Orthopaedic Advances

Orthopaedic Advances: Use of Three-Dimensional Metallic Implants for Reconstruction of Critical Bone Defects After Trauma

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VIDEO 1

ABSTRACT

Multiple successful strategies exist for the management of critical-sized bone defects. Depending on the location and etiology of an osseous defect, there are nuances that must be considered by the treating surgeon. The induced membrane technique and various modifications of the Ilizarov method (bone transport by distraction osteogenesis) have been the most common methods for biologic reconstruction. Despite the versatility and high union rates reported, they may not be practical for every patient. The rapid expansion of three-dimensional printing of medical devices has led to an increase in their use within orthopaedic surgery, specifically in the definitive treatment of critical bone defects. This article proposes indications and contraindications for implementation of this technology and reviews the available clinical evidence on the use of custom nonresorbable implants for the treatment of traumatic bone loss. Clinical cases are presented to illustrate the scenarios in which this approach is viable.

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The management of critical bone defects, suggested to be those greater than 2.5 cm,[1] remains an active area of investigation, study, and innovation. In orthopaedic trauma, bone loss can occur at the time of trauma or can be the result of osseous resection because of infection or nonviable bone. Management of tibial bone defects is commonly discussed given the frequency of complications in the management of both open and closed tibia fractures,[2] but can occur in any location. The challenge with many strategies outlined for bone defect management is that the technique may require intervention or compliance, which is unreasonable for the individual, or require host biology that is absent. Invariably, biologic reconstruction requires multiple surgical procedures and impedes weight bearing and/or return to activity.

The utilization of three-dimensional (3D) printing technology has increased rapidly across orthopaedic surgery and is currently available to most surgeons in some form. This technology is being routinely used in areas such as revision total hip arthroplasty when large areas of pelvic/acetabular bone loss exist. Orthopaedic surgeons routinely acquire relevant imaging and obtain

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multiplanar/3D image reformats for surgical planning of traumatized extremities. Now, 3D models or custom implants can be created from such image files. Production cost and acquisition time have continued to decrease as material options have expanded.[3,4]

Management of critical bone defects is, in a way, an ideal application for this technology. Osseous defects may have an irregular size or shape and vary in location. Placement of a custom metallic (commonly titanium, tantalum, or cobalt chrome) implant may be advantageous in specific clinical scenarios and provides another option for limb reconstruction and salvage. In this study, we will review the application of 3D printed metallic implants in the management of segmental bone defects and explore the role they may occupy in the limb reconstruction algorithm (Video 1).

Current Management of Critical Bone Defects

Modern treatment options for bone defects include four main treatment options. The induced membrane technique, first described by Masquelet, involves placement of a spacer (typically polymethyl methacrylate) within the defect. The body then forms a biologically active foreign body membrane around the spacer. At 6 to 8 weeks, the spacer is removed and graft material is placed within the membrane which is then closed.[5] Bone consolidation is enhanced by growth factors present within the membrane. The success of this technique is generally thought to be greater in areas where soft tissue, muscular coverage, and vascularity are more robust. It is difficult to interpret the literature on the Masquelet technique given the variability in size and location of defects treated, as well as the need for additional grafting procedures.[6]

Bone transport or distraction osteogenesis describes the process of gradually moving a segment of healthy bone across a defect where new bone is formed behind the transported segment. This requires a corticotomy and gradual distraction at a specific rate and rhythm (known as the Ilizarov method). Bone transport may be done by using classic Ilizarov external fixation, hexapod external fixation, cable transport, or all internal transport techniques such as plate-assisted bone segment transport or using a nail specifically designed for bone transport. Integrated techniques, such as lengthening and then nailing or lengthening over a nail, are also possible. Such modern advances have decreased or obviated time in an external fixator. In experienced hands, distraction osteogenesis is a reliable technique for bone defect management.

