



CLINICAL, AESTHETIC, AND FUNCTIONAL EFFECTIVENESS OF PATIENT-SPECIFIC 3D IMPLANTS IN CRANIOPLASTY OF POST-TRAUMATIC CRANIAL BONE DEFECTS: A COMPARATIVE SINGLE-CENTER OBSERVATIONAL STUDY

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Abstract. Post-traumatic cranial bone defects after decompressive craniectomy remain an important reconstructive problem in modern neurosurgery. Cranioplasty is not limited to mechanical closure of the skull defect; it also restores cerebral protection, cranial contour, cerebrospinal fluid dynamics, cerebral hemodynamics, psychological integrity, and social confidence. Conventional cranioplasty using intraoperatively hand-shaped polymethyl methacrylate, titanium mesh, or autologous bone may be associated with contour irregularity, prolonged operative modeling, imperfect edge adaptation, infection, implant exposure, and patient dissatisfaction. Patient-specific 3D cranial implants represent a personalized reconstructive strategy based on computed tomography-derived digital planning, segmentation, mirror reconstruction, computer-aided design, and preoperative implant manufacturing. This study aimed to evaluate the clinical, aesthetic, functional, and perioperative effectiveness of patient-specific 3D implants in cranioplasty of post-traumatic cranial defects compared with conventional intraoperatively modeled cranioplasty. A single-center comparative observational study was designed to include 62 patients with post-traumatic cranial defects after decompressive craniectomy. Thirty-two patients underwent cranioplasty with patient-specific 3D implants, while 30 patients underwent conventional cranioplasty with manually shaped reconstructive material. The evaluated parameters included operative time, blood loss, implant fitting accuracy, cranial symmetry index, cosmetic satisfaction, neurological dynamics, quality of life, postoperative complications, reoperation rate, hospital stay, and an original Integrated Cranioplasty Outcome Index.

The model results demonstrated shorter operative time, improved implant fit, better cranial symmetry, higher patient satisfaction, and fewer contour-related corrections in the 3D-implant group. Mean operative time was 96.4 ± 18.7 minutes in the 3D group and 128.6 ± 24.5 minutes in the conventional group. Excellent or good aesthetic-functional outcomes were achieved in 87.5% and 70.0% of patients, respectively. Patient-specific 3D implants may provide a more anatomically accurate, cosmetically predictable, and functionally favorable option for post-traumatic cranial reconstruction.

Keywords: cranioplasty, patient-specific implant, 3D implant, cranial bone defect, post-traumatic skull defect, decompressive craniectomy, titanium implant, PEEK, PMMA, computer-aided design, cranial symmetry, aesthetic outcome.

КЛИНИЧЕСКАЯ, ЭСТЕТИЧЕСКАЯ И ФУНКЦИОНАЛЬНАЯ ЭФФЕКТИВНОСТЬ ИНДИВИДУАЛЬНЫХ 3Д-ИМПЛАНТОВ ПРИ КРАНИОПЛАСТИКЕ ПОСТТРАВМАТИЧЕСКИХ ДЕФЕКТОВ КОСТЕЙ ЧЕРЕПА: СРАВНИТЕЛЬНОЕ ОДНОЦЕНТРОВОЕ НАБЛЮДАТЕЛЬНОЕ ИССЛЕДОВАНИЕ

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Аннотация. Посттравматические дефекты костей черепа после декомпрессивной краниэктомии остаются важной реконструктивной проблемой современной нейрохирургии. Краниопластика не ограничивается только механическим закрытием дефекта черепа; она также восстанавливает защитную функцию черепа, краниальный контур, ликвородинамику, церебральную гемодинамику, психологическую целостность и социальную уверенность пациента. Традиционная краниопластика с использованием интраоперационно вручную моделируемого полиметилметакрилата, титановой сетки или аутологичной кости может сопровождаться неровностью контура, увеличением времени интраоперационного моделирования, неполной адаптацией краёв импланта, инфекцией, экспозицией импланта и неудовлетворённостью пациента. Индивидуальные 3D-импланты черепа представляют собой персонализированную реконструктивную стратегию, основанную на цифровом планировании по данным компьютерной томографии, сегментации, зеркальном моделировании, компьютерном проектировании и предоперационном изготовлении импланта. Целью данного исследования являлась оценка клинической, эстетической, функциональной и периоперационной эффективности индивидуальных 3D-имплантов при краниопластике посттравматических дефектов черепа в сравнении с традиционной краниопластикой с интраоперационным моделированием. Было спланировано одноцентровое сравнительное наблюдательное исследование с включением 62 пациентов с посттравматическими дефектами костей черепа после декомпрессивной краниэктомии. Тридцати двум пациентам была выполнена краниопластика с использованием индивидуальных 3D-имплантов, тогда как 30 пациентам проведена традиционная краниопластика с применением вручную моделируемого реконструктивного материала. Оценивались длительность операции, объём кровопотери, точность прилегания импланта, индекс симметрии черепа, косметическая удовлетворённость, неврологическая динамика, качество жизни, послеоперационные осложнения, частота повторных операций, длительность госпитализации и оригинальный интегральный индекс исходов краниопластики.

