www.surgicalneurologyint.com



Original Article

Surgical Neurology International Editor-in-Chief: Nancy E. Epstein, MD, Professor of Clinical Neurosurgery, School of Medicine,

State U. of NY at Stony Brook. SNI: Computational

Pieter L. Kubben, MD, PhD Maastricht University Medical Center, Maastricht, The Netherlands



Editor

Personalized 3D-printed cranial implants for complex cranioplasty using open-source software

Vjekoslav Kopačin^{1,2}, Vedran Zubčić^{2,3}, Ivan Mumlek^{2,3}, Dario Mužević^{2,4}, Alen Rončević^{2,4}, Ana-Maria Lazar^{2,3}, Ana Kvolik Pavić^{2,3}, Anamarija Soldo Koruga^{2,5}, Zdravka Krivdić^{1,2}, Ivana Martinović⁶, Nenad Koruga^{2,4}

¹Department of Diagnostic and Interventional Radiology, University Hospital Center, ²Faculty of Medicine, Josip Juraj Strossmayer University of Osijek, Departments of ³Maxillofacial and Oral Surgery, ⁴Neurosurgery, ⁵Neurology, University Hospital Center, ⁶Department of Information Sciences, Faculty of Humanities and Social Sciences, Josip Juraj Strossmayer University of Osijek, Osijek, Croatia.

E-mail: Vjekoslav Kopačin - vkopacin@gmail.com; Vedran Zubčić - takeshi.zubcic@gmail.com; Ivan Mumlek - imumlek@gmail.com; Dario Mužević - dario.muzevic@mac.com; Alen Rončević - alenron@gmail.com; Ana-Maria Lazar - milas.anam@gmail.com; Ana Kvolik Pavić - kvolik.ana@gmail.com; Anamarija Soldo Koruga - anamarijasoldo@gmail.com; Zdravka Krivdić Dupan - zdravka.krivdic@gmail.com; Ivana Martinović - imartinovic@ffos.hr; *Nenad Koruga - nkoruga@gmail.com



*Corresponding author: Nenad Koruga, Department of Neurosurgery, University Hospital Center Osijek, 31000 Osijek, Croatia.

nkoruga@gmail.com

Received: 10 November 2023 Accepted: 19 January 2024 Published: 09 February 2024

DOI 10.25259/SNI_906_2023

Videos available on: https://www.youtube.com/ watch?v=aXodVZZBTJI

Quick Response Code:



ABSTRACT

Background: Cranioplasty is a routine neurosurgery treatment used to correct cranial vault abnormalities. Utilization of 3D printing technology in the field of cranioplasty involving the reconstruction of cranial defects emerged as an advanced possibility of anatomical reshaping. The transformative impact of patient-specific 3D printed implants, focuses on their remarkable accuracy, customization capabilities, and enhanced biocompatibility.

Methods: The precise adaptation of implants to patient-specific anatomies, even in complex cases we presented, result in improved aesthetic outcomes and reduced surgical complications. The ability to create highly customized implants addresses the functional aspects of cranial defects and considers the psychological impact on patients.

Results: By combining technological innovation with personalized patient care, 3D printed cranioplasty emerges as a transformative avenue in cranial reconstruction, ultimately redefining the standards of success in neurosurgery.

Conclusion: 3D printing allows an excellent cranioplasty cosmesis achieved at a reasonable price without sacrificing patient outcomes. Wider implementation of this strategy can lead to significant healthcare cost savings.

Keywords: 3D Printing, Cranioplasty, Implant, Open-source, Patient care, Personalized medicine, Polymethyl methacrylate, Precision medicine, Printing, Prosthetic, Three-dimensional

INTRODUCTION

The neurocranium acts as a barrier between the outer world and the brain. Without its support, even a little head injury could result in harm to the brain parenchyma, which could lead to impairment or even death. Neurosurgeons must restore the bone vault's functional and cosmetic qualities if it is damaged by trauma, tumors, infection, or iatrogenic causes. Since Fallopius employed a gold plate to replace a bone deficiency in the 16th century, cranioplasty as a surgical operation has been known and practiced for a very long time.^[1,35] A decompressive craniectomy (DC) is usually employed after traumatic events and the excision of infiltrative tumors when sections of the calvaria or skull base may need to be largely resected. Cranioplasty with artificial

This is an open-access article distributed under the terms of the Creative Commons Attribution-Non Commercial-Share Alike 4.0 License, which allows others to remix, transform, and build upon the work non-commercially, as long as the author is credited and the new creations are licensed under the identical terms. ©2024 Published by Scientific Scholar on behalf of Surgical Neurology International

