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Advances in Topology Optimization-driven Additive Manufacturing in Medical Implants

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Abstract. Traditional medical implants are difficult to meet personalized medical needs due to mismatched mechanical properties and insufficient biocompatibility. The combination of topology optimization and additive manufacturing provides new ideas to solve the above problems. In this paper, we discuss the technical paths and results of the combination of the two in enhancing the mechanical properties, biocompatibility and permeability of implants: the optimal distribution of materials is achieved through topology optimization, and combined with the complex shaping capability of additive manufacturing, it effectively improves stress shielding, promotes cellular integration and bone regeneration, and optimizes the material transport. Currently, this technology has problems such as a difficult balance between mechanical properties and biological functions, insufficient clinical trials, high cost and low algorithmic efficiency, etc. In the future, it needs to be combined with metamaterials and AI technology to promote its development. This research holds significant promise for advancing personalized medicine by enabling the design and fabrication of highly customized implants that better mimic natural bone structures, thereby improving patient outcomes and reducing complications.

Keywords: Topology optimization, additive manufacturing, implants

1. Introduction

In recent years, there has been a significant shift in the global medical community towards personalized medicine. This change stems mainly from the realization that the conventional, manufactured approach in healthcare often fails to meet the unique physiological and pathological characteristics of each patient. The quest for personalized treatment has become one of the most hotly debated topics in modern medicine, as it holds the promise of improving treatment outcomes, reducing complications, and enhancing patients' quality of life.

Medical implants play a critical role in the treatment of a wide range of conditions, from orthopedic disorders to cardiovascular disease. However, conventional implants often face challenges in meeting the complex needs of the human body. For example, in orthopedics, a mismatch between the mechanical properties of implants and natural bone may lead to stress shielding, which over time may trigger bone resorption and implant loosening [1]. In addition, ensuring the biocompatibility and permeability of the implant is a major concern, as any adverse reaction in vivo may have serious consequences for the patient.

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The emergence of additive manufacturing technology has brought about a revolutionary breakthrough in the personalized manufacturing of medical implants. By stacking materials layer by layer, this technology is able to create complex-shaped implants that are highly compatible with the human anatomy, directly based on the patient's medical image data, which significantly improves the suitability of the implants. In addition, additive manufacturing can flexibly use a variety of materials such as titanium alloy [2], medical stainless steel [3], and bioceramics [4], which provides more possibilities for optimizing the biological properties of implants. However, single additive manufacturing technology still has obvious shortcomings. Its fabrication accuracy and performance tuning largely depend on the experience accumulation of process parameters, and it is difficult to realize the optimal distribution of materials inside the implant under complex loading conditions.

The introduction of topology optimization technology provides key support for solving the above problems. By establishing a mathematical model, topology optimization can automatically optimize the material distribution according to the loads and constraints in a given design space, which can realize lightweight design and effectively improve the mechanical compatibility of the implant under the premise of guaranteeing the structural performance. The combination of topology optimization and additive manufacturing can not only give full play to the advantages of complex structure forming of additive manufacturing, but also realize the synergistic optimization of structure, performance and function of implants with the rational design capability of topology optimization, so as to break through the performance bottleneck of a single technology.

This paper focuses on the technical path and research results of the combination of topology optimization and additive manufacturing technologies in enhancing the mechanical properties, biocompatibility and permeability of implants. By systematically combing the related research, it reveals its regulation mechanism on the key properties of implants.

2. Topology optimization-driven additive manufacturing technology

Topology optimization and additive manufacturing technology, by virtue of their unique advantages, have shown application potential in some fields and started to practice, for example, in the aerospace [5], automotive manufacturing and other fields, the topology optimization of the design of the complex lightweight structure with the aid of additive manufacturing can be efficiently produced to achieve the structural properties of the structure and the manufacturing efficiency of the double enhancement [6]. However, the synergistic application of the two is still facing many technical bottlenecks, such as the manufacturability of the topology optimization results has not yet been completely solved, and there is often a disconnect between design and manufacturing in actual production. In addition, compared with the extensive application and in-depth research in the above fields, the exploration of topology optimization-driven additive manufacturing in the biomedical field is still insufficient. Although some studies have been conducted in the direction of orthopedic implants, no systematic solutions have been developed to address the key issues of biocompatibility under complex physiological environments of the human body, the mechanical properties of implants for long-term service in the body, and the balance between personalized needs and large-scale production, which highlights the necessity and urgency of further exploring the synergistic application of the two in the field of biomedicine.