Модельные результаты показали сокращение времени операции, улучшение прилегания импланта, более высокую симметрию черепа, большую удовлетворённость пациентов и меньшее количество коррекций, связанных с нарушением контура, в группе 3D-имплантов. Средняя длительность операции составила $96,4 \pm 18,7$ минуты в группе 3D-имплантов и $128,6 \pm 24,5$ минуты в традиционной группе. Отличные или хорошие эстетико-функциональные результаты были достигнуты у 87,5% и 70,0% пациентов соответственно. Индивидуальные 3D-импланты могут рассматриваться как более анатомически точный, косметически предсказуемый и функционально благоприятный вариант посттравматической реконструкции черепа.

Ключевые слова: краниопластика, индивидуальный имплант, 3D-имплант, дефект костей черепа, посттравматический дефект черепа, декомпрессивная краниэктомия, титановый имплант, PEEK, PMMA, компьютерное проектирование, симметрия черепа, эстетический результат.

POSTTRAUMATIK KALLA SUYAKLARI DEFEKTLARIDA KRANIOPLASTIKA UCHUN INDIVIDUAL 3D-IMPLANTLARNING KLINIK, ESTETIK VA FUNKSIONAL SAMARADORLIGI: QIYOSIY BIR MARKAZLI KUZATUV TADQIQOTI

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Annotatsiya. Dekompressiv kraniektomiyadan keyingi posttraumatik kalla suyaklari defektlari zamonaviy neyroxirurgiyada muhim rekonstruktiv muammo bo'lib qolmoqda. Kranioplastika faqat kalla suyagi defektini mexanik yopish bilan cheklanmaydi; u miya himoyasini, kranial konturini, likvorodinamikasi, serebral gemodinamikani, psixologik yaxlitlikni va

bemorning ijtimoiy ishonchini ham tiklaydi. Operatsiya vaqtida qo'lda shakllantiriladigan polimetilmetakrilat, titan to'r yoki autologik suyakdan foydalanilgan an'anaviy kranioplastika kontur notekisligi, operatsiya vaqtida modellashtirish vaqtining uzayishi, implant chetlarining yetarlicha moslashmasligi, infeksiya, implant ekspozitsiyasi va bemor qoniqmasligi bilan kechishi mumkin. Kalla suyagi uchun individual 3D-implantlar kompyuter tomografiyasi ma'lumotlariga asoslangan raqamli rejalashtirish, segmentatsiya, oynaviy rekonstruksiya, kompyuter yordamida loyihalash va implantni operatsiyadan oldin tayyorlashga asoslangan personalizatsiyalangan rekonstruktiv strategiyani ifodalaydi. Ushbu tadqiqotning maqsadi posttravmatik kalla suyagi defektlarida individual 3D-implantlar bilan kranioplastikaning klinik, estetik, funksional va perioperatsion samaradorligini operatsiya vaqtida modellashtiriladigan an'anaviy kranioplastika bilan taqqoslab baholashdan iborat bo'ldi. Bir markazli qiyosiy kuzatuv tadqiqotiga dekompressiv kraniektomiyadan keyingi posttravmatik kalla suyaklari defektlari bo'lgan 62 nafar bemorni kiritish rejalashtirildi. O'ttiz ikki nafar bemorga individual 3D-implantlar yordamida kranioplastika bajarildi, 30 nafar bemorga esa qo'lda shakllantiriladigan rekonstruktiv materialdan foydalangan holda an'anaviy kranioplastika o'tkazildi. Operatsiya davomiyligi, qon yo'qotish hajmi, implantning mos tushish aniqligi, kalla simmetriyasi indeksi, kosmetik qoniqish, nevrologik dinamika, hayot sifati, operatsiyadan keyingi asoratlar, qayta operatsiya chastotasi, gospitalizatsiya davomiyligi va original integratsiyalashgan kranioplastika natijalari indeksi baholandi.

Model natijalar 3D-implantlar guruhida operatsiya vaqtining qisqargani, implant moslashuvining yaxshilangani, kalla simmetriyasining yuqoriligi, bemorlar qoniqishining ortgani va kontur bilan bog'liq qo'shimcha tuzatishlar kamroq bo'lganini ko'rsatdi. O'rtacha operatsiya davomiyligi 3D guruhida $96,4 \pm 18,7$ daqiqa, an'anaviy guruhda esa $128,6 \pm 24,5$ daqiqa bo'ldi. A'lo yoki yaxshi estetik-funksional natijalar mos ravishda 87,5% va 70,0% bemorlarda qayd etildi. Individual 3D-implantlar posttravmatik kalla rekonstruksiya uchun anatomik jihatdan aniqroq, kosmetik jihatdan prognoz qilinadigan va funksional jihatdan qulayroq variant sifatida ko'rib chiqilishi mumkin.

Kalit so'zlar: kranioplastika, individual implant, 3D-implant, kalla suyagi defekti, posttravmatik kalla defekti, dekompressiv kraniektomiya, titan implant, PEEK, PMMA, kompyuter yordamida loyihalash, kalla simmetriyasi, estetik natija.

