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Technical Notes

Customized alloplastic cranioplasty of large bone defects by 3D-printed prefabricated mold template after posttraumatic decompressive craniectomy: A technical note

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ABSTRACT

Background: Manufacturing of customized three-dimensional (3D)-printed cranioplastic implant after decompressive craniectomy has been introduced to overcome the difficulties of intraoperative implant molding. The authors present and discuss the technique, which consists of the prefabrication of silicone implant mold using additive manufacturing, also known as 3D printing, and polymethyl methacrylate (PMMA) implant casting.

Methods: To reconstruct a large bone defect sustained after decompressive craniectomy due to traumatic brain injury (TBI), a 3D-printed prefabricated mold template was used to create a customized PMMA implant for cranial vault repair in five consecutive patients.

Results: A superb restoration of the symmetrical contours and curvature of the cranium was achieved in all patients. The outcome was clinically and cosmetically favorable in all of them.

Conclusion: Customized alloplastic cranioplasty using 3D-printed prefabricated mold for casting PMMA implant is easy to perform technique for the restoration of cranial vault after a decompressive craniectomy following moderate-to-severe TBI. It is a valuable and modern technique to advance manufacturing of personalized prefabricated cranioplastic implants used for the reconstruction of large skull defects having complex geometry. It is a safe and cost-effective procedure having an excellent cosmetic outcome, which may considerably decrease expenses and time needed for cranial reconstructive surgery.

Keywords: 3D-prited implant molding, Cranial vault restoration, Decompressive craniectomy, Traumatic brain injury

INTRODUCTION

Decompressive craniectomy is a surgical method for control of intracranial hypertension, which can be sustained by secondary brain damage following a severe traumatic brain injury (TBI).[35,47] However, its ultimate consequence is the creation of large/complex bone defects, which necessitates cranial vault restoration for brain protection, improved cosmetic effect, and

better neurological recovery.[15,41] To overcome this, various cranioplastic techniques and materials are currently available, including frozen autogenous bone flap,[27] and different alloplastic substitutes such as polymethyl methacrylate (PMMA),[1,13,28,31] polyether-ether ketone,[5,6,18] bioceramic,[2,44] carbon-fiber-reinforced polymers,[38] and metallic/titanium mesh.[4,39] Ultimately, whichever implant material is used, it has to be viable and robust enough, fitting well into the cranial defect.

The autologous bone flap is frequently unavailable due to possible bone flap resorption and septic complications, which could lead to prolonged hospital stay and neurological deterioration, requiring a second surgery.[48] Besides, partial bone flap resorption is most likely a normal physiological phenomenon during the bone revitalization process.[29] Hence, alloplastic cranioplasty appeared to be a regular alternative. However, such a technique, if manual, requires an intricate intraoperative implant preparation consisting of molding, adaptation, and contouring, which consume surgical time. Therefore, to adjust cranial reconstruction according to each patient's individual needs better, prefabrication of customized implant using a three-dimensional (3D) modeling and 3D printing has been proposed.[11,16,20,23,24,33,38]

Herein, we demonstrate and discuss a technique of cranial vault restoration after TBI decompressive craniectomy with the help of 3D customized molding of PMMA implant for alloplastic cranioplasty of large bone defects, contemplating its practical aspects, cosmetic effects, and safety.

MATERIALS AND METHODS

During the last couple of years, we have been involved in doing alloplastic cranioplasty by the help of additive manufacturing (3D printing). To repair a large/complex unilateral postcraniotomic bone defect sustained after a TBI, we have successfully used a 3D-printed prefabricated mold template to create a customized PMMA implant for bone repair in five consecutive patients.

All patients involved signed an informed consent allowing their personal data to be used for the purpose of this paper.

Preoperative plain X-rays and multisliced computerized tomography (MSCT) of the head were made in all patients before reconstructive surgery [Figures 1a and b]. Personalized data imaging from preoperative MSCT scans in Digital Imaging and Communications in Medicine (DICOM) format were calculated and converted into Surface Tessellation Language format [Figures 2a and b], preparing data for 3D printing of the mold.

