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Safety and esthetic refinement of methyl methacrylate cranioplasty using the patient head as a mould: our experience

Wael Elmohandes and Ayman F. Hegab

We conducted a prospective study to audit our experience with repairing cranial defects using methyl methacrylate. A total of 14 patients with deformed depressed bony defects of the cranial bone were enrolled in the study, among whom eight patients (57%) underwent reconstruction of full thickness cranial bone defects. A bicoronal flap was used for exposure of the operative sites. The postoperative follow-up period ranged from 24 to 36 months (mean of 28.9 months). Clinical and radiographic evaluation for the site of the cranial bone defect, the causes of the defect, and the duration of the defect will be preformed. Acrylic bone cement was used as an alloplastic implant for reconstruction of all cranial defects in the study. Postoperative evaluation for the esthetic results, patient satisfaction, and complications was performed. We reported good clinical outcomes in all our patients. There was no immediate or delayed incidence of rejection, dehiscence, infection, brain tissue neuropathy, implant

Introduction

Cranioplasty involves the repair of a cranial defect or deformation. The more common causes of skull defects include trauma, neurosurgical procedures, and infections. Increasing indications for cranial decompressive procedures, mainly after traumatic injuries and vascular lesions, have led to a demand for effective bone substitutes for cranial reconstruction, particularly for large and complex bone defects. Cranioplasty is carried out to restore the morphological and functional anatomy of the cranial vault, to protect the brain from external forces, thus avoiding neurological disorders or deficits and changes in cerebrospinal fluid levels. In addition, esthetic and psychosocial implications also need to be considered [1].

The earliest instance of cranioplasty in humans for which a reference can be found is a case reported by Van Meekren in 1670, a Russian nobleman who used a bone from a dog to successfully repair a cranial defect in a man. The graft was successful, but was removed because of opposition from the Church to the use of animal bone in 'marring God's image', and removal of the graft was impossible because of bony union. This case was reported by Grekov in 1901, and is referred to hereafter as Grant and Norcross [2], the original literature not being available.

The ideal material for performing a cranioplasty should be malleable to fit even complicated cranial defects precisely, strong but lightweight, easily securable to the cranium, biocompatible and chemically inert, radiolucent, nonferromagnetic, readily available, and inexpensive. No such material currently exists. Natural bone is the obvious choice for cranioplasty material. Bone sources are diverse, ranging from membranous bone from the cranium itself

fracture, elevation, sinking, or rotation, with good cosmetic results. Cranioplasty can be successfully performed with self-cure poly methyl methacrylate material, which is an inexpensive material that is easily adapted and contoured intraoperatively to a defect of any size, has a great impact on resistance, and does not integrate into the surrounding tissues. *Egypt J Oral Maxillofac Surg* 6:96–101 © 2015 The Egyptian Association of Oral & Maxillofacial Surgeons.

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to endochondral bone from various other sites. Metals and nonmetals serve as bone substitutes. Autologous bone has the obvious advantages of lack of an immune reaction and absent risk of disease transmission. Furthermore, it is readily available and has the potential to grow. The available tissue may not readily fit the defect and usually necessitates a second operative field, with associated morbidity, with limited amounts of donor bone. In addition, the significant bone resorption on using free bone grafts and the enhanced morbidity and risks from harvesting bone grafts cannot be disregarded [3].

Titanium mesh cranioplasties, with or without bone, acrylic, or hydroxyapatite reinforcement, are currently in wide use. Technical problems with cranioplasties using artificial materials include sinking, elevation, and rotation. Technical problems with hydroxyapatite or bone graft cranioplasties include resorption and harvest-site disfigurement. In addition, custom prostheses from three-dimensional computed tomography models of the defect are expensive and require significant preparation in advance [4].

Various acrylic resin materials have been utilized as bone substitutes in dentistry, neurosurgery, and orthopedic surgery. These materials have been used successfully for chin implantation, facial deformities, mandibular defects, orbital repairs, and temporomandibular joint interpositional arthroplasty [5]. Alloplastic cranioplasty can be successfully performed with a variety of different materials [5].

