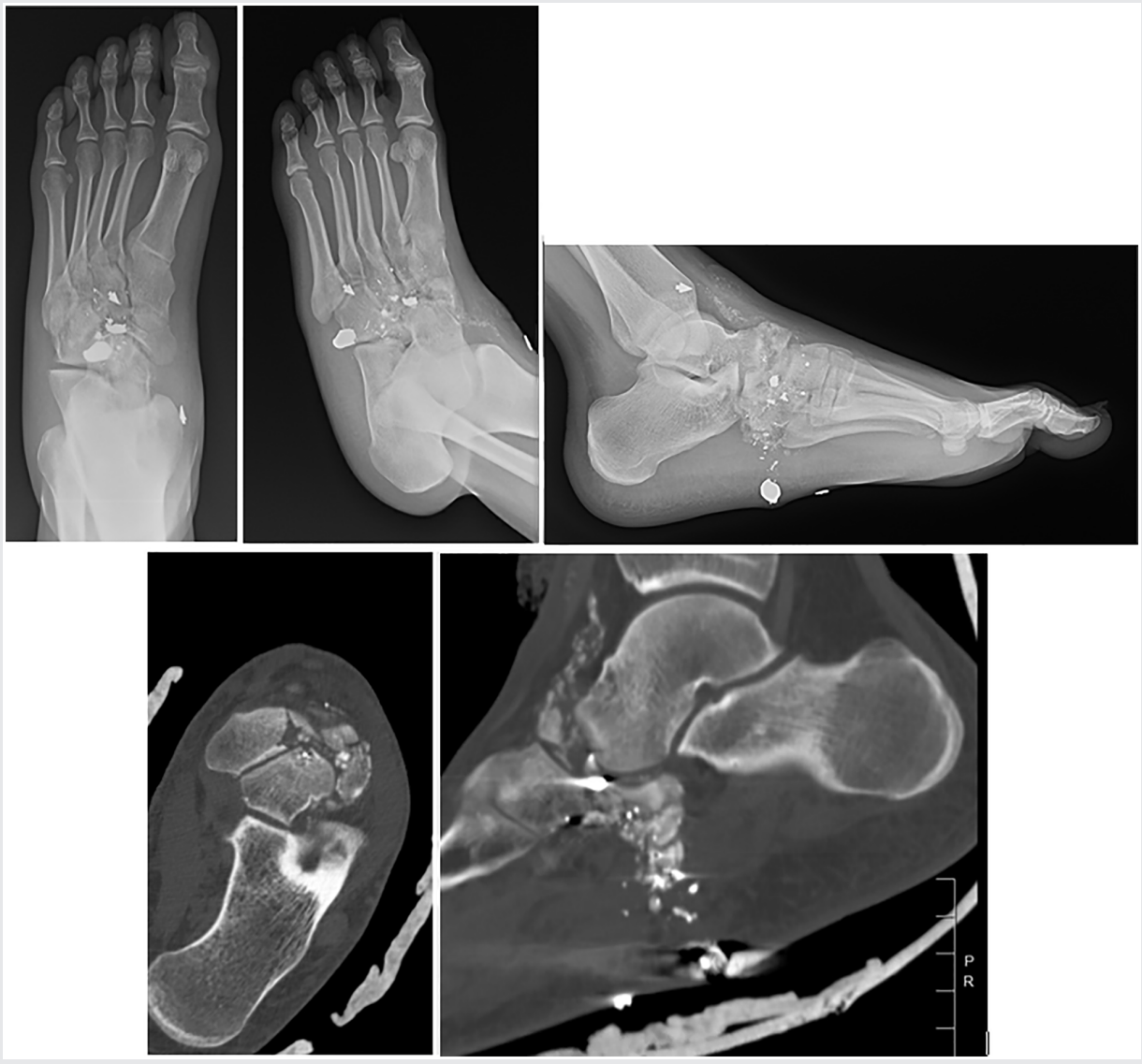
Implant Design

Before discussing the specifics of implant design, it is important to understand the indications and contraindications of using custom 3D-printed metal implants (Figure 2). The indications include cases where standard implants are not feasible. These specific cases can include revision settings of failed arthrodesis or ankle arthroplasty, which commonly results in substantial bone loss. In these cases, standard implants and bone grafting techniques may not provide enough mechanical support to ensure success. Another indication is in the setting of complex deformity, which can commonly be due to previous trauma. Strict contraindications include active infection, vascular compromise, poor surrounding bone quality, and a poor soft tissue envelope. These contraindications would be similar for standard implant techniques as well and in most cases the patient likely would function better with an amputation.

After identifying the patient, a prescription form is required to describe the indicated pathology and document the unique need for a custom implant. Many medical device manufacturers have such prescription forms that typically require the following criteria:

Figure 1.

Injury radiographs and computed tomography (CT) scans. Anteroposterior (AP), oblique, and lateral radiographs demonstrating a comminuted ballistic navicular fracture. Coronal and sagittal slices from the patient's CT scan demonstrating the significant degree of comminution to the navicular—particularly laterally. There is also evidence of ballistic trauma to the talar head.

