Advances and Prospects on Additive Manufacturing Used for Medical Implants

Yaocong Fan

College of Mechanical and Vehicle Engineering, Chongqing University, Chongqing, 400044, China

20213042@cqu.edu.cn

Abstract. Additive manufacturing (AM) is commonly used in the automotive, medical, and aerospace industries. With people concentrating more on healthcare, AM technology provides a more complex and free product structure, a growth spike in the application of AM can be seen in this field. Therefore, this paper focuses on a specific field of the medical industry, implants. This paper focuses on the latest improvements in AM used for implant production. Based on the relevant research reported on the Web of Science and Elsevier over the past five years, this article introduces the principles of the most widely used 3d printing technology for implant fabrication. It discusses the reasons for their successful use in this field. The existing typical technical routes and their advantages and limitations are summarized. This research also shows the latest advancements in those technologies. Based on their current characteristics and situations, this study gives some suggestions about potential further improvements and development prospects. This study provides an in-depth analysis of AM in the field of implants in the industry and points out the development direction of AM in the medical field in the future.

Keywords: AM, Implants, Biomaterials.

1. Introduction

AM, which is known as 3D printing, uses 3D model data to join materials into a part, usually building layer upon layer with the assistance of computer software [1]. This is a special way of adding materials to form a product. In the last five years, AM has been commonly used in different areas especially the medical industry, because compared with traditional manufacturing technologies, AM provides a complex and customizable manufacturing process to adapt to the personal and unique needs of patients. Currently, AM is widely used in different aspects of the medical field such as dental applications [2], the fabrication of tissue engineering scaffolds, implants in different parts of the body, prostheses, drug delivery systems, and so on.

There are seven different categories of AM [1] that are shown in Fig.1. These technologies not only provide users with complete design freedom as the products can be customized for use, prototyping, and manufacturing rapidly, but also minimize the wasting rate (for lower costs), and ultimately a more streamlined manufacturing and distribution network [3]. However, for different materials, different technologies show different performances. For example, material extrusion (ME) and powder bed fusion (PBF) show better performances with polymers and metals, while the materials used in material jetting (MJ) and VAT photopolymerization (VP) must be in a liquid state [4]. In the medical field, especially for implants, the materials and the structure of implants lay solid foundations for their performances, as the implants refer to devices that are grafted into the body, either permanently or temporarily to perform their designed functions.

In addition, the use of AM in the field of medical implantation will reduce matching (patient and compatible transplant organs) and operative time, improve precision, and prepare instruments and clamps suitable for the individual patient in advance. Moreover, the manufacturing cost of customized implants is more affordable and easier to satisfy the requirements of patients than traditional methods.

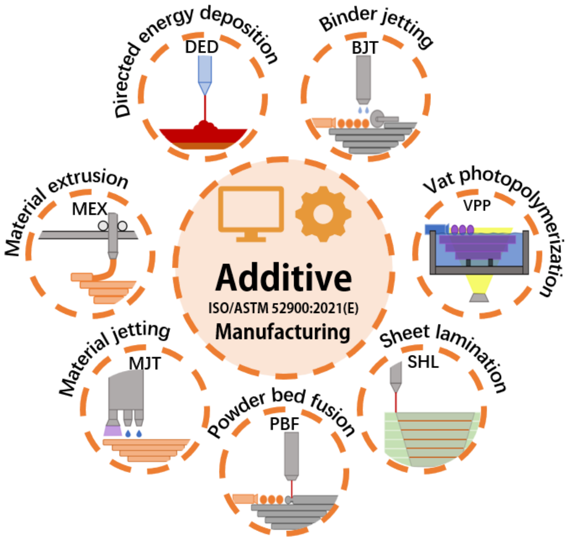

Figure 1. AM classifications (Photo/Picture credit: Original)

Many articles lay emphasis on the application of AM technologies in the medical industry. However, there are a few of researches in the field of implants. This article reviews the latest research on the AM technologies that are being used to improve the performance of implants.