Methyl methacrylate (MMA) was developed in 1939 and first used by Kleinschmidt in 1940. It still is the most frequently used alloplastic material in orthopedic and neurosurgery and is considered the best choice for skull

reconstruction worldwide [6]. Gonzalez Ulloa and Stevens [7] first described the use of MMA for forehead contouring in 1964, and it is now recognized as a useful implant material for augmentations [8]. MMA is a cost-effective, strong material that has a similar density to that of cranial bone. It is inert, with minimal inflammatory reactions, and is nonthermoconductive. The resultant shape is predictable, and it can be managed perioperatively. Furthermore, fine adjustment of an MMA implant can be made by adding additional MMA or by contouring with a burr. MMA has the characteristics of a lack of tissue ingrowth and minimal adherence to bone. These characteristics also make MMA easy to remove when the patients want to do so [8].

MMA is available in either thermally (hot-cure) or chemically (cold-cure, self-cure, autocure) activated forms. When the liquid monomer is mixed with the powdered polymer (in the ratio 2:1), a plastic dough is formed, as the polymer granules are held together by the newly polymerized monomer. A considerable amount of heat is generated as the two elements cure and the resulting plastic paste is sterile. MMA is clear, hard, rigid, and relatively strong. Cured resins may be carved and shaped, and burr holes may be created, as desired. Electron microscopy has revealed that MMA is a composite porous material [9]. Histologically, the tissue reaction to it is characterized by foreign body giant cells lying on the curved surfaces [10]. Once the acrylic resin has formed a mechanical bond, the only reaction seen is the formation of a thin layer of fibrous connective tissue [11].

In the current study, we have been using MMA as an implant for cranioplasty because it has many favorable characteristics: MMA is nonallergenic, nonthermoconductive, inexpensive, induces minimal inflammatory reactions, and yields a predictable resultant shape. Our aim was to evaluate the safety and esthetic refinement of MMA cranioplasty of a deformed and/or depressed bony defect.

Patients and methods

This study was approved by the institutional review board, and it followed the guidelines of the Declaration of Helsinki. Clinical evaluation for the site of the cranial bone defect, the causes for the defect, and the duration of the defect was performed. All patients provided written informed consent for this study.

The indications for cranioplasty are as follows: (i) severe headache and other symptoms of the syndrome of the trephined – dizziness, undue fatigue, vague discomfort at the site of the defect, a feeling of apprehension and insecurity, mental depression, and intolerance to vibration; (ii) epilepsy, when the attacks originate from the injury that caused the defect; (iii) danger of trauma at the site of the defect; (iv) an unsightly defect; and (v) defects that pulsate unduly or that are painful.

The contraindications and exclusion criteria are as follows: (i) the presence of any foreign body, (ii) the presence of any possible infection; (iii) increased

cerebrospinal fluid pressure that is not easily reducible by lumbar puncture.

Clinical and radiographic evaluations for the site of the cranial bone defect, the causes of the defect, and the duration of the defect are preformed (Fig. 1).

