Original research article

Reconstruction of large cranial defects with poly-methyl-methacrylate (PMMA) using a rapid prototyping model and a new technique for intraoperative implant modeling

Claudia Unterhofer a,*, Christoph Wipflinger a, Michael Verius b, Wolfgang Rechais b, Claudius Thomé d, Martin Ortler a

a Clinical Department of Neurosurgery, Innsbruck Medical University, Innsbruck, Austria
b Clinical Department of Radiology, Innsbruck Medical University, Innsbruck, Austria

to

A B S T R A C T

Background: Reconstruction of large cranial defects after craniectomy can be accomplished by free-hand poly-methyl-methacrylate (PMMA) or industrially manufactured implants. The free-hand technique often does not achieve satisfactory cosmetic results but is inexpensive. In an attempt to combine the accuracy of specifically manufactured implants with low cost of PMMA.

Methods: Forty-six consecutive patients with large skull defects after trauma or infection were retrospectively analyzed. The defects were reconstructed using computer-aided design/computer-aided manufacturing (CAD/CAM) techniques. The computer file was imported into a rapid prototyping (RP) machine to produce an acrylonitrile-butadiene-styrene model (ABS) of the patient's bony head. The gas-sterilized model was used as a template for the intraoperative modeling of the PMMA cranialplasty. Thus, not the PMMA implant was generated by CAD/CAM technique but the model of the patients head to easily form a well-fitting implant. Cosmetic outcome was rated on a six-tiered scale by the patients after a minimum follow-up of three months.

Results: The mean size of the defect was 74.36 cm². The implants fitted well in all patients.

Seven patients had a postoperative complication and underwent reoperation. Mean follow-up period was 41 months (range 2–91 months). Results were excellent in 42, good in three and not satisfactory in one patient. Costs per implant were approximately 550 Euros.

Conclusion: PMMA implants fabricated in-house by direct molding using a bio-model of the patients bony head are easily produced, fit properly and are inexpensive compared to cranial implants fabricated with other RP or milling techniques.

© 2017 Polish Neurological Society. Published by Elsevier Sp. z o.o. All rights reserved.
1. Introduction

The reconstruction of large cranial defects is challenging from a functional, cosmetic and economic point of view. Large defects have been repaired with autologous bone, metal or mesh plates, poly-methyl-methacrylate (PMMA), hydroxyapatite ceramics or carbon fiber reinforced polymer. Each material poses specific advantages and problems [25,31].

Implants made from PMMA are stable, biocompatible, chemically inert, nonconductive, radiolucent, and inexpensive and can be easily placed and modified [12,13,30]. Donor site morbidity is eliminated and large volumes of non-infectious material are available. Fabricating large implants with PMMA during surgery can be problematic, especially when defects in the frontal or temporobasal area are to be covered [11]. Implant fabrication can be time consuming and implants sometimes appear flat, asymmetrical and cosmetically unacceptable [7,21]. The surrounding tissue is exposed to polymerization heat and to residual monomer [8,16]. PMMA implants are therefore removed during modeling as soon as the resin begins to polymerize and produce heat, although early removal can distort the implant and affect its contour [35]. Techniques developed to circumvent these problems and to separate the fabrication of PMMA implants and the implantation procedure itself include molding of the defect, fabrication of a negative cast from the mold and production of the implant by heat polymerization [7], the duplication of the original bone flap using a molding technique [15,27] or as a template for the direct shaping of metal plates [4].

The availability of helical high-resolution CT scanning and the combination of computer-aided design/computer-aided manufacturing (CAD/CAM) techniques with rapid prototyping (RP) techniques to build 3-D models has simplified the pre-surgical fabrication of accurate, properly contoured implants [16]. RP includes a host of related technologies, all aimed to build objects by adding and binding material in a layering manner [16]. Several materials including PMMA [1,16,21,29,37] carbon-fiber – reinforced polymer [26,36], titanium [4,5,17,33], hydroxyapatite [10,32] and polypropylene polyester [3,6,19] have been used successfully as cranioplasty materials on the basis of RP-generated (stereolithographic) bio models.