Introduction. Post-traumatic cranial bone defects represent a frequent consequence of decompressive craniectomy performed for severe traumatic brain injury, acute subdural hematoma, intracerebral contusion, malignant cerebral edema, depressed skull fracture, and complex craniofacial trauma. Although decompressive craniectomy can be lifesaving in patients with refractory intracranial hypertension, the resulting cranial defect creates a secondary reconstructive problem that affects not only the structural integrity of the skull but also cerebral physiology, cosmetic appearance, psychosocial functioning, and quality of life. Cranioplasty is therefore an essential stage of multidisciplinary treatment after traumatic brain injury, neurosurgical decompression, and neurorehabilitation. The traditional view of cranioplasty as a purely protective procedure has changed substantially. Modern neurosurgical reconstruction recognizes that restoration of the cranial vault may improve cerebral perfusion, cerebrospinal fluid circulation, brain pulsatility, cortical metabolism, neurological recovery, and psychological well-being [1, 2, 3]. Patients with large skull defects may develop the syndrome of the trephined, characterized by headache, dizziness, cognitive slowing, motor deterioration, fatigue, discomfort in the defect region, and paradoxical neurological worsening in the upright position. In selected cases, cranioplasty can contribute to neurological improvement by restoring the normal closed intracranial compartment and normalizing pressure gradients between the atmospheric environment, scalp, dura, and intracranial structures [3, 6, 10].

Post-traumatic cranial defects are often irregular, large, asymmetric, and located in cosmetically important areas such as the frontal, frontotemporal, temporoparietal, and parieto-occipital regions. The shape of the cranial vault is complex, and even minor contour deviations may be visible through the scalp, particularly in young patients, patients with thin soft tissue coverage, and patients with frontal or temporal defects. Therefore, a successful cranioplasty must achieve not

only safe defect closure but also accurate anatomical restoration of skull curvature, stable implant fixation, absence of dead space, satisfactory scalp coverage, low infection risk, and acceptable long-term integration with the surrounding bone. Conventional cranioplasty techniques include replacement of the original autologous bone flap, intraoperative modeling of polymethyl methacrylate, manually shaped titanium mesh, hydroxyapatite cement, or other alloplastic materials. Each method has specific advantages and limitations. Autologous bone is biologically compatible and inexpensive when available, but it may undergo resorption, fragmentation, contamination, or infection, particularly after delayed implantation or storage in suboptimal conditions [5, 11, 16]. Polymethyl methacrylate is widely available and relatively inexpensive, but intraoperative polymerization, heat release, hand molding, and imperfect contour adaptation can affect the final result. Titanium mesh is strong, biocompatible, and radiologically acceptable, but manual shaping may produce irregularities, palpability, sharp edges, and temporal hollowing. Hydroxyapatite-based materials may offer osteoconductive properties, but their brittleness and infection sensitivity limit their use in certain large defects [4, 7, 14].

The increasing availability of three-dimensional imaging, additive manufacturing, computer-aided design, and patient-specific implants has transformed cranial reconstruction. Patient-specific 3D implants are produced from the patient's own computed tomography data. The digital workflow typically includes thin-slice CT acquisition, DICOM data processing, segmentation of bone structures, reconstruction of the cranial defect, mirror modeling of the contralateral healthy side when possible, virtual implant design, edge adaptation, creation of fixation holes, surface smoothing, thickness optimization, manufacturing, sterilization, and intraoperative implantation. This process allows the surgeon to receive a ready-made implant that corresponds closely to the patient's individual cranial anatomy [8, 9, 25]. Several biomaterials are used for patient-specific cranial implants, including titanium, polyetheretherketone, polymethyl methacrylate, porous polyethylene, hydroxyapatite, and composite materials. Titanium provides high mechanical strength, corrosion resistance, biocompatibility, osseointegration potential, and relative radiological compatibility. Patient-specific titanium mesh implants can be manufactured with variable porosity and predesigned curvature, which reduces the need for intraoperative shaping [10, 13, 23]. PEEK has an elastic modulus closer to cortical bone than titanium, favorable chemical stability, low thermal conductivity, and good radiolucency, which facilitates postoperative imaging, although infection and cost remain relevant concerns [2, 3, 18]. PMMA patient-specific implants may be produced by prefabricated molding or computer-aided milling and can provide good contour restoration at lower cost, but the biological integration is limited compared with porous or osteoconductive materials. The clinical rationale for patient-specific 3D cranioplasty is based on the assumption that preoperative implant design improves anatomical accuracy, reduces intraoperative modeling time, decreases soft-tissue manipulation, improves cosmetic symmetry, and increases patient satisfaction. The accuracy of implant fit may also reduce dead space, minimize implant mobility, decrease fluid accumulation, and shorten operative duration. In neurosurgery, reduced operative time and reduced tissue manipulation may be relevant for infection prevention, wound healing, and perioperative safety. The literature increasingly emphasizes that the success of modern cranioplasty should be evaluated using a multidimensional model that includes clinical, aesthetic, functional, radiological, psychological, and economic parameters rather than complication rate alone [6, 13, 28]. However, the superiority of patient-specific 3D implants over conventional techniques is not absolute in all settings. The advantages depend on defect size, defect complexity, material selection, soft-tissue condition, timing of surgery, surgical experience, infection history, and manufacturing quality. Patient-specific implants may be more expensive initially and require access to digital planning, engineering expertise, certified manufacturing, and regulatory control. In low-resource settings, standard cranioplasty materials may remain more accessible. Therefore, the practical value of patient-specific implants should be assessed through comparative clinical studies that analyze both surgical outcomes and patient-centered endpoints.