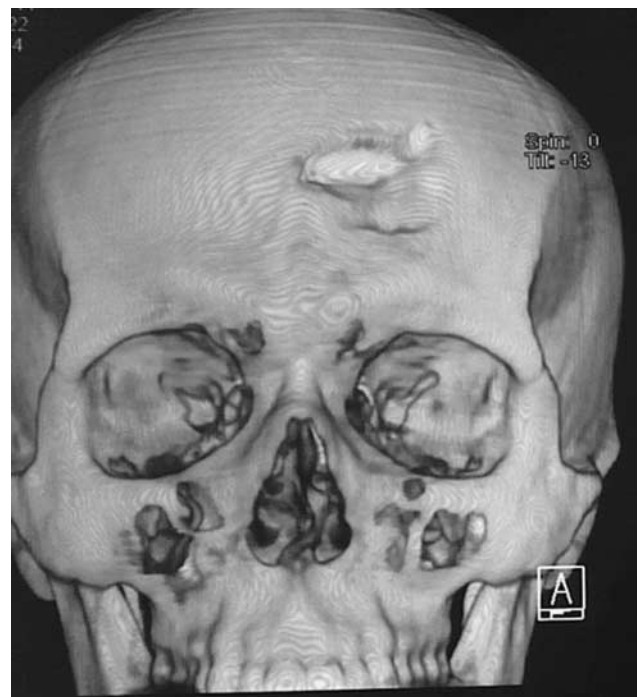
In our study, we performed the cranioplasty months after the first surgery for two reasons: to be sure that there is no infection, and delayed cranioplasty allows the dura a chance to repair itself.

Surgical technique

MMA was used in all patients, and cranioplasties were performed under general anesthesia. The patient's head is fully shaved and a prophylactic intravenous antibiotic is administered in the induction room. The scar of the original injury should be in good condition. If it is not, there should be a preliminary operation to revise it and eliminate any danger of it breaking down from the lack of adequate blood supply or from other causes. A very thin scar should be revised even if adequately nourished. The operative field is exposed through the bicoronal flap. The skin is incised at a distance of at least 3 cm from the defect. A subperiosteal dissection of the cranial defect is performed to expose all margins of the defect. When the defect is exposed, the dura should be well freed around the edge, and any defect in it should be repaired before application of MMA. Dura defects are repaired with watertight sutures or with pericranial fascia (Fig. 2).

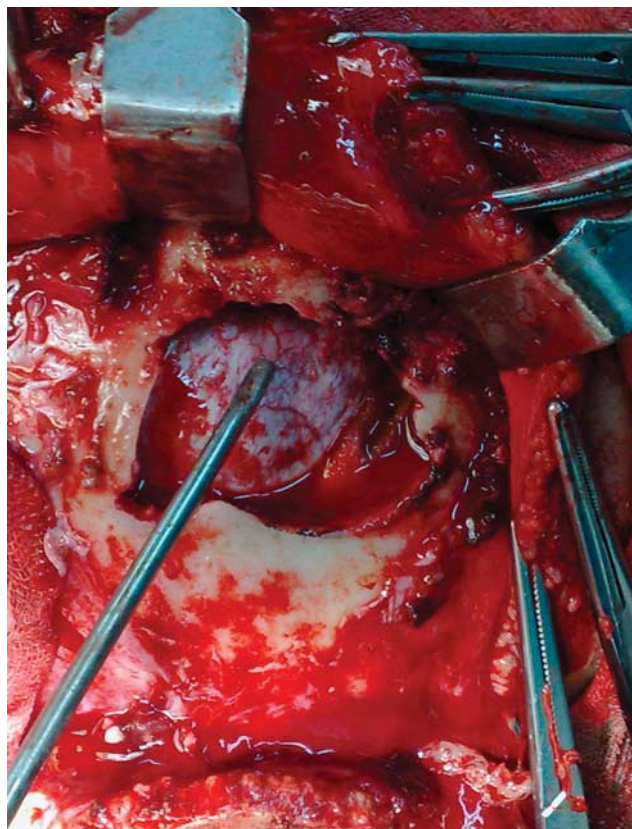
Acrylic bone cement is available in powder and liquid forms. The powder and liquid forms are mixed together until a dough is formed (stage before hardening). A single

Fig. 1



Preoperative three-dimensional computed tomography for evolution of the cranial defect.

