Additive Manufacturing and Topology Optimization in Orthopedic Implants

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Abstract. Compared with traditional manufacturing methods, additive manufacturing (AM) has many advantages in the realm of orthopedic implants, including facilitating the creation of anatomically matched devices and surgical instruments by using the patient's medical image data, manufacturing complex geometric structures, and creating engineered porous structures and internal support structures. The combination of AM with CT or MRI imaging technology has showed great benefits when the patient's bone geometry is not within the specifications of a standard-size implant, or only when a customized solution can deliver better clinical results for the patient. This paper summarizes the AM technology and its application in orthopedic implants, which will be of broad interest to medical researchers.

Keywords: 3D printing, topology optimization, orthopedic implants.

1. Introduction

1.1. Principle of AM Technology

AM technology is commonly known as 3D printing technology, which is also called rapid prototyping technology [1]. Based on digital model files, it uses powder metal, plastic, or other adhesive materials to create three-dimensional entities by stacking and accumulating the material layer by layer. Unlike traditional material technology, AM technology does not utilize factory production and can quickly prepare personalized implants for patients, which may shorten the production cycle and save time and space. However, the production cost is still very high, and it is difficult to find printing materials with favorable biocompatibility and biomechanical properties [2]. Generally, AM technology is based on different forming principles, including layered solid forming, melt deposition forming, stereoscopic light curing forming, and selective laser sintering, which will be discussed in detail in the following parts.

1.2. Advantages of AM Technology in the Application of Bone Defects

It is of great significance to expeditiously reconstruct the topology optimization design according to the requirements of additive manufacturing [3]. In order to combine topological optimization and additive manufacturing, the current research mainly focuses on material structure integration and structure process integration. As shown in Figure 1, the personalized manufacturing capability of AM technology is strongly powerful in multi-scale structural design. The tiny lattice structure not only has lightweight and high strength, but also shows excellent thermal insulation, impact resistance, shock absorption, and noise reduction. The multi-scale structure can reasonably design the material layout from both macroscopic and microscopic scales, and easily achieve lightweight [4].

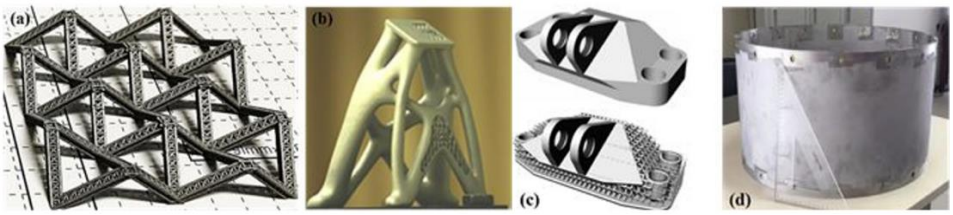


Fig. 1 Scheme of Additive Manufacturing [3]

2. Method

2.1. Product Requirements

The primary goal of the manufacturing process for orthopedic implants is to meet the requirements of patients, which differ from each clinical case and must be defined throughout the development of the product in terms of functionality, geometry, materials, and fixed interfaces.

2.2. Design Process

The design process for AM orthopedic implants is based on reverse engineering principles and the clinical condition of each patient. The imaging data is collected from different angles using medical imaging techniques such as computed tomography CT and MRI [8], and then processed by software algorithms, which may reconstruct a virtual 3D model to accurately reflect the patient's condition. For custom prostheses, the 3D model is used for designing of the implant and determining its structural characteristics, such as implant size, material, osteotomy location, and implant fixation with bone. In addition, it is necessary to draw up a surgical plan and design the corresponding special surgical instruments, and consider the structure design and residual powder removal.

2.3. Production Process

In order to ensure the safety and effectiveness of the products, production quality management standards should be established, to fully verify the product performance for the product quality. At present, ISO, ASTM [9], and other standardization organizations are developing standards for additive manufacturing materials, equipment, environment, process, and product verification, some of which have already been published.

Topology optimization design (integrated structural process design) in AM technology is another kind of research focus, including the consideration of the feature size constraints, connectivity requirements, and hanging angle constraints. Due to the limitation of forming accuracy of AM equipment, it is necessary to control the small branching structure generated by topology optimization. For the topology optimization methods based on the density method and the level set method, the researchers proposed density filtering technology and explicit size control technology to achieve the feature size constraint.

