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Original Research Article

Harnessing generative design algorithms in cranioplasty

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Abstract: Cranioplasty, which is essential for restoring craniofacial functions and aesthetics, has undergone a continuous process of evolution, incorporating increasingly precise and personalized treatments. Cranial patient-specific implants (PSIs) produced by molding or additive manufacturing (AM) represent a notable example of the implementation of tailored patient care pathways. Nevertheless, these tailor-made workflows still necessitate input from the user and must be further automated for their optimal integration at the point of care (POC). This study examines the utilization of generative design algorithms to develop cranial PSIs that are generated autonomously and three-dimensionally (3D) printed using stereolithography (SLA) technology. In this study, three specimens of a PSI mold were generated using the software nTopology and printed with a Form 3B SLA printer. The dimensional accuracy of the molds was validated both before and after sterilization, demonstrating minimal deviations within the acceptable clinical ranges. The generative design algorithm reduced design time from 2 hours to 1.3 minutes and minimized manual labor, yielding high-fidelity implants. The workflow demonstrated superior accuracy and efficiency compared to traditional silicone molds, facilitating easy implant release. The results suggest that this automated 3D-printed mold approach offers a viable, efficient alternative for silicon mold-based cranial PSI manufacturing, pending further clinical validation and regulatory compliance.

I. Introduction

Cranial defect reconstruction, known as cranioplasty, is a crucial procedure for restoring craniofacial functions and aesthetics after tumor removal or trauma. However, standardized cranial implants often fail to accommodate the complex variability of the craniomaxillofacial (CMF) region, necessitating manual adjustments that compromise standardization efforts. Three-dimensional (3D) printing of patient-specific implants (PSIs) offers a personalized solution and has led to the emergence of a diverse range of alternatives to conventional implants [1].

The utilization of advanced materials, such as polyetheretherketone (PEEK), in the 3D printing of patient-specific cranial implants at the point of care (POC) has gained considerable traction over the past years. This is due to the high-quality and time-efficient alternative these implants offer to externally manufactured implants. However, in resource-constrained situations where direct 3D printing of customized implants is not feasible, mold-based fabrication methods are used as an indirect approach. These conventional techniques where a two-component material is pressed into a silicon mold require significant amount of manual labor and involve multiple design and manufacturing steps, in contrast to 3D-printed PSIs.

Furthermore, they are strongly dependent on the manual skills of the individual manufacturing the mold. In addition, the silicon-based material utilized in the creation of such molds induces dimensional variabilities in the casted implant due to their flexible nature. This results in the implant becoming thicker or thinner, depending on the applied force [2,3].

Nevertheless, the exponential research on artificial intelligence (AI) and generative design, coupled with the technological advancements in 3D printing technologies and materials, could potentially offer a solution to the constraints these conventional techniques face [4].

This paper examines the potential of generative design algorithms in the field of cranial reconstruction, with a particular focus on the creation of 3D-printed cranioplasty molds. Through a comprehensive examination of the design process, material selection, and additive manufacturing techniques, the study aims to offer a more accurate, time- and cost-efficient alternative to actual silicon mold-based patient-specific cranial implant generation.

II. Material and methods

II.I. Automated mold design

An already existing cranial implant model from a patient that underwent cranioplasty was selected from the hospital's database at the University Hospital of Basel. The model was imported as a Standard Tessellation Language (.STL) mesh file into the implicit modelling software nTopology (V4.16.3, nTopology Inc., New York, USA) and used as the main input to develop the mould design algorithm.

A series of building blocks were implemented to obtain an automatically generated 2-part mold as an output. A lattice inner structure was coded to further optimize the topology of both mold segments. The meshed model was then exported to the slicing software Preform (V3.33, Formlabs Inc., Somerville, MA, USA) to be 3D printed at the POC.

II.II. Mold additive manufacturing

The stereolithography (SLA) 3D printer Form 3B (Formlabs Inc., Somerville, MA, USA) was chosen to manufacture the 2-part mold using the proprietary Biomed white resin (Formlabs Inc., Somerville, MA, USA). The models were positioned at a 45º angle in reference to the X-axis and support structures were automatically generated with a density of 1.0 and a touchpoint size of 0.3 mm.