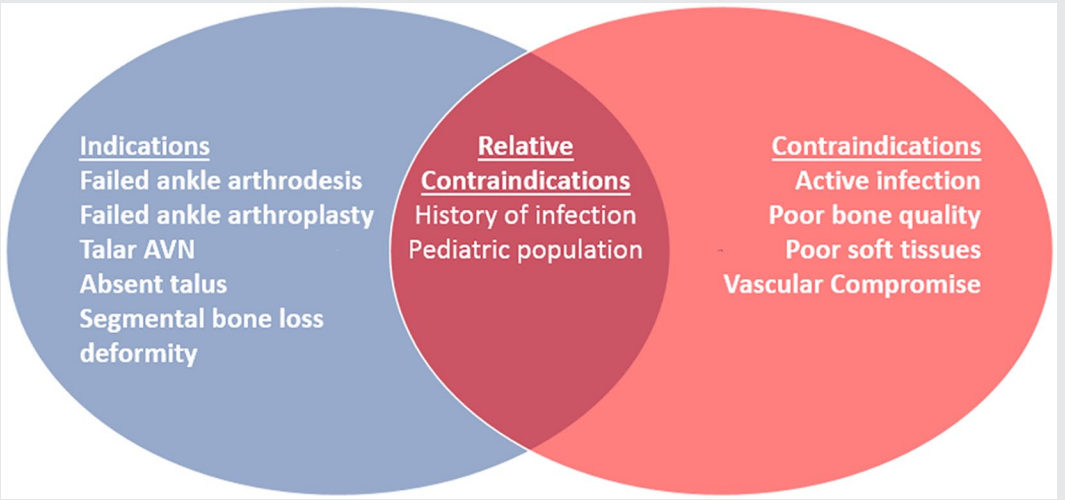


the specific patient's condition, why the condition requires a custom device, and how the custom device will be specific to the patient's anatomy. Additionally, when submitting the prescription form, the clinician includes preoperative imaging studies, typically a CT scan and radiographs, and any preliminary ideas for the goals and function of the implant. The CT scan parameters are crucial as the implant is designed based on this cross-sectional imaging. Typically, files are best stored as Digital Imaging and Communications in Medicine (DICOM) file types, having a pixel size of 0.5 mm of less, and slice spacing of 1.25 mm or less. The images must capture all relevant anatomy and be as recent as possible to ensure the engineering team can successfully reconstruct the anatomy for preoperative planning.

The primary surgeon is heavily involved in the design process, as he or she must provide a clinical perspective of how the implant will be utilized and what the goals for reconstruction are. This process frequently occurs via web meetings, where the reconstructed CT data are displayed as 3D anatomy, and a virtual surgery can be simulated with regard to hardware placement. From the initial design meeting(s), several CAD

Figure 2.