2.4. Post Processing

The post-treatment of the product must be performed in a manner that meets previously identified product requirements with adequate process validation, the way of which depends on the product design, materials, and AM process. For example, heat treatment of metal material can reduce residual stress, remove residual powder of porous structure, and clean processing AIDS in the subsequent machining process.

Due to the residual uncured resin, unmelted powder and auxiliary support need to be removed after AM forming to confirm that there are no closed cavities. The researchers have proposed the virtual temperature field method, the selective generation channel method, and the characteristic cavity center external method. In order to reduce or even eliminate the auxiliary support structures, the design of self-supporting structures has attracted extensive attention. On one hand, the form and print direction of support structures are optimized. On the other hand, the overhanging Angle constraint is introduced to topology optimization to fundamentally eliminate the support structures.

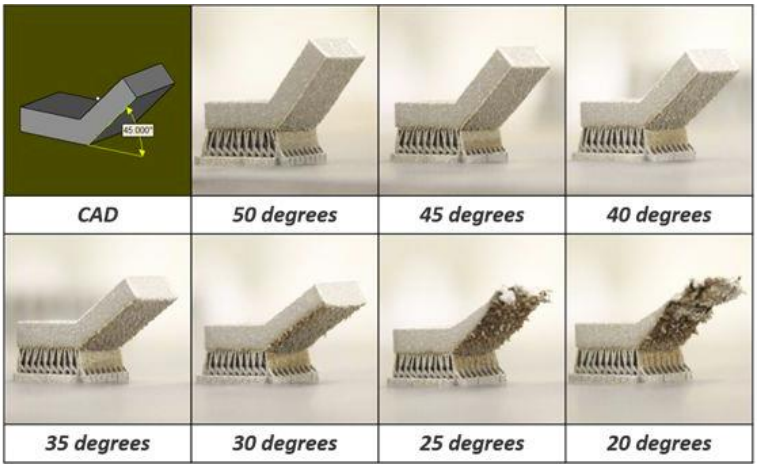


Fig. 2. The forming quality of AM drops with the decreasing of the hanging angle [3]

3. Simulation Case Studies

3.1. Knee Prothesis

Due to the difference in the anatomical structure of each patient, the standard knee prosthesis may have incomplete coverage of the distal femur and poor rotational alignment of the tibial side. These problems can be addressed by increasing the product size and anatomical tibial plateau. ConforMlS Inc. obtained FDA approval for ConforMlS Inc.'s custom knee prosthesis, which uses patient imaging data (CT or MR Scans) through proprietary software to design knee prostheses. Meanwhile, surgical instruments are specialized to meet the geometric and anatomical requirements of a specific patient's knee. After the design model of the knee prosthesis was constructed, the wax mold was printed by AM technology and then used to cast the cobalt-chromium-molybdenum femur and tibia components of the knee prosthesis. At the same time, special surgical tools are designed according to the surgical plan and the patient's anatomical data, such as the guide plate to achieve alignment, positioning, and osteotomy functions, so as to reduce the number of tools and trays and simplify the surgical process.

3.2. Inter Body Fusion Apparatus

Due to the small product size, complex structural design, and the porous surface structure of the inter body fusion device, AM technology shows its advantage as an efficient method. It can introduce a porous structure into the inter body fusion cage, which may decrease the elastic modulus to reduce stress shielding, and facilitate bone growth to increase its stability.

Orthopedics has received FDA approval for 3D-printed bone fillers used for internal foot and ankle fixation. AM technology accompanied with patient CT imaging data is suitable for internal fixation of foot and ankle fractures and osteotomy.

4. Existing Problems

With the development of AM and topology optimization technology, there are some new problems and challenges. The problems include the scale correlation of the lattice structure, anisotropy in AM materials, structural fatigue, and the difficulty in manufacturing functional gradient materials.

