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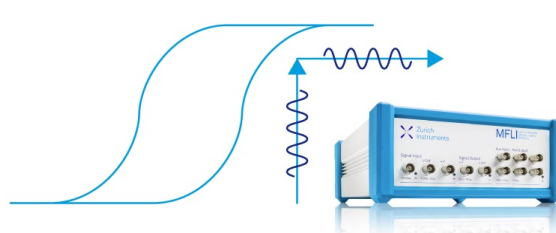
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Patient-Specific Reconstruction Utilizing Computer Assisted 3D Modelling for Partial Bone Flap Defect in Hybrid Cranioplasty

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Abstract. Autologous cranioplasty using a patient's original bone flap remain the commonest practice nowadays. However, partial bone flap defect is commonly encountered. Replacing the bone flap with pre-moulded synthetic bone flap is costly and not affordable to many patients. Hence most of the small to medium size defect was topped up with alloplastic material on a free hand basis intra-operatively which often resulted in inaccurate implant approximation with unsatisfactory cosmetic result. This study aims to evaluate implant accuracy and cosmetic outcome of cranioplasty candidates who underwent partial bone flap reconstruction utilising computer assisted 3D modelling. 3D images of the skull were obtained from post-craniectomy axial 1-mm spiral computed tomography (CT) scans and a virtual 3D model was generated using the Materialise Mimics software. The Materialise 3-Matic was then utilised to design a patient-specific implant. Prefabrication of the implant was performed by the 3D Objet printer, and a negative gypsum mold was created with the prefabricated cranial implant. Intraoperatively, a hybrid polymethyl methacrylate (PMMA)-autologous cranial implant was produced using the gypsum mold, and fit into the cranial defect. This study is still ongoing at the moment. To date, two men has underwent partial bone flap reconstruction utilising this technique and both revealed satisfactory implant alignment with favourable cosmesis. Mean implant size was 12cm², and the mean duration of intraoperative reconstruction for the partial bone flap defect was 40 minutes. No significant complication was reported. As a conclusion, this new technique and approach resulted in satisfactory implant alignment and favourable cosmetic outcome. However, more study samples are needed to increase the validity of the study results.

INTRODUCTION

Decompressive craniectomy is a common life saving neurosurgical procedure in the setting of malignant brain swelling. Patient who survives require reimplantation of bone flap for anatomical reconstruction, cerebral protection, aesthetic restoration, neurophysiological improvement, and prevention of intracranial low pressure syndrome or syndrome of the trephined.¹

An optimal cranial reconstructive procedure should provide precise and complete defect closure with satisfactory cosmetic outcome using durable implant material with good biocompatibility. To date, autologous bone flap using the patient's original bone flap is still the commonest practice as it is easily available with superior mechanical properties and good immunological compatibility.² However, the use of original bone flap is not without challenge as the original bone flap is always incomplete.

In addition to bone resorption, partial bone flap defect can be contributed by the initial traumatic event itself, such as in a case of comminuted skull fracture in which the smaller or comminuted piece of bone may need to be thrown away. Sometimes, edge of the skull defect were rounded or drilled off for better surgical exposure, and this also causes a mismatch between the size of the original bone flap and the skull defect.³ In

a case of tumour, part of the bone might be drilled off due to invasion by tumour. All these causes inaccurate approximation of the implant to the edge of skull defect, which can lead to instability and unsatisfactory cosmetic result.

In current practice, the original bone flap with large defect will be abandoned and replaced with synthetic materials. Whereas those with small or medium size defect will be subjected to partial bone flap reconstruction intra-operatively. In such cases, the bone flap defect will be evaluated during surgery, and implant to patch the defect will be moulded, adjusted and matched with the skull defect on a freehand basis intra-operatively.

Intra-operative moulding is time consuming and it extends the duration of surgery. A longer surgery increases the amount of blood loss and exposes the patient to higher risk of infection. The outcome varies depending on the skills and experiences of the surgeon. It often produces an ill-fitting implant with poor aesthetic outcome. In addition to that, an inaccurate prosthesis also increases the chance of implant movement and displacement.⁴ This rationale the need for a safe and alternative technique for reconstruction of partial bone flap defect in cranioplasty.

MATERIALS AND METHODS

Materials

For this study, a medically graded alloplastic material of polymethyl methacrylate (PMMA), Syncem Cranioplastie, France was used and gypsum type III was used for mould preparation.

Patient population

Fifteen cranioplasty candidates were recruited for this study and two of them have undergone cranioplasty using individualized gypsum molds produced at our institution. Both patients were male. The median patient age at the time of cranioplasty was 20.5 years. The cranial defects were caused by head trauma in both cases. Both of them had a unilateral cranial defect located in the fronto-temporo-parietal region.