Indications/contraindications for custom 3D-printed implants. AVN, avascular necrosis.



(computer-aided design) models of implant designs are engineered, which can be approved by the surgeon, or further iteration can take place (Figure 3). Considerations for the design of the implant from the clinical perspective must include surgical approach, bone resection, arthrodesis versus motion sparing, implant fixation, necessity of sizing trials, and anatomic cutting guides. Furthermore, considerations from the engineering team include principles of "design for additive manufacturing," which requires consideration of part geometry relative to the capabilities and resolution of the printer and needs for subsequent post-processing of the implant to ensure the success of the final parts. After the final design is approved by the engineering team and the primary surgeon, the process of fabricating the implant via 3D printing begins.

Custom implants are permitted for us by the FDA through Section 520(b) of the Food, Drug, and Cosmetic Act (FD&C Act).[11] There are several terms that must apply for these implants in order for them to fall within this category of custom devices. First, each implant is designed for a specific patient at the prescription of a physician. Furthermore, the anatomy or pathology indicated must necessitate use of a custom implant and cannot be treated with an implant that is commercially available in the United States. Thus, the custom implants apply only on a case-by-case basis to manage unique and patient specific pathology.

Types of 3D Printing Processes

Three-dimensional printing is a broad term that refers to the process of fabricating a 3D part from a CAD model, typically in a layer by layer fashion. In fact, 3D printing encompasses seven technologies which can be classified by the means of deposition of the layers; material extrusion, material jetting, binder jetting, powder bed fusion, vat photo polymerization, directed energy deposition, and sheet lamination. These technologies refer to the overarching process and include many subtechnologies that are often referred to by tradenames. Each technology has its own merits, depending on the materials required for the part, the mechanical properties desired, resolution, print speed, and other factors. Most medical models are fabricated via material jetting due to the high resolution, and the ability to mix materials to print full color models. Surgical instruments and cutting guides can be 3D printed in polymeric materials by material extrusion or vat photo polymerization processes. Most metallic implants for orthopaedics are 3D printed via powder bed fusion, which includes laser powder bed fusion (L-PBF) and electron beam melting processes. These processes will be discussed later in the article.

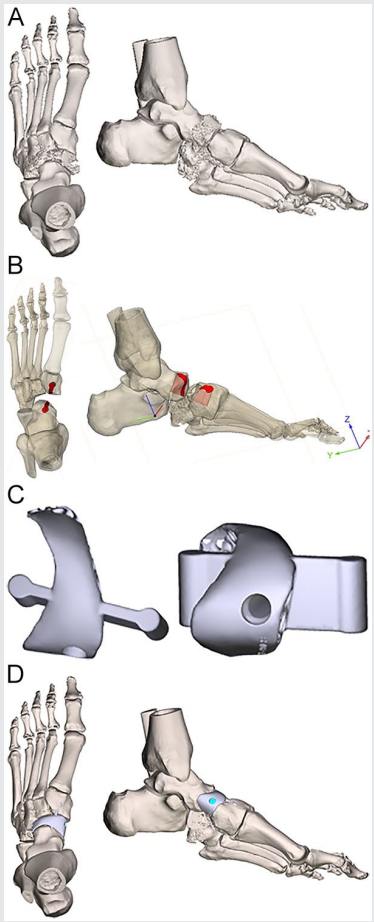
Metal Properties

It is important to understand the different types of metals available when printing custom metal devices. The metal characteristics are crucial to appreciate and the selection of the metal must take into consideration the function of the implant. Orthopaedic implants that require osseointegration attempt to recreate some porous architecture to encourage bone growth into the implant while mimicking the mechanical properties that are essential to active remodeling. Three-dimensional printing technology enables precise control over implant design and can help recreate this internal architecture. Conversely, implants that are designed to articulate with cartilage must be smooth and allow motion without damaging the articular cartilage. There are several types of

