CRANIOPLASTY: AN OVERVIEW OF TECHNIQUES AND EMERGING TECHNOLOGIES IN IMPLANT DESIGN. CURRENT STATE OF THE ISSUE

Khakberdiev Bayramali Shamsiddin Ugli

Magistr Resident of the Neurosurgery Department at the Multidisciplinary Clinic of Samarkand State Medical University.

Aliev Mansur Abdukhalikovich

Scientific director, Assosiate professor, PhD, Head of the Neurosurgery Department at the Multidisciplinary Clinic of Samarkand State Medical University.

140100, Uzbekistan, Samarkand, Amir Temur Street, 18

Despite the lack of unified statistical data on the number of patients with cranial bone defects of various etiologies, the issue of reconstructive neurosurgical interventions remains highly relevant. Cranial bone defects not only cause cosmetic imperfections and associated psychological challenges but can also lead to neurological functional impairments.

Objective:

This review aims to analyze modern techniques and materials used in reconstructive neurosurgical interventions.

Materials and Methods:

An analysis of contemporary domestic and international literature on cranioplasty was conducted. The main materials used for closing cranial bone defects and methods for manufacturing implants were highlighted. Current trends in the production of customized implants for reconstructive neurosurgery were also reviewed.

Results:

The most commonly used materials for repairing cranial bone defects are polymethyl methacrylate (PMMA) and titanium. The optimal choice for cranioplasty is the use of customized implants, with 3D printing being the most promising and efficient method for their creation.

Conclusions:

The use of customized implants is appropriate in neurosurgical practice for cranial bone defects of any size and location. Direct metal laser sintering technology is currently the optimal method in Russia for producing customized titanium implants. To ensure broader and more timely surgical care for patients with cranial bone defects, the creation of a unified registry and system for tracking such patients is essential.

Keywords: reconstructive neurosurgery, cranial bone defects, customized implants, 3D printing.

The Millennia-Long History of Cranial Defect Reconstruction.

The history of cranial defect reconstruction spans thousands of years. Evidence suggests that cranioplasty procedures were performed as early as 7000 BCE [1]. This surgical intervention was practiced by various ancient civilizations, including the Incas, Britons, North African tribes, and Polynesians. Archaeological discoveries indicate that Peruvians used one-millimeter-thick gold plates for cranial repairs as far back as 2000 BCE [2]. Additionally, there is evidence of successful trepanations among ancient civilizations inhabiting the territory of modern-day Russia between the 5th and 3rd centuries BCE. During archaeological excavations in the Altai Republic, three skulls from the Pazyryk culture were uncovered, each exhibiting antemortem artificial cranial defects in different areas of the cranial vault [3].

The success of such operations depends not only on the surgeon’s skill but also on the materials used to close the defect. Throughout the evolution of civilizations and technologies, the search for and improvement of medical materials has been a continuous endeavor. The materials used in cranioplasty can be broadly categorized into two main types: autologous (derived from the patient) and allogenic (foreign). The medical community widely agrees that autologous tissues are the optimal material for reconstructive procedures. Thus, the meticulous preservation of bone fragments during primary surgery is a cornerstone of surgical practice. This approach is regarded as the “gold standard” for craniofacial trauma management. In such cases, removing bone fragments is considered less favorable than performing primary cranioplasty using the patient’s own broken bone fragments, secured with bone sutures, cranial fixators, and miniplates [4].

Autologous and Foreign Materials in Cranioplasty. In cranioplasty, autologous flaps can be obtained either by splitting the cranial vault bones in adjacent areas or by reimplanting a preserved autologous bone flap stored during the initial craniectomy. However, this approach has significant drawbacks. Bone fragment lysis, as reported by various authors, occurs in 20–50% of cases [5–8], while infectious complications reach up to 25.9% in some studies [9]. Additionally, the use of split flaps is not feasible for complex, extensive, or cosmetically significant defects.

Autologous material can also be derived from rib or iliac bone fragments. However, such implants carry an even greater risk of resorption due to differences in their embryonic

development compared to cranial vault bones. They also result in cosmetic defects at the donor site and present difficulties in shaping implants to match the lost cranial structures [4]. Consequently, this approach is rarely employed in modern neurosurgery.