Fig. 2



A subperiosteal dissection of the cranial defect was performed to expose all margins of the defect.

layer of saline-soaked gel-foam is placed over the exposed layer of the dura. This helps insulate the dura from the exothermic reaction that takes place as the MMA hardens. After mixing the acrylic cement, and during the soft stage, the mix is packed to the defect and molded with dural elevator to the defect. Thereafter, the mix is applied to the defect with concomitant copious irrigation to avoid harmful effects of the exothermic reaction of bone cement on the underlying brain tissues. In the case of full thickness defects, a good perfusion coolant using intravenous lines connected to saline bottles prevents any harm to the underlying dura tissues. During this stage (before setting of the material) manual fitting was performed and the material was adapted to the defect site; in addition, manual contouring of the material surface to the surrounding normal cranial bone margins was performed.

Appropriate consistency of acrylic resin material used in this study is easily contoured and shaped and simply inserted in the bony defect in short time (few minutes). Thereafter, the implant is molded with a spoon or a straight dural elevator to the desired shape, the excess being removed and some supplementary paste being added if required.

To ensure accurate placement of the acrylic cement, angulated perforations were made, which help in perfect immobilization and guide reinsertion of the acrylic cement after complete setting. The acrylic cement is

removed from its place and left out of the patient's head until complete setting to avoid exposing the patient to harmful heat from the exothermic reaction of MMA. Trimming of the edge with scissors before solidification and final trimming with rotary burs under copious irrigation were performed. Thereafter, the hard tissue replacement was fit into the defect and secured to the surrounding cranial bone using 1.5 mm titanium microplates and screws (relative rigid fixation; Fig. 3).

In the case of a partial defect, MMA was used as an onlay, and in the case of a complete defect, MMA was used as an inlay. Scalp closure was performed and postoperative antibiotics were administered in a routine manner [1 g cefobid/12 h for 7 days, and 50 mg Cataflam (diclofenac potassium) three times/day for 5 days as an analgesic]. If a drain was used, it was removed within 24–48 h after surgery, depending on the situation of the wound. Postoperative radiographs were obtained (Fig. 4).

Patients were kept in the hospital for 1 week post-operatively; thereafter, they were followed up every week for 1 month, every 1 month for 6 months, and then once per year for 3 years.

Patient and doctor questionnaires were developed to evaluate the grade of satisfaction after surgery. The following is the patient satisfaction grade scale questionnaire:

Choose one of the following statements that best describes your satisfaction with the esthetic result of cranioplasty:

- (1) I am not satisfied with the esthetic result (poor satisfaction 0–5: please specify the reason for your dissatisfaction).
- (2) I am satisfied with the esthetic result:
 - (i) Good satisfaction (5–7)
 - (ii) Very good satisfaction (7–9)
 - (iii) Excellent satisfaction (9–10).

Fig. 3



The hard tissue replacement was fit into the defect and secured to the surrounding cranial bone using 1.5 mm titanium microplates and screws.

Fig. 4



Postoperative radiographs.

- (3) Did you have any medical complications after cranioplasty? (Yes/No: if yes, please describe it).

The following questionnaire with the visual analog scale was used for doctors:

Choose one of the following statements that best describes your satisfaction with the esthetic result of cranioplasty:

- (1) I am not satisfied with the esthetic result (poor satisfaction: 0–5).
- (2) I am satisfied with the esthetic result:
 - (iv) Good satisfaction (5–7)
 - (v) Very good satisfaction (7–9)
 - (vi) Excellent satisfaction (9–10).
- (3) Degree of difficulty in mixing, applying, and trimming MMA (easy, moderate, difficult).
- (4) Intraoperative complications.

Results

A total of 14 patients (nine male and five female), with an average age of 24 years (age range from 23 to 45 years), were treated with acrylic bone cement at our hospital from February 2007 to December 2011. Eight patients (57%) underwent reconstruction of large, cranial bone defects.

In all the patients enrolled in this study, the cranial bone defects rehabilitated well. The esthetic appearance of all patients was significantly improved. The postoperative follow-up period ranged from 24 to 36 months (mean of 28.9 months).

Cranial defects were mainly caused by trauma (71%), whereas tumors contributed to 29% of defects. Most patients had right-sided cranial defects [frontal (50%), followed by temporoparietal (36%) and frontotemporal (14%)]. The duration of surgery ranged from 90 to 200 min, with an average of 140 min.