metals commonly used in orthopedic applications which have been used in fabrication of 3D printed implants. It is important to understand the benefits and drawbacks of each material to best identify applications for each. In general, the materials used in orthopaedics should be tough, biocompatible, and resistant to wear and corrosion. Grade 316L stainless steel is low cost and readily available with acceptable biocompatibility. However, it has a high Young's modulus, and can induce allergic reactions in patients with nickel sensitivities.[12] The high Young's modulus can lead to stress shielding of surrounding bone as steel is much stiffer than cortical bone. Thus, 316L is most often used for temporary devices such as plates and screws. Titanium based alloys have a Young's modulus similar to cortical bone and have excellent biocompatibility, similar to stainless steel, but have increased tolerance to corrosion.[12,13] Moreover, porous implants have an even lower modulus and therefore less chance of stress shielding. In vivo studies have demonstrated more rapid osseointegration with titanium compared to cobalt chrome, making it the ideal choice for implants that require bony integration.[14] Titanium and its alloys, including Ti6Al4V, form a spontaneous surface oxide that improves corrosion resistance. One limitation of titanium is relatively low wear resistance compared with other commonly used metals in orthopaedics, which may lead to implant failure and make it a poor choice as a bearing surface. Some coating technologies have been proposed for improving the wear resistance of titanium, including nitride coating of the surface; however, limited available data support the improved wear properties of such surfaces. Another choice for metal 3D printing, cobalt chromium alloys, including CoCrMo, possess high strength, have excellent wear properties, and high corrosion resistance.[15] Some initial studies of cobalt alloys spray coated with titanium to create a rougher surface have shown increased bone to implant contact and facilitation of osseointegration.[16] Due to the lower coefficient of friction, CoCrMo is considered the goal standard for load-bearing articulating components in arthroplasty. It is important to consider metal properties and select the right material based on the function of the implant to be designed.

Figure 3.

Design prototypes. (A) Preoperative anatomy reconstructed from computed tomography (CT) images. (B) Proposed resection for implant. (C) Prototype implant design. (D) Implant positioned after resection.



Steps to Making the Implant

Creating the Model

The first step is translating the patient's CT scan into a virtual 3D model in CAD software. This process starts with

Figure 4.

Build plate with implants. Build plate removed from the 3D printer with the custom 3D implants attached.

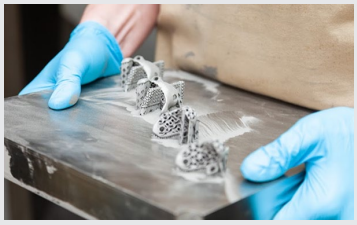


Figure 5.

Cleaning the build plate. Powder is removed from the build plate using a power brush. All powder must be removed before postprocessing steps can begin.

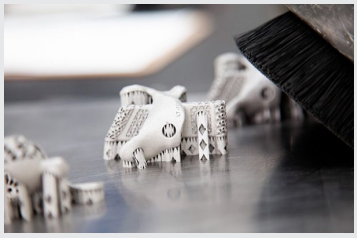


Figure 6.

Electric discharge machining (EDM). The build plate is loaded into the machine for EDM. The 3D-printed parts are removed from the build plate through this process.

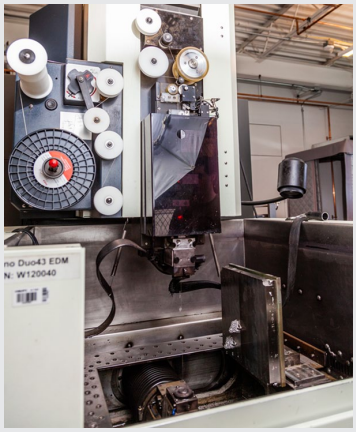


Figure 7.

