Application of Additive Manufacturing Orthopaedic ImplanTable Medical Devices

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Abstract: Additive manufacturing technology, also known as 3D printing technology, as a rapid prototyping technology, its emergence and growing maturity promote the emergence and commercial development of individualized medical implants. Because of the uniqueness of technology, it is necessary to study the quality control of 3D printing medical devices from the whole process, including raw materials, process validation, equipment, data transmission and risk management. The macro-size of the implant and the physiological environment of the defect to be repaired are organically combined to achieve personalized matching therapy and the adjustability of complex microstructures, improve its biomechanical compatibility, slow down the stress shielding of the implant site, and construct a good osseointegration at the bone-implant interface. Strengthen the supervision of the bidding, procurement, acceptance, storage, use, charging, registration and other aspects of orthopedic implanTable medical devices, and establish a standardized and institutionalized management process. The use of additive manufacturing technology to complete the design and manufacture of complex medical device structures, and more and more treatment cases to meet special needs, orthopedic implanTable medical devices based on additive manufacturing technology have gradually become a hot spot in medical research One.

1. Introduction

With the continuous improvement of living standards and the gradual enhancement of national health awareness, the development of medical devices has also become one of the focus of public attention [1]. The research on the application of added material manufacturing technology is not only one of the key tasks of the 13th Five-Year Plan of the Ministry of Science and Technology, but also the development of its application in orthopaedic implanTable medical devices has been highly valued by China's medical device regulatory agencies. Advantages of saving time and fast recovery [2]. However, the change of its manufacturing mode has brought about greater freedom of design and manufacturing. Therefore, in the processing of complex structure and personalized structure, both in cost and delivery time, it embodies the incomparable advantages of traditional technology [3]. Titanium-nickel shape memory alloy scaffolds have biased mechanical effect, shape memory effect and good cold forming characteristics, which are more flexible than stainless steel scaffolds and more in line with human requirements. At this stage, 3D printing technology can be applied to the manufacture of surgical drill models, personalized orthopaedic implant medical devices and tissue engineering scaffolds [4]. Due to the variety, complex specifications, high value, high risk and individual differences of patients, orthopedic implanTable medical devices are the key and difficult points in hospital medical device circulation management. The doctor selects the specific specifications according to the actual situation during the operation, and the remaining implanted devices are returned to the supplier. This makes it clear which implanTable device is used in the surgery only after surgery [5].

Because of the characteristics of implanTable medical devices, unlike drugs in the hospital circulation is basically unchanged, but according to product characteristics, use characteristics and other established a variety of circulation methods [6]. According to the description of medical devices in various countries and the application of medical devices in China, the characteristics of medical devices are usually doctors'special needs to meet patients or doctors' special operations [7]. Additive manufacturing technology can solve the problems of difficult machining and

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time-consuming processing of irregular shape products. For example, it is difficult to realize the porous structure on the surface of orthopaedic implants by conventional technology. Additive manufacturing technology can print irregular porous structure by computer-aided design [8]. This technology can be used to fabricate tissue engineering scaffolds, simulate the three-dimensional environment of cell attachment and tissue growth, and provide certain strength assurance. Compared with traditional technology, its advantages mainly lie in the greater degree of structural freedom in processing and the precise contour fit with human organs and other organs [9]. The recycling system for orthopedic implants is urgently needed to make up for this legal gap, so that the regulatory authorities can rely on the law. At the same time, medical institutions should strengthen institutional development and develop coverage, procurement, and follow-up visits. In recent years, we can often see some news and research on the application of surgical implants for clinical application of 3D printing technology, which fully demonstrates the very broad application prospects of additive manufacturing technology in future medicine. In the manufacture of personalized implants, personalized orthopedic implants have been used for bone tissue repair after bone tumor resection. In the preparation of degradable tissue engineering scaffolds, there are degradable 3D printed meningeal repair materials [10].