The implementation of these technologies has shortcomings as well, especially when unfamiliar new materials are used for the implant. Design and production of model and implant have to be outsourced [10,26,29,32,36]. This may delay surgery for up to several weeks [26] and is expensive. Customarily only one implant is fabricated and a second one may not be available in case the first one does not fit or becomes damaged during surgery.

We therefore sought a method to simplify the production of cosmetically acceptable large cranial implants. We used RP technology available in-house and an inexpensive material with properties familiar to neurosurgeons and trauma surgeons (PMMA). The goal of this communication is to present the details of our technique and the first results obtained in a consecutive series of patients.

2. Clinical material and methods

2.1. Patient consent

Informed consent and photo documentation was obtained from all patients.

2.2. Study population

$N = 46$ patients underwent PMMA craniolasty using the technique described below (Table 1). This was a predominantly adult population (mean age 46 years, and range 7–77 years) with 21 females.

2.3. Procedural steps

Axial CT scans were obtained in all patients scheduled for cranioplasty (slice thickness 1.0 mm, kV 140, mAs 120, 512 × 512 matrix, 250 mm FOV, 0° gantry tilt).

CAD/CAM techniques based on the CT data were used to reconstruct a 3-dimensional surface model of the defect including its inner contour and the surrounding calvaria. All reconstructions were performed using either a commercially available software package such as ANALYZE© (Mayo Clinic, Rochester, Minnesota, USA) or Amira© (Konrad Zuse Institute, Berlin, Germany) or the open-source package ImageJ (National Institutes of Health, Bethesda, Maryland, USA) and proprietary programs written in C++.

The model of the defect was constructed by thresholding segmentation and connected component analysis. Details concerning the mathematical algorithms behind the reconstruction of the inner contour (the casting mold) of the defect are published elsewhere [23]. Essentially, two methods were used, depending on location and size. When limited to one hemisphere, it was possible to mirror the unaffected hemisphere to the side of the missing part. The best possible mirror plane was chosen by an experienced software operator after consultation with the neurosurgeon. Once the mirror plane was found, the skull was divided into two pieces and the unaffected hemisphere was mirrored, rotated and translated to the inner surface of the skull defect to obtain the optimal position for a negative casting mold. Mirroring was not possible in cases with the osteoclastic defect crossing the skull’s symmetry line (i.e. the midline) in three patients. In these patients CT images of a healthy subject of approximately the same age, race and gender as available in the picture-archiving-and-communication system (PACS) of the hospital were used as a master for the reconstruction. This master was fitted to the individual defect by mathematical methods as such as thin plate spline warping. To reduce central-processing-unit time for time-consuming transformation operations, only relevant parts of the master skull were used first. These parts of the master skull were placed closed to the inner side of the patient’s skull to reconstruct the inner surface of the bone implant (Fig. 1).

Once an optimum virtual inner surface of the implant was found, a stereolithographic file (STL) was generated. The computer file was imported into the rapid prototyping machine (Prodigy Plus®, Stratasys Inc., Eden Prairie, Minn,
USA. The machine utilizes fused deposition modeling (FDM), one of several RP technologies, to produce an anatomical model of the patient's head [16,22]. FDM is a non-laser based process that builds the model by depositing layers of thermoplastic material (acrylonitrile butadiene styrene, ABS) one layer at a time [16]. A water-soluble material generates vertical support for all overhanging portions as required during the modeling process. Once the model is completed, the support material is dissolved using a water-based detergent in a heated ultrasonic bath [16].

The gas-sterilized model was used directly in the operating room as a molding form for the application of PMMA. Before starting the PMMA application, a thin (<0.5 mm) layer of bone wax was applied circumferentially to the border of the
reconstructed cranial defect to permit easy removal of the implant after hardening and to provide a perfect fit to the patient’s cranial defect. Bone wax was also used to fill small irregularities along the defects boundaries. Paraffin oil was used to prevent the PMMA to stick to the stereolithographic model.