In the design of multiscale lattice structures, homogenization theory is often used to find the relationship between the microstructure and macroscopic properties. However, the homogenization theory is based on the scale separation hypothesis. It is difficult to accurately describe the mechanical properties of AM lattice structures. Therefore, it is necessary to construct methods, such as the substructure method and the multi-scale finite element method, to characterize the scale correlation effect (as shown in Figure 2). In addition, although the modelling based on beam elements can reflect the scale correlation effect, the location of the beam joint usually produces material volume and

stiffness errors. Therefore, the establishment of the universal compensation method is important to improve the accuracy of beam element lattice analysis. In the process of AM overlay forming, uneven heat dissipation results in different solidification/crystallization/bonding rates of materials in different directions, leading to inhomogeneous microstructure and mechanical properties of materials, as shown in Figure 4a, which is also a new challenge for structural topology optimization design.

Accurately characterizing the mechanical behaviour of forming materials is essential to ensure optimal performance. Based on the transverse-isotropic material model, it is possible to design structures with improved performance by taking full advantage of their homogeneity. Additionally, in the process of additive manufacturing, there are numerous unmelted areas and porosity defects (as shown in Figure 4b), which may lead to weaker fatigue performance of the resulting structural parts when compared to corresponding forgings (as shown in Figure 4c). In addition to the usage of heat treatment (such as hot isostatic pressing) to improve fatigue performance, the fatigue performance index should also be introduced into the structural design to develop a fatigue performance-oriented topology optimization method.

Finally, the functional integration system of graded materials and multi-material structures has wide applications in engineering, but its optimal design is still a challenge. On one hand, the development of multi-material topology optimization technology provides new content for the design of functionally graded materials, allowing for the optimal layout of different materials based on external load conditions. On the other hand, multi-material additive manufacturing (MMP) is the most ideal method for preparation of the functionally graded materials, but the fusion mechanism of different materials, forming process constraints, and other problems are still need to be further studied.

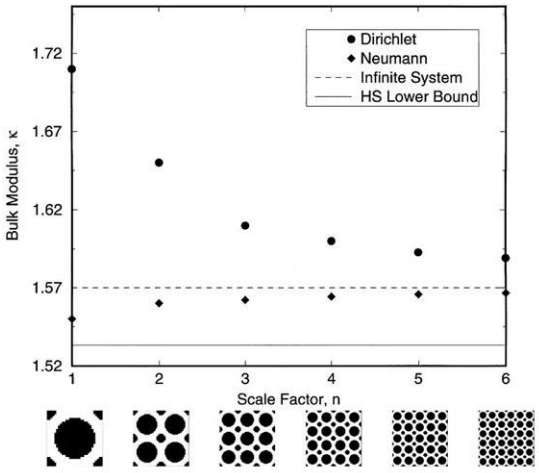


Fig. 3. Effect of lattice structure scale factor on volume modules [3]

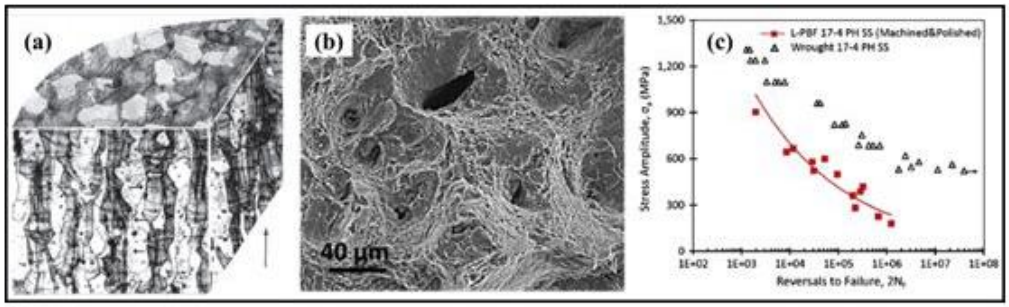


Fig. 4. Mechanical properties od additive 17-4 PH stainless steel [3]

5. Conclusion

Although topology optimization and additive manufacturing have been investigated for more than 30 years, deep integration of the two fields is still difficult. There are still many challenges in the mechanism and technology. Especially, in the accurate characterization of complex lattice

configuration, advanced manufacturing technologies still need to be developed, such as the multi-axis additive manufacturing system, material structure process integration, and the complex multi-material structure function integration system.

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