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Design and Development of 3D-Printed Personalized Femoral Prosthesis Technologies

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Abstract: The femur supports the entire body weight, and any damage or necrosis to this bone can significantly impair normal walking. Therefore, repairing the femur is essential to restoring its function. However, due to variations in human bone structure, standardized prostheses often deliver poor repair outcomes. We used the medical three-dimensional (3D) auxiliary software Mimics to design personalized femoral prostheses to address this issue. The femoral prosthesis filler was porous, and all aspects of the prosthesis were thoroughly studied and analyzed before direct molding using 3D printing technology. The personalized femoral prosthesis filler and bone plate designed using 3D printing technology have positive effects, and the matching between the femoral prosthesis, bone plate, and filler is satisfactory. The pore structure of the 3D-printed femoral prosthesis filler and the bone plate is clear and of high quality, which shortens the research and development cycle and reduces costs, providing a foundation for the direct application of 3D-printed personalized prostheses.

Keywords: femoral prosthesis; 3D printing; porification; reverse engineering; personalized design

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1. Introduction

Prostheses are hand-made or standardized by medical experts. Significant differences in geometric and mechanical properties between prostheses and replacement parts may result in various adverse effects following prosthetic surgery and could disrupt everyday life. For these reasons, it is essential to consider individual differences between patients and design a personalized prosthesis for each patient based on their specific requirements to match the replacement parts [1,2]. Three-dimensional printing technology can use previously obtained computed tomography (CT) data of the femur for reverse design, and then, realize the precise manufacture of a personalized femoral prosthesis using 3D printing equipment, allowing the femoral prosthesis to be wholly adapted to the replacement part and the patient to return to everyday life.

Additive manufacturing technology (3D printing technology) is based on the principle of "layered manufacturing and layered superposition", and special materials are stacked and solidified, layer by layer, to manufacture entities using software and a numerical control system [3]. In recent years, 3D printing technology has opened up new avenues for the advancement of the medical field, particularly the prosthesis industry [4,5]. Some special and complex parts that cannot be manufactured accurately using traditional technology can now be manufactured, which provides the possibility for the development of novel restorations. Furthermore, as living standards increase, patient demand for personalized prostheses is rising, providing impetus for the development of the prosthesis industry and related industries.

Traditional technology cannot precisely prepare the femur due to its complex shape. As a result, when treating patients with femoral injuries, the femoral prosthesis can be configured and replaced by utilizing 3D printing technology, the medical software Mimics, and other 3D auxiliary software packages for reverse design, adding a porous design, and preparation [6]. Femoral prostheses with porous structures can save materials, reduce prosthesis weight, reduce patient burden, make the prosthesis more suitable for human tissues, promote cell adhesion, generate collagen, develop new bones, and improve prosthesis stability [7,8]. More importantly, femoral prostheses produced using 3D printing technology can reduce operating costs. A 3D-printed prosthesis can be directly matched in vitro and does not need to be adapted on the spot during operation, reducing patient pain and operation risk, which is critical to the success of the prosthetic operation and future rehabilitation [9].

Wang et al. used a three-dimensional finite element method to investigate the treatment of acetabular posterior wall fractures with internal fixation with a bone plate, and they discussed the impacts of different gaps between the bone plate and bone surface on acetabular stress distribution [10]. Zhiyuan et al. discussed the surgical efficacy and clinical significance of personalized plate internal fixation using 3D printing in treating severe tibial plateau fractures [11]. Three-dimensional printing and personalized plate internal fixation can reduce operating time, surgical trauma, and patient recuperation time. Cong et al. designed a lattice structure bone plate for 3D printing based on topology optimization and finite element modeling technology to improve the stress shielding effect caused by the excessive elastic modulus of metal bone plates during fracture healing, which increased the average stress of bones by about 4% and reduced the stress shielding effect of bones [12]. Pobloth et al. constructed honeycomb 3D titanium alloy mesh scaffolds with varying stiffness and compared and verified bone growth and healing after scaffold stiffness was changed [13]. The authors found that the honeycomb titanium alloy mesh scaffold reduced stress shielding and promoted the healing and regeneration of large animal bones. Liu et al. created a porous Ti6Al4V bone plate with a personalized elastic modulus similar to the cortical bone using 3D printing technology [14].