After curing ex vivo, the implant was separated from the stereolithographic model, trimmed as necessary, rinsed and implanted into the patient using commercial miniplates and screws for fixation as this represented our standard technique.

2.4. Outcome evaluation

Difficulties and complications of the procedure were noted. Outcome was evaluated retrospectively after a minimum follow-up of 3 months in the outpatient clinic. Cosmetic result was evaluated by the patients using school grades, with grade 1 meaning an excellent result, grade 2 a good, grade 3 a satisfactory, grade 4 an adequate, grade 5 a not satisfactory and grade 6 a poor result.

3. Results

Results are presented in Table 1 and an illustrative example (Patient No.7) is given in Fig. 2. Forty-six patients underwent PMMA cranioplasty with this method from 2006 to 2013. The mean interval between bone removal and cranioplasty was 8.6 months (range 0–60 months). The majority of defects (in 42 of 46 patients) were by definition large, measuring >25 cm². The mean size of the defect was 74.36 cm² (range 20–144.3 cm²).

Mean operating time was 125 min (range 71–261 min). The surgical procedure was carried out without complications in all patients. No distortion of the PMMA was observed by the untimely manipulation of insufficiently cured material. The intra-operative fit of the implants was good in all patients.

One infection was observed (patient No. 24). Two patients (patient Nos. 5 and 25) underwent surgical evacuation of a post-implantation subdural hematoma and two patients underwent evacuation of a post-implantation epidural hematoma (patient Nos. 32 and 44) without further sequelae. Two patients underwent minor surgical revision through stab incisions because of loosening of the fixation system. This was evident on postoperative images (on day 4, patient No. 3) or clinically (during the outpatient visit after 1 month, patient No. 8), respectively.

Mean follow-up period was 41 months (range 3 months to 91 months). Forty-two patients exhibited an “excellent” (grade 1) cosmetic result, in three patients the result was “good” (grade 2), in one patient the result was rated “not satisfactory” (grade 5) by the patient himself. This patient had undergone several interventions for cranioplasty at an outside institution. His expectations were deluded by the postoperatively present visibility of the defect covered by a perfectly contoured implant beneath the paper-thin skin and an atrophic temporal muscle. Loosening of one of the cranial fixation devices requiring re-intervention did further aggravate his subjective dissatisfaction with the procedure.

4. Discussion

Preliminary results indicate that the technique of methylmethacrylate (PMMA) cranioplasty described in this paper might be a clinically valuable alternative to other techniques of cranioplasty that use modern rapid prototyping (RP) technologies. The novel aspects presented here are the fabrication of PMMA implants to cover very large calvarial defects and a shortening of the procedure by using technology available in-house and by eliminating two steps during the RP-fabrication of the implant (the creation of a template and the construction of a molding form). This allowed for a reduction of both costs and time without giving in on cosmetic results.

Bone defects that involve the frontobasal and the temporobasal areas are notoriously difficult to reconstruct, especially when the other side of the head is not available for visual inspection during surgery. Our technique provided excellent cosmetic results in >91% of the patients. Complications that required re-intervention were observed in seven patients (15%).

Several authors have reported on the combination of stereolithography and acrylic casting for calvarial bone reconstruction using slightly different techniques for implant construction. Agner [1] reported on two patients using a stereolithographic model of the skull defect and a mold technique to produce a methyl-methacrylate implant for cranioplasty. The mold was fabricated using dental grade wax and dental stone. D’Urso [9] described excellent results in 30 patients with defects greater than 4 cm in diameter using stereolithography to produce a craniotomy bio-model and a master implant. This master implant was then used to create an impression cavity mold that was filled with heat-curing PMMA. Major and minor trimming of the implant was necessary in six patients. In one patient, the original master was used also for the production of a second implant. Besides requiring two additional steps, namely the manufacturing of a master implant and the manufacturing of a mold, duplicates of the implant might not be immediately available in case of an imperfect fit or in case of damage during implant trimming.

