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Silicone rubber mould cast polyethylmethacrylate-hydroxyapatite plate used for repairing a large skull defect

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SUMMARY. Introduction: **Reconstruction of the cranial vault is performed for various reasons and precise repair of the defect is important. A modified method of cranioplasty is presented using three-dimensional (3D) models and polyethylmethacrylate mixed with hydroxyapatite, cast in a silicone rubber mould.** Patient and method: **A large custom made cranial implant was produced using data acquired from 3D computer tomography, rapid prototyping and cast in a silicone rubber mould. This plate was then applied to a 53 year-old man who had undergone a decompressive fronto-parieto-temporo-occipital craniotomy. The bone flap had been lost due to infection. The cranioplasty was performed at 1 year after the initial operation.** Results: **The cranial plate fitted precisely into the defect and needed no correction at the time of surgery. The stability of the reconstruction plate was increased by the presence of thin margins allowed by silicone rubber elasticity. No complications occurred and the final functional and aesthetic results were good.** Conclusion: **The use of 3D imaging and rapid prototyping allow precise repair of large skull defects, with good aesthetic and functional results. At the same time, silicone rubber moulds permit the production of very thin details needed not only for cosmetic reasons but for reconstruction plate stability as well. © 2006 European Association for Cranio-Maxillofacial Surgery**

Keywords: **cranioplasty; custom made implant; silicone rubber mould**

BACKGROUND

Cranial vault defects result from trauma, infection, tumour ablation or cerebral decompression procedures. Cranial defects produce not only aesthetic but also functional alterations. The so-called 'syndrome of the trephined' can be encountered in such patients (*Dujovny* et al., 1997, 1999). The symptoms are headache, dizziness, irritability, anxiety, intolerance to noise or vibrations, etc. (*Dujovny* et al., 1997, 1999). 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 (*Erdogan* et al., 2003; *Kuo* et al., 2004). Moreover, the blood flow of the extracranial 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 (*Winkler* et al., 2000). *Agner* et al. (2002) observed a significant improvement in major cognitive functions after cranioplasty.

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, xenografts, autografts, and allografts (*Durand* et al., 1997). Today, the modern plastic materials are used often. A good synthetic material must be: biocompatible or inert, low or even non-thermally 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 (*Sader* et al., 1996; *Zeilhofer* et al., 1997). Acrylates fulfill 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 and ease of processing (*Bran* et al., 2002). When PEMA is combined with hydroxyapatite, the advantages are even greater: physical resistance similar to bone, formation of collagen bridges between bone and hydroxyapatite (*Khorasani* et al., 1992; *Florian* et al., 1998). The powder of PEMA containing polymerization initiator was mixed with hydroxyapatite generating the solid component of the composite material.

The paste of PEMA–hydroxyapatite was obtained by adding liquid monomer to the powder and stirring to a perfectly homogenous state.

However, the complexity of cranioplasty increases proportionally with the size of the defect (van Putten and Yamada, 1992). When the defect is located in the frontal, temporal and parietal regions it is very difficult to produce the shape necessary for symmetrical reconstruction. Three-dimensional (3D) imaging and rapid prototyping techniques associated with the use of alloplastic materials allow construction of a cranioplasty plate preoperatively, with a symmetrical repair and comparable thickness. Some dental impression materials offer precise reproducibility and elasticity with virtually no physical change after impression-taking. In this paper a technique of custom cranioplasty plate manufacture is presented using PEMA with hydroxyapatite cast in a silicone rubber mould (a material which is commonly used in industrial casting).

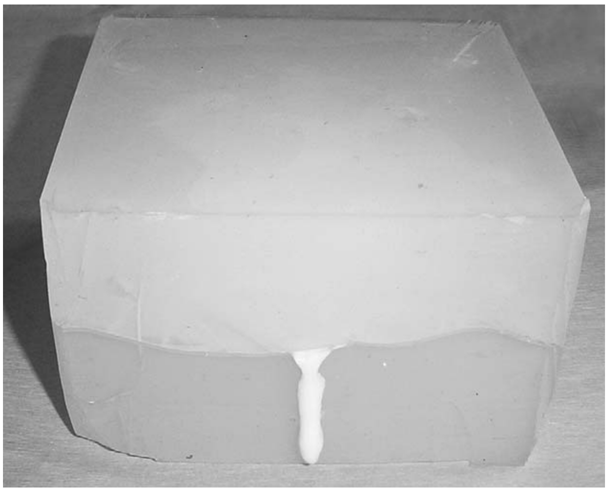

Fig. 1 – Silicone rubber mould in which the polyethylmethacrylate paste was cast. Note the thickness of the mould's walls and the excess material appearing at one of the drain channels.