These studies demonstrate that 3D printing technology for treating orthopedic diseases has made some progress, but it is limited to a few cases and requires additional research. This paper utilizes the medical 3D auxiliary software Mimics to innovate the design of personalized femoral prosthesis fillers and plates, and then, employs 3D printing technology to shape them directly. It is anticipated that this will provide a new approach to the design of high-performance prostheses.

2. Materials and Methods

2.1. Design Constraints

The design constraints can be roughly classified into three categories [15,16], based on the research results of the biocompatibility of the geometric and porous structure design of the desktop 3D printer (FDM) (Shenzhen Aurora Innovation Technology Co., Ltd., Shenzhen, China) and the shape characteristics of the cortical bone in femoral prostheses:

(1) Sharp corners and thin walls impose constraints: Because the nozzle used for the FDM molding of parts has a maximum molding size, producing parts with sharp corners and thin walls smaller than the nozzle's inner hole diameter is impossible. Furthermore, the mechanical properties of thin-walled parts with insufficient wall thickness are difficult to ensure, and they are easy to break and of no practical value.

(2) Characteristics of the hole: Because of the nozzle's inner hole size limit and the influence of heat-affected zone diffusion during processing, the width of the molten channel is greater than the nozzle's inner hole size. The molten channel will block the hole if the aperture is too small, and the size of the hole characteristics perpendicular to the molding direction has a minimum limit. The forming effect is affected by the size of the nozzle's inner hole and the hole characteristics parallel to the forming direction.

Large pores should be avoided because they give rise to "slag hanging", leading to worse shape accuracy and dimensional accuracy, which may lead to molding failure. One should also avoid adding supports to the inner holes, which are difficult to remove. Three-dimensionally-printed parts avoid these pitfalls owing to their minimum and maximum limit sizes.

(3) Biocompatibility requirements: The optimal pore size range of porous structures for bone cell growth is between 100 and 1000 m, and porosities between 50 and 90 percent can simulate cancellous bone structure, which is most advantageous for new bone growth. The greater surface-to-volume ratio of a porous implant correlates with the contact area between the implant surface and the bone and the mechanical stimulation of new bone growth.

2.2. Design Method of Prosthesis at Femoral Replacement Site

CT and nuclear magnetic resonance have become the primary methods for collecting site data due to the complexity of the sites. Using high-precision medical CT, slice data from the injured or necrotic portion of the femur were obtained. The slice data were then imported into Mimics (20.0, 2020, Materialise Company, Flemish District, Belgium) to finalize the 3D reconstruction. The reconstructed point cloud model was then transferred into Geomagic Studio (2020, 2020, Geomagic Company, Morrisville, NC, USA), a piece of engineering software for reverse design, to simulate bone-cutting and extract the outline of the femoral injury or necrosis. The extracted parts were analyzed using the finite element method, and the stress analysis results were used to finalize the modeling in Proe (5.0, 2009, PTC Company, Boston, MA, USA).

2.3. Molding Equipment and Materials

Because only the designed femoral prosthesis was prepared experimentally, we used fuse stacking forming technology (FDM), which has printing manufacturing accuracy comparable to selective laser melting forming technology (SLM). FDM technology is based on the cohesiveness of heated melt and thermoplastic materials and is layered and formed under computer control [17]. FDM technology fabricates the femoral prosthesis, allowing us to identify and resolve design flaws, and resulting in a superior prosthesis.

Polylactic acid (PLA) (Shenzhen Aurora Innovation Technology Co., Ltd., Shenzhen, China) is a thermoplastic material for FDM technology [18]. It is a polymer created through the polymerization of lactic acid, as the primary raw material, and maize and cassava as secondary raw materials. Due to the abundance and regenerative nature of the basic materials, the price is relatively low. The manufacture of poly-PLA material is pollution-free, and the material is biodegradable, allowing for natural circulation. Because it is an optimal green polymer material with high thermal stability and adhesion, it is an excellent material for 3D printing femoral prosthesis test preparations.

