

# RECONSTRUCTION OF THE CALVARIAL DEFECTS USING CUSTOM-MADE CRANIOPLASTY PLATES

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## REZUMAT

**Objective:** Există multiple motive pentru care reconstrucția defectelor calvariei trebuie făcută, precizia acestora fiind esențială pentru a obține rezultate favorabile. Articolul își propune să prezinte o metodă modernă de cranioplastie utilizând modele tridimensionale medicale și implantate personalizate din polietil-sau polimetilmetacrilat. **Material și metode:** Au fost reconstruite defecte craniene cu mărime, formă și localizare diferită, utilizând plăci de cranioplastie personalizate, produse prin tehnicile de fabricare rapidă a prototipurilor. Defectele calvariei s-au datorat în principal traumatismelor, dar și pierderii prin infecție a voletului osos secundar craniotomiei decompressive. Cranioplastiile au fost realizate la un interval de timp variabil (6-14 luni) după operația inițială. **Rezultate:** Plăcile de cranioplastie s-au potrivit corespunzător în defectele pentru care au fost produse, fără a necesita corecturi intraoperatorii. Timpul petrecut intraoperator a fost semnificativ scurtat, reducând astfel stresul bolnavului și morbiditatea. Nu am întâlnit complicații, iar rezultatele finale, funcționale și estetice au fost foarte bune. **Concluzii:** Utilizarea imagisticii tridimensionale și a tehnicilor de fabricare rapidă a prototipurilor permit reconstrucția fidelă a defectelor craniene complexe, cu rezultate estetice și funcționale foarte bune.

**Cuvinte cheie:** cranioplastie, implantate personalizate, modele tridimensionale, fabricare rapidă a prototipurilor

## ABSTRACT

**Objectives:** Reconstruction of the cranial vault is performed for various reasons and precise repair of the defect is essential. A modern method of cranioplasty is presented using three-dimensional models and custom polyethyl- or polymethylmethacrylate implants. **Material and methods:** Calvarial defects, different in size, shape and location, were repaired by means of custom made cranial implants, produced using data acquired from three-dimensional (3D) computer tomography, rapid prototyping and casting in plaster or silicone-rubber mould. The defects resulted from trauma and infection-lost bone flap after decompressive craniotomy. The cranioplasty was performed at a variable time interval (6-14 months) after the initial operation. **Results:** The cranial plate fitted well into the defect and needed no correction at the time of surgery. Intraoperative time was significantly decreased. Thus, the operative stress and morbidity were significantly lowered. No complications occurred and the final functional and aesthetic results were good. **Conclusion:** The use of three-dimensional imaging and rapid prototyping allow precise repair of large and complex skull defects, with good aesthetic and functional results.

**Key Words:** cranioplasty, custom implant, three-dimensional models, rapid-prototyping

## INTRODUCTION

Cranial vault defects result from trauma, infection, tumor ablation or cerebral decompression procedures. Cranial defects determine not only aesthetic but also functional alterations. The so-called “syndrome of the trephined” can be encountered in such patients.<sup>1,2</sup>

The symptoms are headache, dizziness, irritability, anxiety, intolerance to noise or vibrations etc.<sup>1,2</sup> Functional alterations are often observed due to the changes in cerebral blood-flow velocity. This is decreased on the affected side when compared with the healthy hemisphere.<sup>3,4</sup> Moreover, the blood flow of the extra-cranial part of the internal carotid artery is decreased on the side of the defect. This may be induced by postural changes. More important, the cerebrovascular reserve capacity is severely impaired in both hemispheres before cranioplasty. It is significantly increased after repair of the defect in the cranial vault. Some metabolic changes were also noted following cranioplasty.<sup>5</sup> Agner et al (2002) observed a significant improvement in major cognitive functions after cranioplasty.<sup>6</sup>

Thus, the main purpose of a cranioplasty is not only cosmetic repair but also improving the neurological status. Various materials have been used to fill defects in the cranial vault, such as metal,

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xenografts, autografts, and allografts.<sup>7</sup> Today, the modern plastic materials are used often. A good synthetic material must be: biocompatible, inert, low or even non-thermal conductive, capable of generating no artifacts on CT and MRI, of the same weight as the bone or even lighter, strong enough to resist functional stress, simple to work with and not expensive.<sup>8,9</sup> Acrylates are fulfilling these demands. Polymethylmethacrylate (PMMA) is the one mostly used for cranioplasty, but polyethylmethacrylate (PEMA) offers some advantages over PMMA, such as greater elasticity, lower polymerization temperature, easiness in processing.<sup>10</sup>

However, the complexity of cranioplasty increases proportionally with the size of the defect, as well as with the location which raise the necessity to reproduce a complex anatomical shape.<sup>11</sup> When the defect is located in the frontal, temporal and parietal region, it is very difficult to produce a shape that is needed for a symmetrical reconstruction. Three-dimensional imaging and rapid prototyping techniques associated with the use of alloplastic materials allow construction of a cranioplasty plate preoperatively. The defect is repaired symmetrically even in thickness. Some dental impression materials offer exact reproducibility and elasticity but their shape is hardly changed after taking impression. In this paper, a technique of custom cranioplasty plate manufacturing is presented using polyethyl- or polymethylmethacrylate casted in plaster or silicone rubber mould (a material commonly used in industrial casting).