implants can be used to restore the function and form of the skull. Despite being frequently portrayed as a simple treatment, cranioplasty has a high reported total complication rate including implant infection, implant protrusion, bone resorption, and wound dehiscence all of which can lead to implant failure.^[21] Materials used for cranioplasty procedures could be roughly divided into - biological materials that are further divided into xenografts (bone material from animals), allografts (bone material from cadavers), autografts, and synthetic materials (allografts). While autografts in a skull defects larger than 75-100 cm² are prone to bone resorption due to insufficient vascularization and infection, synthetic materials like widely used surgical grade titanium alloy, polymers like poly-methyl-meth-acrylate (PMMA), polyether-ether-ketone (PEEK), poly-ether-ketone ketone (PEKK), and ceramics are less prone to producing unwanted complications, especially in larger skull defects leading to reoperations.^[1,5,14,24] Additive manufacturing (3D printing) technology has been used in craniomaxillofacial (CMF) reconstruction surgeries since the early 1990s, but due to the high prices of technology, it was reserved for rare and complex cases.^[33] Although craniofacial surgeries are complicated procedures, calvarial bone reconstruction is possible even without the use of modern technologies such as virtual surgery/preoperative planning and cranial implant fabrication. Manually fabricated cranial implants often lack precision.^[4,15,40] However, more complex procedures like skull base defects, due to complex anatomy and approach, require the application of advanced visualization technologies that are becoming more accessible with the latest development of computer technology and 3D printing technology. With the appearance of new commercial 3D printing companies on the market, these technologies are being increasingly used in such surgeries.^[8] Few inert materials, such as titanium alloy, PEEK, and PEKK, could be directly used for 3D printing of personalized cranial implants using different additive technologies, but they come at high prices, thus remaining inaccessible for surgeons in affluent countries.^[4,8,37] Therefore, the goal of this article is to present a workflow for planning reconstructive interventions on the skull base and the fabrication of personalized surgical guides and grafts using freely available open-source software.

MATERIALS AND METHODS

DICOM data acquisition

A patient in whom the use of any advanced visualization methods is planned should certainly have one of the available three-dimensional diagnostic imaging methods performed. Due to a good bone tissue depiction, in CMF reconstruction surgery, the most commonly used imaging method is computed tomography (CT), followed by magnetic resonance imaging (MRI), where different soft tissues have excellent contrast to each other.^[33] If needed, images obtained by these two methods could be fused. When CT scanning of desired anatomy is performed, it is recommended that the spatial resolution of the images does not exceed 1.25 mm. Otherwise, the anatomical accuracy of the finished anatomical 3D models could be lost.^[33] Furthermore, lower spatial resolution could lead to the creation of extremely large 3D model files that further slow down the computer, and due to the large number of layers generated, the segmentation process could be slower.^[25,33] Depending on the end goal, a trade-off in scan quality is required.

How we do it: If the affected region contains more anatomical details, thin layers (0.625 mm) are reconstructed, but usually the thickness of the layers does not exceed 1 mm. In the case of tumor changes, the application of intravenous contrast is mandatory using an automated contrast injector (contrast volume and flow depending on the case). Soft tissue and bone reconstructions are sent to picture archiving and communication systems.

Computer-aided design (CAD) 3D model generation and 3D printing of the model for preoperative planning

The process of virtual surgical planning and virtual surgery, personalized surgical guides, and implant fabrication starts with the segmentation of the desired anatomy from obtained DICOM data and the generation of CAD 3D models. For the segmentation and 3D model generation, numerous free and open-source software are available.^[28] Segmentation could be manual, automatic, and semi-automatic.^[33] After the segmentation, postprocessing could be performed in the same software for segmentation or using other open-source 3D modeling software. The final step before the preoperative planning is the 3D printing of the anatomical CAD model. Numerous additive manufacturing technologies are available, but fused deposition modeling (FDM)/fused filament fabrication (FFM) technology is the most available and affordable.^[8,25,33]

How we do it: For the segmentation, the authors prefer 3D Slicer, an open-source software for visualization, segmentation, registration, and analysis of medical, biomedical, and other 3D images and meshes, as well as for planning and navigating image-guided procedures.^[11] It has a strong community that continuously improves and develops various features. Semi-automatic segmentation – a combination of automatic and manual segmentation, proved to be the most useful method considering the existence of extremely thin bony structures in the viscerocranium and neurocranium area, such as naso-orbital ethmoid complex, where a possibility of a loss of anatomical details exists when using automatic segmentation. After the segmentation, potentially generated artifacts, that is, holes in the 3D mesh model, are corrected in the software mentioned above, or,

if any are missed, later in 3D modeling software like opensource Blender or Meshmixer.

Each model is appropriately labeled by adding the patient's name, surname, and year of birth on the opposite side of the visible existing pathology on the model.

The standard tessellation language (STL) file of the model is imported in slicer software where a.gcode file is being created containing previously defined parameters such as material for 3D printing being used and layer height.

FDM/FFF technology-based 3D printer, Prusa i3 MK3 (Prusa Research, Prague, Czech Republic), is used for 3D printing of the haptic 3D model used for preoperative planning. Polylactic acid (PLA) filament, being the most available, most affordable, and easiest for 3D printing, is used for the generation of such anatomical 3D models.

Preoperative planning/virtual surgery

Several studies that have been published show the advantages of using advanced visualization, such as extended reality and 3D printing, in preoperative planning and understanding three-dimensional anatomy compared to conventional imaging (CT or MRI).^[16,26,27,30,44] Therefore, the goal of radiologists is to offer such an opportunity to surgeons so that they all together ensure the best possible patient care, especially for complex cases.