Categories of Foreign Materials.

Foreign materials for cranioplasty can be divided into allografts and xenografts. The use of allografts, such as processed cadaveric bone, has been largely discontinued due to several factors, including a high rate of infectious complications, frequent flap lysis, legal challenges in material procurement, and the risk of transmitting specific infections.

The second group, xenografts, is widely used in neurosurgical practice and includes various materials such as metals, polymers, hydroxyapatite, ceramics, and woven synthetic fibers.

Metals in Cranioplasty.

Among metallic implants, titanium has emerged as the dominant material in modern reconstructive neurosurgery. Titanium is strong, lightweight, corrosion-resistant, and biocompatible, with significantly fewer infectious complications compared to other metallic implants [1, 2, 9, 11].

Polymers in Cranioplast.y

Commonly used polymeric materials in cranioplasty include polymethylmethacrylate (PMMA), polyetheretherketone (PEEK), hydroxyapatite (HA), and the domestically produced material “Reparen” [12, 13]. Less frequently used options include synthetic woven fibers [14] and the relatively new polyetherketoneketone (PEKK), which has recently gained attention but remains less known in Russia.

Causes and Epidemiology of Craniectomies.

The primary indications for craniectomy include traumatic brain injury (TBI), ischemic and hemorrhagic strokes, surgical interventions for fibrous dysplasia, and various tumors. However, despite an extensive analysis of literature and online resources, precise statistical data on the prevalence of skull bone defects in the Russian Federation was not found. Similarly, no official statistics were identified for other countries. This lack of data is likely due to the complexity of tracking such patients and the absence of unified electronic databases.

In a systematic review by S. Yadla and colleagues [15], the causes of craniectomy in 2,254 patients were categorized by pathology:

• Traumatic brain injury accounted for 37.2%,

• Vascular conditions (strokes, aneurysm ruptures) for 31.7%,

• Tumors for 11.2%,

• Congenital abnormalities for 5.7%,

• Bone removal due to infection for 5.5%.

Additionally, 8.7% of cases were associated with other causes, such as radiation-induced deformities, intraoperative hemorrhages, pseudotumors, and arachnoid cysts.

A randomized, controlled, multicenter study (ACTRN12612000353897) [16] provided the following distribution of patients with cranial defects:

• 67% were post-traumatic,

• 16% resulted from decompressive surgeries for ischemic strokes,

• 22% were due to hemorrhagic strokes,

• 3% were associated with tumor surgeries.

In another study by H. Joswig et al., the distribution of cranioplasty patients was reported as follows [17]:

• 52.4% were post-traumatic,

• 13.6% had subarachnoid hemorrhages,

• 6.8% had ischemic strokes,

• 5.8% had intracerebral hemorrhages,

• 21.4% were classified as “other causes.”

It is worth noting that these figures may not accurately reflect the real distribution of pathology in the general population. However, the fact that traumatic brain injuries dominate among the indications for craniectomy is indisputable.

Advances in Reconstructive Neurosurgery

Reconstructive neurosurgical procedures were traditionally considered to be performed solely for protective and aesthetic purposes. However, recent studies have demonstrated additional benefits, such as improved cerebrospinal fluid circulation, normalization of intracranial and

cerebral perfusion pressure, and enhanced cognitive functions following cranioplasty [18-23]. Despite these findings, the indications for surgical intervention remain poorly defined [5]. Typically, surgeons rely on clinical presentation, symptoms of the trephination syndrome, defect localization, its cosmetic significance, and the defect's size.

The necessity of addressing small defects (up to 10 cm^2) without associated symptoms, cosmetic relevance, or clinical indications remains a debated topic.

Once necessary examinations are completed and indications for surgery are established, the decision-making process shifts to selecting the appropriate method and material for cranioplasty. Based on the literature and clinical experience, titanium, PMMA (polymethyl methacrylate), and PEEK (polyetheretherketone) implants are the most commonly used materials in Russia [24-27].

Methods of Cranioplasty

Cranioplasty techniques are broadly divided into two categories:

1. Pre-manufactured custom implants: These are individually tailored implants designed in advance.

2. Intraoperative modeling: These involve the use of standard titanium meshes or polymer compounds, shaped and formed during surgery.