Materials and Methods. This study was designed as a single-center comparative observational analysis of patients who underwent cranioplasty for post-traumatic cranial defects after decompressive craniectomy. The model clinical cohort included 62 patients treated in a

specialized neurosurgical department between 2022 and 2026. All patients had cranial bone defects resulting from previous decompressive craniectomy or removal of contaminated fractured bone fragments after traumatic brain injury. The study compared two reconstructive approaches: cranioplasty with patient-specific 3D implants and conventional cranioplasty with intraoperatively modeled reconstructive material. The first group included 32 patients who underwent cranioplasty using patient-specific 3D implants. The implants were designed from preoperative CT data and manufactured before surgery. Depending on defect morphology, material availability, and clinical indication, implants were produced from titanium, PEEK, or prefabricated PMMA. The second group included 30 patients who underwent conventional cranioplasty using manually shaped titanium mesh or intraoperatively modeled PMMA. Both groups were evaluated using the same perioperative, clinical, aesthetic, functional, and radiological endpoints.

The inclusion criteria were age between 18 and 70 years, post-traumatic cranial defect after decompressive craniectomy, cranial defect area larger than 25 cm², availability of preoperative CT imaging, stable neurological and systemic condition, absence of active intracranial infection, adequate scalp coverage, and informed consent for reconstructive surgery. The exclusion criteria were active wound infection, uncontrolled hydrocephalus, unresolved intracranial empyema, severe scalp necrosis, decompensated systemic disease, malignant tumor-related cranial defect, congenital cranial deformity, and inability to participate in follow-up assessment.

Preoperative evaluation included neurological examination, assessment of cranial defect characteristics, computed tomography of the skull, soft-tissue assessment, laboratory testing, infection screening, anesthesiological evaluation, and rehabilitation status assessment. Neurological examination included Glasgow Outcome Scale Extended when applicable, motor deficit evaluation, speech function, cranial nerve status, cognitive complaints, headache intensity, dizziness, seizure history, and symptoms suggestive of syndrome of the trephined. Functional assessment included daily activity tolerance, self-care capacity, walking independence, and quality-of-life parameters. Computed tomography was performed using thin slices, preferably 0.5–1.0 mm, to obtain adequate spatial resolution for segmentation and implant modeling. DICOM data were imported into medical image processing software. The skull was segmented from the soft tissues and intracranial structures. The cranial defect margins were identified, and the missing contour was reconstructed by mirror imaging of the contralateral side when the defect was unilateral. In bilateral or midline defects, curvature interpolation, anatomical reference landmarks, and virtual contour smoothing were used. The final implant model was exported as an STL file and reviewed by the neurosurgeon and biomedical engineer before manufacturing. The design parameters of patient-specific implants included outer cranial curvature, inner table contour, edge overlap or butt-joint configuration, implant thickness, fixation hole position, drainage channels when indicated, and surface characteristics. Special attention was paid to avoiding excessive implant thickness in the temporal region to reduce cosmetic bulging and to ensuring sufficient edge contact to prevent implant mobility. For titanium implants, porous or mesh-type architecture was used in selected cases to reduce weight and improve tissue integration. PEEK implants were designed as solid patient-specific plates with preplanned screw holes. PMMA implants were prefabricated using the digital mold or CAD/CAM approach.

Conventional cranioplasty was performed using manual intraoperative modeling. PMMA was prepared during surgery and shaped according to the defect margins and surgeon's estimation of cranial contour. Titanium mesh was manually bent and trimmed to cover the defect. The final contour was adjusted intraoperatively, and fixation was performed using mini-plates, screws, or titanium fixation systems. In both groups, the same general neurosurgical principles were used: careful scalp flap elevation, preservation of vascularized soft tissue, epidural dissection, protection of the dura, hemostasis, avoidance of dead space, stable implant fixation, and layered wound closure. The primary endpoints were operative time, implant fitting accuracy, cranial symmetry, cosmetic satisfaction, and overall aesthetic-functional outcome. Secondary endpoints included blood loss, hospital stay, wound complications, infection, epidural or subgaleal fluid collection, hematoma, cerebrospinal fluid leak, implant exposure, reoperation, neurological improvement, quality of life, and cost-related indicators. Implant fitting accuracy was assessed intraoperatively by

the need for additional contour correction and postoperatively by CT-based evaluation of the gap between implant and bone margins. Cranial symmetry was assessed using a Cranial Symmetry Index calculated from postoperative CT reconstruction and external contour comparison. To demonstrate the originality of the study, an Integrated Cranioplasty Outcome Index was developed. This index combined five domains: implant accuracy, aesthetic symmetry, complication status, functional-neurological dynamics, and patient satisfaction. Each domain was scored from 0 to 4, with a maximum total score of 20. A score of 17–20 was interpreted as excellent, 13–16 as good, 9–12 as satisfactory, and below 9 as poor. The index was not intended to replace validated quality-of-life scales but to provide a structured, cranioplasty-specific multidimensional outcome model.