2. Development of Orthopaedic Products Made of Medical Additives

2.1 Standardized Application of Medical Additional Materials Manufacturing

By defining medical devices clearly, we can ensure that the design and application of medical devices are scientific, instead of using gimmicks to cause clinical abuse. Additional material technology has great advantages in making personalized medical three-dimensional models. It can also be used as a means of disease detection. In complex surgery, it can print the model of surgical site to simulate the operation, so as to shorten the operation time and reduce the operation risk. Promote the industrialization process of China's add-on manufacturing technology, strengthen exchanges and cooperation with other countries and organizations in standardization work, and put forward constructive suggestions for the establishment of relevant regulatory regulations for national monitoring departments. Designs can be made directly in the computer's three-dimensional composition software, such as the design of porous structural units of a particular structure and size, by stacking of structural units or in conjunction with other structures to obtain implants of a particular shape and porosity. Internal defects such as micro-cracks and closed pores can be solved by hot isostatic pressing. Inclusions should be avoided by using strict raw material quality control and production process control.

2.2 Standardized orthopaedic products manufactured by augmented materials and their application

In vitro construction of three-dimensional cell structure, i.e. cell printing technology, is used to manufacture orthopedic standardized products with additives. In the field of individualized in vitro model manufacturing, surgical drill models are defined as two types of medical devices. There are already mandibular surgical drill models and hepatectomy models prepared by 3D printing technology for clinical application. It is hoped that porous structures are interconnected and open to ensure the transport of nutrients and metabolic wastes, while periodic porous structures are homogeneous porous structures obtained by periodic arrangement of porous units. Different parts of the same medical device are designed according to biological and mechanical requirements, and different mechanical properties and surface structures are obtained to maximize its bionic characteristics. When processing conditions permit, besides optimizing the design of porous structure, the fatigue resistance of porous structure can also be improved from the point of view of chemical composition and micro-structure. The nominal compressive stress-strain curves of porous structures are shown in Figure 1. The presence of an extension around the implant results in a very small gap between the implant and the contour of the damaged surrounding, which greatly enhances the therapeutic effect and is aesthetically pleasing. The number of orthopedic implants is small, and

the final product cannot be used for performance verification of destructive tests to meet patient needs. The design process of the implant not only needs to be combined with the requirements of the doctor to develop a design plan, but also the production conditions that are produced by the additive manufacturing technology should meet the reasonable preparation conditions, and the product should be verified by mechanical strength, structural precision and the like.