## **MATERIAL AND METHOD**

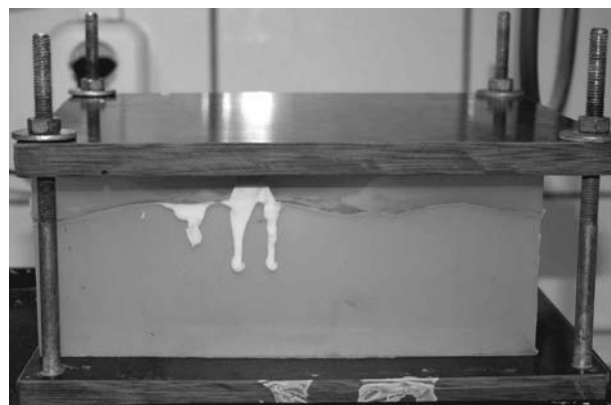
The calvarial defects of four patients were repaired using custom-made cranioplasty plates. One defect was secondary to small bone fragments removal after a comminuted frontal fracture. Three defects resulted due to the infection-driven loss of the bone flap elevated for decompression craniotomy. One flap got infected after it was repositioned on calvaria and the other two were compromised by infection while they were kept in the abdominal subcutaneous tissue. The primary cause for intracranial hypertension was trauma in two cases and ischaemic cerebral vascular accident in one case.

There was a different time interval (6 to 14 months) between initial operation (decompression craniotomy/ bone fragments removal) and cranioplasty. This period was necessary for the neurological rehabilitation of the patients as well as for the definitive removal of infection from the future operative site.

To produce the custom made cranial plates the patients underwent a spiral CT scan of the head (Siemens Somatom; Erlangen, Germany), using Head 3D protocol as defined by the device, from Frankfurt horizontal to vertex. Axial slices were 2 mm thick (continuous). A virtual model of the cranial vault was obtained by means of three-dimensional reconstruction (MIMICS®, Materialise N.V., Leuven, Belgium). The virtual 3D model for the cranioplasty plate to fit the cranial defect was obtained with mirroring procedures, superimposition, and algebraic Boolean operations.

Using selective laser sintering (SLS) for rapid prototyping (Sinter Station 2000, 3D System, Darmstadt, Germany), both virtual models (defect and plate) were transformed into real models of polyamide. After a small manual processing, the plate fitted perfectly into the defect. One exception was made in the case of the smaller frontal defect where the cranioplasty plate model was waxed-up by a dental technician.

The polyamide (by SLS) or wax model of the cranioplasty plate was used in order to make a silicone rubber mould. Radiopaque bone cement (Surgical Simplex® P, Stryker Howmedica Osteonics, Limerick, Ireland) made of polymethylmethacrylate was prepared in the form of a thin paste. The same was done using polyethylmethacrylate combined with hydroxyapatite. This paste was cast in the silicone rubber mould and pressed into form. (Fig. 1)

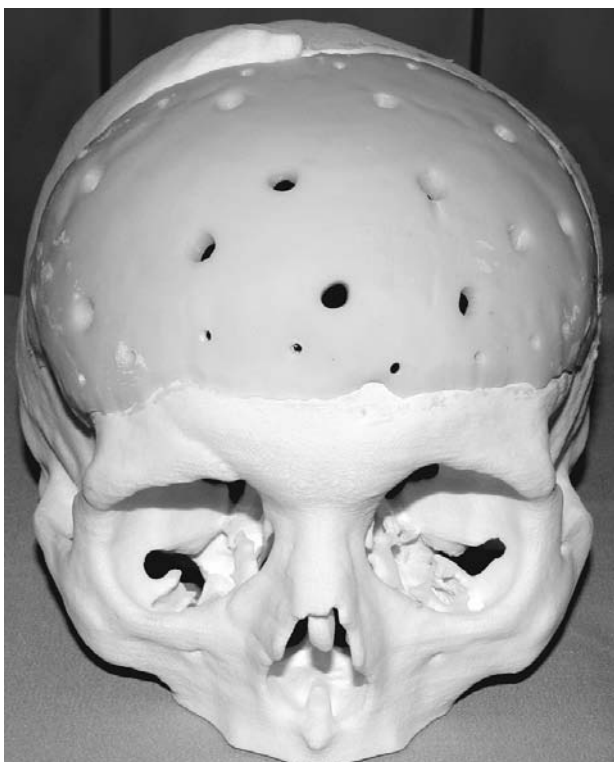


**Figure 1.** Silicone-rubber mould in which the polyethylmethacrylate paste was cast. Note the thickness of the mould's walls and the reflux of the excess material through one of the draining channels.

