PMMA Cranioplasty Making by Using Open Source CAD Softwares, PLA Printers and Silicone Rubber Molds: Technical Note with 2 Illustrative Cases

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Abstract

In this technical report, we talk about the design and producing of PMMA implants, which we successfully applied in two patients using silicone molds, and retrospective review of these patients at the 1 and 6 months intervals. By using open source CAD softwares, 3D printers and the patient’s thin sliced computed tomography (CT) data, we designed and produced the implant template and used it to make silicone rubber molds for intraoperative PMMA casting with good results. As a negative of the implant we created a silicon mold, which can be autoclaved. 2 patients underwent PMMA cranioplasty using this method. Both implants were fitted into the defect without manipulation and the good aesthetic appearance of all patients was achieved. At follow-up 1 and 6 months after the operation, no complication was noted and the patients tolerated the cranioplasty plate well.

Objective

The evolution of cranioplasty parallels the development of technology, the growth of our collective imagination, and our desire to provide maximum benefit with minimum risk and the smallest footprint [1].

Using autografts from other parts of the body, such as the contralateral skull vault or the ribs, is feasible but incurs the cost of additional donor site morbidity [2,3].

Many synthetic materials have been used successfully in cranioplasty [4-6]. Today, in the cranioplasty commonly used synthetic materials include polymethyl methacrylate (PMMA), titanium, ceramics, and polyether ether ketone (PEEK) [6]. The main advantage of PMMA over all these materials is that it is cost-effective, available in cement form and can be moulded intraoperatively. PMMA is an acrylic polymer created when two sterile components (a powder and a liquid) are mixed, while the polymer sets, it can be molded into a specific shape [7]. Once hardened and cooled, it is safe for implant into humans [7,8].

Three-dimensional printing technology also known as additive manufacturing, together with modern computer-assisted design (CAD) and computer aided manufacturing (CAM) systems and rapid prototyping (RP) facilitate the evaluation of cranial defects and allow accurate fabrication of custom-designed objects, and has immense potential in the medical field, particularly for surgical planning and implant production [9]. 3D prints of anatomical structures could be produced with sub millimeter accuracy (< 0.5 mm) compared to the original specimens [10,11]. In a preclinical study, Tan, et al. obtained excellent cosmetic results with patient-specific PMMA implants produced with low-cost 3D printed PLA (PolyLactic Acid) molds [11]. Similar to this study, we also demonstrate how to produce patient-specific implant using desktop 3D printers, but unlike Tan, et al. technique, we did not use PLA molds, but silicone molds to get precise implants intraoperatively, which were successfully used in two patients. Using CAD software and the patient’s neuroimaging data, we designed and produced the implant template and used it to make silicone rubber molds for intraoperative PMMA casting with good results. We created a silicon mold as a negative of the implant based on a 3D reconstructed image of the defect. The silicone mold can be autoclaved.
Patient 2 was a 54-year-old female who suffered 4 years previously from a major traumatic brain injury complicated by left sided subdural hematoma that required immediate left sided decompressive craniotomy. The defect was repaired 2 times with acrylic cranioplasty that got infected and implant removed. She was referred to us after 6 months of last cranioplasty. She suffered from frontal lobe syndrome and epilepsy. The patient underwent preoperatively a cerebral CT scan with thin slices (1 mm) (Figure 1b).

Patient 2 was a 54-year-old female who suffered 4 years previously from a major traumatic brain injury complicated by left sided subdural hematoma that required immediate left sided decompressive craniotomy. The defect was repaired 2 times with acrylic cranioplasty that got infected and implant removed. She was referred to us after 6 months of last cranioplasty. She suffered from frontal lobe syndrome and epilepsy. The patient underwent preoperatively a cerebral CT scan with thin slices (1 mm) (Figure 1b).

The purpose of this paper is to demonstrate our method of creating patient-specific templated silicone molds, assess its safety and practicality and compare it to existing techniques.

Materials and Methods

The Helsinki Declaration guidelines had been followed. Both patients had been informed about this new technique and written informed consent for performing cranioplasty using this method was obtained. Both patients were considered good candidates for investigated method.