3. Results and Discussion

3.1. Acquisition of Patient Position Data

Due to its variable location among patients, the femur has a complex geometric shape and curved surface. Consequently, obtaining an image of a patient's femur using imaging (CT or MRT) for three-dimensional reconstruction is the most effective way to improve the fit of the designed implant to the patient's site, reduce the risk of the implant loosening, and increase the success rate of implant surgery. With the patient's consent, CT or nuclear magnetic resonance is used to scan the femur, as shown in Figure 1 (a CT image of a femoral fracture in the prone position). A porous femoral prosthesis must be designed and prepared for repair and recovery. The following describes a femoral prosthesis design, voiding process, and experimental preparation.

Figure 1. CT image of femoral fracture.

3.2. Design Method of Femoral Prosthesis Filler

Mimics imports CT slice images of the femur. One can select the correct orientation during the import procedure by right-clicking on the change orientation window. In Mimics, the slice images of femoral patients are thresholded, and the separate segmentation areas on the initial thresholding mask are subdivided into subgroups to generate a new mask. The soft tissue serves as the starting point, and after traversing the bone, it serves as the ending point, resulting in a strength interface with the elevated portion serving as the threshold. After threshold segmentation, the slice image is subjected to morphological operations, and small burrs on the segmented mask's boundary are removed using an opening operation (corrosion first, and then, expansion). Region growth divides the binary image into units and eliminates floating pixels. Computed 3D models are used to finalize the three-dimensional reconstruction of the CT model. Smoothing and denoising the reconstructed femoral prosthesis yield the optimized femoral model. As shown in Figure 2a, the site is then removed for pore design, which can reduce prosthesis weight and enhance prosthesis stability. The porous design of the model of the patient's femoral site The porous design of the patient's femur model includes the following two steps.

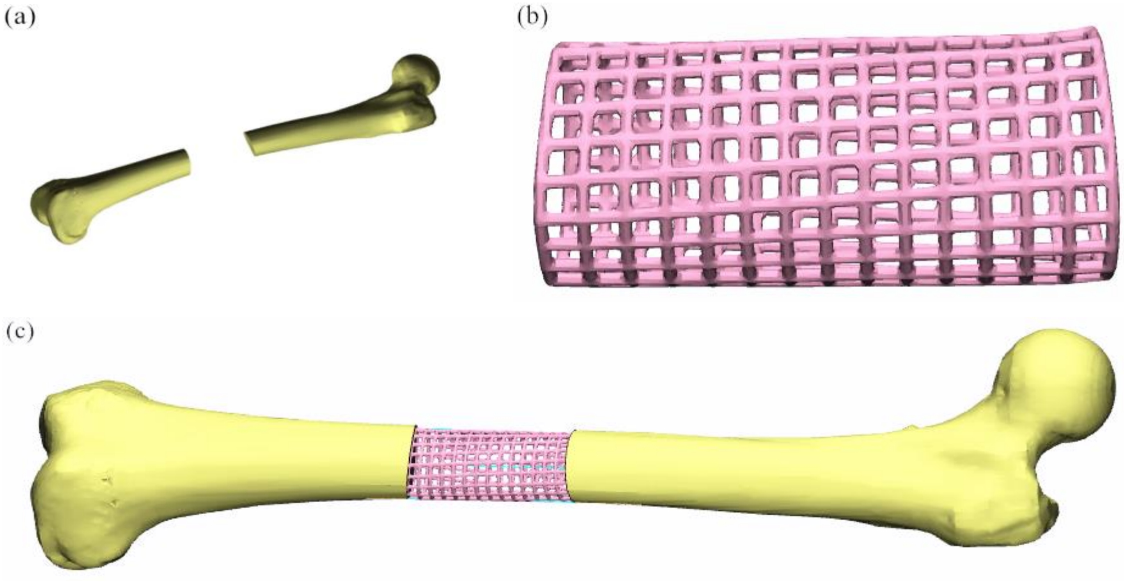

Figure 2. Femoral prosthesis: (**a**) after resection of the site of the patient's femur; (**b**) cage formation of patient's femur site; (**c**) Assembly effect.