With the advent of microsurgical techniques, surgeons have also explored the use of vascularized bone pedicles to fill segmental bony defects. There are many potential donor sites, although the most common are the fibula and rib, with or without a skin paddle. Vascularized fibular transfer is perhaps best suited for bones of similar size, such as the clavicle, radius, ulna, and even humerus. The technique can be used in the lower extremity, although immediate weight bearing may be delayed until sufficient bony hypertrophy of the transferred segment has occurred.

Finally, large allograft segments can be placed across diaphyseal defects. This is more commonly done for reconstruction of defects related to oncologic processes. Because these segments are nonvascularized, it is unclear whether they are ever fully replaced by creeping substitution, but healing can occur at either end with grafting or sufficient compression. The risk of infection is considered higher with this approach given the nonbiologic nature of the allograft. Articular and nonarticular allograft transplantation has been described but is uncommonly done acutely after trauma.

Three-Dimensional Printing for Bone Defects

The rapid evolution of 3D printing has had a profound effect on orthopaedic trauma and limb reconstruction. Faced with the challenge of bone defect management, early reports appeared of custom 3D printed titanium scaffolds for various defects.[7-9] These early nonabsorbable structural implants (commonly titanium) were filled or surrounded

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with bone graft, with the intention being that they would provide immediate structural support and allow osseous healing both around and through the implant. Recently, larger defects with solid or porous 3D printed metallic implants have been described.[10-12] In most cases, such custom patient 3D implants can be created and used under the US Food and Drug Administration's custom device exemption.

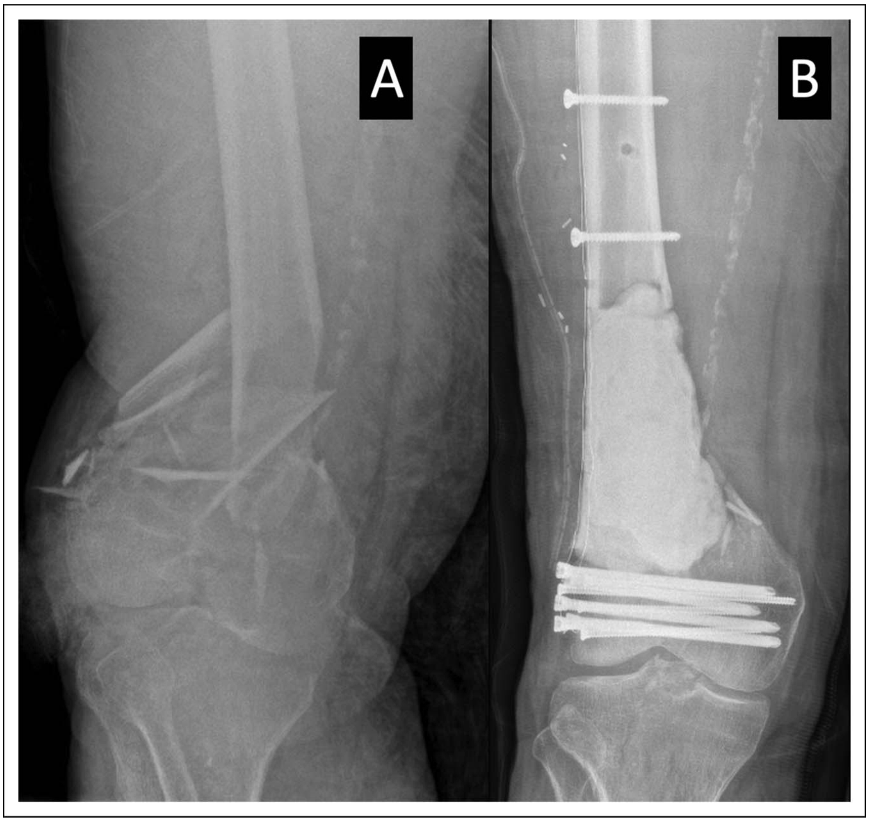
Orthopaedic Oncology

In orthopaedic oncology, 3D printed intercalary prostheses have been used in large osseous defects after tumor resection. In some instances, especially after resection of segments of periarticular bone, there may be little native bone stock remaining for techniques such as distraction osteogenesis or induced membrane. In addition, patients may require perioperative radiation or chemotherapy that challenges biologic reconstruction. Short-term results after large tibial segment reconstruction (16 to 28 cm) with custom 3D printed prostheses have been favorable.[11,13] The use of intercalary prostheses follow the use of large joint reconstruction prostheses in orthopaedic oncology such as proximal/distal/total femoral and partial humeral/tibial arthroplasties.

