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3D CUSTOM-MADE IMPLANTS FOR THE RECONSTRUCTION OF CRANIOFACIAL BONE DEFECTS. EVALUATION AT SEVEN YEARS OF USE

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Abstract: *Important functional and esthetical impairments appear due to bone defects of the craniofacial skeleton. The development of rapid-prototyping technologies offers the possibility of reconstructing some of the bone defects with custom-made craniofacial implants from alloplastic materials. Bone defects of the skull were rehabilitated using custom-made implants of polymethylmethacrilate. The implants were produced by three-dimensional modeling, rapid-prototyping and casting into silicone-rubber molds. Produced for each specific case, the custom-made implants adapted perfectly into the bone defects, assuring an excellent morphological and functional rehabilitation. There were no adverse effects to the materials used. The possibility of producing custom-made implants opened a new era in the reconstructive surgery of the craniofacial area. The advantages of their clinical use proved to be multiple.*
Key words: *three-dimensional, custom-made, implants, craniofacial, reconstruction*

1. INTRODUCTION

Cranial vault defects result from trauma, infection, tumor 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., 1999). Functional alterations are often observed due to the changes in cerebral blood-flow velocity.

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). Polymethylmethacrylate (PMMA) is the one mostly used for cranioplasty between the plastics. However, the complexity of reconstruction increases proportionally with the size of the defect[11] as well as with the location which raise the necessity to reproduce a complex anatomical shape. Three-dimensional imaging and rapid prototyping techniques associated with the use of alloplastic materials allow construction of a custom-made implant preoperatively. The defect is repaired symmetrically even in thickness. In this paper a technique of custom implant manufacturing using polymethylmethacrylate casted in silicone rubber mould, that standed the test of time, is presented along with its critical review.

2. MATERIAL AND METHOD

The calvarial defects of eighteen patients and four facial skeleton defects were repaired using custom made implants. Defects developed secondary to small bone fragments removal after comminuted fractures, infection-driven loss of the bone flaps elevated for decompression craniotomy, bone tumor resection and vicious consolidation of facial fractures.

To produce the custom made implants the patients underwent a spiral CT scan of the head (Siemens Somatom; Erlangen, Germany). A virtual model of the skull was obtained by means of three-dimensional reconstruction (MIMICS®, Materialise N.V., Leuven, Belgium). The virtual 3D model for the patient specific implant was obtained by designing it with Freeform Modelling Plus® v. 9.0 (Sensable, USA).

Using selective laser sintering (SLS) and 3D printing (Sinter Station 2000, 3D System, Darmstadt, Germany, Eden 330, Objet Geometries, Rehovot, Israel), both virtual models (defect and plate) were transformed into physical models. The plate fitted perfectly into the defect.

The pattern of the implant was used to make a silicone rubber mould. Radiopaque bone cement (Surgical Simplex® P, Stryker Howmedica Osteonics, Limerick, Ireland) made of polymethylmethacrylate was casted in the silicone rubber mould and pressed into form.

After unmoulding, the margins of the final custom made implant were slightly manually processed in order to eliminate the excess and to drill holes for fixation. On cranioplasty plate's surface, holes were drilled in order to prevent development of an epidural haematoma. Before surgery, the cranioplasty plates were sterilized using ethylene-oxide.

3. RESULTS

Under general anesthesia the bony defect was exposed. The custom made plates were applied. Fourteen (77.7%) of them fitted perfectly and needed no further processing (Fig. 1). Four (33.3%) of the plates were, in some areas, smaller than the bony defect. This was finally judged as being due to a longer time interval between CT scanning and cranioplasty operation. Moreover, the imprecise fitting of the plate was present in all cases (number) where the CT scanning was performed earlier than 6 months after the initial surgery. Bone remodeling, by resorption, of the defect margins (healing) was the main factor incriminated in this mechanism. One orbital implant (25 %) was larger then needed, determining exoftalmia. It had been adapted intraoperatively.

Fig. 1. Perfect adaptation of the plate to the bone defect

Fore security reasons the plates were fixed with 2.0 silk sutures to the bony margins of the defect and screws were used to fix the facial implants.

There was only one intra-operative complication in a case where the brain herniated through the bony defect from the beginning, due to some cystic degeneration. Thus, the plate was pressed with some force to fit the defect and the result was a fixed midriasis. Plate was immediately removed and the patient recovered. Few days later the plate was applied again leaving a gap between the bone and the plate. In all cases there were no problems of covering the plates with the skin. Starting intraoperatively, an antibiotic treatment was conducted for the next ten days. In the recovery period, the healing process was eventless. 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 one, six months and then yearly after the operation, with clinical and CT examination. Clinically, no complications were noted, patients tolerating well the cranioplasty plate. The esthetical aspect of all the patients operated was significantly improved (Fig. 2). The symmetry was perfectly obtained in all cases (Fig. 3). CT examination showed the implants in place with no meningeal or soft tissue reactions.

Fig. 2. Improved esthetical aspect of the patient

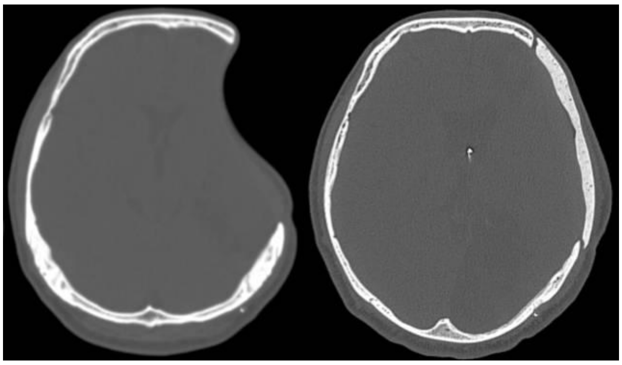

Fig. 3. The symmetry of the reconstruction. Note no soft tissue reaction

4. 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 (Zeilhofer et al.: 1997, Rotaru 2001).

Custom made implants manufactured using rapid prototyping techniques have been introduced already (Binder & Kaye 1994, Eufinger et al., 1995, Chiarini et al., 2004). However, there are some problems in reproducibility. Various authors have used a plaster mould (Chiarini et al., 2004, D'Urso et al. 2004). 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 implant (e.g. margins) during unmoulding. Preserving the thin margins provided a better stabilization. *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. In large defects such as presented above, titanium mesh must be two-directionally bent to mimic the anatomical shape. 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. Casted 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.

In the future, selective laser melted titanium implants can combine the advantages of the titanium with the ones of 3D modeling by rapid prototyping, for the reconstruction of the bone defects. This technology is now emerging in the medical field.

5. CONCLUSIONS

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.

6. ACKNOWLEDGEMENTS

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