3D image of the skull was obtained from preoperative axial MSCT scan [Figure 3]. Digital subtraction mirror imaging of the implant was generated using the unaffected skull side as initial template to produce the implant's image mode by acquiring DICOM data, which were processed and converted to 3D images subsequently [Figure 4]. The contralateral side of the skull preoperative MSCT imaging was chosen as initial template since ipsilateral skull was considered never entirely

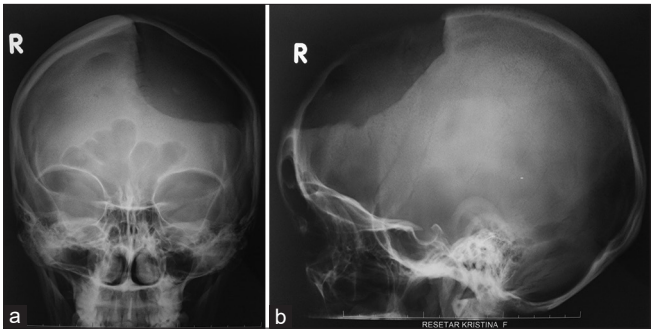

Figure 1: (a) Preoperative plain X-ray craniogram showing unilateral large frontoparietal skull bone defect in AP projection. (b) Preoperative plain X-ray craniogram showing unilateral large frontoparietal skull bone defect in LL projection.

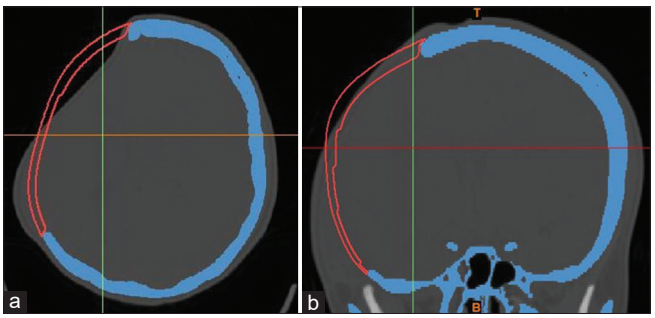

Figure 2: (a) Personalized data imaging from preoperative multislice computed tomography (MSCT) of the head simulating bone defect covering in axial reformation. (b) Personalized data imaging from preoperative MSCT of the head simulating bone defect covering in coronal reformation.

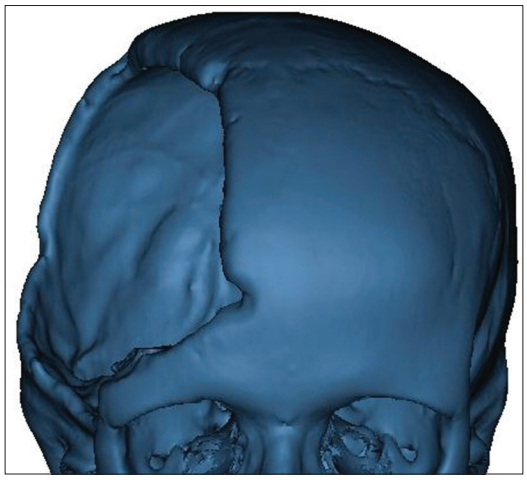

Figure 3: Three-dimensional image of the skull obtained from preoperative multislice computed tomography scan.