2. Application of AM in the Implant Field

3D printing technologies are commonly used to fabricate clinical implants. This procedure facilitates the fabrication of bespoke implants tailored to the distinct anatomical characteristics of individual patients, thereby enhancing integration and functionality within the physiological context. In addition, 3D-printed products can better control the microstructure and mechanical properties of the implant, so medical professionals can achieve better clinical outcomes. The common processes of using 3D printing to build personal implants are as follows:

1) Collect patient-specific data by using imaging technologies such as computed tomography (CT), magnetic resonance imaging (MRI) or 3D scanner

2) The patient's anatomy is represented by constructing a 3D model using the acquired image data. This model is typically generated in Digital Imaging and Communications in Medicine (DICOM) format. The DICOM file is then analyzed and converted to stereolithography (STL) format

3) The process involves importing STL files into design software to create the initial CAD model of the implants. Following this, the CAD model is optimized by software to ensure the implant meets specific mechanical and material distribution requirements

4) The 3D printer generates the implant layer by layer based on the sliced model files. After the post-processing, mechanical, and biocompatibility testing, the implant is surgically implanted into the patient’s body

Among the many 3D printing technologies, PBF is the most suitable for the production of metal and polymer implants. PBF is not only able to process a wide range of metal powder materials but also to manufacture complex geometric shapes with high precision. There are four main types of PBF: Selective Laser melting (SLM), Selective laser sintering (SLS), Electron beam melting (EBM), and laser direct metal deposition (LDMD). The following parts focus on the first three methods of PBF and their applications in producing implants.

2.1. SLS and SLM

SLS is an additive manufacturing technology based on molten powder. Before the printing, the powder bin and the build platforms are typically preheated to a temperature slightly below the material's melting point. During the printing process of each layer, a powder-laying device such as a roller or scraper relays powder into a thin, uniform layer. Then, under the guidance of the vibrating mirror, the powder layers are scanned by the laser beam based on the pre-set pattern, and the particles bond to each other to form a solidified cross-section. The high melting point material in the SLS process is bonded between particles using either a low melting point binder or low melting metal powder, rather than being melted itself. While in the SLM process, the laser completely melts the powder without the need for adhesive. When one layer is finished, the building platform is lowered in preparation for the application of the subsequent layer of spread powder. This process is repeated, layer by layer, until the entire three-dimensional object is built [5]. Fig. 2 shows the process of SLS production. As a straightforward manufacturing technique, SLS eliminates the necessity for supplementary support structures throughout the printing procedure. as the unsintered powder can be used as a support structure. However, SLM has a better performance than SLS in surface quality and mechanical properties, as it does not need the adhesive.

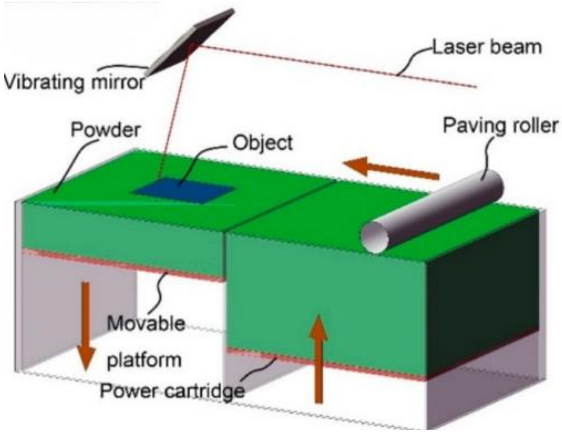

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Figure 2. Schematic of SLS machine [5]

In addition, SLM can handle a wider range of metal materials. Metal implants produced by these two processes show better mechanical performances than traditional manufacturing methods. SLS is also widely employed for 3D printing ceramic powders and polymers, including materials such as polystyrene, polyamides, and thermoplastic elastomers [6]. Ceramics fabricated using SLS generally exhibit lower density and higher porosity relative to cast ceramics, even after undergoing subsequent sintering post-treatment [7].

Han et al. [8] employed SLS to fabricate composite scaffolds of polycaprolactone (PCL) with varying borate bioactive glass (BBG) concentrations. Their study revealed that the BBG/PCL composite scaffold containing 20% BBG, significantly enhanced osteoblast proliferation. In addition, these scaffolds maintain sufficient mechanical strength to ensure structural integrity when repairing critical-size bone defects (CSBD).