There were no cases with overlying scarred tissue. Hence, there was no need for a soft-tissue expansion procedure. Four cases showed dural tissue perforation, which repaired before application of reconstructive material.

An average of 40 min was needed for mixing and application of the reconstructive material to the defect. Surgeons and patients were surveyed after each implantation. The surgeons reported that the implant fit was excellent. Fixation of the implant was easy and the implant was stabilized using microplates and screws. There were no problems when covering the implant plates with skin. During the recovery period, there was no sign of infection, plate rejection, or wound dehiscence. No complications were encountered during implant setting and its fixation to the surrounding bone. Implant handling was easy in terms of performing fixation and contouring to the required size and shape.

All of the patients were subjectively satisfied with their postoperative appearance. Generally, we evaluated the postoperative appearance 3 months after surgery. No major complications were encountered, such as infection, prolonged postoperative headache, delayed hematoma, or seroma. However, an objective evaluation of postoperative results conducted for esthetic purposes is not sufficient, because the subjective satisfaction of the patient overwhelms the other objective evaluations. In this study, an evaluation that maximally reflected the subjective judgment of the patient was also conducted by evaluating the postoperative results in terms of the rate of reoperation caused by patient dissatisfaction and complications, rather than by simply assessing the degree of patient satisfaction. In our study, no patients showed poor esthetic satisfaction results. No patient underwent reoperation for improvement of esthetic results. All patients were pleased with the cosmetic results. Patient satisfaction ranged from good to very good in all cases. No fair or poor satisfaction was recorded.

With regard to doctor satisfaction grade, all the patients showed good to very good results. No intraoperative complications were encountered. Evaluation of the degree of mixing, application, and trimming was easy in all cases enrolled in our study.

There was no evidence of rejection, resorption, dehiscence, infection, and brain tissue neuropathy and/or implant fracture. No patient showed cranial bone osteomyelitis or exposure of the acrylic bone cement. The postoperative course was uneventful. The cosmetic result was good both immediately and throughout the follow-up period, and no complications were detected during the follow-up period.

Discussion

Large defects of the cranial vault could have resulted from trauma, ablative tumor resections, bone-flap infections, decompression craniotomies, or congenital abnormalities. These patients may show a spectrum of symptoms varying from headaches and motion intolerance to seizures.

However, most of these complaints are not reliably altered by cranioplasty. Cranioplasty can reliably improve protection of the cerebrum and cosmetic appearance [9]. The goal of cranioplasty is to achieve a lifelong, stable, and structural reconstruction of the cranium covered by a healthy skin and scalp flap. Many techniques and materials have been advocated for this reconstruction [4].

In the most basic analysis, a successful clinical outcome relies upon the following factors: selection of an implant material to reproduce the rigid framework of the skull, preparation of the recipient bed to optimize implant stability and ensure good vascularity, recognition that a dead space commonly results from the restoration of a collapsed cranial vault. The choice of implant material has been controversial [12]. On the basis of their processing, implant materials can be divided into prefabricated and intraoperatively fabricated materials. Generally, alloplastic materials have the advantage of no donor site morbidity and an abundant material supply. For these reasons alloplasts have been popular in uncomplicated primary cranioplasty [13,14].

The inherent problem with an alloplast is that it remains permanently as an inert, avascular foreign body. Its use is therefore contraindicated in problematic recipient beds in which external erosion of the soft tissues or internal paranasal sinus exposure may eventually lead to implant infection or exposure. Furthermore, late exposure and failure of alloplastic cranioplasties have been repeatedly reported in the literature [15,16].

Treatment of cranial bone defects using individually prepared implants is a well-established clinical procedure in the field of cranioplasty. However, the disadvantages of prefabricated implants are their high costs because of the advanced technology needed and their occasional sensitivity to high or low temperatures (with titanium implants) due to thermal conductivity [17].

