



Polylactic Acid Implant for Cranioplasty with 3-dimensional Printing Customization: A Case Report

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Abstract

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BACKGROUND: Cranioplasty is aimed to restore the structure and function of the lost portion of the skull defect. Many materials can be used for cranioplasty, such as the bones of the patient (autograft), the bones of other patients (allograft), bones of animals (xenograft), or synthetic materials such as acrylic or titanium mesh. These materials are quite expensive and sometimes require complex processes. Manual shaping of material for cranioplasty is also quite time-consuming and prone to cause esthetic dissatisfaction. The author will discuss the case of using polylactic acid (PLA) implant with 3-dimensional (3D) printing customization as a cheap and accurate cosmetic solution for cranioplasty procedures.

CASE REPORT: We report 2 cases of skull defect underwent cranioplasty. The first case, female, 20-year-old, had a history of severe traumatic brain injury (TBI) and epidural hematoma. She underwent decompression craniotomy on the left frontotemporoparietal region of her skull. The second case, male, 46-year-old, had a history of spontaneous intracerebral hemorrhage due to arteriovenous malformation (AVM). He underwent decompression craniotomy on the right frontotemporoparietal region of her skull. Both the data of computerized tomography (CT) scan were reconstructed to get 3D model of skull defect. Prosthesis was made by 3D printer accordingly using PLA as material. There was no complication reported postoperatively and cosmetic satisfaction was obtained on both cases.

CONCLUSION: The use of PLA implant with 3D printing customization was proved to be cost-effective and good cosmetic satisfaction with no complication reported following cranioplasty procedure.

Background

Cranioplasty has a purpose to restore defect into a nearly close anatomical landmark of the skull to aim functional and cosmetic satisfaction [1]. Many materials can be used for cranioplasty, such as the bones of the patient (autograft), the bones of other patients (allograft), bones of animals (xenograft), or synthetic materials such as acrylic or titanium mesh [2]. Manual shaping of material for cranioplasty is also quite time-consuming and prone to cause esthetic dissatisfaction [3].

The most widely used autograft material is cranial bone from the patient itself, while materials such as tibia, ribs, scapula, and fascia, as well as the sternum and ileum, have begun to be abandoned because it is difficult to adjust bone flaps with defects in the skull [4]. Various other synthetic materials have been investigated to replace skull bone, such as hydroxyapatite, titanium mesh, alumina ceramics, and polyether ether ketone (PEEK). Each of these ingredients is proven safe to use, but all of them require a substantial cost [2], [5].

PLA is a Food and Drug Administration (FDA) – approved material that has been widely used for medical implants [6]. PLA can be used as customized 3-dimensional (3D) printing material. 3D printing technology itself has been widely used in industry and began to be used in the medical world [7]. 3D printing makes it possible to make implants with high accuracy for complex anatomy where manual shaping has weaknesses in accuracy and time consuming [8]. We present two cases of cranioplasty with PLA implant material with a 3D printer at our institution.

Case Report

The first case was a 20-year-old female with a skull defect in the left frontotemporal region. She underwent decompression craniotomy due to severe traumatic brain injury (TBI) and epidural hematoma lesion 4 years before admission. She actually had undergone cranioplasty but the bone was removed due

to infection. The patient regularly did checkup in our hospital and decided to be performed cranioplasty due to cosmetic reasons. Physical examination revealed sufficient general conditions with a stable vital sign. No neurological deficit was reported. Head computed tomography (CT) scan revealed unilateral skull defect in the left frontotemporal region. Digital Imaging and Communications in Medicine (DICOM) data were processed to obtain 3D reconstruction model (Figure 1).

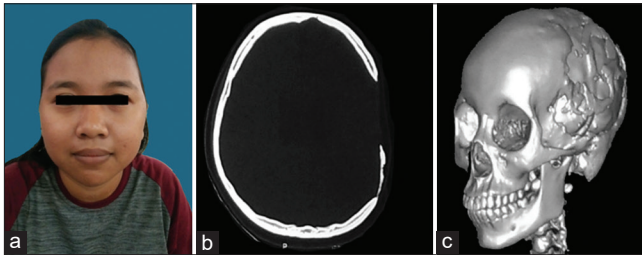


Figure 1: Pre-operative clinical photograph of a female with a skull defect in the left frontotemporal region (a) and head computed tomography with axial view of bone window (b) and 3-dimensional reconstruction (c)

The second case was a 46-year-old male with a skull defect in the right frontotemporal region. He underwent decompression craniotomy because of spontaneous intracerebral hemorrhage due to arteriovenous malformation (AVM) 1-year before admission. The patient came to our hospital to be performed cranioplasty due to esthetic reasons. Physical examination revealed sufficient general conditions with a stable vital sign. No neurological deficit was reported. Head CT scan and DICOM were obtained to render 3D reconstruction model (Figure 2).