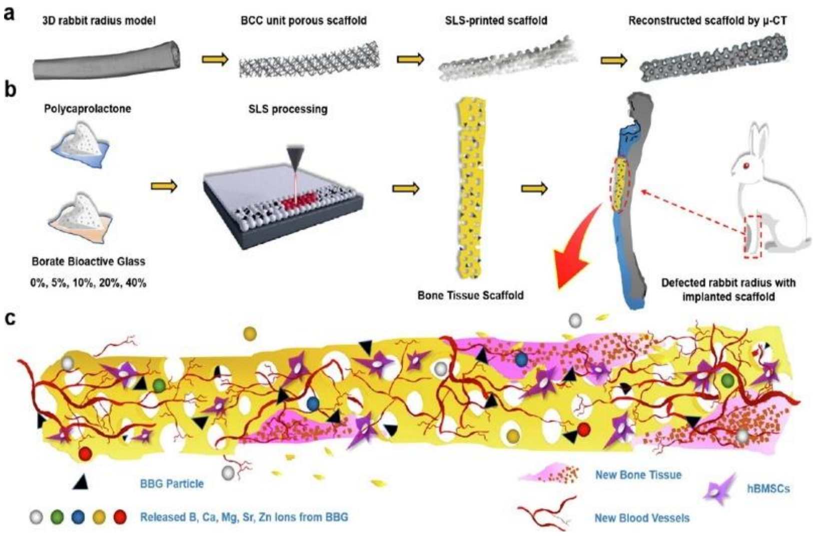

Figure 3. Process of repairing critical-sized radius bone defects in rabbits [8]

Fig. 3 shows the process of using SLS to print scaffolds to repair radius bone. Results prove that compared with traditional manufacturing methods and other 3D printing technologies, the size and structure of scaffolds produced by SLS are the same as the shape and size of the rabbit's missing radius, and they also show fully interconnected internal porous structures in all directions.

Pandav et al [9]. used SLS to design and manufacture hollow capsule shells (HCSs) with common capsule sizes in the market, and verified the sinter property and feasibility of SLS-mediated sintering technology to draw HCSs. Fig. 4 illustrates the process of printing an HCS by SLS. At the same time, different sizes of HCSs have different maximum filling capacities, capable of delivering drugs from 240mg to 10mg. They also demonstrated through experiments that all sizes of HCSs have excellent mechanical properties and improved release characteristics.

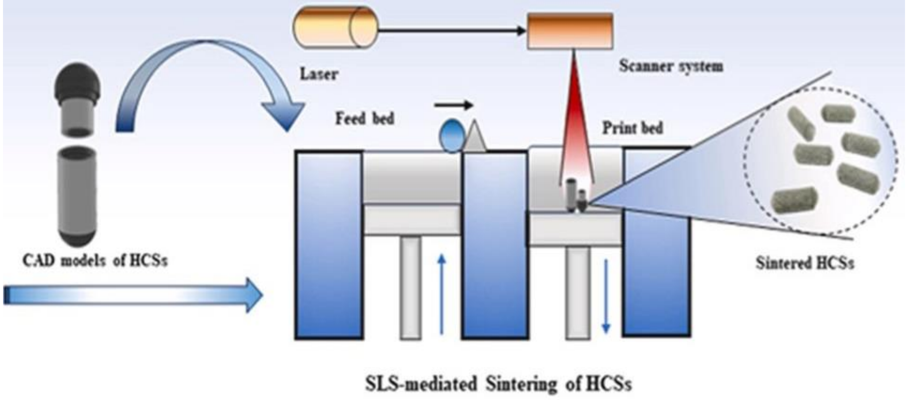

Figure 4. Process of producing hollow capsule shells [9]

During this research, SLS technology demonstrates its ability to selectively sinter mixed materials together. Hybrid printing of two thermoplastic pharmaceutical-grade polymers shows the original properties of the material. Their next step may be to try to evaluate the breakdown and dissolution profiles of SLS-mediated 3D-printed HCSs.

On the other hand, SLS leads to isotropic material properties, which limits the choice of the material types, and restricts the use of this method. In addition, both SLS and SLM need postprocess cleaning and have a crucial requirement of the environment to prevent oxidation. Besides those, they are expensive and time-consuming.