3.2.1. Structure of the Femoral Prosthesis Cage

The completed prosthesis model is imported into Mimics, and the cage structure is selected; that is, the designer chooses the artificial face to obtain a prosthesis with a cage structure, which can be combined with some fillers with a porous structure to make the prosthesis more personalized and rational (Figure 2).

3.2.2. Porosity Filling Structure Design

Using Materialise Magics (23.0, 2018, Materialise Company, Flemish District, Belgium), we developed a cell void-filling structure that can be layered seamlessly. The porous structural unit depicted in Figure 3a is porous on a unit cube due to topology optimization, which conserves materials, reduces the prosthesis weight, improves its stability, and lessens the patient burden. The porous filling structure is then constructed by smoothly superimposing several porous filling structures. Lastly, as shown in Figure 3b, the porous infill structure of Figure 3a is filled in the cage-type structured prosthesis of Figure 2a using software, and the porous structure is formed through cooperation.

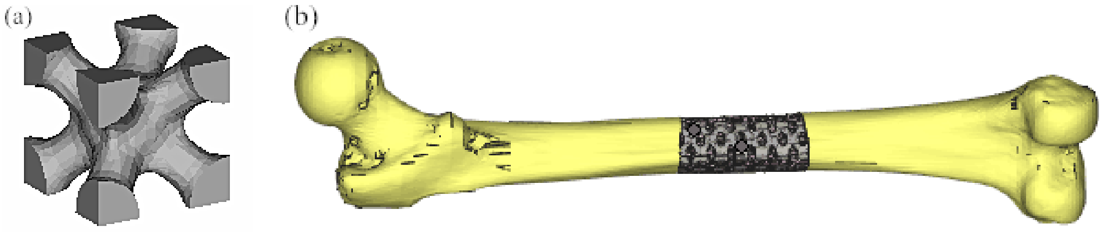

Figure 3. Interstitial design of femoral prosthesis: (**a**) porous structural unit; (**b**) porous filling of the femur.

3.2.3. Fusion of Cage Structure and Filler

It is necessary to combine the cage structure and infill. The most common fusion method is the Boolean operation, and in Magics 22.0, the cage structure and infill are fused using this operation, as depicted in Figure 4a. The figure shows a transition bump between the fused cage structure and the infill that affects subsequent processing and application. Figure 4b shows that the cage structure and infill are imported into Rhino software, and the scalar field is programmed to fuse. Figure 4b also shows that the fusion effect between the cage structure and the filler is strong, and the transition is seamless.

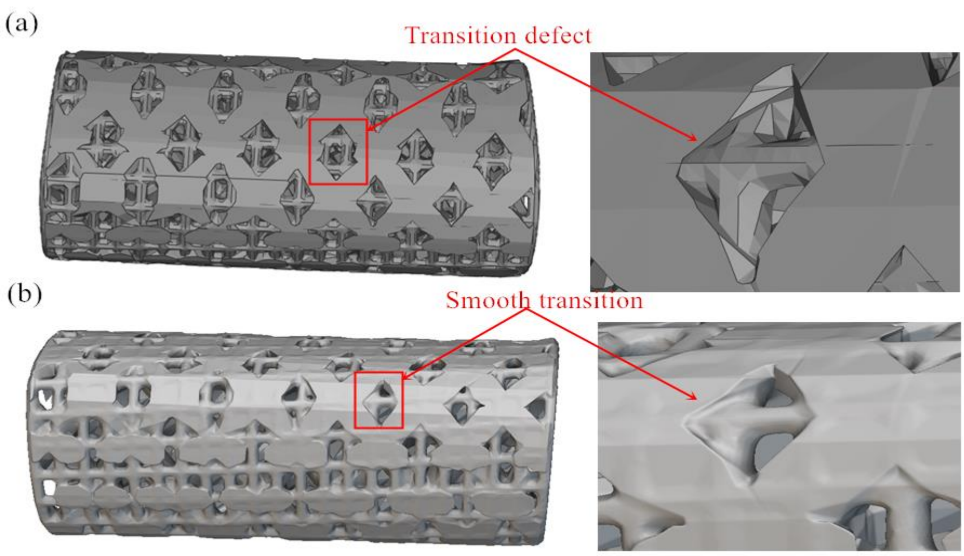

Figure 4. Fusion of cage structure and filler: (**a**) Boolean operation fusion; (**b**) scalar field fusion.