METHODS

The procedure to produce custom made cranial plates was as follows:

Step 1: The patient underwent a spiral cranial CT scan (Siemens Somatom; Erlangen, Germany), from the Frankfurt horizontal to the vertex with 0° tilt. Axial slices were 2 mm thick (continuous). Using 3D reconstruction, a virtual 3D model of the vault and defect was obtained and a cranioplasty plate was constructed with mirroring procedures, superimposition, and algebraic Boolean operations.

Step 2: Using selective laser sintering (SLS) for rapid prototyping, both virtual models (defect and plate) were transformed into real models of polyamide. After minor manual finishing, the plate fitted perfectly into the defect.

Step 3: The pattern of the cranioplasty plate made of polyamide (by SLS) was used to make a silicone rubber mould. A thinner paste of PEM combined with hydroxyapatite was prepared by mixing a powder of PEM with hydroxyapatite granules and liquid ethylmethacrylate. This paste was cast in the silicone rubber mould and pressed into form (Fig. 1). Originally, the silicone rubber mould was used in industrial casting of molten plastics. In order to obtain a precise model, and to avoid mould deformations, the casting process used a thin paste of PEM and a mould with thicker walls. Sizable drainage channels were cut into the margins of the mould to drain excess of the material. The cover of the mould was pressed against its base with hand pressure and, after complete closure, it was retained in position by fixing the mould in a press without significant pressure. After autopolymerization (an exothermic reaction), the whole piece was slowly thermopolymerized for 24 h at 60 °C in order to eliminate all the traces of monomer. During thermopolymerization, the silicone rubber mould was kept in the press in the same position as during autopolymerization.

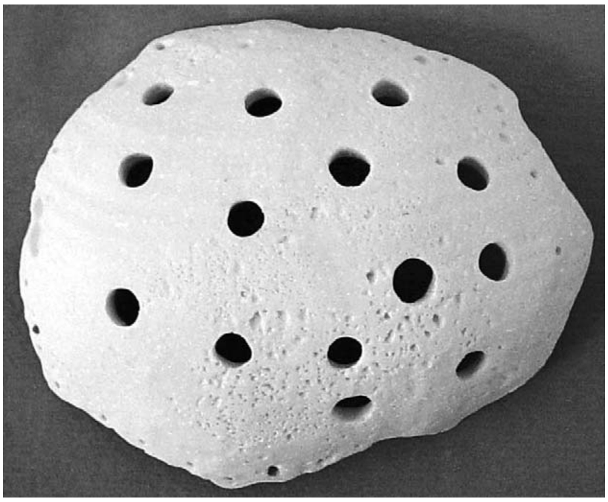

Fig. 2 – Custom made cranioplasty plate (before implantation).

Step 4: After removal from the mould, 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. In the centre, 5–7 mm holes were drilled in order to prevent development of an epidural haematoma (Fig. 2). Before surgery, the polyethylmethacrylate–hydroxyapatite (PEM-HA) plate was sterilized using ethylene-oxide (a method not in use anymore in the EU).

PATIENT

A 52 year-old man with a history of chronic obliterative arteriopathy of the inferior limbs had been admitted to the Department of Neurosurgery due to an ischaemic cerebral vascular accident in the right sylvian territory. At presentation he was in a light coma, displaying left hemiparesis. The patient underwent intensive drug therapy to reduce the cerebral oedema. However, the symptoms did not subside. Repeated cranial CT examination revealed a progressive cerebral oedema. A decompressive hemicraniectomy was performed leaving a great bony defect of the right cranial vault and the neurological status improved. The removed portion of the cranial vault, which had been implanted within the subcutaneous abdominal tissue, had to be removed due to an infection. The cranial defect resulted not only in a cosmetic defect but also in the shortcomings of a craniectomy status (Fig. 3).