Originally, the silicone rubber mould was used in industrial casting of melted plastics. In order to obtain a precise model, and to avoiding mould deformations, the casting process used a thin paste and a mould with thicker walls. Significantly large draining channels were cut in the margins of the mould to drain the excess of the material. The cover of the mould was pressed against the bottom only with hand pressure and,

after complete closure, it was sustained in position by introducing the mould into a press without tightening it. After autopolymerization (an exothermic reaction), the whole piece was slowly thermopolymerized for 24 hours at 60°C in order to eliminate all the traces of monomer. During thermopolymerization phase, the silicone rubber mould was kept into press in the same position as during autopolymerization.

After un moulding, the margins of the final custom-made cranioplasty plate were slightly manually processed in order to eliminate the excess and to drill holes for fixation. On its surface, 5-7 mm holes were drilled in order to prevent development of an epidural haematoma. (Fig. 2) Before surgery, the cranioplasty plates were sterilized using ethylene-oxide.



**Figure 2.** Custom-made cranioplasty plate applied on the 3D model.

## RESULTS

Under general anaesthesia the bony defect was exposed and prepared subperiostally through the old scar. The custom-made plates were then applied. Three of them fitted perfectly and needed no further processing. (Fig. 3)

One of the plates, reconstructing the small frontal defect, was, in some areas, smaller than the bony defect. This was finally judged as being due to a longer time interval between 3D model and plate production and cranioplasty operation. During this period the cranial vault bone remodeled.



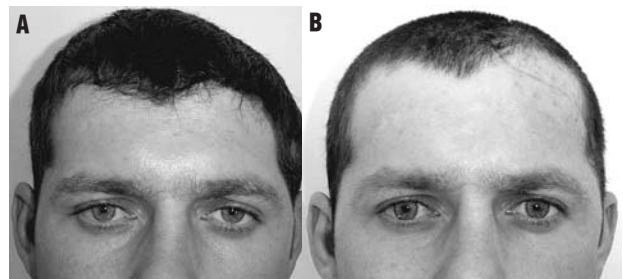
**Figure 3.** The intraoperative aspect of the custom-made cranioplasty plate settled in place. Note the perfect marginal adaptation.

For security reasons the plates were fixed with 2.0 silk sutures to the bony margins of the defect.

There were no intra-operative complications. In all cases, there were no problems of covering the plates with the skin. Starting intraoperatively, an antibiotic treatment was given for the next ten days. In the recovery period, the healing process evolved well. There were no infectious episodes or wound dehiscences encountered and the patients were discharged on the seventh day postoperatively after stitch removal.

Follow-up was at one and six months after the operation, with clinical and CT examination. Clinically, no complications were noted, patients tolerated well the cranioplasty plate. The esthetical aspect of all the patients operated was significantly improved. (Figs. 4-6)

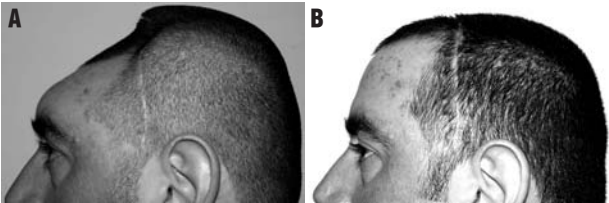
CT examination showed the plates in place reconstructing not only the external surface of the defect but the thickness as well. The symmetry of the cranial vault was perfectly obtained in all cases. (Figs. 7-9) No meningeal reactions could be seen on the CT scan at the site of the reconstruction.



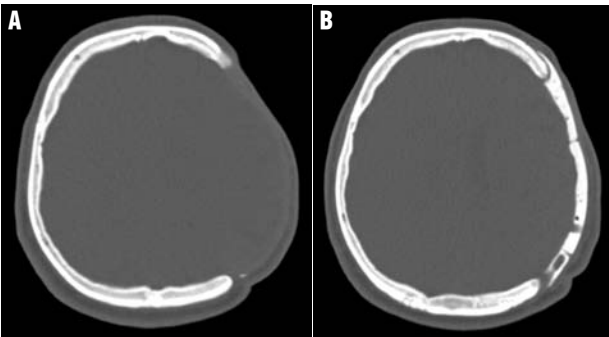
**Figure 4.** The comparative clinical aspect of left hemispheric defect reconstructed with the custom-made cranioplasty plate. A. Preoperative; B. Postoperative.



