Transactions on Additive Manufacturing Meets Medicine
Trans. AMMM, Vol. 4, No 1, Article ID 647, 3 Pages

Infinite Science Publishing

Original Research Article

Additive manufacturing of custom-made cranial PEEK implant and postoperative evaluation

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Abstract: For cases where standard implant solutions are insufficient, additively produced patient-specific implants are developed. The steps to obtain a correct patient-specific implant require knowledge of medical and engineering sciences, thus doctor-engineer cooperation. This study aimed to create a personalized implant design using the fused layer modeling/manufacturing (FLM) additive manufacturing technique for bilateral cranial defect and implant fabrication. Medical image processing software is allowed to the design engineer to convert computed tomography of the patient into 3D models. For surgery planning, 3D anatomical models of the patient were printed using SLA technology. Adopting the design per the additive manufacturing rules, the implant design was made through medical-certified software. Determining technical requirements, such as the mechanical behavior of the material after application, the region's biological requirements, and the material's manufacturability with the selected AM technology, have been key points for the selection of the additive manufacturing technology-material combination. According to these, the implant was produced from polyetheretherketone (PEEK) material using FLM technology. As a recently emerging technique in the biomedical field, printing ready-to-use, medical-grade PEEK material requires optimization of process parameters. Studies have been done and a comparative analysis has been made between digital and physical implant models. After implantation, clinical experience was reported, and radiological results were evaluated.

I. Introduction

Patient-specific implants are revolutionary treatments in the field of craniomaxillofacial (CMF) orthopedics due to their physiological and psychological remedy. CMF implant development is one of the most abundant research areas for additive manufacturing (AM) and materials due to the complexity of anatomical geometry, reducing inflammatory responses, and increasing rapid osteo-integration responses.

In the field of biomedical engineering, the mentioned multifaceted problems are solved by applying biocompatible materials with additive manufacturing technologies. For example, Titanium and its alloys have been used for years in this area as a biocompatible metal material with its application in powder bed fusion AM technologies. However, when the implants produced with this material and then implanted are examined in terms of mechanical properties, it causes a stress shield effect in the long run, since the modulus of elasticity is quite high compared to bone [1]. In addition, due to the bioactive nature of Ti-6Al-4V, one of the most widely used Ti alloys, it has been mentioned in the follow-ups with an excessive immune response [2].

Considering these reasons, polyetheretherketone (PEEK) has been used as an alternative to metals and alloplastics due to its inert nature, especially in reconstruction surgery. The fused layer modeling/manufacturing (FLM) method has made it possible to create PEEK geometries with complex anatomical shape that is fully adaptable to the defect site. In this study, a workflow is presented to create patient-specific PEEK implants using FLM technology. In this article, the clinical applicability of the design and production parameters will be discussed by considering the case of bilateral cranioplasty.

II. Material and methods

The methods can be explained in three aspects. The workflow has been followed in the study demonstrated in Figure 1.

II.I 3D Model of the patient

The 3D model of the patient is obtained by processing the biomedical imaging methods of the patient. In this study, after the computerized tomography (CT) of the patient was taken, the Digital Imaging and Communications in Medicine (DICOM) data was transferred to the medical imaging software (Mimics 24.1, Materialise, Leuven, Belgium) and the image processing process was started. In this process, the values of Hounsfield units were determined, hard tissue segmentation was performed, and a 3D model of the skull was created.

II.II Patient-specific implant design

This model was used in medically validated computer-aided design software (3-matic Medical 16.0, Materialise, Leuven, Belgium) to create accurate head prostheses. By using the mirroring method of this patient-specific model, a head structure is created towards the side of the cavity. Wall thickness analysis was performed on the created head structure and the part was exported in standard tessellation language (.STL) format. The STL file was then imported into the 3D slicer (Simplify3D 4.1.2, Simplify3D, Cincinnati, USA) and pre-production planning was done.

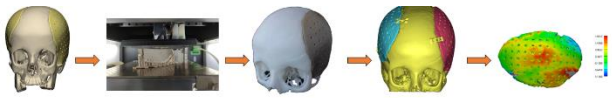

Figure 1: Schematic demonstration of the study evolution from left to right (1) implant design, (2) FLM additive manufacturing, (3) assessment of the implant with anatomical model (4) assessment of the implant radiography after implementation (5) dimensional comparison

II.III Additive manufacturing process

Since the FLM method was preferred, a PEEK 3D printer (M220, Apium Additive Technologies GmbH, Karlsruhe, Germany) was used, which provides a sterile environment in compliance with biocompatibility standards (ISO 10993). The printing environment was a closed chamber with controllable airflow temperature.