3.3. Design and Fixation of Femoral Prosthesis Fixation Plate

Following the design of the femoral prosthesis, the subsequent stage is to fix the prosthesis using a fixed plate. The design of the fixed plate must satisfy the following criteria: (1) It must have a moderate surface area and thickness, and its volume and weight should be kept as low as feasible to lighten the load on patients while maintaining adequate use strength. (2) Since the femur resembles a cylinder, when the fixing plate is attached, the shape of the corresponding femur must have a specific curvature, resulting in a comfortable fit.

In Mimics software, four fastening plates are added to the femoral prosthesis, which is used on the prosthesis' symmetrical sides and the femur's remaining portion. As shown in Figure 5, the fixing holes on the prosthesis and the intact portion of the femur are opened, eight holes are drilled to meet medical requirements, and then, special screws are used to secure the prosthesis, which reduces damage to the prosthesis' structure and the intact portion of the femur; this procedure makes the prosthesis fixation more stable and reliable.

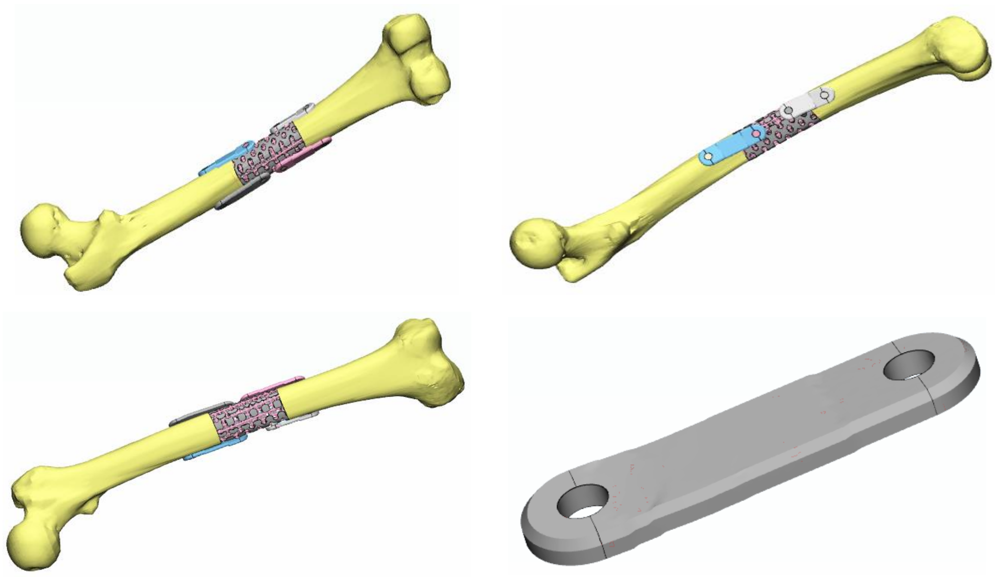

Figure 5. Design and assembly drawing of fixed plate.

3.4. Three-Dimensional Printing Analysis of Femoral Prosthesis

3.4.1. Wall Thickness Analysis

Because 3D printing technology typically employs laser focusing or nozzle extrusion, there are processing limitations, such as the thickness of pointed corner walls. Wall thickness is the distance between a model's surface and its corresponding surface; it is the cause of several printing issues. Because the porous structure of the femoral filler is complex, with sharp corners and thin walls, the wall thickness of the femoral filler is primarily analyzed. The designed porous structure of the femoral filler is first imported into the analysis software Magics 22.0, and the model to be analyzed is chosen. The wall thickness range is then set to 0.5 mm–1.5 mm per wall thickness requirement, and the analysis results are shown in Figure 6, which shows that the porous structure with a wall thickness of less than 1 mm is most visible in the pillar part. When the printed layer thickness of an FDM printer is less than the set layer thickness, only one layer is printed. Because the pillar part ensures a molding effect, the non-pillar part's overhang is insufficient to complete the molding; however, there may be some defects, so the sharp corners of this part can be smoothed.