Intraoperative modeling typically prolongs the duration of surgery, as the surgeon must spend additional time shaping the implant to fit the defect accurately. To enhance the aesthetic outcome, some authors recommend using intraoperative navigation to verify the curvature and fit of the implant [4, 5]. However, this technique further increases operating time.

In contrast, custom-made implants significantly reduce the surgical duration, simplifying and expediting the procedure.

Innovations in Custom Implant Development

In Russia, the development of individualized implants was pioneered by Academician of the Russian Academy of Sciences, Professor A.A. Potapov [5, 25-27]. His contributions have paved the way for advancements in the field, making personalized cranioplasty a practical and efficient solution for addressing skull defects.

The technology involves creating implants based on a digital model of the patient's skull, which has defects or bone defects, followed by the use of stereolithographic anatomical skull models and molds. The individual implant is made by casting polymethyl methacrylate (PMMA) into the obtained molds. After curing, the implant is checked for fit against the defect area using

the stereolithographic model. Once verified, the implant is sterilized and ready for surgical use.

Currently, the production of custom implants is more widely carried out by specialized medical industry enterprises. These implants are delivered to clinics and are ready for implantation after sterilization. Both foreign and domestic companies are involved in this field, using well-known materials such as polymers (PMMA, PEEK, PEKK) and titanium meshes. The manufacturing process closely follows the steps described above.

Production Process Steps:

1. CT Scan and Data Acquisition: The first step involves performing a multi-slice computed tomography (CT) scan of the patient's head. The scan produces layered images of the skull, which are exported as a series of digital images in DICOM format for 3D modeling.

2. Creation of the 3D Model: Using specialized software, a three-dimensional polygonal model of the patient's skull is created. Then, a virtual implant is designed to close the defect in the skull.

3. Physical Implant Creation: The physical creation of the implant can be achieved by various methods:

• Using dense silicone molds, where the polymer material is cast.

• Using 3D milling machines, which layer by layer cut a polymer blank to form the desired implant.

For creating custom titanium implants, a perforated titanium alloy sheet is used, which is shaped according to the 3D anatomical model of the patient's skull. The model is printed at a 1:1 scale using a 3D printer. This approach is employed for the production of domestic titanium implants in Russia.

A significant number of researchers advocate for the use of custom implants in cranioplasty. For instance, F. Schwarz and colleagues [28] report unsatisfactory cosmetic outcomes in reconstructive procedures for large skull defects when "hand-made" implants—those made from polymer materials during the surgery—are used for closure. Eolchiyan S.A. [24] emphasizes that custom implants made using CAD/CAM technologies from titanium and PEEK-Optima materials demonstrate undeniable advantages, including high precision, reduced trauma, shorter operation times, and ultimately predictable and stable functional and cosmetic results. In the study by M. Cabraja and colleagues [29], it was shown that cranioplasty using CAD/CAM-designed custom titanium implants is suitable for any skull defects, regardless of size or complexity. This approach demonstrates a minimal complication rate and does not interfere with subsequent tomographic follow-up studies. Titanium implants are the material of choice for

secondary cranioplasty in patients with post-decompressive craniectomy following traumatic brain injury or other urgent neurosurgical conditions. In the work led by J. Höhne [17], the results of cranioplasty performed between 2006 and 2013 were compared using two different methods. The first group (60 cases) involved patients who underwent surgery with intraoperatively made PMMA implants, while the second group (60 cases) used pre-formed titanium mesh implants based on anatomical models. The operation time in the second group was significantly shorter, and these patients showed fewer complications and better cosmetic results. In a study by J.M. Luo and colleagues [30] conducted between 2005 and 2011, 161 patients were divided into two groups: those with titanium mesh implants molded during the surgery (78 cases) and those with titanium mesh implants pre-molded before the surgery using CAD/CAM software (83 cases). The authors demonstrated that the use of implants designed based on the patient's 3D skull model before the surgery reduces operation time, uses fewer screws to secure the implant, lowers postoperative complications, and achieves better aesthetic outcomes. Kwarcinski J. and colleagues [31], in their systematic review, concluded that the risk of postoperative infectious complications is significantly increased by prolonged surgery and repeated surgical interventions [32]. However, when comparing implants made from different materials, they were unable to definitively identify the ideal material that demonstrates the lowest risk of infection. The authors also hypothesize that the structure of the implant, which promotes better integration with surrounding tissues (such as porosity and roughness), may help reduce postoperative trophic disturbances and, consequently, decrease the frequency of implant infections.

