

Information Statement

Three-Dimensional (3D) Printing in Orthopaedic Surgery

This Information Statement was developed as an educational tool based on the opinion of the authors. It is not a product of a systematic review. Readers are encouraged to consider the information presented and reach their own conclusions.

Three-dimensional (3D) printing is a rapidly advancing technology that has enabled fabrication of previously impossible geometries, including almost limitless, 3D structures that can be created from an expanding variety of materials, including metals, plastics, and even living cells. The benefits of 3D printing include extreme flexibility to customize shapes, increase intricacy/complexity of manufactured products elimination of assembly steps, reduction in material waste, and the promise of “just in time” manufacturing capabilities. Such technology has given the medical field, and specifically orthopaedics, the ability to create anatomic models for use in pre-operative planning. In addition, medical device companies have been able to develop patient-specific instrumentation and implants ranging from complex, non-custom, “off-the-shelf” devices to custom implants that can obtain FDA approval for use in patients.

The American Academy of Orthopaedic Surgeons (AAOS) believes that orthopaedic surgeons should be at the forefront of new procedures and technologies to optimize patient care, and should lead with an evidence-based approach.

Technology

Orthopaedic surgeons, partnered with device manufacturers, can use medical imaging in conjunction with advanced computation design and 3D printing technologies to improve upon preoperative planning and operative techniques for difficult surgeries. Today, this technology provides orthopaedic surgeons with the capabilities to treat complex pathologies involving deformity, segmental bone loss, and joint articulations. Like all new technologies, 3D printing cannot be considered a solution for all orthopaedic dilemmas and should be utilized with caution.

3D Printing Process

3D printing (or additive manufacturing) refers to the process of creating a 3D object in a layer by layer manner. The process encompasses many different 3D printing technologies that range in material selection, part size, accuracy, and costs. The layer-by-layer fabrication enables the creation of parts with much more complex shapes, compared to those produced through traditional manufacturing. This technology can create underhangs, overhangs, interconnected pores, spaces within the implant, and more features that are not possible with machining or molding. The ability to create complexity is advantageous in orthopedic implants at both the macroscale, allowing creation of anatomically matched geometries, as well as the meso/microscale, to create porous architectures design for bone ingrowth.

Custom metallic implants are most commonly 3D printed with powder bed fusion technology. In this technique a thin layer of metal powder is deposited on the build platform of the printer, and then a source of thermal energy, which is either a laser or electron beam, selectively fuses the appropriate region as indicated by the original design. After the energy sources fuse the powder to the prior layer, the building platform is lowered by a predetermined layer thickness, another layer of powder is deposited, and the appropriate regions of the powder are fused once again. This process continues until each layer has been fused properly, resulting in the desired implant shape.

After printing an implant must undergo additional post-processing steps to be removed from the build platform and prepared for surgery. During powder bed fusion, the first layer of metal powder is fused to the building platform. The custom implant must be removed via a process called electric discharge machining. After removal, the implant may undergo high-temperature annealing or stress-relieving treatments to optimize strength and fatigue resistance. Surface treatment of 3D-printed implants is commonly used to alter the surface roughness or chemistry. Physical treatments including micro-blasting or mixed-media mechanical polishing processes are often employed.

The most common indications for custom implants are for fusion to surrounding bone, articulation with adjacent cartilage, or both. The most used metals for 3D-printed custom implants are titanium and cobalt-chromium alloys. It is important to consider metal properties and select the right material based on the function of the implant to be designed.

Cost

Although the cost of 3D printed implants and devices vary across the country, the costs have decreased over the past six years. Moreover, specifically for limb salvage, the upfront cost of implants may be less of a burden to the healthcare system than multiple external prostheses. Surgeons should weigh the benefits of 3D-printed custom implants versus off-the-shelf implants in improving patients' lives.

FDA Regulation

When a patient is identified as possibly needing a custom implant derived from 3D printing, the first step is to ensure that the proposed implant will meet the U.S. Food and Drug Administration (FDA) requirements for a custom implant. The FDA defines a custom implant as one that is not generally available in the US, is designed to treat a unique pathology or physiologic condition that no other device is available to treat, and is manufactured on a case-by-case basis under the order of a physician¹. The clinical indications include pathologies and anatomic variants that are currently available "off-the-shelf" implants will not be sufficient to achieve the desired result for patients.

Custom devices are exempt from Premarket Approval (PMA) requirements and subsequently do not have to meet the usual performance standards for other orthopedic implants - for example, fatigue resistance of the shaped implant or clinical trial data surrounding safety and efficacy. Custom Devices do need to be produced by a facility that maintains a Quality System, including Design Controls, and must be compliant with Medical Device Reporting to the FDA, including information on how many devices have been implanted and any associated complications.

The AAOS supports the use of 3D printing that adheres to FDA Guidance on Custom Device

Exemption and has sufficient evidence of safety and efficacy to satisfy the surgeon and patient utilizing the custom device.

Patient-Specific Implant Development

There are many 3D printed implant successes reported, however, this new technology lacks long-term safety and efficacy data. Patients must be informed about the lack of data related to the use of these implants. Once a patient has been identified to move forward with a 3D custom implant, the surgical team must contact a 3D printing medical device company and complete a prescription form which is also a custom device requirement by the FDA. The prescription typically indicates the patient's condition, the necessity for a custom device, and how the custom device will be specific to the patient anatomy.

The clinician must also provide preoperative imaging studies consisting of a computerized tomography (CT) scan and radiographs. Currently, almost all custom implants are generated from CT scan data to enable the design to match with the patient's anatomy. Therefore, a high-quality CT scan is crucial to creating a precise implant. The CT scan must include information beyond the region of interest to ensure the engineering team can successfully reconstruct the alignment and anatomy for implant planning. Engineers from the implant company reconstruct the anatomy from the CT scan through a process including image segmentation and computer-aided design (CAD) rendering. This rendering produces a 3D model of the pathological anatomy to be used for the preoperative planning and implant design process.

The orthopaedic surgeon works with the engineering team throughout the design process by providing the clinical perspective of how the implant will be utilized and the intended goal for reconstruction. This process typically takes place via a series of web-based meetings, in which the surgeon instructs the engineers on several aspects of the surgical plan including the repositioning of the 3D anatomy, indication of the surgical approach, identifying any bone(s) to be resected, and structures to be avoided. This process results in a 3D model of the anatomy which the engineers use to then design the anatomically matched implant. 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 printed device and needs for subsequent post-processing of the implant to ensure the success of the final parts.

The completed design is sent to the orthopaedic surgeon, in the form of a PDF, for approval. Alterations are made until the final design is approved by the engineering team and the surgeon. Once final, the implant is delivered to the hospital for sterilization. This process can be done in as little as two weeks if the case necessitates urgency.

This process to develop customized implants through 3D printing will continue to evolve as the technology continues to advance and as long-term outcomes become more readily available.

The AAOS supports the use of 3D printing by approved medical device companies in concert with orthopaedic surgeons and care teams to improve upon surgical technique and preoperatively plan for difficult surgeries. There is a need for more data on the safety and efficacy of 3D devices used as implants to facilitate patient and surgeon decision making around the use of these implants.

References:

1. <https://www.fda.gov/media/89897/download>

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Information Statement 1054

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