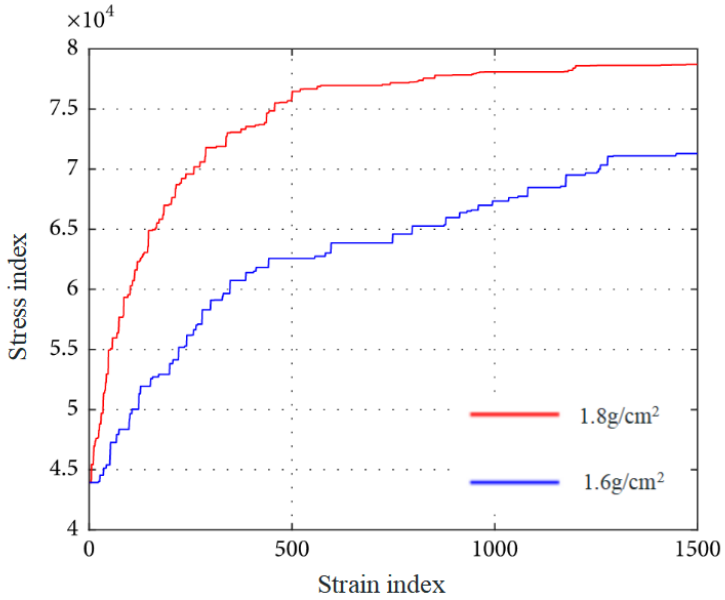

Fig.1. Nominal Compressive Stress-Strain Curves of Porous Structures

Customized orthopaedic implants are relatively risky and face greater challenges in raw materials, product design and performance evaluation. Compared with standardized implants, the advantages of customized orthopaedic implants lie in the rapid and accurate design of implants according to the needs of doctors and better matching of patients'physiological and anatomical structures. Because the computer-aided two-dimensional reconstruction implant can achieve nearly anatomical accuracy, it can accurately understand and grasp the condition and make personalized surgical treatment plan. High-risk medical devices should be strengthened supervision. For the medical device software used to reconstruct the shape and structure of customized medical devices and to make surgical plans, it is considered whether it is included in the management according to the limitation of the use of the software, and classified according to the risk. Strengthen the strength of the tissue-material fusion interface and promote the formation of bone tissue in the three-dimensional structure. The biocompatibility of the material can be further enhanced by subjecting the formed structural member to HCL, NaOH post treatment or coating of a bioceramic coating. Progressive pore structure allows for better mechanical properties transfer between implant and bone tissue, standard for process stability verification methods; clinical 3D data acquisition, modeling, output reliability and stability criteria . A higher stiffness core can be used to carry the load, and a higher porosity outer layer can reduce the overall stiffness of the implant, while the presence of pores can further promote bone length.

3. Quality Control Key Points of Medical Products Made by Additional Materials

3.1 Material Addition Manufacture of Medical Implants

Medical augmentation technology can be divided into the application of individualized in vitro model manufacturing, such as simulation before glioma surgery, which will help to improve the accuracy of surgery. In addition to skull defect, which is a kind of non-load-bearing structure, material-adding technology can also be used to process complex bone prosthesis for the treatment of special structural bone defect in load-bearing part. Medical devices are exempt from PMA requirements and meet mandatory performance standards, but cannot exempt quality system specifications, including design controls, medical device reports, instructions and labels, corrections

and removals, and corporate registrations and lists. The hospital equipment department must review whether the type and quantity of the equipment recorded on the use record are consistent with the pre-acceptance record, and whether the product information of the implanted device matches the information of the acceptance record. Meet the needs of individualized manufacturing: With a high degree of design freedom, it is possible to design and process implants with specific shapes, structures and sizes on a macro level to achieve a good fit between the implant and the surrounding environment;

3.2 Standardization of Medical Additional Materials Manufacturing Technology

It is necessary to quickly establish the relevant standards of medical devices based on added material manufacturing, establish the basic technical criteria to ensure the safety and effectiveness of products, and guide manufacturers to better research and innovation. To provide technical support for the formulation of regulatory guidelines such as special risk analysis and risk control; to establish technology and methods, raw material standards, equipment standards and process standards. The aperture is suiTable for the growth of bone tissue in the range of 100-500μm. The filling of the tissue in the hole makes it closer to the elastic modulus of the body tissue, which is beneficial to the conduction of the interface stress, greatly increasing the impact resistance of the implanted human body and keeping the interface sTable. Through reasonable structural design (such as hollowing and internal grid structure), the maximum weight loss is achieved under the premise of ensuring mechanical properties. The weight of the prosthesis is only slightly larger than that of the human mandible. Before the EBM equipment is processed, the 3D CAD model of the part is determined, and then layered and sliced according to a certain thickness, thereby discretizing the 3D data of the part into a series of 2D data, and then introducing the obtained model into the molding apparatus.

The wide range of Machinable materials, metals, polymers, gels and even liquid materials can be molded into medical device products through 3D printing. Secondly, sophisticated and complex structures and personalized structures can be manufactured. The mechanical properties of the moulded parts obtained by adding material manufacturing technology are enough to match the traditional process, but sometimes some subsequent heat treatment is needed to obtain better performance, such as eliminating the residual thermal stress of the parts, refining the micro-structure, improving the plasticity, toughness and fatigue resistance, etc. According to computer data, three-dimensional automatic assembly of various materials and cells is carried out by AM technology. Form a composite whole of cells and scaffolds of degradable materials. After implantation in a suiTable in vitro tissue engineering culture stage, the patient is implanted. Skull implants based on porous warp-based apatite materials have good effects on mechanical strength, biocompatibility, shape matching, and image inspection, and can be used as materials for three-dimensional printing. At the same time, it is necessary to combine rich clinical experience and product awareness to ensure the safety and effectiveness of orthopedic implant products and reduce the risk of product use. Therefore, it is necessary to establish relevant management regulations for each stage of the product life cycle. Particularly important.