How we do it

A multidisciplinary team consisting of maxillo-facial, neurosurgeons, and radiologists is assembled when the patient requires some cranial base surgery and reconstruction is being presented. A haptic, 3D-printed model of pathologically altered anatomy and a CAD 3D model are being presented to the team. Together, they decide on the osteotomy margins.

3D modeling and 3D printing of the surgical guides and matching implant molds

The majority of surgical cutting guides or personalized implant production remains within the realm of commercial biomechanical engineering companies, necessitating outsourcing and incurring significant costs. Although commercial software options exist, they typically come with a higher price.

European Union (EU) Regulations on medical devices (MDR 2017/745, item 30) state that it is possible to use open-source solutions for in-house and non-industrial scale production of medical devices, that is, surgical cutting guides and implants. Therefore, it is no wonder that clinicians in the EU, as well as others around the world, already widely accept such free solutions in CMF surgeries.^[8-10,28,29,32,39]

How we do it

We concluded that the most affordable and equally effective method for us is the 3D printing of surgical guides and molds into which PMMA will be injected. A detailed presentation and video tutorial can be found in the link given in the Supplementary Material.

There are a number of free solutions available for the 3D modeling process, and it is best to use the ones you are most familiar with. The authors prefer open-source 3D modeling software Blender and Meshmixer-first, the.STL file of the 3D model is imported into the Blender. If the file is large, the decimate function on the 3D model is performed, or a part of the unnecessary anatomy is deleted to reduce the number of facets and thereby speed up the computing power of the computer and 3D modeling process. In case there is significant bone destruction and the bone is missing at the site of the planned cranioplasty using a personalized implant, mirroring of the healthy, contralateral half of the skull can be done. Suppose there is a diagnostic imaging study performed before pronounced bone destruction. In that case, it is possible to make and import a 3D model of healthy anatomy that is later used in the design of the implant, or it is possible to manually model and close the bone defect, obtaining a "healthy," unaffected region.

According to the preoperative plan, the width between the destroyed bone and the surgical guides is usually around 10 mm to ensure a healthy margin. The width of the cutting guide must be sufficient to contain the hole for the fixing screws (the diameter depends on the manufacturer. Usually it is 3 mm) and at least 2–3 mm from the edge so that it does not break – usually 8–10 mm is enough. In places where there is extremely little space for manipulation, such as the orbit, it is possible to design narrow guides, and then fixation screw holes are not placed on these segments.

It is preferable to design the guides so that the osteotomies are not perpendicular to the calvaria but that the corresponding implant sits like a wedge in place, thus ensuring a larger contact surface with the bone and reducing the load on the osteosynthetic material. At the base of the skull, due to the geometry, this will often not be feasible, and then the angle of the osteotomy can be perpendicular to the bone.

After the surgical guides design and according to the osteotomy plane, the next step is the generation of the implant and the two-part mold for injection.

Although there are some publications where the use of polycaprolactone and PLA in the production of personalized medical devices is mentioned, the authors believe that more studies with a longer follow-up time are needed to confirm their safe use in personalized implant fabrication, so we do not use them regularly.^[8] Therefore, we use another, still affordable method for the fabrication of the surgical guides and molds

- an ISO and FDA-certified desktop SLA 3D printer Form 2 (Formlabs, Somerville, Massachusetts, USA) based on stereolithography (SLA) technology that offers biocompatible resins. There are also other, third-party biocompatible resins, but authors do not have experience with them.

After the 3D printing, surgical guides and molds were sterilized in a low-temperature sterilizer with hydrogen peroxide plasma. Implants are prepared during the surgery.

RESULTS

Preoperative planning

All patients were thoroughly clinically and radiologically evaluated according to the need for cranial surgery and the possible use of 3D-printed molds. Preoperative 3D-printed anatomical models were used for more precise craniotomy to spare healthy anatomical borders and to reduce bleeding and the timespan of surgery [Figure 1a and b]. Furthermore, the 3D-printed surgical guide was semi-circularly screwed at the edge of the craniotomy [Figure 1c]. Manufacturing of the 3D models did not prove to be a difficult process compared to the other anatomical sites. The greatest challenge during the whole process was to achieve a more meticulous model regarding the bony prominences of the cranium and its complex geometry [Figure 1d-f]. No significant printed failures and discrepancies were noted. It resulted in an acceptable 3D model, structured consistently according to CT scan data and ready to be implanted.

Surgical technique

All patients underwent surgery in general anesthesia in a regular fashion and surgeries were done multidisciplinary. Furthermore, all patients underwent craniotomies at tumor sites according to preoperatively planned approaches. On the operative day, the molds were pretreated, sterilized placed in plastic bags. The PMMA components were mixed, and the dough-like PMMA mixture was placed between the two mold parts, which were then clamped together. The molds and PMMA are placed in a cold saline solution during polymerization. Excess PMMA material exits the mold through the installed chimney holes in the molds, and it was removed after the polymerization. Edges of polymerized PMMA were cautiously examined and were additionally drilled or removed by the Luer pliers if necessary. After the implant was completed and ready, it was repeatedly sterilized in the alcoholic solution. Care was implemented to avoid contact with any non-sterilized surfaces before implantation. Operculum was then implanted at the site of craniotomy and fixed with mini-plates and screws (Stryker cranial fixation system, Stryker, MI USA) [Figure 1f]. The exact number of fixation materials depended on the size and geometry of the implant itself. The closure of the wounds went uneventfully, in a general manner. All surgeries went uneventfully, and no