Besides the mentioned advantages for the high-performance polymer printing, Apium shows typical FLM behaviors: layer-by-layer filament melting by a moving print head in desired coordinates. Before printing the implant, the machine has been calibrated for 0.1 mm in the Z direction and 0.5 mm in the XY resolution. The nozzle diameter was 0.4 mm.

The filament was chosen as a medical grade 1.75 mm PEEK filament (Evonik VESTAKEEP ® i4 G resin, Evonik Industries AG, Essen, Germany). Among the most important biocompatible properties of PEEK, it has been a consistent choice because of its bioinertness, high chemical resistance, and low density (1.32 g/cm2) [3]. In addition, special process parameters (layer thickness, nozzle temperature, and ambient temperature) have been developed, and implants that can be attached to the patient can be produced by applying appropriate post-processing to the material. Process parameters optimization studies have been made according to the visual evaluation of the printed parts. Postoperative CT is collected 3 months after the implantation. DICOM data was transferred into medical imaging software. Linear measurement analysis for the part in every step (Fig. 2) and part comparison analysis were performed.

III. Results and discussion

It has been shown that the roughness of the implant is low compared to the clinical perspective, except for the areas where the support structures are located, with the effect of the optimized process parameters (Table 1) and the subsequent processes of the obtained product. Thanks to the controllable printing conditions, and the closed chamber build platform, a light tan color was observed, a sign of good thermal dissipation, and a high level of crystallization [4].

Table 1: Optimized process parameters

Parameter	Unit	Value
Layer Thickness	µm	0.1
Infill Rate	%	100
Nozzle Temperature	˚C	480
Airflow Temperature	˚C	140
Infill Pattern	-	Rectilinear

Postoperative radiological results showed that the implants were successfully implanted at the defect site. A comparative analysis of the implant showed a clinically acceptable size difference between the digital and physical implant models. The deviations ranged from 1.9 mm to -1.16 mm (p-value ≤ 0.05). The variations in Table 2. are explained as follows,

1. After 3D printing of the implant, post-process has been applied and it caused texture loss on the implant surface.
2. During the post-operative evaluation, identifying and segmentation of the PEEK part from radiological images were challenging due to its radiolucent surface.

Clinicians stated that the application was successful since the precise design and optimal manufacturing process.

Figure 2: Dimensional validation from left to right (1) implant design footprint, (2) FLM additive manufacturing dimensional analysis (after post-process), (3) dimensional analysis of the implant segmented from the CT image taken after implantation

Table 2: Linear comparison measurements of the digital and physical implant model

Development step	Y (cm)	Z (cm)
Design (Fig. 2.1.)	142.3	94.2
Additive Manufacturing (Fig. 2.2)	140.2	93.3
Post-operative Evaluation (Fig. 2.3.)	141.4	93.9

IV. Conclusions

This study demonstrated not only the design and manufacturing workflow developed for patient-specific PEEK cranial implants but also how well engineers can work with surgeons and how clinical trials in the personalized implant industry can produce positive results with the right surgical planning. In addition, FLM processing parameters for PEEK cranial implants were developed and clinically evaluated. The designed, fabricated and implanted parts have been dimensionally compared and the whole development process has been validated. The absence of radiopaque markers usage in the operation limited the accuracy of the part comparison analysis between the designed and implanted model. Segmenting of the PEEK part has been eased with the help of Titanium screws used in fixation. Despite this drawback of the PEEK material radiolucency, it should be underlined that radiological follow-up of the metal implants is much more difficult due to artifacts and scattering in data [5].

In conclusion, the additive manufacturing process has proven once again that the accessibility of this alternative therapy is increasing without hesitation.

The personalized CMF implant, which is classified as class 2b within the scope of Medical Device Regulation (MDR), can be offered to the market with self-declaration (MDR annex XIII).

A technical file is created within the scope of analysis and validation reports showing that it meets the basic requirements given in MDR Annex I. Therefore, TraBtech Medical Advanced Technologies fulfilled the requirements from MDR perspective to fabricate the patient-specific implant and provide it to the hospital with self-declaration.

Author's Statement

Conflict of interest: Authors state no conflict of interest. Informed consent: Informed consent has been obtained from all individuals included in this study. The medical application has been used with commercial purposes in TraBtech. Ethical approval: The research related to human use complies with all the relevant national regulations, institutional policies and was performed in accordance with the tenets of the Helsinki Declaration, and has been approved by the authors' institutional review board or equivalent committee.

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