Table 1. Original Integrated Cranioplasty Outcome Index

Domain	4 points	3 points	2 points	1 point	0 points
Implant fitting accuracy	Perfect fit, no correction	Minor correction only	Moderate edge adjustment	Significant intraoperative modification	Poor fit or unstable fixation
Cranial symmetry	Near-normal contour	Minimal visible asymmetry	Moderate asymmetry	Marked asymmetry	Major deformity or contour failure
Complication status	No complication	Minor self-limited event	Treatable complication without reoperation	Complication requiring procedure	Implant removal or major complication
Functional-neurological dynamics	Clear improvement	Mild improvement	Stable status	Mild deterioration	Major deterioration
Patient satisfaction	Very satisfied	Satisfied	Acceptable	Dissatisfied	Very dissatisfied

Postoperative follow-up was performed at discharge, 1 month, 3 months, 6 months, and 12 months. CT imaging was performed early after surgery or within the first 3 months to evaluate implant position, epidural collection, contour restoration, and complications. Long-term follow-up focused on implant stability, wound status, late infection, neurological dynamics, aesthetic satisfaction, and social reintegration. Statistical analysis was performed using descriptive and comparative methods. Continuous variables were expressed as mean $\pm$ standard deviation. Categorical variables were presented as numbers and percentages. Intergroup comparisons were performed using standard statistical tests appropriate for independent samples. The significance threshold was set at $p < 0.05$. Because this manuscript is prepared as a model academic article, all numerical values should be replaced with real institutional data before journal submission.

Results. The study cohort included 62 patients with post-traumatic cranial defects. The patient-specific 3D implant group included 32 patients, while the conventional cranioplasty group included 30 patients. The two groups were comparable in age, sex distribution, traumatic mechanism, neurological baseline, defect localization, defect size, and interval between decompressive craniectomy and cranioplasty. The mean age was 38.7 ± 11.6 years in the 3D-implant group and 40.1 ± 12.4 years in the conventional group. Male patients predominated in both groups, reflecting the epidemiological pattern of severe traumatic brain injury. The most common defect localization was frontotemporoparietal, followed by temporoparietal, frontal, and parieto-occipital defects. Large defects exceeding 75 cm² were more frequent in the 3D-implant group, because complex cranial contour was considered an indication for patient-specific reconstruction. The mean interval from decompressive craniectomy to cranioplasty was 5.8 ± 2.6 months in the 3D group and 6.1 ± 2.9 months in the conventional group. No patient had active infection at the time of reconstructive surgery.

Table 2. Baseline characteristics of the study cohort

Parameter	Patient-specific 3D implant group, n = 32	Conventional cranioplasty group, n = 30
Mean age, years	38.7 ± 11.6	40.1 ± 12.4
Male/female ratio	24/8	22/8
Severe traumatic brain injury as initial cause	26 patients	25 patients
Depressed skull fracture with contaminated bone removal	6 patients	5 patients
Frontotemporoparietal defect	15 patients	13 patients
Temporoparietal defect	9 patients	8 patients
Frontal defect	5 patients	6 patients
Parieto-occipital defect	3 patients	3 patients
Mean defect area, cm ²	86.5 ± 24.8	81.2 ± 22.6
Mean interval to cranioplasty, months	5.8 ± 2.6	6.1 ± 2.9
Preoperative motor deficit	11 patients	10 patients
Headache or discomfort related to defect	21 patients	19 patients

In the patient-specific 3D implant group, titanium implants were used in 18 patients, PEEK implants in 10 patients, and prefabricated PMMA implants in 4 patients. Titanium was selected predominantly for large and irregular defects requiring high mechanical strength and thin-profile reconstruction. PEEK was preferred in cosmetically sensitive areas and in patients requiring favorable postoperative imaging conditions. Prefabricated PMMA was used in selected cases where cost containment was important and defect geometry was suitable for accurate mold-based reconstruction.

Table 3. Characteristics of patient-specific 3D implants

Implant characteristic	Titanium PSI	PEEK PSI	Prefabricated PMMA PSI
Number of patients	18	10	4
Mean implant area, cm ²	92.4 ± 21.8	78.6 ± 18.2	69.5 ± 14.7
Mean thickness, mm	1.2 ± 0.3	4.5 ± 0.8	5.2 ± 0.9
Preplanned fixation holes	18/18	10/10	4/4
Need for intraoperative contour correction	1 patient	0 patients	1 patient
CT-based satisfactory fit	18 patients	10 patients	4 patients
Main indication	Large irregular defects	Cosmetic contour and imaging	Cost-sensitive reconstruction

Perioperative analysis demonstrated a shorter operative time in the patient-specific 3D implant group. Mean operative time was 96.4 ± 18.7 minutes in the 3D group and 128.6 ± 24.5 minutes in the conventional group. The difference was mainly related to reduced intraoperative implant modeling and reduced need for repeated contour adjustment. Mean blood loss was also lower in the 3D group, although the difference was less pronounced. The mean time required for implant positioning and fixation was 18.2 ± 6.4 minutes in the 3D group and 39.5 ± 12.7 minutes in the conventional group.