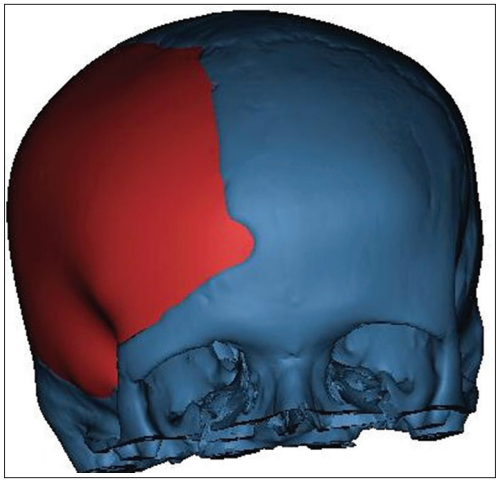

Figure 4: A digital subtraction mirror imaging method employed to produce the 3D implant's image model.

intact due to possible effects of TBI on the affected cranial side integrity and geometry.

In the second phase, a customized 3D model of the implant was designed according to the initial images, which were employed to create an individualized prefabricated mold by the help of a PolyJet additive technology. The reason for designing a new model instead of using mirrored images was the natural asymmetry of the skull.

Synthetic mold was produced in a test center, sterilized, and brought to the operating room [Figure 5], to create an on-site customized PMMA implant, which was fitted into the cranial defect after a slight trimming of the margins, and fixed by titanium microplates and screws [Figure 6]. The method was comparable to the one described previously,[12] confirming its advantages further. However, the follow-up period for our series' patients was much longer, since the first patient was operated on in 2014 and the last one in 2020.

No prophylactic oral antibiotic covering was used peri- and postoperatively.

In all patients, plane cranial X-rays were performed immediately postsurgery to check the implant's position and contours [Figure 7a]. A head MSCT scans were performed at 1-month follow-up to confirm the cosmetic outcome [Figure7b].

Patients' personal satisfaction with the outcome of reconstructive surgery was assessed on regular follow-ups too.

RESULTS AND DISCUSSION

Five patients with large one-sided frontoparietal-temporal skull defects (>100 cm^2) underwent alloplastic PMMA cranioplasty over a 6-year period (2014–2020) [Figures 1a and b]. All suffered a moderate-to-severe TBI and

Figure 5: A photo of prefabricated 3D-printed two-piece sterilized silicone mold prepared for the PMMA implant casting.

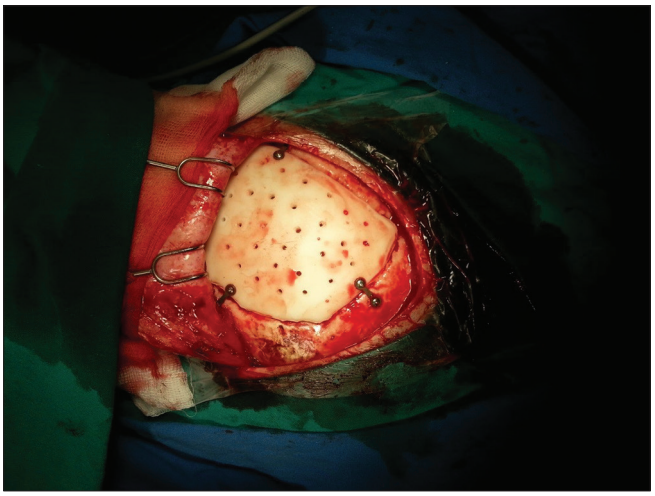

Figure 6: An intraoperative photo of the PMMA implant, which was fitted and fixed into the cranial defect by microscrews and titanium plates.

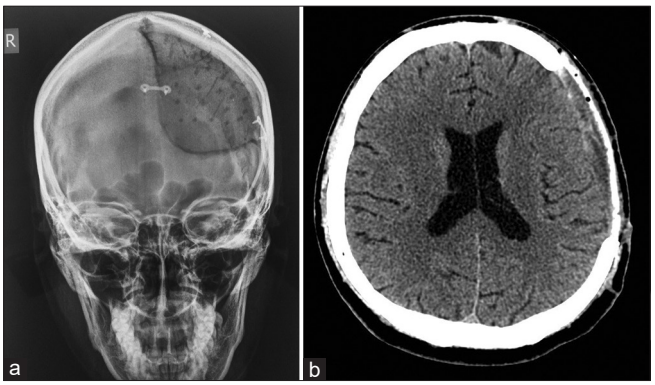

Figure 7: (a) Postoperative plain X-ray AP craniogram showing the implant perfectly fitted into the left frontoparietal cranial defect. (b) Postoperative axial MSCT scan of the head showing the implant perfectly fitted into the left frontoparietal cranial defect.