4. Conclusion

New breakthroughs and achievements in the manufacturing technology of additional materials also need the cooperation and efforts of enterprises, doctors and regulatory departments led by advanced medical devices, so as to jointly promote the better development of medical devices. The advantages of good biocompatibility and biomechanics have wide application and promotion prospects. To control the safety and effectiveness of medical devices in terms of risk and quality is not only helpful to encourage enterprises to achieve independent innovation, but also helpful to promote the sTable and healthy development of the medical device industry. The impact in the medical field is not only product manufacturing, but also the whole process from diagnosis to diagnosis and treatment. Therefore, it is necessary to invest a lot of R&D costs in process verification and product development in order to obtain independent intellectual property rights of

3D printing medical devices. The circulation management of medical devices is changing with each passing day. The specification of orthopaedic implanTable medical devices requires long-term adherence and exploration. The operation methods and rules should be implemented according to the actual situation in the field of medical device circulation. Try to combine a certain bioactive ceramic material, degradable metal or degradable polymer with titanium metal powder, organically combine the excellent comprehensive mechanical properties of titanium alloy with the bioactivity of ceramics and the degradability of polymers. Standardization organizations and various stakeholders should stand at the height of the whole industry and complement each other and unite to ensure that the standardization work has made substantial progress, thus achieving healthy and orderly development of standards and industries.

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National Key Research and Development Program 2018 Muscle-skeletal System Repair Materials and Implantation Devices and Surface Modification Engineering Technology Project No. 2018YFC 1105403 Project 3 Key participan: ZHU WEIQIANG

References

[1] Morrison R J, Kashlan K N, Flanangan C L, et al. Regulatory Considerations in the Design and Manufacturing of ImplanTable 3D-Printed Medical Devices[J]. Clinical and Translational Science, 2015, 8(5):594-600.

[2] Whitaker D A, Buchanan F, Lennon D, et al. The Application of Computational Chemistry and Chemometrics to Developing a Method for Online Monitoring of Polymer Degradation in the Manufacture of Bioresorbable Medical Implants[J]. Communications in Computer & Information Science, 2014, 461(9):215-225.

[3] Torres-Sánchez, Carmen, Pérez-López, Ana M, Alqahtani M N, et al. Design and manufacture of functional catalyst-carrier structures for the bioorthogonal activation of anticancer agents[J]. New Journal of Chemistry, 2019, 43(3):1449-1458.

[4] Marie-Claire Bélanger, Marois Y, Roy R, et al. Selection of a Polyurethane Membrane for the Manufacture of Ventricles for a Totally ImplanTable Artificial Heart: Blood Compatibility and Biocompatibility Studies[J]. Artificial Organs, 2015, 24(11):879-888.

[5] Yang M, Zhang Z, Hahn C, et al. Assessing the resistance to calcification of polyurethane membranes used in the manufacture of ventricles for a totally implanTable artificial heart[J]. Journal of biomedical materials research, 1999, 48(5):648-659.

[6] Poppendieck W, Sossalla A, Krob M O, et al. Development, manufacturing and application of double-sided flexible implanTable microelectrodes[J]. Biomedical Microdevices, 2014, 16(6):837-850.

[7] Krzyzanowski M, Svyetlichnyy D, Stevenson G, et al. Powder bed generation in integrated modelling of additive layer manufacturing of orthopaedic implants[J]. The International Journal of Advanced Manufacturing Technology, 2016, 87(1-4):519-530.

[8] Sena da Rocha, André Luiz, Pledson G D M, Lee Ho L. Economical control chart with supplementary rules to monitor the average number of defects[J]. The International Journal of Advanced Manufacturing Technology, 2015, 76(5-8):881-891.

[9] Chiu M C, Lin Y H. Simulation based method considering design for additive manufacturing and supply chain[J]. Industrial Management & Data Systems, 2016, 116(2):322-348.

[10] Wang M. Nanocomposites and additive manufacturing for multifunctional tissue engineering scaffolds[J]. Plant Pathology Journal, 2014, 21(2):158-162.