Table 4. Perioperative outcomes

Parameter	Patient-specific 3D implant group	Conventional cranioplasty group
Mean operative time, min	96.4 ± 18.7	128.6 ± 24.5
Estimated blood loss, ml	145.8 ± 54.2	186.7 ± 68.5
Implant positioning and fixation time, min	18.2 ± 6.4	39.5 ± 12.7
Intraoperative implant remodeling	2 patients	24 patients

Drain placement	28 patients	27 patients
Mean hospital stay, days	6.2 ± 1.8	7.4 ± 2.1
Early mobilization within 24 hours	27 patients	22 patients
Need for postoperative intensive observation beyond 24 hours	3 patients	4 patients

Postoperative CT evaluation showed better implant-bone adaptation in the 3D group. The mean marginal gap was 1.4 ± 0.6 mm in the patient-specific implant group compared with 3.8 ± 1.5 mm in the conventional group. Step-off deformity along the outer cranial contour was less frequent in the 3D group. The mean Cranial Symmetry Index was $96.8 \pm 2.1\%$ in the 3D group and $90.4 \pm 4.8\%$ in the conventional group. In frontotemporal defects, the difference in cosmetic contour was especially visible because manual reconstruction of the temporal line and frontal convexity was technically more difficult.

Table 5. Radiological and aesthetic reconstruction parameters

Parameter	Patient-specific implant group	3D	Conventional cranioplasty group
Mean marginal gap, mm	1.4 ± 0.6		3.8 ± 1.5
Visible contour step-off on CT	3 patients		12 patients
Mean Cranial Symmetry Index, %	96.8 ± 2.1		90.4 ± 4.8
Temporal hollowing after surgery	2 patients		8 patients
Need for secondary aesthetic correction	0 patients		3 patients
Surgeon-rated excellent fit	26 patients		10 patients
Patient-rated high cosmetic satisfaction	28 patients		18 patients

Clinical and functional outcomes improved in both groups. Headache, local discomfort, dizziness, and subjective vulnerability of the cranial defect decreased after reconstruction. Patients in the 3D group reported higher satisfaction with head shape, scalp contour, and social confidence. Neurological improvement was observed in a subgroup of patients, particularly those with preoperative symptoms consistent with syndrome of the trephined. Motor deficit improved by at least one Medical Research Council grade in 5 of 11 patients in the 3D group and 4 of 10 patients in the conventional group. Cognitive complaints and fatigue improved subjectively in several patients after restoration of the cranial vault.

Table 6. Clinical, functional, and patient-centered outcomes at 12 months

Outcome parameter	Patient-specific implant group	3D	Conventional cranioplasty group
Reduction of defect-related headache	19/21 patients		15/19 patients
Improvement of dizziness or positional discomfort	12/15 patients		9/14 patients
Motor improvement in patients with preoperative deficit	5/11 patients		4/10 patients
High patient satisfaction with appearance	28/32 patients		18/30 patients
Return to social activity within 3 months	25/32 patients		19/30 patients
Subjective improvement in self-confidence	27/32 patients		18/30 patients
Quality-of-life improvement	26/32 patients		21/30 patients

Complication analysis showed that overall complication rates were lower in the 3D group, although the model sample size does not allow definitive statistical conclusions. In the 3D group, one superficial wound infection was treated successfully with antibiotics and local wound care. One

subgaleal fluid collection required puncture aspiration. One patient developed a small epidural hematoma without mass effect and was managed conservatively. No implant exposure or implant removal occurred in the 3D group. In the conventional group, two wound infections, three subgaleal fluid collections, two epidural hematomas, one cerebrospinal fluid leak, and three secondary aesthetic corrections were documented. One patient in the conventional group required implant removal due to deep infection.

Table 7. Postoperative complications and reoperations

Complication	Patient-specific implant group	3D	Conventional cranioplasty group
Superficial wound infection	1		2
Deep infection requiring implant removal	0		1
Subgaleal fluid collection	1		3
Epidural hematoma without surgery	1		1
Epidural hematoma requiring evacuation	0		1
Cerebrospinal fluid leak	0		1
Implant exposure	0		1
Seizure aggravation	1		1
Secondary aesthetic correction	0		3
Total reoperations	0		3

The Integrated Cranioplasty Outcome Index demonstrated better global outcomes in the patient-specific 3D implant group. Excellent outcomes were achieved in 18 patients in the 3D group and 9 patients in the conventional group. Good outcomes were achieved in 10 and 12 patients, respectively. Satisfactory outcomes were observed in 4 patients in the 3D group and 6 patients in the conventional group. Poor outcomes occurred only in the conventional group, mainly due to infection, implant removal, or cosmetically unacceptable contour.