Foot and Ankle

The use of 3D printed implants in acute and posttraumatic reconstruction of complex foot and ankle trauma is an area of increasing utilization.[14] This anatomic location is commonly affected by high-energy trauma; bone loss; and posttraumatic degenerative joint disease, including talar osteonecrosis.[15] Tibiotalar fusion and subtalar fusion are commonly conducted operations and often components of limb salvage in severe foot and ankle trauma. As such, early reports of custom 3D printed technology in this area involved implants that were used in conjunction with hindfoot fusion nails.[7,8,15,16] Dissimilar to most oncologic reconstructions, salvage procedures about the foot and ankle commonly occur in the setting of other risk factors of infection or failed biologic reconstruction: open fracture, previous surgery and/or compromised soft-tissue or vascular supply. In the setting of complex pathology in which reconstructive biologic options may be limited given the osseous architecture and

Figure 1



A, Anteroposterior (AP) radiograph of the right knee demonstrating a comminuted metadiaphyseal femur fracture with intra-articular extension. **B,** AP radiograph of the right knee status post ORIF with a carbon fiber lateral distal femoral locking plate and PMMA spacer within the defect. ORIF = open reduction and internal fixation, PMMA = polymethyl methacrylate.

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anatomy of the ankle/hind and midfoot, placement of a structural allograft or 3D printed implant may be the only option available before amputation.