Bonda D.J. and colleagues [33], in their review, note that the use of custom implants based on three-dimensional modeling and printing methods is the most promising direction for reconstructive neurosurgery.

Discussion

Analyzing the literature and our own experience with various types of implants for cranioplasties, we have concluded that the use of custom implants is justified in all cases of cranial bone defect closure. This viewpoint, of course, will spark considerable debate, but from the perspective of rational resource utilization, this assertion is quite reasonable. The use of custom implants, compared to standard prefabricated cranioplasty plates, reduces the time spent by the surgeon on implant formation during the operation. Custom implants eliminate potential gaps and space between the plate and bone, requiring fewer screws and ensuring better fitting and fixation to the skull. In contrast, after surgeries using standard titanium plates, there are often leftover cut fragments that are typically not reused. When considering this in a large city, this leads to a significant amount of material being discarded each year without any possibility of recycling.

The methods of creating custom implants by molding based on the anatomical model of the patient's skull, as well as using molds, are not without their drawbacks. As the surgical procedure is carried out, items such as the anatomical model and the mold remain unused and

require disposal. Currently, 3D printing is a rapidly developing field in the medical industry and is the most cost-effective from a material usage standpoint. We have reviewed the most commonly used additive manufacturing methods in the Russian Federation: FDM (Fused Deposition Modeling), SLA (Stereolithography), SLS (Selective Laser Sintering), and DMLS (Direct Metal Laser Sintering) [34]. Among these, SLS and SLA printing are comparable in terms of model accuracy, while products created using these methods outperform those made with FDM in terms of mechanical strength. However, none of these methods currently use biocompatible materials approved for medical use and implantation, which prevents the direct production of the required implant. Thus, these methods can be used to create prototypes of implants, but to manufacture the actual medical device, a mold based on the prototype must be made, which is then filled with a hardening medical polymer, such as PMMA, or the implant is molded using the prototype as an anatomical model.

The DMLS (Direct Metal Laser Sintering) technology, on the other hand, allows for the direct creation of titanium implants without intermediate products (such as molds or anatomical models). When producing custom titanium implants with this method, any unused material can be recycled after removal from the working chamber, which minimizes raw material losses. The process is virtually waste-free, which gives DMLS a clear advantage over subtractive technologies like milling. It also allows for the simultaneous production of multiple models, limited only by the size of the working chamber [35]. The model construction process takes hours, which is vastly more efficient than the casting process, which can take months, including the full production cycle.

The DMLS method was chosen by us as the optimal approach for creating custom implants for reconstructive surgeries on the cranial bones. The manufacturing process using DMLS technology differs from the previously described methods primarily in how the product is directly fabricated. After the individual implant is designed in the virtual environment, the third and final stage involves printing the implant from titanium (Ti64) powder on a 3D printer. As a form of double-checking, during the same stage, a fragment of the patient’s skull at the defect site was also printed using the SLS (Selective Laser Sintering) method from polyamide (Figure 1). Creating an anatomical model allows for preoperative verification of the congruency of the implant. Once the implant has passed the verification step, it is sent for sterilization by autoclaving, and the implant is then ready for implantation [34, 36, 37].

The production of implants using this method allows surgeons to participate in the design process: from selecting surface textures and fixation methods (Figure 2) to adding additional elements such as ribs for stiffness, centering guides, extra holes for draining the subimplant space, and additional fixation points for soft tissues, among other features.

Figure 1. Individual titanium implant manufactured using the DMLS 3D printing technology, alongside the anatomical model of the patient’s skull.