Preparation of mold

3D images of the skull were obtained from post-craniectomy axial 1-mm spiral computed tomography (CT) scans and a virtual 3D model was generated using the Materialise Mimics software. The Materialise 3-Matic was then utilised to design a patient-specific implant (Fig. 1). Prefabrication of the implant was performed by the 3D Objet printer (Fig. 2), and a negative gypsum mold (Fig. 3) was created with the prefabricated cranial implant. The mould was then sterilized by autoclave.



FIGURE 1: 3D image of implant generated using Materialise Mimics Software.



FIGURE 2: 3D cranial implant printed using 3D Objet printer.



FIGURE 3. Gypsum mold created using the pre-fabricated cranial implant

Surgical technique

All patients underwent cranioplasty under general anesthesia. After aseptic draping, skin incision made along previous surgical scar. Scalp tissue retracted. The hybrid polymethyl methacrylate (PMMA) – autologous cranial implant (Fig 4) was constructed during the dissection procedure. The gypsum molds were wrapped with two layers of sterilized plastic in order to prevent adhesion between the implant and the mold. The PMMA resin was prepared by mixing polymer powder with a liquid monomer. In the liquid state, the PMMA resin was poured into the gypsum molds and the molds were compressed to each other. The mold and plastic were separated from the PMMA implant after hardening. The implant required minor trimming around the margins in order to achieve an exact fit into the skull defect. The end product was fixed to the skull defect using titanium plates and screws.



FIGURE 4. Hybrid polymethyl methacrylate (PMMA) – autologous cranial implant

RESULTS AND DISCUSSIONS

This study is still ongoing at the moment. To date, two patients have undergone partial bone flap defect reconstruction utilizing this technique and both revealed satisfactory implant alignment with favourable cosmesis (Fig. 5A, 5B). Mean implant size was 12cm² and no significant complication was reported.



The commonest practice for cranioplasty in the current setting involves re-implantation of a patient's original bone flap to the skull defect. However, the original bone flap is always found to be incomplete or smaller than the skull defect. Replacing the bone flap with pre-moulded synthetic bone flap is costly and not affordable to many patients. Hence most of the small to medium size defect was topped up with alloplastic material on a free hand basis intra-operatively which often resulted in inaccurate implant approximation with unsatisfactory cosmetic result.

In this study, we developed a computer-generated model that was transformed into prefabricated cranial implant using the 3D Objet printer. A negative gypsum mold was created using the prefabricated cranial implant which can be use intra-operatively to produce a hybrid PMMA-autologous cranial implant that fit well into the anatomical defect. A well-fitted implant improves cosmetic outcome and reduces the risk of implant movement or extrusion.

Most often, the degree of mismatch between the bone flap and skull defect can only be appreciated intra-operatively as the bone flap will not be taken out from the bone bank till the day of surgery in order to maintain its sterility. Hence, the size, shape and sites of bone flap defect can only be evaluated during the traditional cranioplasty and the outcome of intra-operative moulding relies heavily on the creativity and experience of the operator. Nevertheless, this problem became negligible with our technique, as with the gypsum mold that we have produced, the re-construction and production of hybrid PMMA-autologous bone flap implant can be done at the same rate regardless of the size, shape and sites of the bone flap defect.

PMMA is the most frequently used alloplastic material for craniofacial reconstruction as it can be molded easily into the shape of the cranial defect. It also has good biocompatibility with low radiopacity, lighter in weight, has strong resistance to stress with relatively low costs. However, when PMMA is constructed *in situ*, it can induce exothermic and potentially toxic nature of polymerization. This polymerization can damage the dural and subdural structures and release monomers into the patient's circulation.^{5,6,7} The exothermic polymerization reaction during in situ reconstruction also induces surrounding bony necrosis and toxic local reaction resulting in encapsulation of the material by fibrous tissue and incapability of the implant to integrate with surrounding bony tissue, resulting in poor osteoconductivity and osteointegration. The technique illustrated in our study has the advantage to prevent these potential complications of PMMA. In our study, PMMA was constructed in the gypsum mold intra-operatively and polymerization occurred prior to re-implantation of bone flap. Hence, the exothermic and toxic effect of polymerization on the brain and surrounding structures can be avoided. However, less is known whether ex vivo polymerized PMMA would differ in term of its bioactivity.⁸

Individualized prefabrication of cranial implant follow by the production of a negative gypsum mold is more cost-effective compared to customized cranial prostheses. The cost of a customized cranial prosthesis is RM 10,000-15,000 depending on the size of cranial defect. Whereas the cost for production of an individualized hybrid PMMA-autologous bone implant using prefabricated cranial implant and gypsum mold is RM3,000-4,000.

CONCLUSION

In conclusion, cranioplasty using this new technique and approach resulted in satisfactory implant alignment and favourable cosmetic outcome. In addition, our customized cranioplasty model may have advantages with respect to cost. However, more study samples are needed to increase the validity of the study results.

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