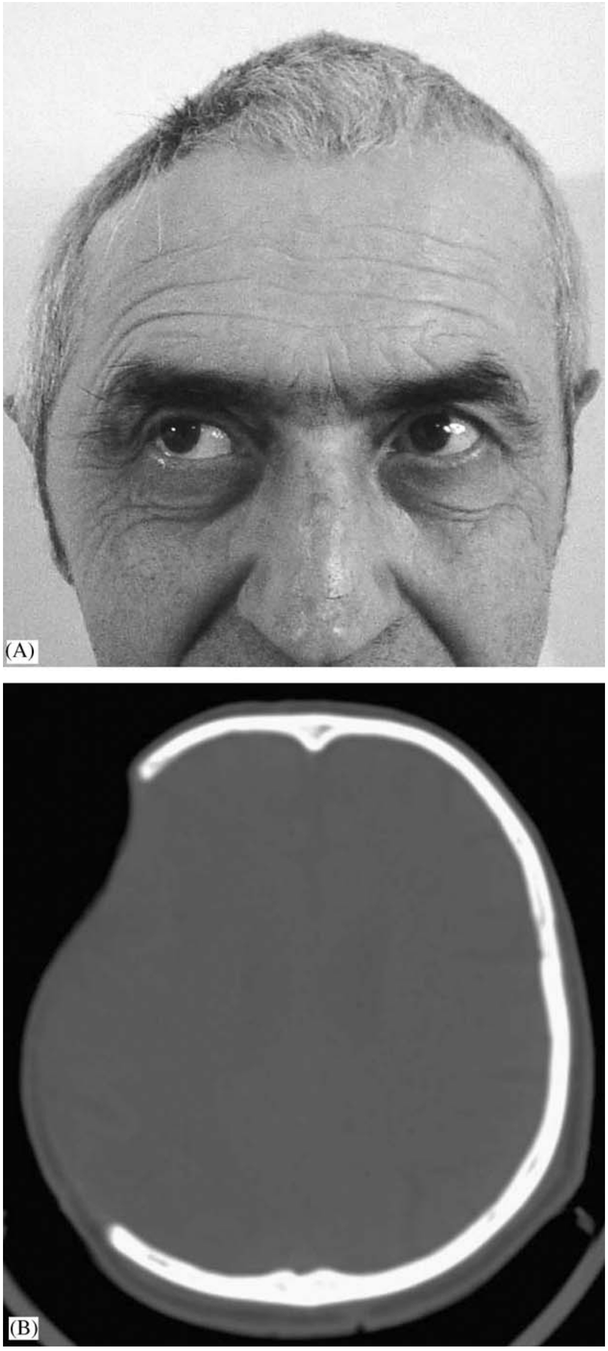

Fig. 3 – Fifty two year-old male. (A) Preoperative aspect with right-sided hollowing of the skull due to calvarial bone defect and (B) preoperative CT scan revealing the size of the defect.

Fig. 4 – Perfect adaptation intraoperatively, no overlapping at defect margins.

After 1 year of neurological recovery, the patient exhibited only a mild motor deficit in the left side, left lateral hemianopia, and short-term memory disturbances. He was not aphasic, presented no speech impairment and was autonomous. In order to eliminate the drawbacks of a craniectomy status, a customised cranioplasty was planned and a plate was made as described.

Under general anaesthesia the bony defect was exposed and prepared using the old scar. The custom made plate was applied, fitted perfectly and needed no further processing. It was fixed with 2.0 silk sutures (Fig. 4).

There were no intra-operative complications, healing progressed well and the patient was discharged on the seventh day postoperatively. At follow-up 1 and 6 months after the operation, no complication was noted and the patient tolerated the cranioplasty plate well (Fig. 5).

DISCUSSION

To repair large skull defects, either reconstruction of the vault intra-operatively or a 'custom made cranial implant,' may be chosen preoperatively. The disadvantages of intra-operative repair are time, increased risk to the patient, insufficient protection from trauma and infection, and often, suboptimal cosmesis. In contrast thereto, custom made cranioplasty implants have the advantages of reduced operative time, less invasive surgery, improved cosmetic results, faster recuperation, and reduced costs due to a short operative time (*van Putten* and *Yamada*, 1992; *Zeilhofer* et al., 1997; *Rotaru*, 2001; *Dean* et al., 2003).