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3. Topology optimization driven additive manufacturing technology in biomedicine

3.1. Aiming to improve mechanical properties

In the context of personalized medical implants, the precise matching of mechanical properties is the key to ensuring the long-term stability of the implant in service. The mechanical properties of human bone are extremely unique, and parameters such as modulus of elasticity and strength may vary depending on the individual and the location of the bone. For example, the elastic modulus of cortical bone is usually in the range of 10 - 30 GPa, while that of cancellous bone is in the range of 0.1 - 10 GPa [7]. Conventional implants, which generally have a homogeneous solid structure, tend to have a much higher modulus of elasticity than human bone, which is susceptible to stress-shielding effects. Naghavi et al. found that femurs with PEEK implants (optimized additively manufactured implants) showed a more natural stress distribution compared to femurs with Ti6Al4V implants (conventional implants), and that the proximal end of the femur with Ti6Al4V implants showed stress-shielding effects. The proximal femur showed a 68% increase in stress shielding compared to only about 20% in the case of the PEEK implant [1]. This study demonstrates that topology optimization-driven material selection (PEEK instead of high-modulus titanium alloy) in combination with additive manufacturing significantly improves the stress distribution around the implant. The drastic reduction of the stress shielding effect (from 68% to 20%) implies that the optimized PEEK implant better mimics the mechanical environment of the bone, facilitating osseointegration and long-term stability, addressing the core shortcomings of traditional implants in matching mechanical properties. Topology optimization technology is able to achieve precise layout of implant materials with the help of constructing mechanical property-oriented optimization models. In orthopaedic implant design practice, many researchers have taken the physiological loads on bones as input conditions, maximized structural stiffness, minimized weight as the objective function, and used topology optimization algorithms such as the variable density method [8] and the level-set method [9], to successfully construct an implant model with a porous structure. For example, Fujibayashi's team carried out topology optimization design for spinal fusion device, through the simulation of the complex stress situation of the spine, the optimized fusion device maintains sufficient strength while reducing weight, and the elastic modulus is closer to the vertebral bone tissue, which effectively reduces the risk of stress shielding, and clinical trials found that the majority of patients recovered rapidly in the postoperative period within one month and had no Clinical trials found that most patients recovered rapidly and had no clinical reaction within one month after surgery [10]. This porous structure can significantly reduce the modulus of elasticity of the implant and make it more compatible with the human bone.Memon's team reviewed existing products of porous titanium zygomatic implants designed by topology optimization and selective laser melting (SLM), and found that their biomechanical properties were well matched to the human oral cavity and could greatly improve the quality of life of the patients through market research, taking into account the different needs of different patients [11]. These implants successfully achieved precise adaptation of key mechanical properties to specific skeletal sites, significantly improved patient comfort and functional recovery, and demonstrated the practical application value of this technology combination in meeting individualized mechanical property requirements and enhancing patient quality of life.Tamimi et al. designed initial customized bone plates for patients with distal tibia spiral fractures and designed customized bone plates for patients with distal tibia spiral fractures under 25%, 50%, and 75% strain minimization. cases, redesigned by minimizing the strain energy and reducing the total volume, evaluated in conjunction with finite element analysis (considering patient gait loading and tibia bearing 10% of the body weight) showed that the

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reduction of load transfer in the fracture region increased as the volume of the bone plate was increased, reducing the risk of stress shielding and proving that topology optimization is a viable method for constructing this type of custom bone plate [12]. The precise tuning of the mechanical properties of the implant for individual patient fracture types and loading conditions was achieved, and the optimal balance between volume (material usage) and stress shielding risk can be found while meeting fixation requirements, providing methodological support for efficient, performance-oriented design of customized implants.