Final implant.

identifying each individual bone on the CT scan slices. This information is collated and used to recreate a 3D representation of the anatomy. With the anatomy in 3D form the designer/engineer is able to manipulate the bones, restore native anatomy, and simulate surgical operations such as osteotomies. Then the designer creates a nominal (native anatomic size) device that facilitates the desired correction. The nominal design can also be modified to create options that account for potential intraoperative issues such as wound closure or soft tissue restriction. Additional sized implants can also be designed. Once the device(s) are designed and approved by the prescribing physician, the 3D designs are converted from the CAD software into .STL (standard triangle language) files. This turns the device into a mesh-based volume that is used as an input for 3D printing software systems.

Slicing

The .STL file is then translated into "printing instructions" that can be understood by the 3D printer. This process is called slicing and is usually performed by software that is linked to the printer chosen for use based on the desired implant material. This software takes the .STL file and creates a G code (geometric code) file that is the blueprint for the object to be printed. The G code is a sequence of tool paths based on 2D horizontal cross-sections. The 3D printer uses this G code to actually print the object layer by layer.

Three-Dimensional Printing

As introduced previously, there are many 3D printing technologies used in the biomedical field. For the purposes of this case study, the authors will discuss the 3D printing process for metallic implants, most typically powder bed fusion. In powder bed fusion, a source of thermal energy, either from a laser or electron beam, selectively fuses regions of a thin layer of powder according to the desired design to form each 2D layer. This process is repeated until each layer has been fused together, rendering the 3D object desired.[12] The printing process typically occurs over the order of hours, but up to many days depending on the number of parts and total volume. Figure 4 demonstrates the build plate along with the custom navicular implant was created. Figure 5 demonstrates the process by which any residual powder is removed from the build plate before any post processing steps can begin.