were submitted to decompressive unilateral craniectomy as a method of early surgical management. Following the initial surgery, all recovered fully before cranioplasty. The median

time between the initial decompressive craniectomy and cranioplasty was 6.4 months.

The group consisted of three females and two males, ranging in age between 21 and 57 years. The mean patients' age at the time of cranioplasty was 37.3 years.

The median surgical time for cranioplasty was 96 ± 17 min, while the mean duration of the intraoperative molding process was 21 ± 8 min.

Postoperative X-rays and MSCT head scans showed excellent restoration of symmetrical cranial contours and curvature, in addition to well-fitting implants in all patients [Figure 7a and b].

Patients were followed up in the period between 5 and 1 year postcranioplasty with careful assessment of their clinical status, morphological appearance, and personal satisfaction. The median follow-up period was 25 months (ranging 12–28 months).

Postoperative infection developed in one patient who developed an open wound defect postcranioplasty. This patient underwent a repeated late PMMA cranioplasty after the infected implant removal and consecutive broad antibiotic treatment, leading to complete wound healing. The time elapsed between the two cranioplasties was 9 months.

The outcome was clinically favorable and cosmetically excellent in all patients. All were very satisfied with the result of reconstructive surgery and felt comfortable with their final cosmetic effect.

In this paper, we discussed the use of 3D printing additive technology for the construction of a mold by which a PMMA implant for the restoration of huge/complex unilateral skull bone defect was produced. We also addressed the practical advantages and pitfalls of the procedure, comparing it to other contemporary cranioplastic techniques. Finally, we reviewed the literature and debated over future perspectives of the technology.

Reconstruction of a cranial vault is particularly demanding surgical procedure.[8] Cranioplasty after posttraumatic decompressive craniectomy aims to restore esthetic appearance, improve cerebrospinal fluid dynamics, and assure cerebral protection to enhance neurological recovery.[26] Nonetheless, it can be related to noteworthy morbidity. To optimize its outcome and to lessen morbidity, a consensus agreement has been reached about the best material for use and the appropriate timing of cranioplasty lately.[25]

Cranioplasty with an autologous bone flap after decompressive craniectomy has been the preferable treatment for cranial reconstruction.[21] Since partial aseptic bone resorption is a common physiological phenomenon during the bone revitalization process,[29] such a procedure is frequently burdened by bone flap insufficient reintegration,[14,22,49] and the increased risk of infective complications. Alternatively, when alloplastic cranioplasty is concerned, manual shaping of the bone cement (alloplastic material) is challenging and time consuming and may not always lead to a satisfactory result.[32,45] Hence, the use of patient-specific alloplastic implants is in constant demand now, but it is often limited due to a lack of expertise or due to high production costs.[7] Therefore, it could be virtually planned, less cheap, and much better performed with the help of 3D printing additive technology, which is an easy to perform and affordable cost procedure.[1,3,13,23,32,34] The concept is to employ 3D designed cranial model geometric data to create a 3D patient-specific implant or mold to rebuild complex skull anatomy accurately and to endorse better recovery. Such a procedure, which is based on the computer-aided design (CAD) and 3D printing of cranioplastic implant, is always beneficial when compared with the conventional noncustomized, free-hand time-consuming implant casting. Nonetheless, creation of CAD patient-specific direct implants is often associated with long production times and high costs. To overcome this, some authors suggest a technique of intraoperative implant production using a 3D-printer-assisted patient-specific molding,[40] which may be way cheaper than the closest marked related products.[46] Others suggest that an implant mold may be inserted between a negative form of patient's own bone flap and the original bone flap, obtaining exactly the same shape, thickness, and implant's dimensions.[32]