2.2. EBM

EBM is another widely used AM technology applied for orthopedic metal implants. It is particular for metal, as most plastic and ceramic materials are not electrically conductive [5]. Fig.5 shows the EBM operating process. EBM technology uses high energy and speed electron beams to bombard metal powders, melting them and stacking them layer by layer to form products. The electron beam is emitted by a filament heated at above 2,500C, accelerated through an anode. The trajectory and focal point of the electron beam are meticulously regulated through a system of electromagnetic coils. Compared with SLS and SLM, the high-energy electron beam of EBM facilitates the creation of a localized vacuum environment. Before melting, the powder particles fall from the hopper due to gravity to form a flat powder layer and preheat to improve the molding quality. The electron beam also has high energy efficiency and high material absorption, the vacuum environment and high-temperature melting allow EBM printed parts to have high density, superior strength, and minimal risk of deformation [10]. Printed productions also have low residual stress due to the preheating step and vacuum environment. Although the surface of EBM printing can be rough, this roughness is beneficial for medical applications and helps in bone integration of the implant.

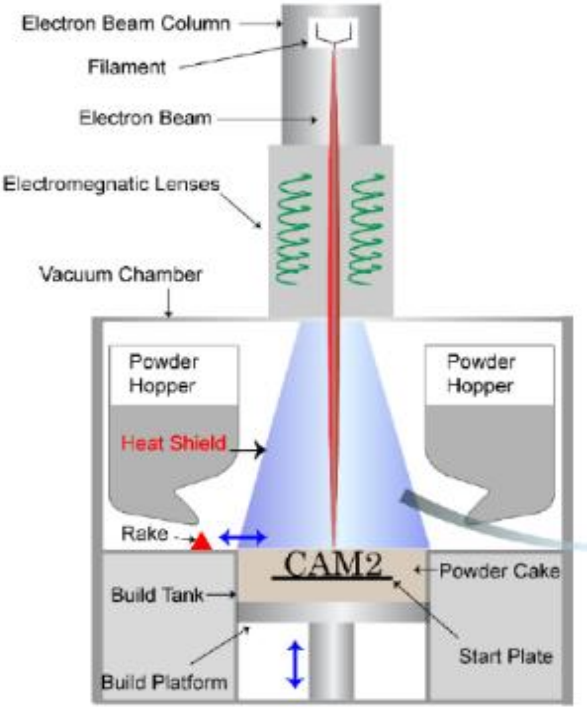

Figure 5. Schematic of EBM machine [11]

However, due to the vacuum environment, the time to cool down the implants in EBM could be longer than that in SLM. In addition, fabricated implants adherent a substantial quantity of partially melted particles, adhering to them, similar to the surface characteristics found in SLM technology [12]. Besides, it also has shortcomings such as low precision and expensive equipment that need improvement.

EBM technology is commonly used in the production of implants with porous structures and mechanical characteristics that match the anatomical structure because of its ability to precisely control the melting and solidification of metal powders, allowing the creation of complex geometry and fine lattice structures. The high-energy electron beam in EBM enables the fabrication of implants with customized porosity, which is essential for promoting bone integration and enhancing the implant's mechanical compatibility with bone tissue.

Festas et al. [13] produced Functional hip prosthetics cones using Ti alloy by EBM technology and evaluated their machinability and functionality relative to wrought titanium. They found that the specific cutting force of titanium produced by EBM is approximately 20% lower than that of wrought titanium. Compared with forged titanium, EBM showed lower machining force, albeit with slightly higher roughness values, indicating similar or favorable machinability. Although a broader range of workpiece configurations and tool geometries need to be utilized in the same machining evaluations, their work has successfully proven that EBM samples are superior to forged samples in machinability, and for finishing operations, EBM products are suitable for applications requiring precise surface textures or finishes. Hybrid manufacturing and its potential applications also underscore the significance of EBM in medical fields.