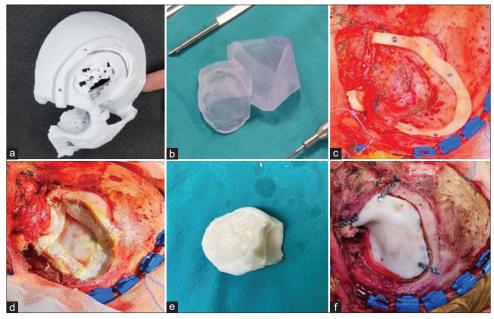


Figure 1: (a) Preoperatively 3D printed model of the pathologically altered anatomy and concomitant surgical guide, (b) 3D printed molds, (c) 3D printed surgical guide fixed with the screws in order to achieve appropriate craniotomy, (d) the surgical site completely prepared for a prosthesis, (e) Polymethyl-meth-acrylate (PMMA) prosthesis ready for the fixation, (f) operculum fixed with miniscrews, surgical site anatomically reshaped.

cerebrospinal fluid (CSF) leak, hemorrhage, wound infection, or wound dehiscence were noted during an early postoperative period and later follow-up period. During the follow-up in the timespan of up to 6 months, no complications were noted. All wounds healed properly with an excellent cosmetic effect in all patients. The authors present several surgical cases:

Case 1

A maxillofacial surgeon primarily treated a 75-year-old male patient due to an aggressive calvarial tumor. The patient neglected aggressive carcinoma, which pierced the parietal bone and skin of the scalp, confirmed by a CT scan [Figure 2a and b]. During the preoperative period, pathohistological verification confirmed planocellular carcinoma. Surgery was complicated by a tumor spreading into the sagittal sinus, and surgeons were confronted with extended bleeding after craniotomy. Venous bleeding from the sinus was stopped and prevented by compression and using Tachosil [®] and Surgicel [®]. The postoperative period went uneventfully, and a follow-up CT scan revealed an excellent position of the operculum [Figure 2c and d].

Case 2

An 80-year-old female patient noticed an unusual convexed hard consistency process on the left-sided orbit. MRI

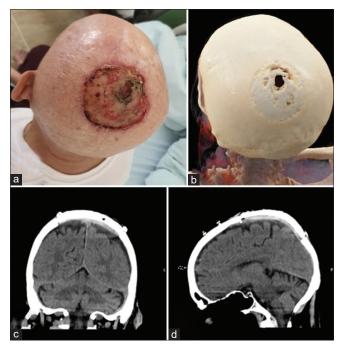


Figure 2: (a) Preoperative finding of planocellular carcinoma with continuous spread through the calvarial skin and parietal bone, (b) Cinematic rendering (CRT) of the head CT scan showing bone destruction, (c) coronal and (d) sagittal plane of the postoperative, non-enhanced CT scan one week after the surgery revealed an excellent implant fixation.

scanning confirmed tumoral tissue which occupied the frontal bone and spreaded extracranially as well as intracraniallyextradurally [Figure 3a]. An invasive ductal breast carcinoma was pathohistologically confirmed. Intra- and postoperative periods went uneventfully. A Follow-up CT scan revealed an excellent position of operculum at the surgical site [Figure 3b].

Case 3

A 17-year-old boy noticed an unusual edema painful after finger compression at the site on the right-sided orbit [Figure 4ac]. Preoperative cytologic biopsy pointed at eosinophilic granuloma, which was later confirmed postoperatively by pathohistological verification. The patient underwent surgery in a general fashion after a bi-coronal approach. Intra- and postoperative periods went uneventfully, and the postoperative CT scan revealed an excellent position of the operculum [Figure 5]. The anatomical and geometrical boundaries of the skull and the newly made operculum were completely restored.

DISCUSSION

In terms of preserving esthetically attractive results, the human skull is one of the most complicated parts of the body. The creation of individualized endoprostheses by cranioplasty is necessary in the case of a posttraumatic or postoperative defect to give affected individuals a respectable quality of life.^[45] Although commonly used titanium endoprosthesis frequently produces good results, they are frequently too pricey for people with limited financial resources. Titanium causes a considerable artifact in CT and MRI imaging while having excellent biocompatibility, and polypropylenepolyester prostheses emerged as the most frequently used when cranioplasty is needed.^[6] The first ever described cranioplasty procedure was performed by Dutch surgeon van Meekeren using canine bone as an implant in 1668.^[1] At present, a wide spectrum of methods and materials significantly expand surgeons' armamentarium and

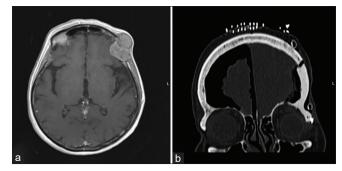


Figure 3: (a) Preoperative contrast-enhanced T1-weighted axial MRI scan revealed an intra- and extracranial metastatic tumor of the left-sided frontal bone, (b) postoperative CT scan revealed the appropriate position of the implant, the left orbit and zygoma were anatomically reshaped.