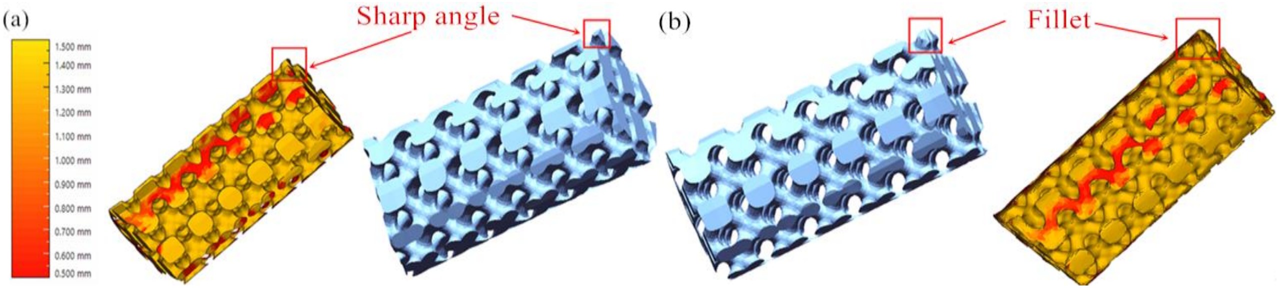

Figure 6. Wall thickness analysis and improvement measures: (**a**) wall thickness analysis; (**b**) fillet.

3.4.2. Processing Risk Analysis of Parts Placement Mode

Because the model may be damaged during printing, it must be analyzed before processing. Because the femur and fixed plate are simple in structure and easy to form, processing risk analysis of the porous structure of the femoral filler is primarily performed. The risk analysis of the optimal placement of femoral fillers in Magics 22.0 is shown in Figure 7, which shows that different colors represent different risks. Green represents the risk-free portion of the diagram, yellow represents the less risky portion, and orange represents the riskier portion. Figure 7 shows a few orange parts at the two bottom ends of the porous structure. After careful examination, the reason for this situation is that the bone-cutting surface is inclined. The risk of damage during printing can be reduced if the two bottom ends are placed vertically. After completing the wall thickness analysis and risk analysis of the 3D printing of the femoral prosthesis model, the non-conforming parameters are adjusted and re-analyzed. Only when all the data meets the design specifications can 3D printing begin.

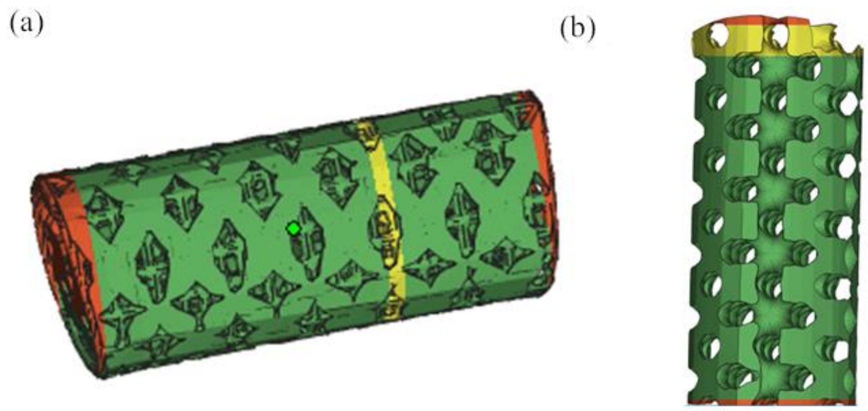

Figure 7. Processing risks and improvement measures: (**a**) processing risk analysis diagram; (**b**) vertical placement method.