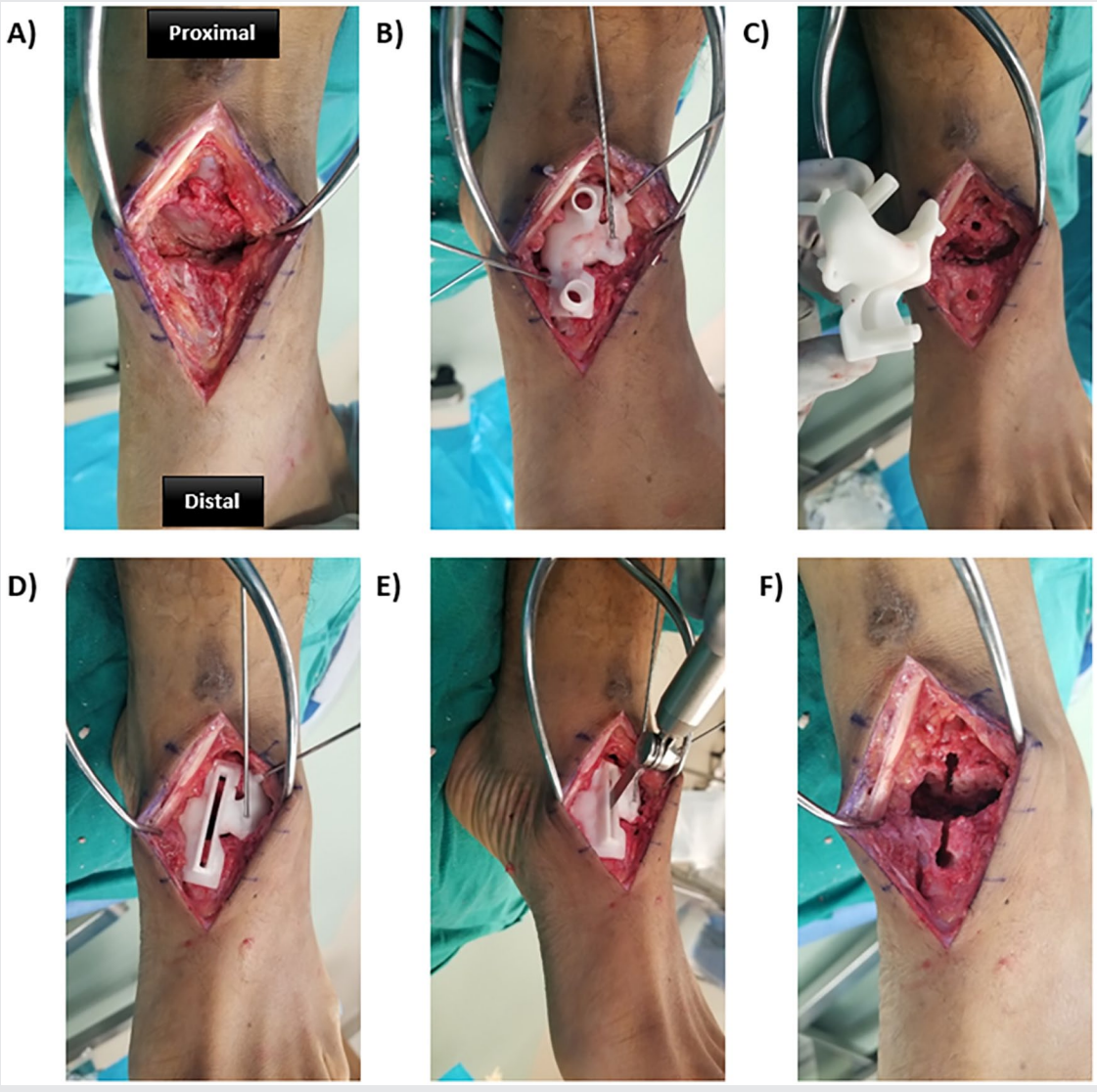
Selective laser melting (SLM) and electron beam melting (EBM) are the 2 most common powder bed fusion processes, and each has unique merits depending on the desired material microstructure, mechanical properties, surface roughness, build rate, and other factors. According to a report by the FDA, 66% of cleared 3D-printed devices were produced by laser powder bed fusion, compared with 25% by EBM.[17] EBM has less dimensional accuracy than SLM due to the higher energy used to melt. Thus, it may not be ideal for implants that require porous architectures and finer features as the resolution is limited. EBM also produces a rougher surface but this can be altered via machining or chemical treatments so that its surface roughness is similar to that seen with SLM.[18,19] The implants created for this case were created via SLM powder bed fusion. Based on the earlier discussion, the implants for this specific case were made with titanium alloy as the goal was to promote bony ingrowth onto the implant.

Postprocessing Heat Treatments

Following powder bed fusion processes, postprocessing heat treatments are typically applied to homogenize the material microstructure of the printed parts. For titanium parts, hot isostatic pressing (HIP, "hipping") is most commonly used, and involves a high pressure and temperature treatment, to relieve residual thermal stresses, induce equiaxed grain structure, and close internal void defects. HIP has been shown to improve the ductility and fatigue resistance of the material.[20] Additionally, high temperature annealing or stress relieving treatments can be used

Figure 8.

Surgical procedure. (A) The cavity present after removal of the comminuted remains of the navicular. The talar head had evidence of ballistic trauma with articular damage. (B) A custom drill guide is placed and it serves 2 purposes: (1) it allows sizing of the implant to be used and (2) provides the drill holes for the pegs. (C) The cutting guide is designed to fit directly into the drilled holes. (D) The custom cutting guide for the implant is then placed into the previously drilled peg holes. (E) The cutting guide is used to make accurate cuts for the implant. (F) The cavity is then cleaned and irrigated in preparation for the implant.



to achieve similar results without the pressurized environment.