Wu et al. [14] used EBM to produce porous implants with Voronoi and randomized structures and performed tensile, shear, and wear tests to evaluate their mechanical properties. The schematic images of the model and its object are shown in Fig. 6. The result shows that compared with randomized structures, Voronoi structures show higher mechanical strength than random structures, which is attributed to Voronoi structures having a uniform pore size distribution and radially oriented pore geometry. Due to the sample size and boundary effect, the stress distribution of random structure is not uniform, leading to a strength decrease.

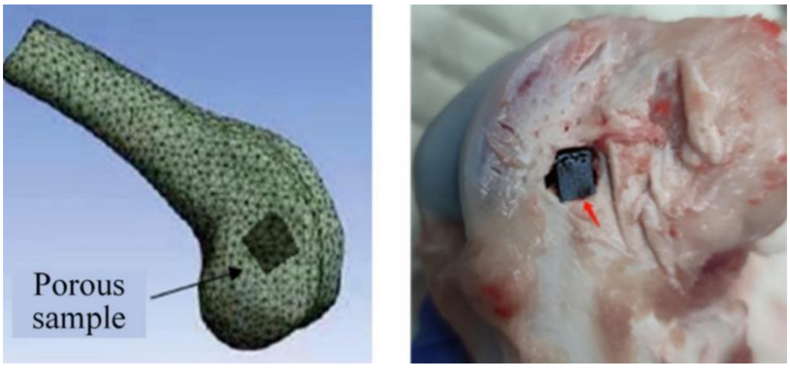

Figure 6. Schematic images and porous implants for dog femur [14]

What's more, Voronoi structures also show a higher bone ingrowth ratio, making it easier for bone cells to grow. Regardless of the porous design, pillar thickness is only related to manufacturing resolution, and EBM provides more detailed porosity. The next step of this research may focus on prioritizing pore structure and size to improve its mechanical properties and biocompatibility.

2.3. Other AM technologies

Other AM technologies that are commonly used in producing implants are laser direct metal deposition (LDMD), and fused deposition modeling (FDM). The operational principle of LDMD, akin to SLS technology, involves additive manufacturing techniques where the material is incrementally deposited to form objects that use gas assistance to transport metal powder to a molten pool formed by a laser on a metal substrate to generate a sedimentary layer. 3D parts are produced by adding multiple layers. The LDMD coating process is capable of creating robust metallurgical bonds between diverse materials, like titanium and Co-Cr alloys. LDMD technology offers controllable surface characteristics that can achieve an optimal porous surface with maximum porosity, desired pore size, and optimal roughness. LDMD can produce a porous structure resembling human cancellous bone while preserving mechanical strength, thereby enhancing mechanical stability. [15]. Ryu et al [15]. also found that whether in vitro or in vivo, applying LDMD to produce a titanium porous coating on cobalt-chrome alloy, does not induce chronic inflammation. which shows the biocompatible characteristics of this technology. However, during laser irradiation, the metal exists in a liquid state, resulting in challenges in regulating the distribution of particles within the bulk after solidification. Additionally, significant thermal gradients can lead to issues such as cracks or pores, which are common in LDMD part printing.

FDM also known as Fused Filament fabrication, utilizes thermoplastic materials to fabricate structures. The core concept of FDM includes regulating the extrusion of thermoplastic filament through nozzle heating. The thermoplastic filament is methodically delivered into the extruder head where it undergoes heating to reach a precise temperature. Upon reaching the molten state, the filament is extruded through the nozzle and deposited onto the printing bed in a sequential, line-by-line manner, initiating the formation of the object. The extruded filaments rapidly cool, solidify, and adhere to the printing bed. This layer-by-layer deposition continues until the complete object is meticulously constructed according to the design specifications.

3. Discussion

AM technology can be flexibly applied to the production of personalized implants. Different processing methods can process a variety of materials and realize the fusion processing of a variety of materials, and the printed products can fully reflect the excellent characteristics of different materials, such as good biocompatibility, appropriate mechanical strength, good rigidity, and provide a bionic environment for cell attachment. In addition, 3D printing technology makes it easier to create porous structures with adjustable porosity than traditional manufacturing methods, and it is easier to promote the effective integration of implants and human tissues. Secondly, the AM method of medical implants reduces the waiting time and can quickly meet the individual needs of patients. At the same time, 3D printing technology helps surgeons to clearly understand the clinical situation in advance, and targeted pre-surgical training to increase the probability of successful surgery and reduce the operation time. At the learning level, 3D-printed parts help medical interns have a better understanding of the disease. Table 1 summarizes the materials, advantages, applications, and limitations of the main methods of AM mentioned before.