3.5. Direct Manufacture of Femoral Prosthesis

3.5.1. Selection of 3D Printers

The principle of a 3D printer is to load digitized data and printed materials into the 3D printer, and then, print and manufactured entities with the assistance of its supporting numerical control system. These unique and complex components that cannot be manufactured accurately using traditional processes can now be manufactured while improving manufacturing efficiency and lowering production costs. Because the 3D printer manufactured by Shenzhen Aurora Innovation Technology Co. Ltd., Shenzhen, China. has high molding precision and a high-quality surface finish, the Z-603S industrial high-precision 3D printer manufactured by Shenzhen Aurora Innovation Technology Co., Ltd., Shenzhen, China. was chosen to manufacture femoral implants, as shown in Figure 8. PLA is used as the molding material, the printing layer thickness is set to 0.1 mm, and the packing density is set to 20%. To avoid warping deformation caused by an excessive temperature difference between the molded parts and the substrate, the wall thickness is 0.6 mm, the printing temperature is 190°, and the substrate is preheated to 50°.

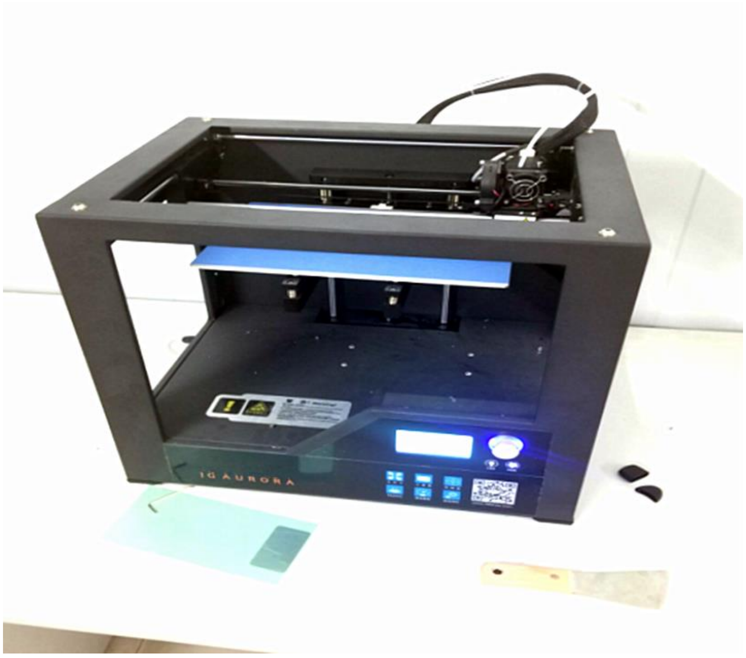

Figure 8. Aurora Evo FDM 3D printer.

3.5.2. Preparation and Implementation of 3D Printing

The designed femoral prosthesis model must be imported into an STL file and viewed in the JGcreate software before 3D printing. The software will generate a three-dimensional model and automatically or manually support it to prevent collapse during printing. As depicted in Figure 9a, this software can modify the model's placement and support and move it into a suitable position before printing. Nevertheless, Figure 9b shows that this software can simulate the printing path, highlighting the 3D printer's superior performance. The printer is started up when all work is complete, and it performs accurate and automatic printing based on the wire routing of the printed trajectory simulation map.

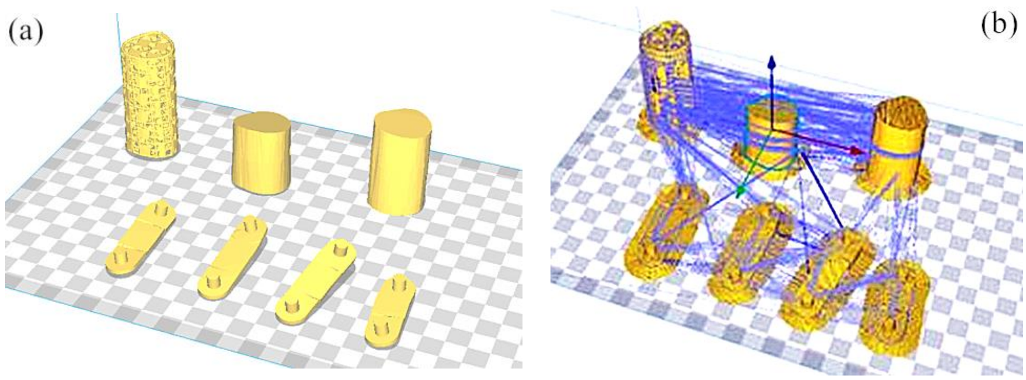

Figure 9. Data processing of 3D printing of femoral prosthesis: (**a**) model printing layout; (**b**) print track simulation diagram.