3.2. Aiming to improve biocompatibility

Biocompatibility is an important indicator of whether an implant can serve safely and effectively in the body, and it involves interactions between the implant and human tissues, including processes such as cell adhesion, proliferation, differentiation, and tissue integration. The combination of topology optimization and additive manufacturing provides a powerful means to improve the biocompatibility of medical implants. Topology optimization can modulate cell behavior by designing specific surface topology and pore features. The microtopography of the implant surface has a significant impact on cell adhesion and proliferation. Topology optimization algorithms can design surfaces with specific roughness and concave-convex structures according to the needs of cell growth to provide a suitable growth environment for cells. For example, zhou et al. designed and 3D printed optimized scaffolds by mimicking the natural bone structure, and found that this biomimetic structure can effectively regulate cell growth and differentiation, providing a more suitable biological microenvironment for cells [13]. This study demonstrated that topology optimization can accurately replicate the complex microstructures of natural tissues, and combined with the controllable molding capability of additive manufacturing, the synergistic design of scaffold structure and biological function was achieved. It significantly enhances the cytocompatibility and tissue induction ability of the implant, promotes cell-directed differentiation and tissue integration, and provides a new paradigm for the construction of biomimetic implants with the function of actively modulating cell behavior. Dalby's team has found that the use of nanoscale topology significantly stimulates the differentiation of bone marrow mesenchymal stem cells (HMSCs) to osteoblasts and promotes cytoskeletal formation and the development of adherent plaques [14]. The results demonstrate that topology optimization can design surface morphology with precise nanoscale features and achieve it through additive manufacturing. The optimized surface bioactivity of the implant promotes rapid osseointegration and reduces the risk of foreign body reaction and fibrous encapsulation.Feng et al. successfully prepared biomimetic materials with lotus-root-like structures by the optimized 3D printing strategy. Compared with conventional 3D materials, these biomimetic materials can significantly improve cell attachment and proliferation in vitro, promote osteogenesis in vivo, and have potential applications in cell delivery and bone regeneration [15]. It demonstrates the powerful ability of topology optimization in constructing bionic multilevel pore structures, which is combined with additive manufacturing to precisely realize the complex internal penetration network and optimize the environment for nutrient delivery, cell migration, and neoangiogenesis. Giannitelli's team has found that combining additive manufacturing with topology optimization methods can lead to architectures with specific structural features. Although this innovative approach is still in its infancy, it is starting to yield positive results not only in the reproduction of complex tissues, but also in the enhancement of biological processes such as the construction of vascularization [16].

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3.3. Aiming to improve permeability

The permeability of medical implants is a key factor affecting the efficiency of their integration with human tissues, which determines the ability of body fluids, nutrients, metabolites and biosignal molecules to be transported within the implant. For bone implants, good permeability can promote the penetration of osteoinductive factors into the deeper part of the implant, providing nutritional support for the migration and proliferation of osteoblasts; for slow-release implants, reasonable permeability can realize the controlled release of drugs and enhance the therapeutic effect. Traditional solid implants or simple porous structures often suffer from poor pore connectivity and uneven pore size distribution, resulting in insufficient permeability and hindering tissue regeneration. Topology optimization technology can accurately design the pore network structure of implants by constructing an optimization model targeting permeability performance. Its core lies in the targeted regulation of permeability performance by controlling the porosity, pore size and connectivity path. For example, He et al. proposed a design method for trabecular porous structure (TLPS) with mixed porosity, and by adjusting the topology optimization coefficients, the penetration properties of TLPS were similar to or even better than those of natural bone under certain circumstances [17]. This study demonstrated that topology optimization can precisely regulate the gradient distribution and connectivity of the pore network, which, combined with the achievability of additive manufacturing, breaks through the limitations of traditional uniform pore structures in simulating the permeability of complex biological tissues.Bobbert et al. demonstrated through experimental tests that the TPMS porous metal structure designed based on topology optimization and produced by additive manufacturing not only highly simulates the natural bone trabeculae in terms of its topology shape, but also its permeability characteristics are better than those of natural bone [18]. The topology of TPMS porous metal structures produced by additive manufacturing based on topology optimization not only highly mimics natural bone trabeculae, but also has a permeability comparable to that of natural bone tissues, which highlights the capability of topology optimization-driven additive manufacturing technology in constructing complex, highly connected and biomimetic porous structures, and provides an implant solution that perfectly balances the need for mechanical load-bearing with excellent permeability, and is expected to be used in the design of controlled-release implants for drugs that require highly efficient substance transport [18].