However, implant's design and materials are not standardized yet. Different materials with different mechanical properties dissimilar to that of the lost bone at the site of implantation are in use currently.[1,2,5,13,28,31,38,43] To accomplish the best surgical and cosmetic outcome and to preserve the mechanical properties while improving the bioactivity, porosity, and biocompatibility, the ideal implant is supposed to be well built and strong enough, as well as appropriate for the entire bone defect closing.[43] According to our experiences and results from literature, a PMMA is a supreme material for the cranial vault reconstruction. It is a robust engineering organic thermoplastic polymer, having high biocompatibility, biostability, and antibacterial properties,[12,43] which maintains its physical and chemical characteristics infinitely.[16] Its elasticity, resistance, rigidity, and toughness, as well as its thermoplastic and radiolucent properties, are comparable to that of cortical bone, which makes it among most motivating materials when compared to other alloplastic implants.[21,43] Although the custom-made PMMA implants have shown a significant improvement in cranial vault precise reconstruction and symmetry,[9,28,37] creation of implant directly on the cranial defect is burdened by the exposure of neural tissue to the heat of polymerization.[48] Therefore, we advocate the intraoperative implant casting into the 3D-printed mold, which proceeds the implant's creation. It is a short, safe, and undemanding

process, which is simple and technically practical, assuring minimal exposure of the material to the operating room environment. The median surgical time, as well as the mean duration of intraoperative molding process in this series, were comparatively shorter than previously reported.[28, 32] Furthermore, the median follow-up period of 25 months for the patients from our series was much longer than specified before.[12]

In this series, we have opted for an intraoperative PMMA implant molding based on the use of prefabricated 3D-prited mold where PolyJet additive manufacturing technology was employed. It consists of jetting a thin layer of photosensitive polymer material in a form of fine droplets, followed by curing with a source of ultraviolet light.[17] During the production of the mold's complex parts, 3D printer uses both the model and support material, while jetting a layer. Layer thickness can be set to 16 μm or 32 μm. After finishing one layer, build platform is lowered down for the next layer thickness and process is repeated until finishing the entire part. Afterward, the support material should be removed from finished 3D-printed part with water jetting.[19]

Considering the above-mentioned advantages of the technique, we believe that a personalized prefabrication of the mold template to produce a PMMA cranioplastic implant is more effective and less costly technique than previously reported use of other tailored cranial implants,[11,16,20,38] having comparable cosmetic satisfactory results. This finding is well-supported by the results from most recent studies too.[1,10,30,34]

Nevertheless, further advances in virtual reality, additive manufacturing, and 3D image-based reconstruction practice will result in even faster data processing and manufacturing of more demanding, ideally adjusted cranioplastic implants.[36] Future patient-specific personalized implants will be made with the aim to create a 3D-printed biodegradable scaffold to guide bone regeneration, stimulating the patient's own bone grow to achieve the required cranial proportions.[42]

Seeing our results and remembering the paper limitations arising from small number of patients in this series, supplementary research is needed to confirm practical applicability of this technique on a broader setting.

CONCLUSION

The 3D printing technology is a valuable and modern technique to advance manufacturing of personalized prefabricated cranioplastic implants used for the reconstruction of large skull defects having complex geometry.

Customized alloplastic cranioplasty using a 3D-printed prefabricated mold for casting PMMA implant is a safe and easy to use bone defect reconstruction technique after decompressive craniectomy following TBI. It ensures a favorable clinical outcome and excellent cosmetic effect as well as decreases the time needed for reconstructive surgery and the risk of postoperative complications.

Authors' contributions

All coauthors were included in substantial contribution to conception and design and final approval of the version to be published.

Ethical approval

The research reported in submitted paper has been conducted in an ethical and responsible manner and is in full compliance with all relevant codes legislation.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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