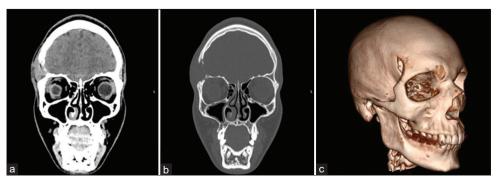


Figure 4: (a) Coronal plane of the preoperative, non-enhanced CT scan of the head, soft tissue window, (b) bone window, and (c) Volume rendering technique (VRT) revealed a defect of the right-sided frontal bone.



Figure 5: CRT of postoperative head computed tomography scan revealed an excellent implant position; anatomy of the frontal bone is restored and anatomically reshaped.

possibilities; allografts, autografts, xenografts, or other bone substitutes are used to cover bone defects after DC.^[2,12,31,42] The use of bone for cranioplasty that was obtained from the same patient's decompressive operation through allograft is frequently linked to bone resorption, auto-immunologic responses, and a significant risk of infection and is frequently impractical due to skull fractures.^[22] DCs are most usually used to reduce an elevated intracranial pressure after brain trauma, occasionally in surgeries with radical tumor resection and consequent edema. Therefore, such neurosurgical approaches might cause a bone defect along the cranial convexity. In such patients, cranioplasty should be implemented to reconstruct the cranial vault to protect the brain tissue and restore the cranial vault's esthetics. Furthermore, successive re-establishing of the CSF dynamics is expected. The process of rehabilitation is expected to be more successful after the closure of the cranial vault; moreover, the newly created barrier prevents further possibilities of brain injuries. There is still no firm common consent regarding the timing of cranioplasty due to the clinical status of the patient and its initial surgical diagnosis.^[17,34,46] In general, the accepted routine regarding cranioplasty is at a 3-month interval, and besides the improvement above of CSF circulation, some authors emphasized better outcomes in cognitive function and wound healing; nevertheless, there was no difference in

infection rates.^[23] Furthermore, there were no significant differences in the development of hydrocephalus among these patients.^[13,36] From our experience, considerable attention is devoted to avoiding infection, even though infections might occur due to numerous factors. General principles were followed to prevent further complications; cranioplasties were thoroughly preplanned, bony edges were adequatly exposed, and the dura was meticulously preserved. In cases of iatrogenous dural lacerations, it was stitched usually by 4-0 monofilament or patched with Tachosil®. Before the final placement of 3D 3D-printed PMMA operculum, its edges were softly drilled to avoid the possibility of subcutaneous necrosis. Closure of the skin was performed in the usual manner with extreme caution of an appropriate alignment to avoid possible necrosis of the skin. Antibiotics were intravenously administered to diminish the possibility of infection. To avoid bleeding, CSF leaking, or delaying the anticipated recovery in already compromised cortical functions, the newly generated encephalomyosynangioses during cranioplasty should be conserved as much as feasible.^[7] In the past decade, 3D printing emerged as a new technology to obtain precisely fitted low-cost bone implants. From our experience, it allows an excellent preplanning, which includes the use of a molded guide which alleviates the need for more precise skull opening and improves the cosmetic effects. Furthermore, preplanning is important to plan incision lines in patients who underwent the first surgery to obtain better cosmetic outcomes compared to patients who already obtained the large DC and in which surgeons use the same scar trajectory. It is also important to emphasize that 3D printing molded guides shortens the overall surgery time and alleviates modeling of the implant to the perfect size, thickness, and shape compared to freehand modeling. According to this advancement, a better and more precise adjustment of the prosthesis can be achieved. The development of 3D-printed bone prostheses has become more simple and widely accessible according to the implementation of newer advancements in 3D printing technology. The release of newer, improved materials and accessibility of 3D printers

facilitated its use even on the premises of medical facilities. Even so, the price emerged as the primary issue regarding the use of 3D-printed prostheses. Although patient-specific implants are seen to be the best option, their usage is typically restricted or unfeasible in low- and middle-income countries (LMICs). Despite advancements made by medical technology, it is frequently followed by considerable financial expense which leads to further innovations. The difficulty most LMICs-oriented innovations have is that most of their design and execution take place in high-income countries (HICs), with little or no involvement from LMICs. While it might seem that a successful innovation created in an HIC will have an impact locally, the truth is somewhat different. The cost may be incorrectly estimated as being cheap because none of these nations actually have access to the necessary supplies and equipment.^[3,41] Patients, neurosurgery providers, and healthcare systems all face unexpected costs as a result of the stark discrepancies between HICs and LMICs' health systems. The availability of 3D printers and particular computer software has increased in some HICs due to cost reductions, but in LMICs, these technologies are still rare. Most hospitals in LMICs still face prohibitive upfront expenses for adopting 3D printing. With the price of commonly used personalized titanium implants reaching around USD 5000 and those made of PEEK costing over USD 7000, it is reasonable to infer that these prices approach financial levels that are out of reach for patients with medium- to low incomes.[8] Although information and communication technologies have had a significant impact on clinical practice and the standard of healthcare services, this trend has largely been observed in developed countries. In contrast, the real benefits of electronic health tools have been hindered in developing nations due to numerous economic and social problems. The open-source method stands out as a promising alternative for these underserved areas because the cost of its purchase and maintenance is the biggest obstacle to the adoption of electronic health record software in LMICs. Prefabricated implants can cost up to \$10,000, and PEEK or titanium 3D printers can cost between \$37,000 and \$310,000. Therefore, price is arguably the most crucial factor in LMIC, where the median monthly income is around US\$500. Given the low cost, PMMA is a tempting choice. It should be noted that postoperative toxic reactions have been described in the literature for PMMA cranioplasties.^[19] Interestingly, in the same review, Las et al.^[19] discuss the toxic effects of materials used for cranioplasties and conclude that all of them are potentially toxic, with PMMA being among the most toxic. Although concerning, these findings were questioned by a systematic review and meta-analysis by Leão et al.[20] - there were no significant differences regarding complication rates for PMMA, titanium, and autologous bone cranioplasties. Taken together, the topic of potential PMMA toxicity must be further studied in experimental models to achieve better postoperative results for patients. Although we did not