A raft structure was added to each model to avoid cupping issues. Once printed, all models were washed in an isopropyl alcohol bath (IPA, ≥ 99%) for 10 minutes using the FormWash (Formlabs Inc., Somerville, MA, USA) washing station. Following a drying period of 30 minutes at room temperature, the molds were cured under ultraviolet (UV) light for 60 minutes at 60ºC using the FormCure station (Formlabs Inc., Somerville, MA, USA). Lastly, the support structures were manually removed using the ultrasonic cutter Wondercutter S (Cutra Co. Ltd., Incheon, Republic of Korea) and residual rough surfaces were polished using a precision tool.

II.III. Effect of sterilization on dimensional accuracy of molds

Three specimens of the same mold design were scanned using the S 9300 cone-beam computed tomography (CBCT) scanner (Carestream Dental LLC, Atlanta, GA, USA). A voxel size of 250 µm, a tube current of 4.0 mA and a peak voltage of 85 kV were used to digitize the models. Subsequently, all specimens were steam sterilized (autoclave) at a temperature of 134ºC and a steam pressure of 2.1 bars for 18 minutes and rescanned using the same imaging protocol.

To assess potential dimensional variations attributed to the sterilization process and determine the overall accuracy of the fabricated molds, the pre and post-sterilized digital specimens were compared. The Digital Imaging and Communications in Medicine (DICOM) data was imported into a medical imaging software (MIMICS 21.0, Materialise, Leuven, Belgium) and a 3D mesh model of each scanned model was obtained though threshold-based segmentation. Consequently, a 3D part comparison analysis was performed (3-matic medical 13.0, Materialise, Leuven, Belgium) between the pre and post-sterilization digitized 3D models and the root mean square (RMS) value was used to quantify the overall 3D deviations.

II.IV. Mold-based implant manufacturing

The high-viscosity bone cement Palacos R (Heraeus Medical GmbH, Wehrheim, Hessen, Germany) was used to shape the PSI by using the 3D printed 2-part mold. According to the manufacturer's guidelines, the liquid methyl methacrylate (MMA) monomer was mixed with the pre-polymerized poly(methyl methacrylate) (PMMA) powder in a 1:1 ratio for two minutes until the obtention of a malleable non-sticky viscoelastic mixture.

The polymer was then applied into the pre-lubricated (Vaseline, FINO GmbH, Bad Bocklet, Bayern, Germany) mold and pressed to shape the implant. A tight fit between both mold surfaces was ensured by using 50 mm long M8 stainless steel butterfly screws (Ayce, CH-Import and Distribution Jumbo-Markt AG, Dietlikon, Switzerland). The PMMA-filled molds were cured at room temperature for 12 minutes until the polymer fully hardened before releasing the final implant. The excess material located on the outer contour of the implant caused by the presence of overflow wells was trimmed using the Ergoret CC milling cutter (REITEL Feinwerktechnik GmbH, Bad Essen, Lower Saxony, Germany).

III. Results and discussion

An automated mold generation workflow was successfully achieved by the developed generative design algorithm, reducing the design timeframe from 2 hours to 1.3 minutes. The design underwent several iterations during the development process, with improvements being made in various areas. These included the addition of guided assembly rods for enhanced fitting, built-in threads for fixture screw fixation, and ejection boxes for better implant release (Fig. 1).

Even if some manual input by the user was permitted, for example, to fine-tune the position of the ejection boxes, the overall manual labor required was minimal. This reduced

the level of expertise required, making the workflow accessible to those without previous experience and improving its implementation at the POC.

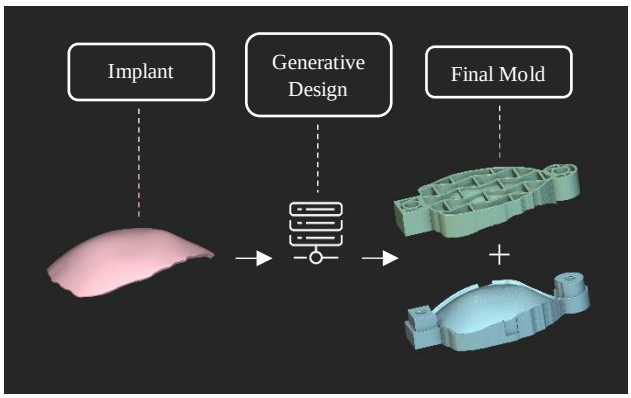

Figure 1: Schematic representation of the generative design algorithm-based workflow.