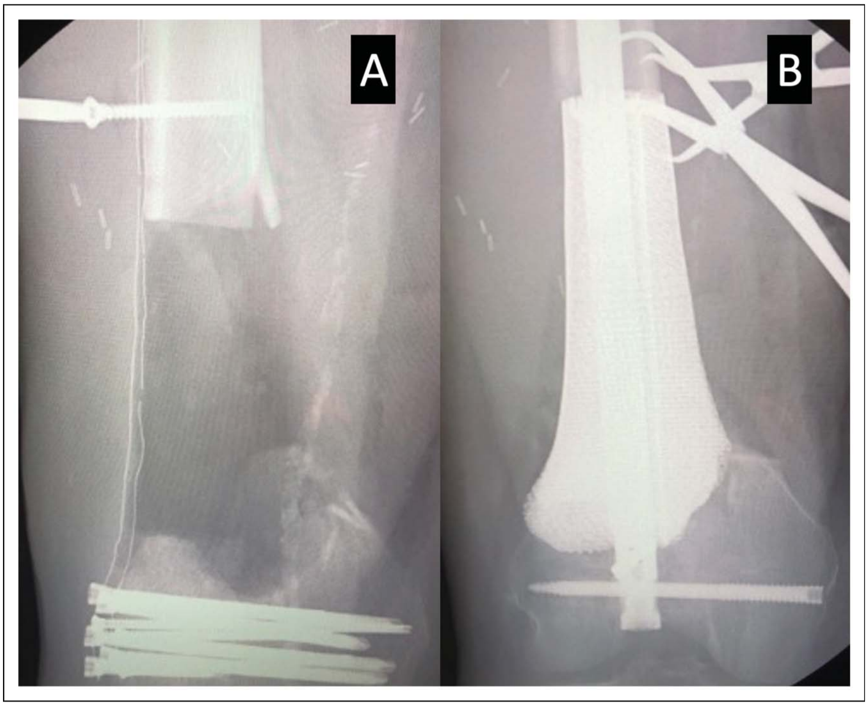
Orthopaedic Trauma

Orthopaedic traumatologists have similarly explored implementation of 3D image analysis, planning, and printing in the treatment of extremity bone defects.[9] Similar to foot and ankle reconstruction, defects often result from traumatic bone loss or infection. Thorough débridement is commonly followed by placement of an antibiotic-impregnated cement spacer. This is important because it provides local delivery of antibiotics and allows for soft-tissue rest. In addition, this functions as the first stage of the induced membrane technique and allows for the merger of reconstructive techniques because many reports have described placement of bone graft within the custom 3D printed trusses.[9,17] The main purported advantage of using a 3D implant is the immediate stability provided by the implant over the time needed for osseous consolidation of graft or regenerate bone with biologic reconstruction.

Design

Two general approaches have been taken in the design of 3D printed nonresorbable intercalary prostheses for osseous defects. Both provide immediate structural stability, but differ in their mode of healing. A size-matched metallic scaffold can be placed within a defect and then filled with graft. This method relies on bony healing to occur throughout the structure because the metallic prosthesis itself is often not designed for full weight bearing. The scaffold also acts to both contain and maintain graft distribution. These implants are commonly used in conjunction with an intramedullary nail and in hosts with biologic potential to heal large, grafted defects.[7,15,17] This approach has been also used with 3D printed resorbable graft structures.[18] Another approach is to create an intercalary prosthesis with greater density that relies on osseous incorporation at the proximal and distal bone interfaces. This approach has been used more frequently in oncologic lesions and does not require incorporation of large grafted segments. These high-strength implants can support physiologic loads and offer a matrix to facilitate ingrowth over time.[19]

Figure 2



A, Radiograph showing an AP intraoperative fluoroscopic image demonstrating the osseous defect after spacer removal and initiation of plate removal before placement of a 3D metallic implant. **B,** Radiograph showing an AP intraoperative fluoroscopic image after placement of the custom metallic implant and compression medullary nail. Pointed clamps are used for provisional reduction and stability. 3D = three-dimensional.

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Indications and Contraindications

The decision to proceed with a 3D printed metallic structure for reconstruction of a critical bone defect is multifactorial. Tetsworth et al[9] reported that their primary indication was large distal femoral defects (>8 cm) where the remaining articular surface fragment is small (<2 cm) but preserved, in compromised hosts/wounds. The available literature on defect management with a 3D printed metallic prosthesis comprises case studies or small series. As 3D printing technology improves and becomes more widely available, surgeons continue to explore and contemplate ways in which custom metallic prostheses can be implemented into their practice.

Patients who are unable or unwilling to undergo limb reconstruction with a ring fixator or internal magnetic medullary nail, but who desire to avoid amputation, are ideal candidates. Regardless of the technique, patients (or their caregivers) must have the intent, and ability, to actively participate in the use and care of a ring fixator or magnetic nail. External fixation devices require attention to the pin/wire interfaces and strut adjustments. Magnetic nail technology allows for an "all-internal" means of distraction osteogenesis, but similarly requires use of the external device which controls the nail. Other factors are the known morbidity associated with long-term ring fixator application such as pin tract infections and additional surgical procedures for pin/wire loosening. Some patients are also unwilling to have an external device on their extremity for months. Finally, additional surgical procedures are often an expected component of distraction osteogenesis. Wires, pins, or interlocking bolts may require exchange, and bone grafting procedures may be required.

Besides the care and maintenance of these unique reconstruction devices, the patient must possess the biology for distraction osteogenesis and successful formation of new regenerate bone. Host biology may be compromised by age, medical comorbidities, local or systemic therapies, or multiple surgical procedures. The size and the location of bone defect are also important components of the treatment algorithm. For free osseous transfer, if a vascular comorbidity or injury is present in

Figure 3

A, Immediate postoperative AP radiograph showing placement of the 3D metallic implant within the bone void and supplemental fixation with compression medullary nail and lateral locking plate. **B,** AP radiograph of the right knee 2 years after fixation. Bone growth is seen over the metallic implant at the proximal and distal bone interface. 3D = three-dimensional.