Patients

Patient 1 was a 21-year-old male who was admitted in hospital 3 years ago with traumatic brain injury and underwent an immediate right sided decompressive craniotomy. He suffered from Broca-type aphasia and left sided hemiparesis. The patient underwent preoperatively a cerebral CT scan with thin slices (1 mm) (Figure 1a).

Patient 2 was a 54-year-old female who suffered 4 years previously from a major traumatic brain injury complicated by left sided subdural hematoma that required immediate left sided decompressive craniotomy. The defect was repaired 2 times with acrylic cranioplasty that got infected and implant removed. She was referred to us after 6 months of last cranioplasty. She suffered from frontal lobe syndrome and epilepsy. The patient underwent preoperatively a cerebral CT scan with thin slices (1 mm) (Figure 1b).

Clinical consideration of the CAD algorithms and their potential application in this study are briefly outlined. Contiguous 1-mm reconstructed slices were produced from the CT data volume. The data, in DICOM format, was transferred to a computer workstation for editing in open-source image-editing software. We use open-source image-editing software and desktop 3D printers, which are briefly described below. With computer software (3D Slicer 4.11.0; Surgical Planning Laboratory), image segmentation was performed using the threshold method, based on density ranges of the Hounsfield units, the 3D model of the region of interest was obtained, the data being exported in the STL format (Standard Tessellation Language) later on.
Next, using 3D modeling software (Mesh Mixer 3.5; Autodesk Inc., San Rafael, CA, United States), the STL file was then analysed and reverse engineering was performed to make solid CAD (Figure 2a and Figure 2b) from the STL file so that operations like editing, modelling and Boolean operations could be performed. Then using Blender software (Blender 2.8 beta, Blender Foundation, community) a mirror image of the normal model was created, resized (Figure 3a and Figure 3b), and overlapped onto the mirror model (Figure 4a and Figure 4b). The Boolean operation was performed on the superimposed solids. After performing the subtraction, the contours that were not closed and small missing spaces were repaired and small protruding areas were cropped. The resulting mesh was then exported in STL format to get the file. The mirrored part was subtracted from the defect, leaving the missing part. The two designed prototype models are shown in Figure 1a and Figure 1b. Both the STL files (models of the defective skull and implant) generated were converted into slices in the G-code format to be printed in PLA material using fusion deposition modeling (FDM) technique. The 3D models of both the defective skull and the implant template were “sliced” with computer software (Cura15.04.3; Ultimaker Industries) with the following settings: infill, 15%; shells, 0.8; layer height, 0.2 mm;
two printed models are shown in Figure 5a, Figure 5b and Figure 5c. The silicon rubber moulds were made by using Elite Double 22 Fast duplicate silicon. The silicon mold is sterilized by steam autoclave just prior to the procedure and presented to the surgeon (Figure 6a) once the defect is exposed. We exposed the dural edges until the full thickness of the skull surrounding the defect (Figure 7a). PMMA (Mendec Cranio Radioopaque bone cement; Tecres S.p.A.) is mixed and placed in the mould. The bone cement was allowed to harden and
the design of the digital models were completed in 60 minutes. The implant template was printed in about 4 h. Then using the templated silicone molds we created the implants intraoperatively. 2 units of PMMA were used to form the acrylic cranioplasty implant. Application of the bone cement in its putty form to the silicone mold was simple. Both implants were fitted into the defect without manipulation and the good aesthetic appearance of all patients was achieved. At follow-up 1 and 6 months after the operation, no complication was noted and the patients tolerated the cranioplasty plate well. No septic complications were noted postoperatively. Fitting the implant to the craniotomy defect did not require any further drilling or modification. There were no intraoperative complications, the drain was withdrawn when the flow rate was < 50 ml in the postop 24 h and the patients were discharged on the second and third days postoperatively. At follow-up 1 and 6 months after the removal from the mould (Figure 6b). 5-7 mm holes were drilled in the centre of cranioplasty plate to prevent development of an epidural haematoma. The thickness of the implant produced for each case was of 5 mm. The thickness of the prosthesis matched the patient’s cranial vault thickness. A drain was placed and then the plate was secured in place with titanium miniplates and screws (Figure 7b and Figure 7c). Prophylactic antibiotics were given routinely prior to the incision. The defect is routinely closed in available layers. No complications were observed in either of the cases intraoperatively. Figure 8a and Figure 8b shows postoperative CT images with bone reconstruction.

