Improving Patient Care through Additive Manufacturing

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The medical industry has been one of the early adopters of additive manufacturing (AM) technologies. The primary reason behind this synergy is the industry's need for highly customizable high-value products. Orthopedic products lend themselves well to AM processes as their small sizes are typically well within the build envelopes of available equipment. While these devices are not mass produced, production volumes in the thousands require an efficient, flexible, and precise manufacturing solution. The ability to create components with new materials is also a driving factor.

An example is the use of Arcam AB's electron beam melting (EBM) technology to produce the acetabular cups used in hip replacements. Since 2007, over 60,000 acetabular cups have been manufactured using this electron beam powder bed fusion (EB-PBF) process and have been successfully implanted. In addition, by early 2013 over 6,000 additively manufactured spinal implants had already been used in surgery.[1] A suite of orthopedic devices built using EB-PBF is pictured in Figure 1.

Figure 1: Orthopedic devices built using EB-PBF New Design Capabilities

NEW DESIGN CAPABILITIES

The paradigm shift toward technologies that add material only where required, compared to conventional subtractive manufacturing processes, has led to entirely new design strategies. These strategies align well with the needs of the medical implant industry. It is now possible to build intricate shapes such as naturally optimized cellular structures that offer high strength-to-weight ratios, and to create objects with varying material densities.

Over the years, porous coatings have been used with medical implants to create the surface properties required to ensure bone ingrowth. However, these coatings are prone to adherence issues with the substrate, which may lead to poor biomechanical compatibility. AM enables the design and manufacture of components with integrated cellular structures that can closely replicate naturally occurring trabecular bone tissues. These structures improve osseointegration, the process that is necessary to build the required connection between living bone and an load-bearing artificial implant. (Figure 2).

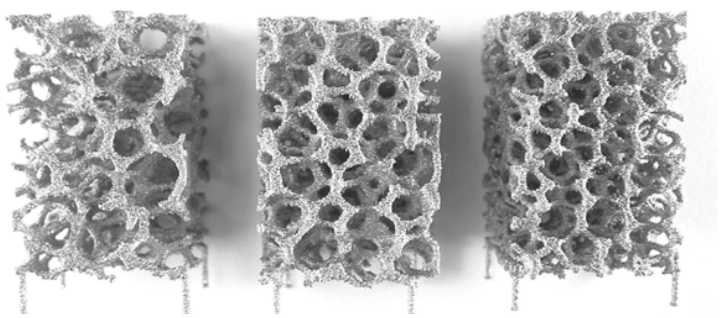

Figure 2: Open cellular foams designed from CT scan data replicating trabecular bone structures[2]

IMPROVED PATIENT OUTCOMES THROUGH CUSTOMIZATION

AM allows medical professionals to address the specific needs of their patients more efficiently. Today, doctors are able to study physical renditions of their patients before surgery. Computed tomography (CT) scans or magnetic resonance imaging (MRI) data can be used to create the three-dimensional (3D) computer-aided design (CAD) files required to additively manufacture customized medical implants such as hip and knee replacements, facial prosthetics, and skull plates. Such customization can reduce operating time, improve patient comfort, reduce failure rates, and potentially reduce the overall cost of surgery and recovery time.

MEDICAL-GRADE MATERIALS FOR ADDITIVE MANUFACTURING

Both plastic and metal AM materials have been used successfully in the medical industry. The dental industry, for example, is one of the major consumers of biocompatible plastic AM materials for physical renditions and temporary in-mouth placements such as aligners. Surgical cutting guides are also 3D printed using biocompatible plastics to ensure proper positioning during implant surgeries.

In the case of metal AM, the orthopedic and prosthetic industry is on the forefront. Ti-6Al-4V is the go-to material for medical implants due to its high resistance to corrosion and fatigue, high strength, and low stiffness. Each of these attributes improves the longevity of devices made from this titanium alloy. An example of a femoral stem made from Ti-6Al-4V is provided in Figure 3. Other biocompatible materials such as 316L stainless steel, cobalt chrome alloys, and tantalum are also being widely used to produce medical components with AM technologies.

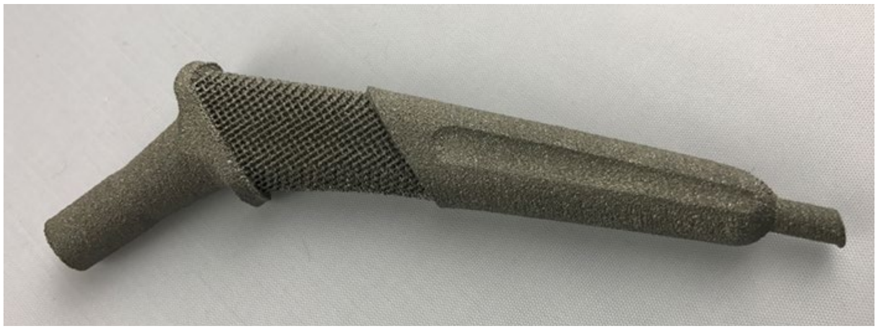

Figure 3: Ti-6Al-4V femoral stem manufactured using EB-PBF (Photo provided courtesy of Arcam AB)

Current medical-grade materials are optimized for traditional manufacturing processes that use casting and subtractive techniques. The next generation of medical-grade materials must be tailored to meet the requirements of AM processes such as laser and EB-PBF. This will help the medical industry leverage the benefits of AM such as improved microstructures and mechanical properties, bio-absorbability, bio compatibility, and the ability to closely replicate human bone structures.

MEETING THE CHALLENGES OF A HIGHLY REGULATED INDUSTRY

Since the medical device industry is so highly regulated, optimizing every aspect of the AM production cycle from powder source to post treatment is an ongoing challenge. In addition, rapid advancements in AM technology have increased the need for new inspection and qualification techniques to ensure the quality of additively manufactured medical devices. The U.S. Food and Drug Administration (FDA) is focusing on developing technical guidelines specific to devices built using AM techniques. These guidelines will focus on design and manufacturing, as well as inspection and testing.

EWI CAN HELP

Our experienced team can provide expertise at each step of the medical AM process cycle including design, materials development, technology selection, process optimization, and post-build inspection. Our facilities house a suite of cutting-edge capabilities across all seven AM technologies. In addition, EWI now also offers a customized, implementation-focused Advanced Manufacturing Implementation Strategy advisory service and planning tool, which can help manufacturers ensure that AM can be successfully deployed to create and maintain a unique competitive advantage. If you'd like to learn more about how EWI's experts can help you explore the potential that AM holds for your company, please contact us at **info@ewi.org.**

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[1]Retrieved from http://www.prnewswire.com/news-releases/4web-medical-announces-launch-of-3d-printed-posterior-spine-truss-system-300159449.html
[2]Murr et al. "Next-generation biomedical implants using additive manufacturing of complex, cellular and functional mesh arrays", Phil. Trans. R. Soc. A 2010 368 1999-2032, March 22, 2010. DOI: 10.1098/rsta.2010.0010.

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