observe any complications with cranioplasties presented in this article, our case series is small, and potential toxicities could be better described in a larger cohort.

However, compared to implants created using preoperative CT scan-based 3D printing, freehand PMMA sculpting has generally produced worse results in terms of both material and technique. These outcomes include a higher prevalence of wound healing disorders, higher rates of early re-operative revisions, a higher prevalence of extradural hematoma, CSF leak, poor radiological accuracy, and inferior cosmetic results. Using a home 3D printer with the absolute minimum requirements and free software, it is possible to benefit from PMMA's affordability while improving its cosmetic accuracy, with the minimum amount of difficulty.^[3] According to Kim et al., their study revealed that graft materials were not predictive factors for surgical site infection. Furthermore, the same study confirmed the superiority of 3D-printed implants in terms of providing precise fit and satisfying esthetic results after cranioplasty; synthetic materials were not recognized to have a higher risk of infection after cranioplasty. They also identified the safety of patient-specific 3D-printed implants with necessity of continuous follow-up to confirm long-term safety.^[18] The other important issue regarding the use of 3D printed prostheses is the restoration of the cranial vault with an aim to restore its natural shape and symmetry which improves the patient's mental state and further psychosocial development.^[38] Therefore, we have to emphasize that emotional issues in patients after DC emerged as one of the main postoperative difficulties. The development of emotional lability, anxiety, depression, and temper outbursts has been recognized. Besides intracranial issues after traumatic brain injury (TBI) or a large brain resection, cosmetic effects also play a role in the development of these symptoms. The bestknown instrument after TBI is Quality of Life after Brain Injury (QOLIBRI), founded by an international task committee. The committee used data from two multilingual studies involving more than 2000 people who had suffered from TBI to create the QOLIBRI. It is a thorough questionnaire that consists of 37 items and measures six aspects of health-related quality of life following TBI. The questionnaire provides the quality of life profile and the overall score; it is appropriate for use in research investigations, healthcare settings, and demographic surveys.^[43] In summary, personalized 3D-printed bone prosthesis may be excellently adjusted to the defect of the cranial vault and result in a high cosmetic outcome. In cases of larger and more complicated cranial deficits, more customized implants are needed. Besides restoring anatomical shape, cosmetic effect, and time-sparing surgery, the time on patient care is also decreased with a possibility of quicker recovery and hospital discharge.

CONCLUSION

Cranioplasty is a common surgical procedure widely accepted and performed all over the world. The advantages of its use include a

simple and fast process of production, availability of materials, and excellent cosmetic effects. Nevertheless, some disadvantages emerged, such as the selection of the best suitable producing materials as well as its price. The use of the most appropriate, biocompatible, strong, and durable materials remains the main goal of its production. The possibility of homemade production of 3D-printed implants might play a significant role in lowincome countries, although in some cases, its price is immensely increased. We have to emphasize that despite some shortcomings and disadvantages, the use of 3D-printed implants remains the best feasible option in everyday use in terms of time sparing, anatomical accuracy, and consequent cosmetic effects.

Ethical approval

The Institutional Review Board approval is not required.

Declaration of patient consent

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

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

REFERENCES

- 1. Alkhaibary A, Alharbi A, Alnefaie N, Almubarak AO, Aloraidi A, Khairy S. Cranioplasty: A comprehensive review of the history, materials, surgical aspects, and complications. World Neurosurg 2020;139:445-52.
- Arnaoutakis D, Bahrami A, Cohn JE, Smith JE. Cranioplasty using a mixture of biologic and nonbiologic agents. JAMA Facial Plast Surg 2018;20:9-13.
- 3. Ashraf M, Choudhary N, Kamboh UA, Raza MA, Sultan KA, Ghulam N, *et al.* Early experience with patient-specific low-cost 3D-printed polymethylmethacrylate cranioplasty implants in a lower-middle-income-country: Technical note and economic analysis. Surg Neurol Int 2022;13:270.
- Bonda DJ, Manjila S, Selman WR, Dean D. The recent revolution in the design and manufacture of cranial implants: Modern advancements and future directions. Neurosurgery 2015;77:814-24.
- 5. Bowers CA, Riva-Cambrin JA, Hertzler DA, Walker ML. Risk factors and rates of bone flap resorption in pediatric patients

after decompressive craniectomy for traumatic brain injury. J Neurosurg Pediatr 2013;11:526-32.