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 the case of large defects, however, problems may arise

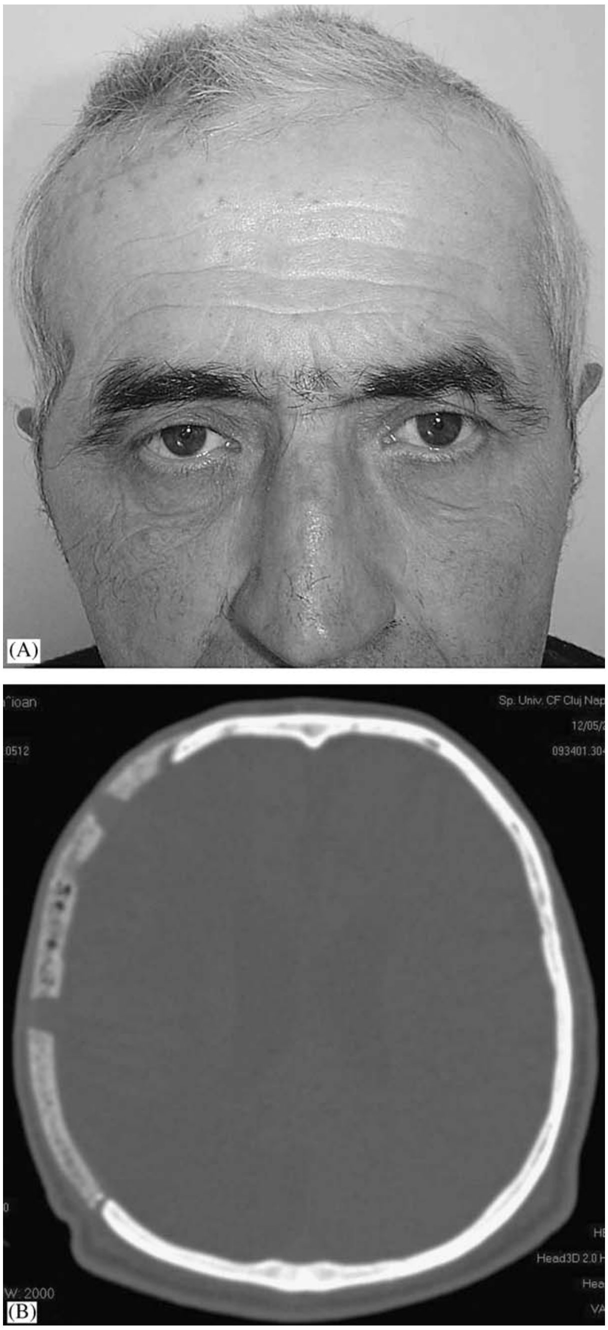

Fig. 5 – (A) Postoperative aspect revealing the restored symmetry and (B) postoperative CT, note the perfect marginal adaptation of the reconstruction plate.

such as donor site morbidity, insufficient quantity or quality of donor material, and difficulty in crafting the correct shape. Grafts may also show some degree of resorption and require further surgery for adjustment (*Moreira-Gonzales* et al., 2003; *Grant* et al., 2004). Alloplastic materials like metal plates have been used to cover cranial defects from ancient time (*Kleinschmidt*, 1941; *Durand* et al., 1997). Today, the alloplastics used most frequently are hydroxyapatite cements, acrylics (especially PMMA), titanium, and carbon fibre reinforced plastics (*van Putten* and *Yamada*, 1992; *Eufinger* et al., 1995; *Zeilhofer* et al., 1997; *Rotaru*, 2001). The main disadvantage of alloplastic materials is their high susceptibility to infection (*Grant* et al., 2004; *Matic* and *Manson*, 2004; *Durham* et al., 2003) but they allow the repair of large defects with no donor site morbidity and lower costs. When shaped by 3D techniques, they permit accurate reconstruction of anatomical contours.

Custom made implants manufactured using rapid prototyping techniques have already been introduced (*Binder* and *Kaye*, 1994; *Eufinger* et al., 1995; *Wehmoeller* et al., 1995; *Heissler* et al., 1998; *Chiarini* et al., 2004). However, there are some problems in reproducibility. Various authors have used a plaster mould (*D'Urso* et al., 2004; *Chiarini* et al., 2004). The method presented here used a silicone rubber mould. When compared with 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 good stabilization and there was no need for rigid fixation. The latter could cause secondary damage to the brain during drilling and screwing. *Chiarini* et al. (2004) recommended that the acrylic prosthesis should overlap the bone surroundings by 10 mm in order to avoid possible incorrect prefabrication of the plate. In large defects such as presented here, titanium mesh must be bent in 2 dimensions 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 the surface of the skull well but they do not only repair the defects. They must overlap the margins of the defect for stability reasons and must be fixed using screws or wires.

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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