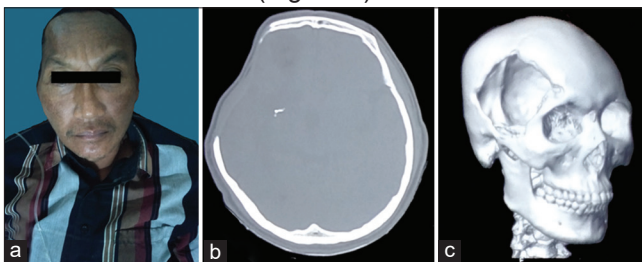


Figure 2: Pre-operative clinical photograph of a male with a skull defect in the right frontotemporal region (a) and head computed tomography with axial view of bone window (b) and 3-dimensional reconstruction (c)

In each case, 3D reconstruction was required from CT scan with each slice size of 1 mm × 1 mm. The DICOM file from the CT scan was used as a reference to create a three-dimensional model of the patient's craniofacial model using LightWave 3D (software by NewTek) program. Using Materialise Mimics (Software by Materialise, Belgium), the DICOM image was translated into a 3D model by Flash Print, software made by the company's 3D printer, Flashforge. The printer used was a fused deposition modeling (FDM) 3D printer (Hardware by Anycubic). The results of the reconstruction were then printed. The time need for 3D reconstruction of skull/craniofacial phantom model was around 24–30 h. The defects of decompression are also

analyzed and measured to then make a negative mold model. The mold is based on the contour of the intact contralateral skull. The mold material used was PLA filament. The negative mold model was sterilized before in plasma system sterilization. The mold consisted of two pieces. During surgery, antibiotic was applied to the surface of the mold. Sterile PLA powder was mixed with sterile normal saline until its consistency became jelly-like materials. PLA was applied to synthetic skull mold according to the size of the defect and was waited for 15 min for hardening. After the material was hardened, PLA implant was acquired. The implant was then placed over the defect and was fixed using miniplates and screws (Figure 3). A good reconstruction result was achieved and no complication was found during and after surgery.

Both patients were discharged <1 week after cranioplasty with the normal condition and no neurological deficit. Patients were advised to avoid direct impact on the site of surgery and maintain good hygiene. Both patients came regularly in bimonthly basis to do a medical checkup. No complication was reported and cosmetically satisfactory results were obtained. The cost was spent for 3D craniofacial model and negative mold was around 50–150 USD and for PLA was around 60–125 USD (conversion from author's currency, Rupiah).

Discussion

Skull defects can be caused by direct trauma or post-operative craniectomy of other causes. Therapeutic decompressive craniectomy (DC) operative surgery involves an increase in convex cranial bone flaps that are stored either *in vivo* (e.g., abdominal or thigh subcutaneous pouches) or in *ex vivo* media (cryogenically) and tissue bank). Cranioplasty aims to restore the defects in the skull to their original anatomical form which is close to normal anatomy so that they can provide protection to the brain and restore cosmetic aspects. Cranioplasty is challenging due to the various shapes, sizes, and complexity of the defect itself.

Cranioplasty involving frontal bone will be more difficult when compared with temporal and parietal bone due to its complex convexity anatomy. Frontal bone also has an orbital roof structure and more visible regions for cosmetic aspects impose more challenges for reconstruction [9].

The defect reconstruction with computer-assisted 3D reconstruction allows more accurate anatomical form and it removes the time-consuming manual carving stage, although there is no clinical difference in outcome [10]. 3D reconstruction can provide the latest anatomical picture because the defect shape and soft tissue can change over time since DC is