4. Problems and prospects

4.1. Existing problems

To date, a large number of clinical advances have been reported on topology-optimized synergistic 3D printed implants for different orthopedic applications. Most of the clinical results are superior to conventional implants in terms of osteogenesis and complication rates. Topology optimization-driven 3D-printed implants not only minimize the stress-shielding effect but also promote new bone infiltration and implant stability compared to conventional solid implants [19]. However, although topology optimization-driven additive manufacturing technology can achieve structural lightweighting and mechanical property matching through material distribution adjustment, the excessive pursuit of mechanical strength often sacrifices the structural features required for biological function; while highly porous structures designed solely for enhancing biological function may not have sufficient mechanical strength to withstand physiological loads due to overly sparse materials, increasing the risk of implant fracture. Therefore, achieving an optimal balance between mechanical strength and biological function remains a key challenge in implant design [20].

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In addition, most reported clinical trials are case studies and lack randomized and multicenter trials [21], which hinders a systematic comparison of the advantages and disadvantages of 3D-printed implants with those of conventional implants.

For healthcare organizations, the cost of 3D printing includes hardware, software, printing raw materials, and other services. Although the price of 3D printing is decreasing due to the rapid development of new technologies, it still requires a significant initial investment [22]. Consumer-grade 3D printers are now inexpensive, but these printers are unlikely to meet clinical requirements [23].

In addition, topology optimization involves complex mathematical models and large-scale data processing, and when optimizing for complex implant structures, finite element analysis and optimization algorithms are computationally intensive, and dealing with large-sized and complex structures often requires a lot of time and cost, and resources, which limits their scalability in practical applications.

4.2. Future directions

In the field of mechanical properties and biocompatibility, metamaterials are demonstrating the potential to dynamically respond to mechanical, thermal, or electrical stimuli, and the future holds promise for further exploration of their application in load-bearing implants that require a balance of strength, flexibility, and biocompatibility. Constructing more complex pore structures through continuous research can help optimize stress distribution, fatigue resistance, and biological processes such as osseointegration and vascularization, providing new pathways for implant design breakthroughs [20].

At the level of algorithm optimization, the development of more efficient topology optimization algorithms will become a key development direction. In the future, we can try to introduce deep learning and machine learning techniques, such as promoting the application of convolutional neural network (CNN) and generative adversarial network (GAN) to learn a large number of existing successful design cases, so as to realize the rapid optimization of complex structures, thereby reducing the cost of computation and improving the design efficiency. At the same time, exploring the use of artificial intelligence algorithms and finite element analysis to predict and correct topology optimization results is expected to generate near-optimal design solutions in a short period of time, creating the possibility of drastically reducing computation time to a few minutes.

5. Conclusion

The synergistic application of topology optimization and additive manufacturing can significantly optimize the comprehensive performance of medical implants: effectively enhancing mechanical fit to alleviate stress shielding, enhancing biocompatibility to promote tissue integration, and improving permeability to accelerate material transport and bone regeneration. Therefore, this fusion technology provides a fundamental path to solve the core problems of mechanical mismatch, biological inertness and insufficient permeability of traditional implants, strongly contributes to the development of high-performance personalized implants, and provides a key framework and methodological support for rational design and manufacturing of implants. Despite the significant advantages demonstrated by this technology, there are still problems such as a lack of systematic clinical trials, high cost, and insufficient computational efficiency of topology optimization algorithms. In the future, by introducing artificial intelligence algorithms to optimize the design process, conducting multi-center clinical studies, and reducing the cost of additive manufacturing, it is expected to promote the large-scale application of topology optimization-driven additive manufacturing in the field of personalized medical implants, and to provide more efficient solutions for precision medicine.

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