- Codubix proteza kości czaszki niejałowa. Available from: https://www.matopat24.pl/codubix-proteza-kosci-czaszkiniejalowa_7341-14736 [Last accessed on 2022 Jun 19].
- Csámer L, Csernátony Z, Novák L, Kővári VZ, Kovács ÁÉ, Soósné Horváth H, *et al.* Custom-made 3D printing-based cranioplasty using a silicone mould and PMMA. Sci Rep 2023;13:11985.
- 8. Czyżewski W, Jachimczyk J, Hoffman Z, Szymoniuk M, Litak J, Maciejewski M, *et al.* Low-cost cranioplasty-a systematic review of 3D printing in medicine. Materials (Basel) 2022;15:4731.
- Egger J, Gall M, Tax A, Ücal M, Zefferer U, Li X, *et al.* Interactive reconstructions of cranial 3d implants under MeVisLab as an alternative to commercial planning software. PLoS One 2017;12:e0172694.
- Evins AI, Dutton J, Imam SS, Dadi AO, Xu T, Cheng D, et al. On-demand intraoperative 3-dimensional printing of custom cranioplastic prostheses. Oper Neurosurg (Hagerstown) 2018;15:341-9.
- 11. Fedorov A, Beichel R, Kalpathy-Cramer J, Finet J, Fillion-Robin JC, Pujol S, *et al.* 3D Slicer as an image computing platform for the quantitative imaging network. Magn Reson Imaging 2012;30:1323-41.
- Ganau M, Cebula H, Fricia M, Zaed I, Todeschi J, Scibilia A, et al. Surgical preference regarding different materials for custom-made allograft cranioplasty in patients with calvarial defects: Results from an internal audit covering the last 20 years. J Clin Neurosci 2020;74:98-103.
- 13. Garg R, Aggarwal A, Salunke P. Importance of calvaria in cerebrospinal fluid dynamics: A case of ventriculomegaly and sinking flap syndrome after decompressive craniectomy. Asian J Neurosurg 2018;13:128-9.
- 14. Goldstein JA, Paliga JT, Bartlett SP. Cranioplasty: Indications and advances. Curr Opin Otolaryngol Head Neck Surg 2013;21:400-9.
- 15. Gooch MR, Gin GE, Kenning TJ, German JW. Complications of cranioplasty following decompressive craniectomy: Analysis of 62 cases. Neurosurg Focus 2009;26:E9.
- Hurson C, Tansey A, O'Donnchadha B, Nicholson P, Rice J, McElwain J. Rapid prototyping in the assessment, classification and preoperative planning of acetabular fractures. Injury 2007;38:1158-62.
- 17. Iaccarino C, Kolias A, Roumy LG, Fountas K, Adeleye AO. Cranioplasty following decompressive craniectomy. Front Neurol 2020;10:1357.
- Kim MJ, Lee HB, Ha SK, Lim DJ, Kim SD. Predictive factors of surgical site infection following cranioplasty: A study including 3D printed implants. Front Neurol 2021;12:745575.
- Las DE, Verwilghen D, Mommaerts MY. A systematic review of cranioplasty material toxicity in human subjects. J Craniomaxillofac Surg 2021;49:34-46.
- 20. Leão RS, Maior JR, Lemos CA, Vasconcelos BC, Montes MA, Pellizzer EP, *et al.* Complications with PMMA compared with other materials used in cranioplasty: A systematic review and meta-analysis. Braz Oral Res 2018;32:e31.
- 21. Lönnemark O, Ryttlefors M, Sundblom J. Cranioplasty in brain tumor surgery: A single-center retrospective study investigating cranioplasty failure and tumor recurrence. World Neurosurg 2023;170:e313-23.
- 22. Malcolm JG, Mahmooth Z, Rindler RS, Allen JW, Grossberg JA,

Pradilla G, *et al.* Autologous cranioplasty is associated with increased reoperation rate: A systematic review and meta-analysis. World Neurosurg 2018;116:60-8.