The visual evaluation of the PMMA implants manufactured by the 3D printed molds demonstrated satisfactory results in terms of dimensional accuracy and surface finish. The anatomical fidelity of the obtained PSIs assessed by fit testing the models with the existing 3D printed model of the defective skull demonstrated a high degree of congruence.

No discernible gaps or discontinuities along the borders where the implant interfaces with the defect contour were observed (Fig. 2).

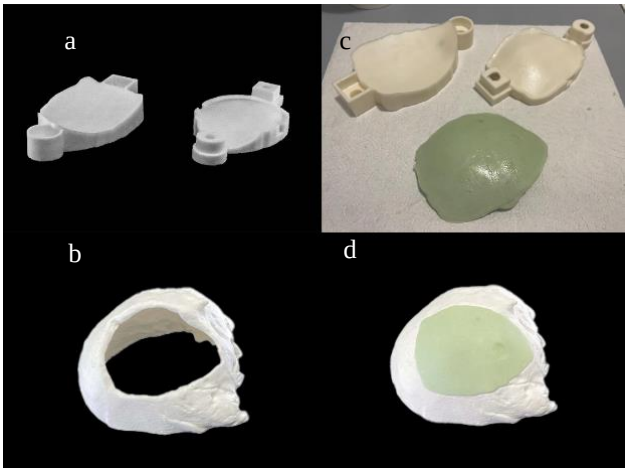

Figure 2: Schematic representation of a PMMA PSI manufacturing using 3D printed molds (a) SLA 3D printed molds, (b) skull template, (c) casted PMMA implant, (d) PMMA implant anatomical fit test.

In addition to the excellent dimensional accuracy, the ability to easily release the implant from the mold while using a rigid polymer compared to the conventional silicon material, proved SLA technology and the biomed white resin to be suitable elements to transition to a fully automated AM workflow for PSI mold generation.

Furthermore, the medical-grade certification of the resin material facilitates the integration of the workflow into the clinical environment in terms of regulatory compliance.

Regarding the effects of steam sterilization, slight deviations were noticed mainly on the guiding rod section of the molds with a peak deviation of 0.7mm (Fig. 3). However, minimal deviations were observed overall with an average deviation of 0.0599 mm, a standard deviation of 0.0473 mm and a Root Mean Square (RMS) value of 0.0763 mm with consistent findings across the lower and upper mold sections.

The results demonstrate that the influence of steam sterilization on the overall dimensional accuracy of the molds remains within the clinically acceptable range.

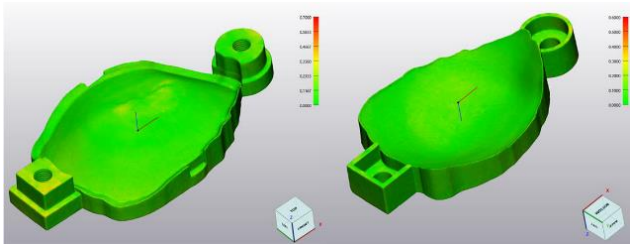

Figure 3: Part comparison analysis.

IV. Conclusions

The efficacy of the developed generative design algorithm, when combined with the use of 3D printing, offers an optimized approach for the manufacturing of PSI molds at the POC. The automated workflow reduces the required designing time and expertise while generating highly accurate models. 3D printed molds exhibit superiority over the traditionally employed silicone molds with higher geometrical accuracy of the fabricated implants and require minimal manual interventions making them more time-efficient and less reliant on employee experience.

However, in order to determine the boundaries of the design algorithm for complex defects and to evaluate the implementation of such a workflow in the clinical environment, further testing from experienced surgeons is required. In addition, compliance with regulatory guidelines and quality management systems should be ensured to guarantee the safety and efficacy of the proposed method.

Nevertheless, the findings of this study indicate that there is a viable prospect for the transition from hybrid manufacturing to 3D printing of patient specific cranial molds at the POC.

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Author's statement

Authors state no conflict of interest. Informed consent was obtained from all individuals included in this study.

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