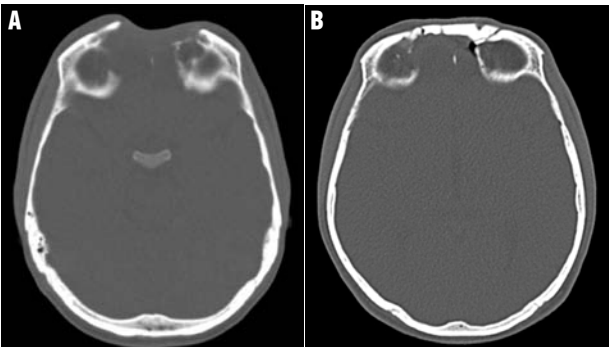
**Figure 5.** Preoperative (A) and postoperative (B) clinical aspect of a complex frontal defect reconstructed with custom implant.



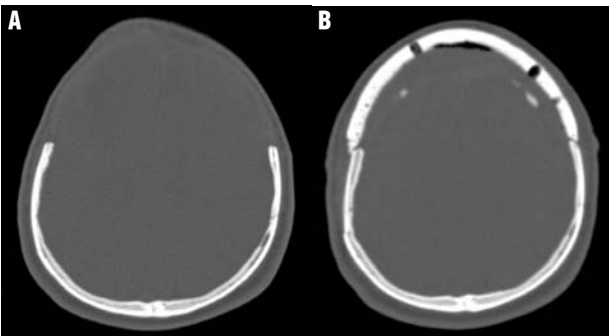
**Figure 6.** Comparative clinical aspect of a custom-made cranioplasty in the case of a bilateral large frontal defect. A. Preoperative; B. Postoperative.



**Figure 7.** CT aspect of the left hemispheric defect. A. Preoperative; B. Postoperative. Note the perfect symmetry restored not only in surface but in thickness as well.



**Figure 8.** Preoperative (A) and postoperative (B) CT aspect of the complex frontal defect reconstructed with custom implant.



**Figure 9.** Axial CT images of the bilateral frontal defect reconstructed with custom-made cranioplasty plate. A. Preoperative; B. Postoperative.

## DISCUSSION

To repair large, complex, skull defects one can choose either to reconstruct the vaults strictly intra-operatively or to prepare a so called “custom-made cranial implant,” prior to the operation. The disadvantages of intra-operative repair are time-consuming, increasing risk to the patient, insufficient protection from trauma and infection, often resulting in suboptimal cosmesis. However, custom made cranioplasty implants have the advantages of a reduced operative time, less invasive surgery, improved cosmetic results, faster recuperation, and reduced costs due to a short operative time.<sup>9,11-13</sup>

On the other hand, every time a cranial vault reconstruction is planned, the choice of materials is an important issue. Autografts have the advantage of better toleration and successful incorporation. In case of large defects, however, problems may arise such as donor site morbidity, insufficient amount or quality of donor material, and difficulty in crafting the correct shape; grafts may also show some degree of resorption and may require further surgery for correction.<sup>14,15</sup> Alloplastic materials like metal plates have been used to cover cranial defects from the ancient time.<sup>7</sup> Today, alloplastics used most frequently are hydroxyapatite cements, acrylics (especially polymethylmethacrylate) and carbon fibre reinforced plastics.<sup>9,11,12</sup> The main disadvantage of alloplastic materials is their high susceptibility to infection, but they allow the repair of large defects with no donor site morbidity and smaller costs.<sup>15-17</sup> When shaped by three-dimensional techniques, they permit an accurate reconstruction of anatomical contours.

Custom-made implants manufactured using rapid prototyping techniques have been already introduced in clinical practice.<sup>18-22</sup> However, there are some problems in reproducibility. Various authors have used a plaster mould.<sup>22,23</sup> The method presented here used mainly a silicone rubber mould. Compared to plaster, the main advantage of silicone rubber is that it allows preservation of very thin details of the plate (e.g. margins) during unmoulding. Preserving the thin margins of the plate provided a better stabilization and there was no need of rigid fixation. The latter could prevent secondary damage to the brain during drilling and screwing. Chiarini et al. (2004) recommended the acrylic prosthesis to overlap the bone surroundings by 10 mm in order to avoid a possible incorrect prefabrication of the plate.<sup>22</sup> In large defects such as presented above, titanium mesh must be two-directionally bent to mimic the anatomical shape of

the cranial vault. When doing this, sharp edges are generated on the surface of the mesh. This, in fact, happens to every rigid plate that is simultaneously bent in two directions. Cast titanium preformed plates reshape well the surface of the skull but they do not repair the defect. For stability reasons, they must overlap the margins of the defect and must be fixed using osteosynthesis material.

## CONCLUSION

Custom-made cranial implants prepared in a silicone-rubber mould are particularly useful for repairing large and complex-shaped defects and have many advantages when compared with intraoperative production.

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