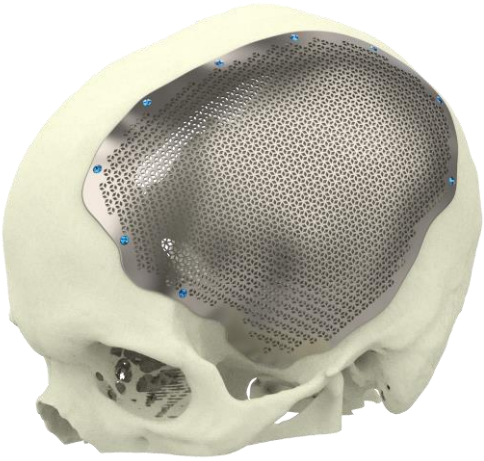
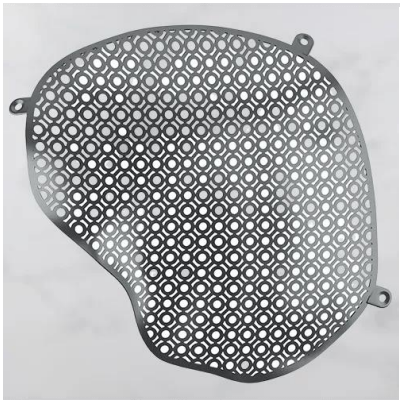
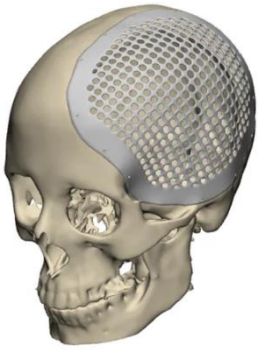
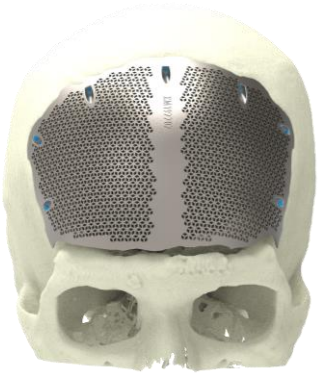


Figure 2. Main types of fixation for individual implants: a) with loops; b) overlapping; c) end-to-end.







Currently, a number of authors are presenting their work on methods to create inexpensive individual implants, as the average cost of such products abroad ranges from 3000 to 7000 euros, depending on the material used, which is still quite high even for developed Western countries [24, 38].

For example, in the work by Eddie T.W. Tan et al. [38], it is noted that the creation of individual implants can be carried out by the surgeon themselves, provided they possess basic computer modeling skills. The authors suggest using a low-budget desktop 3D FDM printer to manufacture molds from PLA plastic, into which a biocompatible polymer is poured (the authors used Surgical Simplex P Radioopaque bone cement by Stryker Corporation). Thus, the surgeon can independently create the required implant without external assistance. According to the authors, the cost of such implants is several times lower than the commercial analogs offered in Europe and North America.

According to Pham B.M. et al. [39], reducing the cost of individual implants for cranioplasty can be achieved through 3D modeling of the required product directly by the surgeons in the clinic.

However, the authors note that this requires specialized knowledge in CAD/CAM modeling. In our clinic, this approach for creating individual implants was tested in 2014-2015 and compared with products made in specialized medical factories. In our opinion, optimizing surgeons' working time and the quality of the resulting products are priority tasks. Therefore, the production of individual surgical implants should be carried out at licensed medical industry enterprises using specialized equipment. At the same time, the price of individual products can be reduced not by shifting the task of 3D modeling onto the doctors, but by developing software that allows for automatic or semi-automatic modeling of the required implant [40]. It is also relevant to study biocompatible polymers (PEEK-FDM, PC-ISO, ABS-M30i, FDM Nylon 12), already used in 3D printing, to assess their safety as raw materials for implants. These approaches will increase the accessibility of medical care using individual products obtained through 3D printing.

CONCLUSIONS:

1. The use of individual implants is appropriate in neurosurgical practice for any size and location of bone defects.

2. The technology of Direct Metal Laser Sintering (DMLS) is currently the optimal method for creating individual titanium implants in Russia.

3. To ensure broader coverage and timely surgical care for patients with skull bone defects, it is necessary to establish a unified registry and tracking system for patients with this pathology.

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