Fig. 1 – Stereolithographic model of the forehead with the reconstructed inner surface of the implant.
when using this technique. Gronet [16] also reconstructed a bio-model of the osteoclastic defect using RP. The lost cranial surface was reproduced by applying a wax pattern to the bone defect in the bio-model. An acrylic implant was fabricated from the wax pattern by creating a gypsum mold and eliminating the wax pattern thereafter. This technique was used successfully in two patients. Yacubian [37] used a molding technique with success in two patients. Solaro [29] reconstructed the PMMA implant for one patient in the operating room by injection of PMMA into a mold fabricated with CAD/CAM techniques. Finally, Lee [21] also used a mold technique in a subgroup of 17 patients in a study comparing three types of cranioplasty in patients with defects >100 cm². The use of heat-cured prefabricated PMMA prostheses allowed operation time, blood loss and infection rate to become comparable to patients in whom the own bone was available.
for reinserion. Three patients required reoperation either because of wound infection, or aseptic wound dehiscence, or an epidural hematoma.

Using our technique and PMMA as the implant material, a gas-sterilized bio-model ready for operating room use is available within 48–72 h. To produce the model from the CT data requires up to 8 h of software operator and technician time, typically 45 h for the automated plotting process and additional 5–8 h for the cleaning process in the ultrasonic bath. Plotting time can be reduced further by limiting model fabrication to the bone defect and its immediate surroundings. The intraoperative modeling of the final implant is accomplished within minutes. This compares well with time frames cited by authors using commercially supplied, CAD/CAM-constructed alloplastic cranial implants [10,26,29,32,36].

Material costs for CAD/CAM-designed PMMA implants are low, amounting to 81 Euros for the PMMA and approximately 450 Euros for the bio-model (corresponding to overall costs of approximately US$ 650). D’Urso [9] calculated the cost for the acrylic to be approximately US$ 300 and for the bio model to be around US$ 1000. Lee [21] calculated the costs for a CAD/CAM prefabricated PMMA prosthesis produced in-house to be about US$ 800. The need of dedicated technicians to survey the CAD/CAM of the bio-model and hardware requirements (when not available in-house) is disadvantageous. Rapid prototyping machines are available for 30,000–250,000 Euros (US$ 37,000–310,000). Such a machine may serve a variety of disciplines including neurosurgery, maxillofacial and craniofacial surgery, orthopedics, ENT surgery, vascular and basic research in a larger hospital or research institution [2,14,20,24,28,34,38].

Cranioplasty materials other than PMMA modeled so far with the help of CAD/CAM techniques included titanium [4,5,17,18,33], carbon fiber reinforced polymer [26,36] and porous hydroxyl-apatite [10,32]. The handling of these materials requires special expertise that usually is not available in neurosurgical departments. Outsourcing of implant fabrication is expensive. Hydroxyl-apatite implants cost approximately 7000 Euros (about US$ 8000) [32], implants made from carbon-fiber reinforced polymers are reported to cost 6800 Euros (US$ 8300) per patient [36].

The technique presented here has many advantages. First, the ability to reconstruct even large or complicated defects with a cosmetically acceptable result; second, the use of an inexpensive material (PMMA) with well-known physical and biological properties; third, the avoidance of contact between implant and nervous tissue during the exothermic polymerization process; fourth, the immediate repeatability of the procedure in case of poor fit of a first implant (due to incongruities or deformation arising during the polymerization process) or in case of fracture of the implant during trimming; fifth, the avoidance of implant deformation during polymerization or sterilization (since not the implant but a model of the defect is sterilized); sixth, the cost reduction associated with the in-house availability of RP technology, and seventh, the prospect to be ready for cranioplasty within 72 h after CT scanning. Our technique can be performed at the fraction of the costs charged by commercial suppliers and does not require the transmission of sensitive patient data out of the hospital environment via hard disk or internet.

5. Conclusion

PMMA implants fabricated in-house by direct molding using a stereolithographic bio-model of the patient’s head are easily produced, fit properly and are inexpensive compared to cranial implants fabricated with similar RP techniques.

Conflict of interest

None declared.

Acknowledgement and financial support

None declared.

Ethics

The work described in this article has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans; Uniform Requirements for manuscripts submitted to Biomedical journals.

REFERENCES