Another possible disadvantage of prefabricated implants is their size and shape. However, this disadvantage can be overcome with intraoperatively fabricated implants. Furthermore, the results from long-term follow-up in this study showed that acrylic bone cements have high tissue tolerance without or with few complications [5].

Compared with silicone implants, MMA implants more closely fit the underlying bone on augmentation. Augmentation can be performed as a single-stage procedure with perioperative molding. MMA is physically similar to bone; hence, the patient may feel the presence of a foreign body in the forehead to a lesser extent and the surgeon can adjust contouring during the operation.

With regard to acrylic bone cement (intraoperatively fabricated implants), the cost is low and no advanced technology is needed. Besides, acrylic bone cement is relatively insensitive to temperature changes. This material shows simple mixing, application, contouring, and fixing processes with the surrounding bone. However, the exothermal reaction associated with the mixing process of acrylic bone cement necessitates copious and continuous saline irrigation until complete setting of the

material to prevent any insult to the underlying vital tissues and to wash away the free monomers that arise when the material is setting. Intraoperatively fabricated acrylic resin materials have been utilized successfully as bone substitutes in neurosurgery, orthopedic surgery, and maxillofacial surgery for reconstruction of frontal bone, orbital floor, facial deformities, and knee joints.

MMA is reported to be well tolerated by bone and soft tissues, which has been confirmed in our study. The stabilized MMA blocks allow the overlying skin to heal without delay or wound breakdown. There was no significant bone resorption and minimal evidence of granulation tissue. However, one of the most important points to be followed during the exothermic reaction stage is copious irrigation of the setting MMA with saline or removal from bone contact to avoid damage to the adjacent tissues.

The incidence of toxicity of MMA is low. There are reports of allergy to the monomer and occasional reports of hypotension and cardiac arrest following its use in joint surgery. However, there is a possible correlation with these complications when large amounts of unbound monomer are applied to a large bone surface area or a 'plunger' effect results in fat embolism [18–20]. In addition, MMA has been reported to be detectable in both plasma and breast milk following joint surgery, and considering its widespread use, MMA has a low incidence of associated complications [21,22]. The primary problem reported with MMA implants in regions other than facial bones is infection, with rates near 20% at 1 to 2 years after implantation [23–25]. These findings are supported by Govila [26], but Benoist [23] reports an infection rate of up to 25% in his series.

Cranioplasty failure is manifested in terms of poor esthetic results and inadequate cerebral protection. Implant infection is the most common pathway leading to failure. In our study, there was no sign of infection at the site of the surgery, which means that acrylic bone cement can be used safely as an implant material in full thickness cranial bone defects without fear of infection to the underlying vital tissues, as well as the surrounding tissues.

In contrast to metal implants, synthetic materials like MMA allow primary molding of the skull bone defect. The setting phase of these materials, however, involves an exothermic chemical reaction, and temperatures of more than 100°C can be reached, causing necrosis in the surrounding tissue in cases of inadequate saline irrigation. Foreign body reactions in the surrounding tissue can be observed, as well as fibrous encapsulation of the synthetic implants [27]. Small dural perforations of less than 1 cm, especially with no cerebrospinal fluid leaks, did not need repair. However, large perforations of more than 1 cm, with cerebrospinal fluid leaks, needed pericranial tissue grafting to prevent these leak, as well as to protect the underlying vital tissues.

In our study, patients tend to consider an overaugmented shape as more unacceptable compared with an underaugmented shape. Hence, this should be kept in mind

during the preoperative interview with the patient. Some immediate postoperative hematoma occurred, but no recurrence occurred after aspiration. Seroma, which is commonly associated with augmentation using silicone implants, did not occur in our patients.

The present method of cranioplasty reconstruction is safe, easy, cheap, and immediately available for cranioplasty of deformed depressed bony defects, with acceptable esthetic results. Both patient and surgeon satisfactions were high in the majority of patients treated.

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Conflicts of interest

There are no conflicts of interest.

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