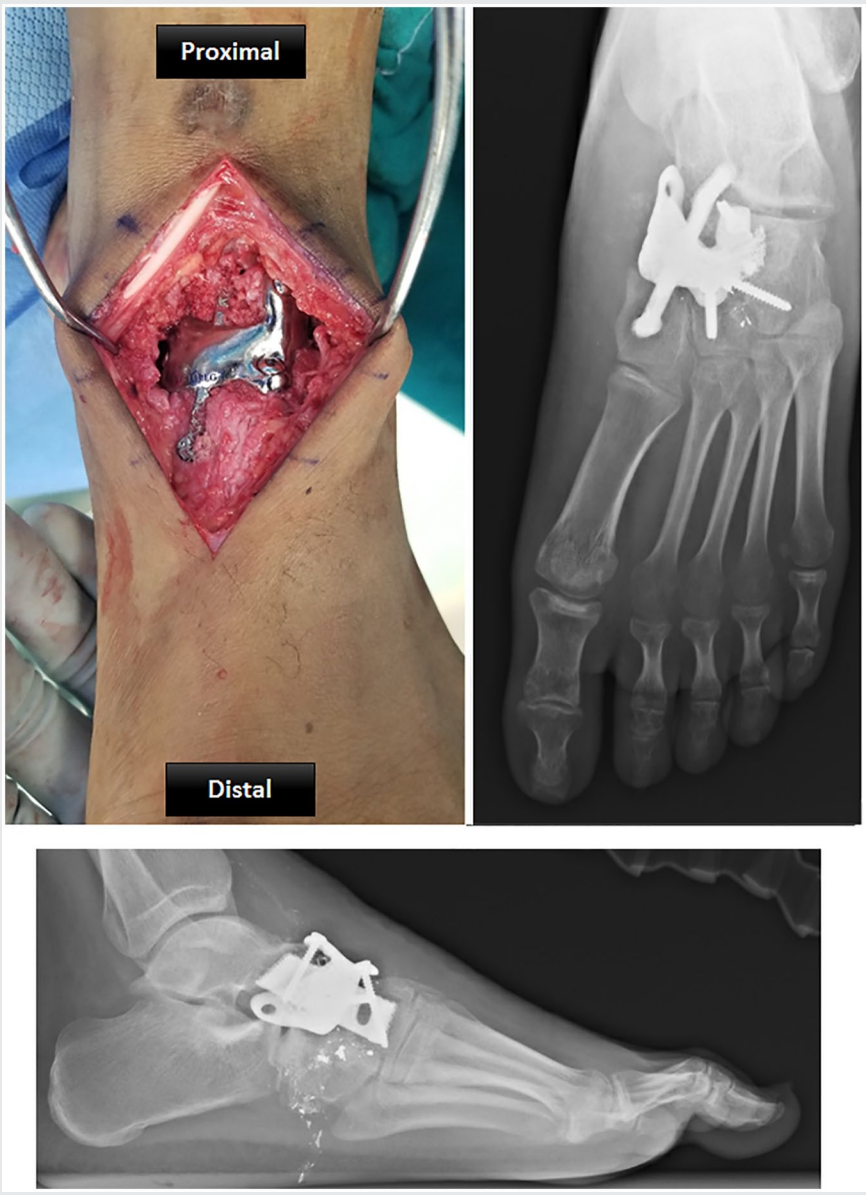
Electric Discharge Machining and CNC Machining

Electrical discharge machining (EDM) is typically used to remove the 3D-printed parts from the build platform. EDM is a thermoelectric process whereby material is removed by a series of electric sparks generated between 2 electrodes with a high potential difference applied across them. These sparks create localized regions of high temperatures, which cause melting and vaporization of the material of the implant.[21] This is a well-established machining process for the manufacturing of hard materials with complex shapes. Figure 6 demonstrates the build plate with the navicular implants loaded onto the EDM.

For some implants, additional machining processes are needed to achieve features that are not well suited to be 3D printed. Computerized numerical control (CNC) machining mills away material along a

Figure 9.