- Malcolm JG, Rindler RS, Chu JK, Grossberg JA, Pradilla G, Ahmad FU. Complications following cranioplasty and relationship to timing: A systematic review and metaanalysis. J Clin Neurosci 2016;33:39-51.
- 24. Matsuno A, Tanaka H, Iwamuro H, Takanashi S, Miyawaki S, Nakashima M, *et al.* Analyses of the factors influencing bone graft infection after delayed cranioplasty. Acta Neurochir (Wien) 2006;148:535-40.
- 25. Mitsouras D, Liacouras P, Imanzadeh A, Giannopoulos AA, Cai T, Kumamaru KK, *et al.* Medical 3D printing for the radiologist. Radiographics 2015;35:1965-88.
- Moore EJ, Price DL, Van Abel KM, Janus JR, Moore ET, Martin E, *et al.* Association of virtual surgical planning with external incisions in complex maxillectomy reconstruction. JAMA Otolaryngol Head Neck Surg 2021;147:526-31.
- Muff JL, Heye T, Thieringer FM, Brantner P. Clinical acceptance of advanced visualization methods: A comparison study of 3D-print, virtual reality glasses, and 3D-display. 3D Print Med 2022;8:5.
- 28. Ostaș D, Almășan O, Ileșan RR, Andrei V, Thieringer FM, Hedeșiu M, *et al.* Point-of-care virtual surgical planning and 3D printing in oral and cranio-maxillofacial surgery: A narrative review. J Clin Med 2022;11:6625.
- 29. Pöppe JP, Spendel M, Schwartz C, Winkler PA, Wittig J. The "Springform" technique in cranioplasty: Custom made 3D-printed templates for intraoperative modelling of polymethylmethacrylate cranial implants. Acta Neurochir (Wien) 2022;164:679-88.
- 30. Poukens J, Haex J, Riediger D. The use of rapid prototyping in the preoperative planning of distraction osteogenesis of the cranio-maxillofacial skeleton. Comput Aided Surg 2003;8:146-54.
- Qin L, Yao S, Zhao J, Zhou C, Oates T, Weir M, *et al.* Review on development and dental applications of polyetheretherketonebased biomaterials and restorations. Materials (Basel) 2021;14:408.
- 32. Ritschl LM, Kilbertus P, Grill FD, Schwarz M, Weitz J, Nieberler M, *et al.* In-house, open-source 3d-software-based, CAD/CAM-planned mandibular reconstructions in 20 consecutive free fibula flap cases: An explorative cross-sectional study with three-dimensional performance analysis. Front Oncol 2021;11:731336.
- 33. Rybicki FJ, Grant GT. 3D printing in medicine: A practical guide for medical professionals. Germany: Springer; 2017.
- 34. Sahuquillo J, Dennis JA. Decompressive craniectomy for the treatment of high intracranial pressure in closed traumatic brain injury. Cochrane Database Syst Rev 2019;12:CD003983.

- 35. Sanan A, Haines SJ. Repairing holes in the head: A history of cranioplasty. Neurosurgery 1997;40:588-603.
- Satapathy D, Nadeem M, Shukla DP, Prabhuraj A, Devi BI. Cosmetic outcome of cranioplasty after decompressive craniectomy-an overlooked aspect. World Neurosurg 2019;129:e81-6.
- 37. Sharma N, Aghlmandi S, Dalcanale F, Seiler D, Zeilhofer HF, Honigmann P, *et al.* Quantitative assessment of point-of-care 3D-printed patient-specific polyetheretherketone (PEEK) cranial implants. Int J Mol Sci 2021;22:8521.
- 38. Shih FY, Lin CC, Wang HC, Ho JT, Lin CH, Lu YT, *et al.* Risk factors for seizures after cranioplasty. Seizure 2019;66:15-21.
- Šimić L, Kopačin V, Mumlek I, Butković J, Zubčić V. Improved technique of personalised surgical guides generation for mandibular free flap reconstruction using an open-source tool. Eur Radiol Exp 2021;5:30.
- 40. Stephens FL, Mossop CM, Bell RS, Tigno T Jr., Rosner MK, Kumar A, *et al.* Cranioplasty complications following wartime decompressive craniectomy. Neurosurg Focus 2010;28:E3.
- 41. Tan ET, Ling JM, Dinesh SK. The feasibility of producing patient-specific acrylic cranioplasty implants with a low-cost 3D printer. J Neurosurg 2016;124:1531-7.
- 42. van de Vijfeijken SE, Münker TJ, Spijker R, Karssemakers LH, Vandertop WP, Becking AG, *et al.* Autologous bone is inferior to alloplastic cranioplasties: Safety of autograft and allograft materials for cranioplasties, a systematic review. World Neurosurg 2018;117:443-52.e8.
- von Steinbuechel N, Wilson L, Gibbons H, Hawthorne G, Höfer S, Schmidt S, *et al.* Quality of life after brain injury (QOLIBRI): Scale validity and correlates of quality of life. J Neurotrauma 2010;27:1157-65.
- 44. Wang P, Que W, Zhang M, Dai X, Yu K, Wang C, *et al.* Application of 3-dimensional printing in pediatric living donor liver transplantation: A single-center experience. Liver Transpl 2019;25:831-40.
- 45. Worm PV, Finger G, do Nascimento TL, Rynkowski CB, Collares MV. The impact of cranioplasty on the patients' quality of life. J Craniomaxillofac Surg 2019;47:715-9.
- Yue JK, Rick JW, Deng H, Feldman MJ, Winkler EA. Efficacy of decompressive craniectomy in the management of intracranial pressure in severe traumatic brain injury. J Neurosurg Sci 2019;63:425-40.

How to cite this article: Kopačin V, Zubčić V, Mumlek I, Mužević D, Rončević A, Lazar A, *et al.* Personalized 3D-printed cranial implants for complex cranioplasty using open-source software. Surg Neurol Int. 2024;15:39. doi: 10.25259/SNI_906_2023

Disclaimer

The views and opinions expressed in this article are those of the authors and do not necessarily reflect the official policy or position of the Journal or its management. The information contained in this article should not be considered to be medical advice; patients should consult their own physicians for advice as to their specific medical needs.

SUPPLEMENTARY FILE

Supplementary Material: Video tutorial: https://www.youtube.com/watch?v=aXodVZZBTJI