Results

Total of two patients underwent PMMA cranioplasty using a silicone mold. The implant model was designed and manufactured successfully. The generation and design of the digital models were completed in 60 minutes. The implant template was printed in about 4 h. Then using the templated silicone molds we created the implants intraoperatively. 2 units of PMMA were used to form the acrylic cranioplasty implant. Application of the bone cement in its putty form to the silicone mold was simple. Both implants were fitted into the defect without manipulation and the good aesthetic appearance of all patients was achieved. At follow-up 1 and 6 months after the operation, no complication was noted and the patients tolerated the cranioplasty plate well. No septic complications were noted postoperatively. Fitting the implant to the craniotomy defect did not require any further drilling or modification. There were no intraoperative complications, the drain was withdrawn when the flow rate was < 50 ml in the postop 24 h and the patients were discharged on the second and third days postoperatively. At follow-up 1 and 6 months after the

Figure 7a, Figure 7b and Figure 7c: a) Defect exposed after the elevation of the scalp in patient 2; b and c) Fixation of the prosthesis into the defect in patient 1 a) and patient 2 (b) Note a implanted prosthesis having exact shape and size as of skull defect.

Figure 8a and Figure 8b: a) Postoperative CT image in patient 1 and b) Postoperative CT image with bone reconstruction of the same patient.
operation, no complication was noted and the patients tolerated the cranioplasty plate well. Thanks to use of this method both patients had the excellent cranial contour.

**Discussion**

Considerably cost saving is achieved by using describing method of creating a templated silicone mold, which is the negative of the patient-specific implants. The silicone mold can be autoclaved preoperatively, which allows the surgeon to create a sterile implant that matches the defect perfectly. Sepsis in cranioplasty is a well-known complication, Kwarcinski, et al. in their meta-analysis of materials, manufacturing techniques and infection risk demonstrated an overall sepsis rate of 6.99% in pre-manufactured PMMA implants, 10.98% in hand-formed PMMA implants and 6.86% in templated PMMA implants [12]. This was comparable with titanium mesh and plates which had 7.71% and 8.31% average reported infection rates [12]. In our study, no septic complications were noted. The main advantage of silicone rubber is that it allows preservation of very thin details of the plate (e.g. margins) during unmolding, which provided good stabilization and there was no need for rigid fixation [13]. One of the other advantages of the silicon mold is the ability to re-use it if necessary as the mold is simply resterilised in theatre and a new PMMA implant created [14]. In our study, we demonstrated the safety and practicality of making cranial implants by using open source CAD softwares, a PLA 3D printer, PMMA, and autoclavable laboratory silicone. The implant created matched to the craniecomy defect perfectly. We used PLA to create both the defective skull and the implant template. PLA is a biodegradable and biocompatible thermoplastic with widespread applications in both medical and nonmedical fields [15,16]. It has been used for implantation in the human body for functions ranging from soft tissue fillers to fracture fixing screws [17,18]. With a glass transition temperature of 55 °C, it is unsuitable for the autoclave [10]. Since the PLA is not autoclave-resistant, we did not use PLA molds for intraoperative molding.

**Conclusions**

In this study, we showed that, patient specific silicone rubber molds using PMMA to create cranial implants intraoperatively are safe, have excellent cosmetic results and are a very cost-effective option to treat large and complex cranial defects.

**Conflicts of Interest**

There were no conflicts of interest during the writing or submission of this case.

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This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

**Ethical Approval**

The study was approved by the Ethics Committee of Ankara City Hospital. The study protocol will be conducted in accordance with the Declaration of Helsinki. The writing and editing of the article will be performed in accordance with the Standard Protocol Items.

**Consent**

Written informed consent was obtained from the patient for publication of this case report and accompanying images. A copy of the written consent is available for the review of the Editor-in-Chief of this journal on request.

**References**