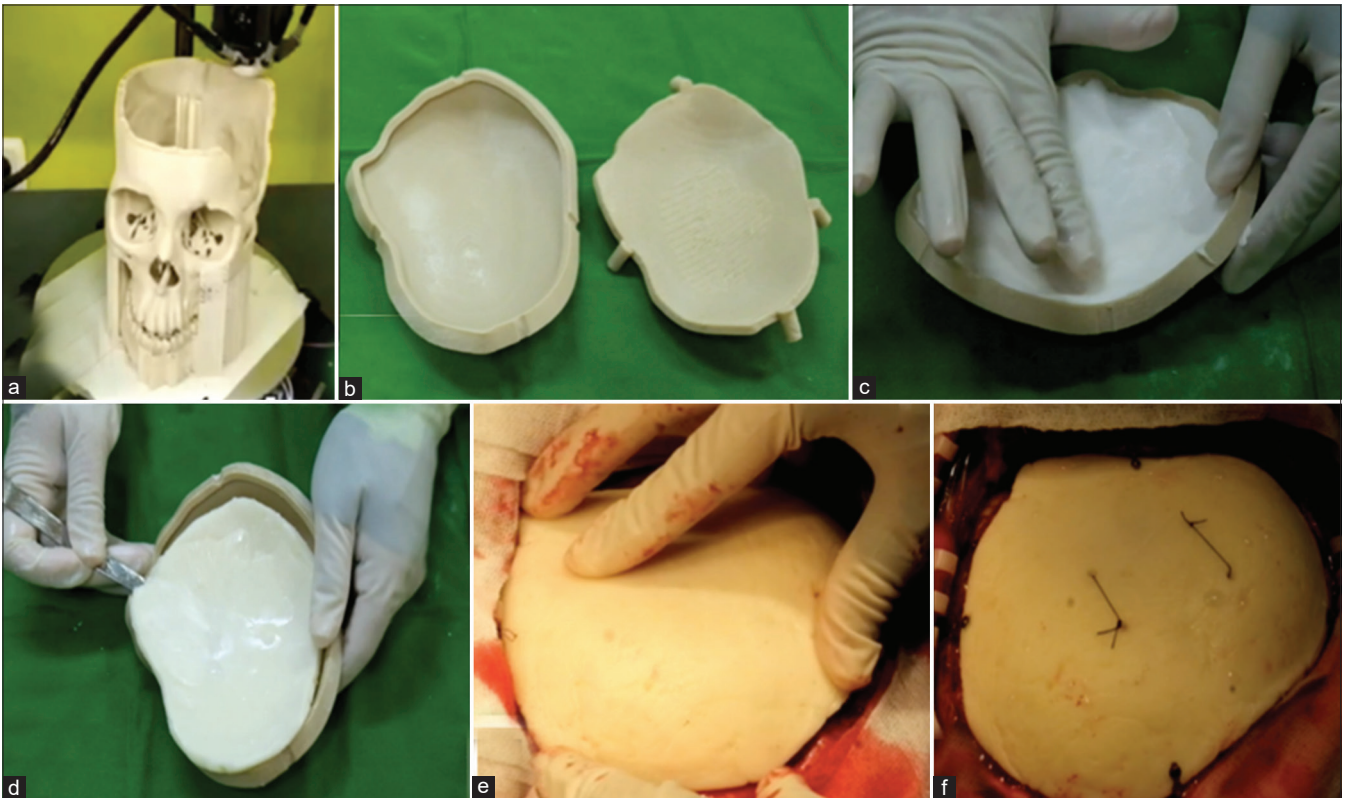


Figure 3: Implant remodeling process and placement scheme. Printing of skull phantom model with defects according to the patient's DICOM image (a); craniofacial model molds according to three-dimensional reconstruction (b); application of PLA to molds (c); synthetic skull formed according to the size of the defect (d); placement of synthetic skull implant made from PLA into the site of the defect (e and f)

done. These anatomical changes can prolong operating time because the implant becomes difficult to modify in-theatre [11].

Autograft cranioplasty is the best choice for economic reasons and compatibility with patients. However, in certain circumstances, autograft cranioplasty cannot be performed because of the destruction of the skull bone (e.g., due to trauma or invasion of the tumor). Various materials have been investigated as a basic component to replace the skull bone, such as hydroxyapatite, titanium mesh, alumina ceramics, and polyether ether ketone (PEEK). Each of these materials is proven safe to use, but all of them require a substantial cost.

In this study, we use polylactic acid (PLA) as materials for both the skull phantom model and mold. PLA is thermoplastic and biodegradable which nontoxic characteristic for the human body. PLA can be processed by injection molding so it is suitable for customized applications for 3D printing [12]. PLA has been used for a medical implant for the last decades due to its safety. PLA has a melting point in the range of 180–220°C and glass transition temperature about 57 °C [12], [13]. Due to its low melting point and glass transition temperature, PLA is not suitable for autoclave sterilization. Plasma system sterilization can be used for PLA which based on low-temperature hydrogen peroxide sterilization [14]. PLA had been approved as a safe material for the implant by the

US Food and Drug Administration (FDA) [6]. PLA degradation and absorption *in vivo* may vary depends on the size and shape of the plates, circulation, thickness of the soft tissue, and the transplant site. The smaller and less volume plates tend to have faster degradation and absorption [15], [16], [17]. Several studies stated PLA degradation and absorption in human body take up to 5–8 years for the material to be absorbed [18], [19], [20].

The PLA cost was spent for 3D craniofacial model and negative mold was around 50–150 USD and for PLA was around 60–125 USD (conversion from author's currency, Rupiah) in our study. PEEK implant cost was approximately 10,450 USD, manually shaped titanium implant cost was 10,265 USD and hydroxyapatite implants cost was around 7840–8960 USD [21], [22], [23], [24]. These costs were significantly cheaper compared to other materials. In this study, we used 3D printer with cost around 250 USD and publicly provided software which are much cheaper than industrial hardware and software.

There was no complication reported postoperatively and cosmetic satisfaction was obtained on both cases in our study. PLA implants were reported to give accurate anatomical restoration. PLA implant for cranioplasty had the cranial index of symmetry around 96.2%, it showed that PLA implant with computer-aided reconstruction was strongly accurate [25]. In a study with 22 consecutive patients undergoing cranioplasty

with an implant using a desktop 3D printer, there was no sign of infection, implant rejection, wound dehiscence, or implant removal during the recovery period and 6-month follow-up [26].

Conclusion

The use of PLA implant with 3D printing customization was proved to be cost-effective and good cosmetic satisfaction with no complication reported following cranioplasty procedure. This technique can be an option for a cranioplasty procedure.

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