Chapter 1

Introduction: Additive Manufacturing for Medical Devices

1.1 ADDITIVE MANUFACTURING FOR MEDICAL DEVICES – AN OVERVIEW

Additive manufacturing (AM) has been referred to as the "Fourth Industrial Revolution" (Ervin, 2023) for its benefits and applications to multiple industries. This description

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resulted, in part, from the ability to take different materials and "layer the material" or "add" material to the previous layer and "build up" to the desired end product, all originating from a computer-aided design (CAD) model. AM technologies allow the user to imagine and then create, with little to none of the constraints of traditional manufacturing, such as computer numerical control (CNC) and forging. The orthopedic industry has been dipping its toe into the AM space, but there are special requirements and potential pitfalls about which manufacturers should be aware prior to adopting AM. The enthusiasm of this technology is shared by clinicians, surgeons, scientists, and engineers and is evident by the volume of publications around AM and medical devices. Evidence for this can be found using typical internet searches. To date, there have been over 200 papers published that can be found with the search terms "additive manufacturing" and "medical devices," and there have also been multiple books published on this topic (Hitesh Lal, 2018).

The uniqueness and potential impact of this book is that it addresses all aspects of AM in the application of medical devices (orthopedics) and the complete design and life cycle of any implant system. The contents of this publication cover the benefits to the surgeon and, therefore, to the patient, which are always the central foci in any publication related to medical devices. Also covered by the authors are the types of AM equipment available, an important area of advancement in orthopedics, specifically the advancements of the past decade. Content included in this book also address design considerations and materials available to use for medical applications, both historically and recently. The following chapters address all aspects of AM that must be considered and tackled during the manufacturing process, including postprocessing, powder recycling, and facility requirements. Next, quality confirmation activities, including process validation (installation qualification [IQ]/operational qualification [OQ]/performance qualification [PQ]), powder recycling, and lot release testing are addressed with the latest known questions and concerns heard from many regulatory agencies. Lastly, this publication addresses regulatory pathways for medical devices and other technologies being used in parallel with AM to further enhance the performance of the medical device. The intention of this publication is to provide potential and current users with a practical and comprehensive introduction and overview of AM from design through end-market delivery.

1.2 ADDITIVE MANUFACTURING FOR MEDICAL DEVICES – THE BENEFITS AND DRAWBACKS

AM, as a technology to solve patient problems in the medical field, has already experienced an incredibly fast evolution and will continue to morph in the future. Initially, AM was also referred to as "Rapid Prototyping" (Prototal UK, 2022). Rapid prototyping allowed engineers to design, using one of many CAD software packages, what the surgeon partner was envisioning and then create a fast model to see if the physical model met the ideological solution. This speed in iteration of design saved a tremendous amount of time (saved time translates to saved money) in any product development cycle. This represents one of the many benefits of AM in medical devices (Vaishya, et al., 2018).

Initial applications of AM in the medical field, besides creating rapid prototypes, included manufacturing of instruments, guides, and anatomical models of patients with complex pathologies. The three-dimensional (3D) printed model allowed the surgeon to have a visual and tactile understanding of the patient-specific anatomy and pathology. The critical benefit of printing anatomical patient models allowed the patient to understand exactly what the surgeon would be navigating, called accurate preoperative planning before wielding a scalpel, and allowed the surgical team to plan a complicated surgery with more precision than had ever been previously possible. The obvious benefit from these 3D anatomical models includes reduced risk to the patient, including reduced surgical times, and an increased success rate in complicated surgeries.

The next big leap in AM medical applications was patient-specific orthopedic implants. Patient-specific implants followed anatomical models, with AM applications morphed into custom casts, splints, and prosthetics. Orthopedic companies have also used AM for standardization of products, including trauma plates, spinal implants, and components of hip and knee implant systems, as well as dental implants. However, it could be said that the largest positive impact of AM is patient-specific implants (Singh, 2024).

Patient-specific implants are created in three steps:

1. Accurate medical imaging of the patient's anatomy via magnetic resonance imaging (MRI), computed tomography (CT) scan, or other imaging technology that creates high-resolution data and a 3D model of the patient's anatomy.
2. Patient image postprocessing via digital imaging and communications in medicine (DICOM) that translates the data to a CAD software program via standard triangulation language (STL) format for the AM equipment to understand.
3. AM equipment prints, with biocompatible material, the implant that matches the individual patient's anatomy (Javaid & Haleem, 2018).

Thus, AM has design freedom to match the patient's specific and unique geometry. In other words, AM allows for complex geometries, which would be cost prohibitive by traditional manufacturing methods, to be created and used.

Additional benefits of AM in medical devices include some obvious and some unforeseen. The ability to have complete freedom in the design and then manufacturing of a device means that the density of the device can be changed from traditional titanium or cobalt chrome to match the density of the patient's surrounding tissue or be designed to be closer to that of healthy cortical bone. This also translates to the implant having less weight. In the case of spinal interbody fusion devices (IBFDs), a less-dense titanium implant translates to potentially less chance of endplate damage and subsidence. Printing a porous outer layer of the implant also aids in the promotion of bony ingrowth and fusion. Besides these benefits, the medical industry is witnessing unprecedented partnerships between companies that design and manufacture metal and polymer parts with software companies, as well as other strategic partnerships that had not existed previously.

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What follows is a summary of some of the more salient benefits of AM in medical applications (Javaid & Haleem, 2019):

- Unlimited geometric and design freedom to manufacturing
- Ability to design and manufacture patient-specific implants, including any anatomical defects
- Ability to design and manufacture desired material density
- Ability to design and manufacture to a desired lattice structure and/or surface roughness
- Cost savings for one patient-specific part vs. traditional manufacturing costs and timelines
- Overall shorter build times (for patient-specific parts)

As is often the case, when there are benefits, there also exist drawbacks. Although saving time usually translates to saving money, the cost of AM technology is very high. A total cost of using AM includes software, hardware, facilities, quality activities, as well as highly trained human resources. As the demand for AM technologies increases, there are limited options in the supply chain, and the industry has a shortage of relevantly skilled professionals, from design using AM benefits, programming, data translation, postprocessing, and quality activities, to regulatory and safety understanding (risk assessments). As AM technology continues to advance and become more common in practice, having the support structure and resources to maintain high quality and patient safety is imperative to the success of this industry application.

1.3 ADDITIVE MANUFACTURING – MARKET SIZE FOR MEDICAL DEVICES

With the evolution of AM in the medical industry, ensuring patient safety via high-quality assurance processes, robust risk assessments, highly skilled personnel, etc. is critical to the continued market growth. Why is this important? A headline in a news story stated, “Global Healthcare Additive Manufacturing Market expected to reach USD 9.9 billion by 2030 at a CAGR of 22.6%” (Research & Markets, 2022). Almost 10 billion dollars in less than 10 years from today. To put this in context, the same market was valued at USD 1.6 billion in 2021. Plato famously wrote, “Our need will be the real creator” (Plato, 2010), which was molded over time into the English proverb “Necessity is the mother of invention.” In the case of AM, patient outcomes and safety comprise the necessity, and AM technologies are creating inventions that are translating to a remarkable potential for market size and a healthy share in the total dollars spent yearly for manufacturing medical devices.

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