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the extremity, this type of reconstruction may not be possible.

Multiple reports have shown the use of custom metallic implants about the distal tibia and ankle, especially when the desired result involves fusion across the tibiotalar or subtalar joint. Similarly, as noted, larger defects about a short or partial articular segment may provide an opportunity for these implants, but fusion across the shoulder, elbow, or knee results in greater functional limitation than fusion about the ankle and hindfoot.

The presence or concern for active or latent infection is a major contraindication to placement of a custom prosthesis. Similarly, the soft-tissue envelope must be healthy without concern for perioperative wound breakdown or dehiscence. Infection after placement of a 3D implant is a serious complication, one that potentially could result in complete implant removal and further bone loss. Availability and cost may also be limiting factors for implementation, but this must be compared with the notable cost of multiplanar ring fixators, magnetic medullary nails, as well as long-term maintenance and replacement of contemporary amputation prosthetics.

Cases

Distal Femur Segmental Bone Loss

A 68-year-old man with multiple severe medical comorbidities presented after motor vehicle collision. He sustained an open right tibial plateau fracture and an open ipsilateral comminuted distal femur fracture with intra-articular extension (Figure 1A). The patient underwent initial débridement and irrigation, followed by application of a knee spanning external fixator and antibiotic spacer placement within the 10-cm defect. After a lengthy discussion with the patient about treatment options, including amputation, the patient elected to proceed with limb salvage surgery. Discussion was held regarding the induced membrane technique, bone transport with either a nail or circular frame, plate-assisted bone transport, or a custom 3D implant.

Figure 4

A, AP radiograph of the right tibia demonstrate a comminuted displaced distal tibia and fibula fracture with retained metallic ballistic fragments within the soft tissue. **B,** AP radiographs of the right tibia 6 months after treatment with a medullary tibial nail. Images show atrophic nonunion of the fracture with minimal bridging callus.

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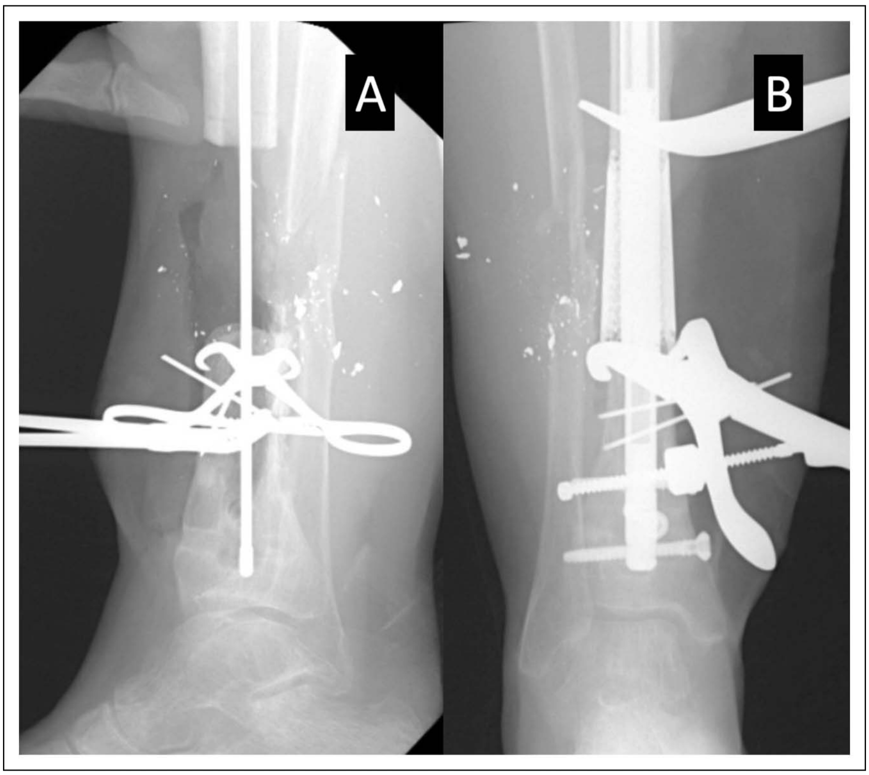
Two weeks later, the patient underwent irrigation and débridement and open reduction and internal fixation with a carbon fiber plate (Carbofix) and placement of a revised antibiotic spacer (Figure 1B). Six weeks after revision open reduction and internal fixation and 2 months from the date of injury, the patient elected to proceed with large-segment reconstruction using a 10-cm 3D printed custom distal femur of laser powder bed fusion medical grade titanium alloy (extra low interstitials [ELI]) (restor3d) (Figure 2, A and B) and Medshape Dynanail retrograde hindfoot intramedullary nail (DJO Global) (Figure 3A). This Nitinol-containing implant was selected to maintain active compression at the bone-implant interface to prevent stress-shielding and bone resorption. The patient is now 2 years postoperative from implantation and doing well without complications (Figure 3B).