Table 1. Different classifications of 3D printing methods for implants

Technology	Suitable materials	Advantages	Applications	Limitations
SLS	Medical grade nylon Ceramic Polymeric material	Complex geometry High material utilization, the unsintered powder can be reused	Customized bone replacements and surgical guides	Limited variety of materials Requiring post-printing process Weak mechanical properties
SLM	Ti and Ti alloy cobalt-chromium (Co-Cr)	High strength High density Higher accuracy than SLS (0.02 mm)	Hip and dental implants Functional parts with high-added value	High cost Low speed Post-treatment (e.g. heat treatment) is required to release stress
EBM	Ti and Ti alloy Co-Cr nickel-based alloy	Low residual stress high surface quality and accuracy High forming efficiency	Hip, knee, and spine implants	Poor surface finish and requires the post-printing process Expensive equipment Time-consuming
LDMD	Almost all metal alloys	Suitable for manufacture and repair of large structural parts Simultaneous processing of multiple materials	Large metal implants Surgical tools	Poor surface roughness Less accurate Expensive equipment
FDM	Medical grade PLA, ABS, PETG Biocompatible composites Thermoplastic materials	Low cost High speed Simplicity	Surgical guides and temporary implants Advanced composite parts	Weak mechanical properties Limited materials Warping and deformation of components

4. Limitation and Future Scope

While AM enables structural printing of almost any geometry, parts such as overhangs that do not use support structures cannot be directly produced using 3d printing, and additional support is added, which also means additional surface roughness processing steps. In addition, the largest portion of the cost of AM of patient-specific medical devices is the cost associated with the design, not the cost associated with the manufacturing process. Another limitation of the technology is the time cost. The time required is variable from patient to patient, not only depending on the patient's condition, but also depending on the type of data collection, data analysis, and process selection.

In the future, 3D-printed parts could be used to simulate different medical conditions and be used in the education industry to train doctors. At the technical level, the time cost and economic cost of 3d printing should be reduced to maximize its efficiency. At the same time, it tries to maintain good surface roughness while printing models with more complex structures and reducing the residual powder adhesion on the surface.

5. Conclusion

This article first affirms the advantages of AM technology over traditional manufacturing technology in the field of medical implants. Through the analysis of several of the most used additive printing technology processes and the latest practical applications, the potential of AM for future applications in the medical field is demonstrated.

AM is a manufacturing method that quickly generates 3D objects from digital models, especially for the implant field. This technology has found widespread use in the field of medical implants, enabling customization based on the unique disease characteristics of each patient, resulting in personalized and suitable implants. The patient's waiting time and operation time are reduced, and the success rate of operation is increased. For SLS, it can produce complex geometry structures and rough surfaces, with a high materials utilization. SLM provides a higher accuracy and the products commonly show high strength and high density. EBM is often used to manufacture complex geometric structures with high surface roughness but high material utilization. LDMD provides higher precision, and its products typically exhibit higher strength and density. In FDM, the product typically has lower accuracy and strength but is suitable for rapid prototyping. This technology will have potential in multiple areas of healthcare and will reduce treatment costs and improve treatment efficiency. However, those technologies are not possible to directly produce parts that do not use support structures (such as overhangs), requiring additional support, resulting in increased surface roughness processing steps. In addition, the largest cost of AM for custom medical devices in time and manufacturing needs to be taken into consideration seriously.

This study only focuses on the several technologies that are commonly used for implant production, there are many other kinds of methods that perform well in this field but do not take count. By incorporating these diverse approaches into future investigations, researchers can uncover new possibilities for improving implant design, manufacturing processes, and clinical outcomes. Furthermore, comprehensive studies on these alternative methods could pave the way for innovative solutions that address current limitations in implant technology, such as material strength, integration with biological tissues, and personalized implant fabrication. future research should broaden its scope to include a comprehensive exploration of emerging methods.

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