3.5.3. Analysis of Formation Results

Figure 10a shows that the femoral prosthesis model and other components are generated after several hours of 3D printing. There are a few bumps and hairs on the freshly printed portions. Figure 10b shows that the femoral prosthesis is assembled after surface treatment such as polishing. Figure 10b demonstrates that the porous femur, fixation plate, and femur are well-matched, which satisfies the application requirements and lays the groundwork for the future direct fabrication of metal implants.

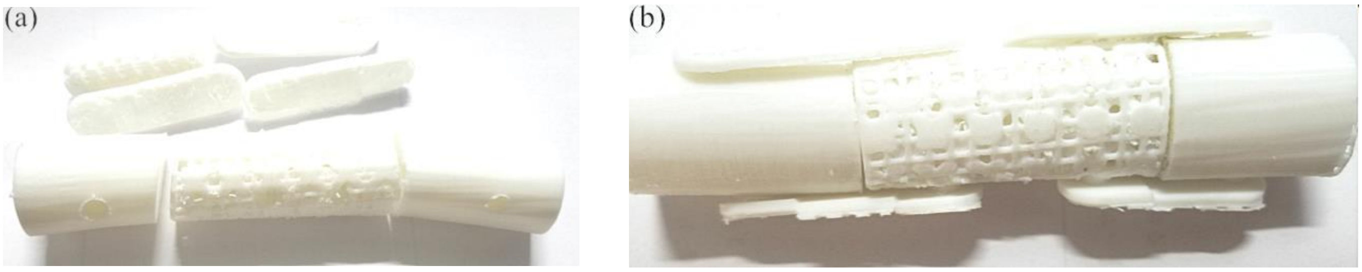

Figure 10. Three-dimensionally-printed femoral prosthesis: (**a**) parts photograph of femoral prosthesis; (**b**) assembly photograph of femoral prosthesis.

Observation with the unaided eye reveals that deformation occurred during the printing process and that after molding, the prosthesis wall is thin, the pore size deviates from the design size, and inadequate space is reserved at the femoral prosthesis joint. These issues lead to errors, resulting in a prosthesis that is dissimilar to the design, leading to inapplicability and waste. However, following the identification of the issue and the ensuing period, parameters such as size are adjusted (uniaxial stretching 1 mm perpendicular to the datum plane), and the design specifications are met after debugging.

4. Conclusions

This paper introduces the design of a femoral prosthesis, the analysis method prior to printing, and the experimental preparation using emerging 3D printing technology. Clinical research data show that femoral prostheses are critical for enabling patients with femoral injury or necrosis to regain normal walking ability. The design and preparation of femoral prostheses is critical. Because each person's femur differs in size and shape, it is necessary to design personalized femoral prostheses for patients, use various medical software and other three-dimensional software to construct a prosthetic model that is entirely consistent with the replacement site, and conduct a series of tests and analyses to meet the patient's needs. This research is focused on the porous design of femoral prostheses. Our design meets the requirements of medical design and the needs of patients, and reduces the use of materials, reducing the weight and cost of the prosthesis and improving service life and manufacturing efficiency. As a result, the design and preparation of porous-structure femoral prostheses offer hope to patients with femoral injury or necrosis. The current state and future development prospects of 3D printing technology and femoral prosthesis are briefly discussed in this paper, which will serve as a guide for future development. The design and preparation of medical prostheses using 3D printing technology will progress rapidly. This paper proposes a feasible scheme for future research and development based on individual cases. Future research can improve the design and preparation of femoral prostheses using appropriate technical means, and the application scope of 3D printing technology in the medical field can be verified and broadened to meet the needs of patients for personalized femoral prostheses.

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Institutional Review Board Statement: The bone model in this study was downloaded from the public database of Mimics software, and the data are publicly available, so ethical review was not necessary.

Informed Consent Statement: Not applicable.

Data Availability Statement: Not applicable.

Conflicts of Interest: The authors declare no conflict of interest.

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