Distal Tibia Segmental Bone Loss

A 68-year-old woman presented after accidental gunshot injury to the right lower extremity. She sustained an open, displaced comminuted fracture of the right distal tibia and fibular diaphysis (Figure 4A). Angiogram demonstrated disruption of the anterior tibial artery with patent flow in the remaining vessels. The patient was initially treated with débridement, irrigation, and stabilization of the tibia with a tibial intramedullary nail. At 6 months, there was minimal evidence of healing (Figure 4B). Given the large segmental bone defect, revision surgery was advised. We discussed the induced membrane technique, bone transport with either a nail or circular frame, plate-assisted bone transport, or a custom 3D implant. After a long discussion with the patient, revision with a custom 3D implant was planned.

Ten months after the initial trauma, she underwent nonunion repair. Extensive débridement and curettage of the nonunion site was performed. A custom 3D printed cutting guide (restor3d) was placed within the tibia defect, and the proximal and distal cuts were made with a bone saw. Trial implants were first used. Next, a custom tibial implant using laser powder bed fusion medical grade titanium alloy (ELI) (restor3d) was placed with a locked magnetic intramedullary nail (NuVasive Specialized Orthopaedics) placed through the implant

Figure 5



A, Radiograph showing an intraoperative fluoroscopic lateral image of the tibia after resection of nonviable bone and preparation of defect for the 3D metallic implant. Guidewire for medullary reaming is seen within the tibial canal. **B,** Radiograph showing an intraoperative fluoroscopic AP image demonstrating placement of the 3D metallic implant within the defect and placement of a magnetic medullary tibial nail. 3D = three-dimensional.

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Figure 6

A, Immediate postoperative AP radiograph showing placement of the 3D metallic implant within the bone void and supplemental fixation with a compression magnetic medullary nail. **B,** AP radiograph of the right tibia 6 months after fixation. Bone growth is seen over the metallic implant at the proximal and distal bone interface. 3D = three-dimensional.

(Figure 5, A and B). In this case, the magnetic nail was used to apply continued compression at the bone metallic implant interface. Postoperatively, the external magnet device was used at 2 and 4 weeks to maintain compression and prevent stress-shielding and prevent bone resorption at the bone-implant interface (Figure 6A). She was last seen 8 months from revision surgery and was doing well with no ambulatory deficits or pain (Figure 6B).

Conclusion

The rapid evolution of 3D printing technology has provided another option within the reconstructive and limb salvage algorithm for surgeons to manage critical bone defects. While existing techniques have a high success rate, they are time and labor-intensive for the patient and surgeon and may not be realistic. Use of custom 3D printed metallic implants, with and without additional bone graft, has shown promise, especially in the lower extremity. With increased use and as more outcomes data become available, indications and contraindications will continue to be refined and best practices established.

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