Table 8. Integrated Cranioplasty Outcome Index results

Outcome category	Score range	Patient-specific implant group	3D	Conventional cranioplasty group
Excellent	17–20	18 patients, 56.3%		9 patients, 30.0%
Good	13–16	10 patients, 31.2%		12 patients, 40.0%
Satisfactory	9–12	4 patients, 12.5%		6 patients, 20.0%
Poor	<9	0 patients		3 patients, 10.0%
Excellent and good combined	13–20	28 patients, 87.5%		21 patients, 70.0%

Discussion. The present study suggests that patient-specific 3D implants provide clinically relevant advantages in cranioplasty of post-traumatic cranial bone defects compared with conventional intraoperatively modeled cranioplasty. The most important findings were reduced operative time, improved implant fitting accuracy, superior cranial symmetry, higher patient satisfaction, fewer contour-related problems, and favorable aesthetic-functional outcomes. These findings support the concept that modern cranioplasty should be evaluated not only as a protective procedure but also as an anatomical, physiological, aesthetic, and psychosocial reconstruction [11, 12, 20]. The reduction in operative time is one of the most practical advantages of patient-specific 3D implants. In conventional cranioplasty, a significant part of surgery may be spent on shaping PMMA or titanium mesh, repeatedly checking the contour, trimming edges, adjusting thickness, and achieving stable fixation. This process is technically demanding in large frontotemporoparietal defects, where the surgeon must reconstruct the frontal convexity, temporal curvature, sphenoid region, and parietal arch. A prefabricated 3D implant reduces intraoperative uncertainty because the implant has already been designed according to the patient's CT anatomy [15, 17, 27]. In the present model cohort, implant positioning and fixation time was reduced by more than 50% in the 3D group.

From a surgical safety perspective, shorter operative time may reduce anesthesia exposure, tissue desiccation, wound contamination, and blood loss. Although infection after cranioplasty is multifactorial, prolonged operation and repeated manipulation of implants and soft tissues are recognized risk factors. Patient-specific implants may reduce manual handling and repeated bending, which can theoretically lower contamination risk. However, implant material, scalp vascularity, previous infection, timing of cranioplasty, diabetes, smoking, cerebrospinal fluid disturbance, and hydrocephalus remain important determinants of infection [7, 14, 19]. The improvement in cranial symmetry is particularly relevant in post-traumatic patients. Unlike small burr-hole defects, large cranial defects affect the visible shape of the head. Cosmetic deformity can produce psychological distress, social avoidance, reduced self-esteem, and dissatisfaction even when neurological recovery is acceptable. In frontal and frontotemporal defects, small irregularities are especially noticeable. The present study showed a higher Cranial Symmetry Index and higher patient-rated satisfaction in the 3D group. This supports the use of CT-based virtual reconstruction and mirror modeling in cosmetically important cranial regions. Implant fitting accuracy is another important outcome. Poor fit may create gaps, dead space, implant mobility, edge prominence, scalp irritation, and fluid collection [16, 23, 30]. The mean marginal gap was smaller in the 3D group, reflecting the advantage of preoperative CAD-based planning. Accurate implant-bone contact may improve mechanical stability and reduce the need for excessive screw fixation. It may also decrease the risk of contour step-off and palpability. Nevertheless, accuracy depends on CT quality, segmentation precision, design workflow, manufacturing tolerance, sterilization-related deformation, and intraoperative positioning.

The material of the patient-specific implant is a key consideration. Titanium is widely used because of its mechanical strength, biocompatibility, and long surgical history. It is suitable for large defects and can be manufactured as a thin mesh-type implant with preplanned curvature. However, titanium may create imaging artifacts, conduct heat and cold, and be palpable under thin scalp [21, 24, 31]. PEEK offers favorable radiolucency, chemical stability, and elastic modulus closer to bone, but it is expensive and biologically inert unless surface-modified. PMMA is accessible and cost-effective, but it lacks osseointegration and may be less suitable for very complex defects if not prefabricated accurately. No single material is ideal for all cases; therefore, material selection should be individualized [12,13]. The neurological improvement observed in some patients after cranioplasty is consistent with the concept that cranial reconstruction can influence intracranial physiology. Restoration of the rigid cranial vault may improve cerebral blood flow, normalize atmospheric pressure effects, restore cerebrospinal fluid hydrodynamics, and improve cortical function in selected patients. In this study, neurological improvement was not the primary differentiating feature between groups, but some patients demonstrated better motor function, decreased headaches, improved positional tolerance, and better participation in rehabilitation after cranioplasty [23, 30, 32]. This reinforces the importance of timely reconstruction in patients with large decompressive defects. The Integrated Cranioplasty Outcome Index proposed in this study provides a structured model for evaluating cranioplasty results. Traditional studies often focus on infection, hematoma, or implant failure. However, patients and surgeons also care about cranial contour, symmetry, functional recovery, satisfaction, and social reintegration. A patient may have no infection but remain dissatisfied because of visible deformity, temporal hollowing, implant edge palpability, or asymmetry. Conversely, a technically accurate implant may not be successful if wound healing fails. A multidimensional index can better reflect the real-world success of cranioplasty. The originality of the present study lies in combining clinical, aesthetic, functional, radiological, and patient-centered outcomes. The article does not evaluate patient-specific implants only as a technological novelty; it evaluates whether the digital workflow translates into measurable clinical benefit. The use of cranial symmetry, implant fit, satisfaction, neurological dynamics, and complications in one integrated model may help standardize future comparative studies. This approach may be particularly useful in post-traumatic cranial defects, where anatomical irregularity and psychosocial consequences are pronounced [1, 10, 13, 32].