Postoperative radiographs and clinical image. Clinical picture with the implant and screw fixation in place and postoperative radiographs.



computer designated path to refine the shape of the product. Milling processes may be used for threaded features, through holes, or interlocking component interfaces.

Surface Treatment

Surface treatment of 3D-printed implants is commonly used to modulate the surface roughness or chemistry. Physical treatments, including micro-blasting, or mixed media mechanical polishing processes. Micro-blasting involves blowing small particles or tiny beads in high pressure at the final product to remove surface topography typical of the powder bed fusion process and clean off the surface of the implant. Media polishing is typically achieved via tumbling of parts with various abrasive media to smooth the surface.[18] Additionally, chemical surface treatments can be used to reduce surface roughness and modulate the chemistry of the oxide layer.[18,22] As discussed above, the surface oxide layer of metallic implants is crucial to corrosion resistance. Chemical passivation processes are utilized to further enhance material properties of

the metal by promoting the formation of an ultrathin insert oxide layer on the metal, which improves its resistance to corrosion.[23,24]

Cleaning and Inspection

Prior to final cleaning steps, the implant should be carefully inspected to ensure critical dimensions and other engineering specifications are verified. Final cleaning and packaging steps then occur prior to implant sterilization. Figure 7 demonstrates the final implant. The implants are cleaned via a standardized process prior to being shipped to the hospital but are re-sterilized at the facility prior to being used in the operating room.

Case Presentation: Surgical Technique

Figure 8A-F shows the surgical procedure. A longitudinal incision centered over the navicular was utilized. The skin was incised sharply, and blunt dissection was utilized to find the interval between the tibialis anterior (TA) tendon and extensor hallucis longus (EHL) tendon. Dissection proceeded carefully in this interval and care was taken to protect the tendons and any nerves/vessels that were encountered. The talonavicular joint capsule was identified and confirmed fluoroscopically. The joint capsule was incised longitudinally and extended distally to find the naviculocunieform joints as well. The navicular fracture was severely comminuted and articular damage was evident on the talar head from the ballistic trauma. The remaining navicular and comminuted fragments were then carefully removed. Any viable bone from the navicular was grinded up to be used as autograft later in the procedure. The remaining joint surfaces of the talar head and the cuneiform were then denuded of any residual articular cartilage down to healthy cancellous bone. There was already significant articular injury to the talar head from the initial ballistic injury. After prepping the joint surfaces, the sizer and drill guide for the pegs was inserted to determine the appropriate size of the implant and to drill for the pegs. This custom drill guide was pinned in place. After drilling the pilot holes for the pegs, this guide was removed and a second custom cutting guide was placed using the previously drilled holes. This custom guide was designed to cut the pathway for the struts that extended from the implant to the pegs. The second custom cutting guide was then pinned in place and a sagittal saw was used to make the cuts for the struts. The wound is irrigated thoroughly to remove any soft tissue and bony debris. The cage of the implant was then filled with autograft/allograft material to promote bony union. The implant was then placed into the foot. The implant had four options for additional fixation using 3.5-mm cortical screws based on the patient's anatomy. Three of these screw options were utilized as the most proximal and plantar screw hole in the implant was difficult to safely access through the dorsal incision. Final radiographic and clinical images confirmed appropriate placement of the implant and screws (Figure 9).

Conclusions

Three-dimensional printing technology has many applications with the field of medicine. Orthopaedic surgeons can use this technology to improve on surgical technique, plan for difficult surgeries, and create patient specific instrumentation and implants. Complex foot and ankle pathology can involve deformity and segmental bone loss—both of which can be managed with custom 3D printed instrumentation and implants. As this technology continues to improve and becomes more widely available, its clinical applications will continue to expand.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Dr. Samuel Adams has stock options in Restor3d and 4web. Dr. Samuel Adams is a consultant for stryker, medshape, conventus, RTI, depuy.

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Not applicable.

Informed Consent

Not applicable.

Trial Registration

Not applicable.

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