The economic aspect of patient-specific implants deserves attention. Patient-specific titanium or PEEK implants may have higher preoperative manufacturing costs than manually

shaped PMMA or standard titanium mesh. However, the total cost of treatment depends not only on implant price but also on operative time, anesthesia duration, hospital stay, reoperation, infection, cosmetic correction, and long-term patient satisfaction. In large or complex defects, the higher cost of a patient-specific implant may be offset by reduced operating room time and fewer contour-related revisions. A formal cost-effectiveness analysis should be included in future prospective studies. Timing of cranioplasty remains controversial. Early cranioplasty may improve neurological recovery and reduce the duration of skull defect-related symptoms, but it may be associated with higher risk if brain swelling, infection, hydrocephalus, or wound instability persists. Delayed cranioplasty allows soft-tissue recovery and infection resolution but prolongs vulnerability and cosmetic deformity. In this study, surgery was performed after stabilization of the patient and exclusion of active infection. The choice of timing should be individualized according to neurological status, CT findings, scalp condition, systemic condition, and rehabilitation plan. Soft-tissue condition is critical for successful cranioplasty [3, 10, 18, 27]. Even the best-designed implant can fail if scalp vascularity is poor, scar tension is excessive, or wound closure is compromised. Post-traumatic patients may have previous scalp lacerations, scars, contamination, skin grafts, or compromised vascular supply. Preoperative evaluation should include scalp thickness, scar direction, vascularity, tissue mobility, and risk of exposure. In complex cases, collaboration with plastic and reconstructive surgeons may be necessary. Patient-specific implants should be designed not only according to bone geometry but also according to soft-tissue limitations.

Hydrocephalus and cerebrospinal fluid disturbances are also relevant. Patients after decompressive craniectomy may develop post-traumatic hydrocephalus, subdural hygroma, or altered cerebrospinal fluid absorption. Performing cranioplasty in the presence of untreated hydrocephalus may increase the risk of fluid collection, wound complications, and implant-related pressure problems. Conversely, cranioplasty may improve cerebrospinal fluid dynamics in selected patients. The timing and sequence of shunting and cranioplasty should be planned carefully. In the present model cohort, patients with uncontrolled hydrocephalus were excluded to reduce confounding. The results of this study should be interpreted with caution. The cohort is model-based and intended for academic article preparation. Real clinical publication requires verified data, ethical approval, statistical validation, and complete follow-up. The sample size is moderate, and the study design is observational rather than randomized. Selection bias may exist because larger and more complex defects may preferentially receive patient-specific implants [4, 14, 19, 25]. Material heterogeneity within the 3D group also limits direct comparison between titanium, PEEK, and PMMA. Despite these limitations, the proposed structure provides a realistic framework for clinical research in cranial reconstruction. Future research should include prospective multicenter studies comparing patient-specific titanium, PEEK, PMMA, and conventional techniques using standardized aesthetic and functional endpoints. Three-dimensional photogrammetry, CT-based volumetric symmetry analysis, patient-reported outcome measures, and validated quality-of-life scales should be incorporated. Artificial intelligence-based automatic implant design may further reduce planning time and increase accessibility, particularly in regions where biomedical engineering resources are limited [5, 16, 20, 31]. Long-term studies are also needed to evaluate implant survival, infection, bone integration, scalp thinning, pediatric growth issues, and late revision rates.

Conclusion. Patient-specific 3D implants appear to provide important advantages in cranioplasty of post-traumatic cranial bone defects, particularly in large, irregular, and cosmetically sensitive defects. Compared with conventional intraoperatively modeled cranioplasty, 3D implants may reduce operative time, improve implant fitting accuracy, enhance cranial symmetry, decrease the need for intraoperative contour adjustment, improve patient satisfaction, and reduce secondary aesthetic corrections. These benefits are most evident when digital planning is based on high-quality CT data, accurate segmentation, careful implant design, appropriate material selection, and stable fixation. Cranioplasty should be understood as a multidimensional reconstructive procedure that restores protection, contour, intracranial physiology, psychological confidence, and social reintegration. The Integrated Cranioplasty Outcome Index proposed in this study may help evaluate

results beyond complication rate alone by incorporating anatomical accuracy, cosmetic outcome, complications, neurological dynamics, and patient satisfaction.

Patient-specific 3D cranioplasty is not universally superior in every clinical situation. Its success depends on patient selection, defect complexity, material properties, scalp condition, infection control, manufacturing quality, cost considerations, and surgical expertise. Nevertheless, for post-traumatic cranial defects with complex geometry, patient-specific 3D implants represent a highly promising reconstructive strategy and should be considered an important component of modern personalized neurosurgery.

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