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

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Purpose: Decompressive craniectomy is a life-saving procedure in the setting of malignant brain swelling. Patients who survive require cranioplasty for anatomical reconstruction and cerebral protection. Autologous cranioplasty remains the commonest practice nowadays, but partial bone flap defects are frequently encountered. The authors, therefore, seek to develop a new technique of reconstruction for cranioplasty candidate with partial bone flap defect utilizing computer-assisted 3D modeling and printing.

Methods: A prospective study was conducted to evaluate the outcome of a new reconstruction technique that produces patient-specific hybrid polymethyl methacrylate-autologous cranial implant. Computer-assisted 3D modeling and printing was utilized to produce patient-specific molds, which allowed real-time reconstruction of bone flap with partial defect intra-operatively.

Results: Outcome assessment for 11 patients at 6 weeks and 3 months post-operatively revealed satisfactory implant alignment with favorable cosmesis. The mean visual analog scale for cosmesis was 91. Mean implant size was 50cm^2, and the mean duration of intra-operative reconstruction was 30 minutes. All of them revealed improvement in quality of life following surgery as measured by the SF-36 score. Cost analysis revealed that this technique is more cost-effective compared to customized cranial prosthesis.

Conclusion: This new technique and approach produce hybrid autologous-alloplastic bone flap that resulted in satisfactory implant alignment and favorable cosmetic outcome with relatively low costs.

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Received March 22, 2019.
Accepted for publication May 7, 2019.

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This study was supported by the Universiti Sains Malaysia (USM) Research University Grant (RUT grant) (1001/PPSG/852004) from Universiti Sains Malaysia (USM), Kubang Kerian, Kelantan, Malaysia. The third author was supported by USM fellowship scheme.

The authors report no conflicts of interest.

Supplemental digital contents are available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Web site (www.jcraniofacialsurgery.com).

ISSN: 1049-2275
DOI: 10.1097/SCS.0000000000005713

Key Words: 3D printing, computer-aided design, cranioplasty, hybrid implant, partial bone flap defect

Decompressive craniectomy is a common life saving neurosurgical procedure in the setting of malignant brain swelling. Patient who survives require re-implantation 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 might be 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, edges of the skull defect were roungeured 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] All this 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, and 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 molded, adjusted and matched with the skull defect on a freehand basis intra-operatively.[1,4]

Intra-operative molding is time-consuming and extends the duration of surgery. A longer surgery increases the amount of blood loss and exposes the patient to higher risk of infection.[5] Outcome varies depending on the skills and experiences of a surgeon. It may produce an ill-fitting implant with poor aesthetic outcome. In addition to that, an inaccurate prothesis also increases the chance of implant movement and displacement.[6] This rationale the need for a safe and alternative technique for reconstruction of partial bone flap defect in cranioplasty.

METHODS

Patient Population

Thirteen cranioplasty candidates were recruited for this study and all of them have undergone cranioplasty using individualized gypsum molds produced at our institution. Subjects included 12 males and 1 female, aged 16 to 51 years (mean = 26.7 years). Initial diagnoses consisted of 11 head injuries and 2 cerebral hemorrhages. Informed consents were taken from all subjects before cranioplasty. This study was approved by the local research and ethics committee (ref: USMKK/PPP/JEPeM/[259.3(2)].

Preparation of Mold

Post-craniectomy computed tomography (CT) scans of all study subjects were collected and imported to work station. The Materialise 3-Matic software was used to generate a virtual 3D model and design a patient-specific implant (Fig. 1A), which was printed out by a 3D Object printer (Fig. 1B). Following that, a negative gypsum mold (Fig. 1C) was created using the prefabricated cranial implant. The mold was then sterilized together with a flask by autoclave.

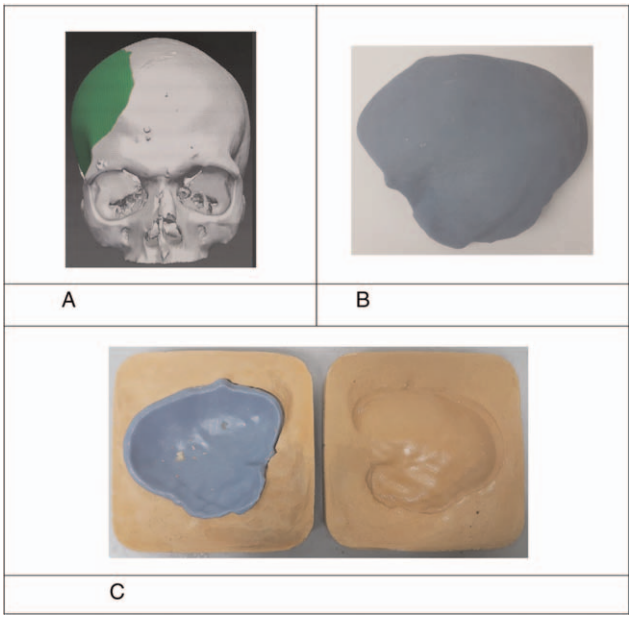

FIGURE 1. Preparation of mold (A) 3D image of implant generated using Materialise Mimics Software (B) Pre-fabrication of implant using 3D Objet printer (C) Negative gypsum mold created using the prefabricated cranial implant.

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 was reconstructed during the dissection procedure. Gypsum molds (Fig. 2A) were wrapped with 1 layer of sterilized plastic (Fig. 2B) in order to prevent adhesion between the implant and the mold. Patient's autologous bone flap retrieved from bone bank and placed into the gypsum mold (Fig. 2C). The PMMA resin was prepared using Synicem Cranioplastie; each box contained 2 packages of material. Each package composed by: 1 packet of sterile polymer powder consisting of 29.49 g polymethyl methacrylate (98.30% w/w) and 0.51 g of benzoyl peroxide (1.7% w/w); 1 ampoule of 17mls liquid monomer sterilized by ultrafiltration consisting of 16.80 mL Methyl Methacrylate (98.8% w/w), 0.20 mL of N, N dimethyl p-toluidine (1.2% w/w), and 18 to 20 ppm of Hydroquinone. For each patient, 1 packet of polymer powder was mixed with 1 ampoule of liquid monomer to form the PMMA resin. In liquid state, PMMA resin was poured into the gypsum mold that contained patient's autologous bone flap and the molds were compressed to each other using a flask (Fig. 2D). The mold and plastic were separated from the hybrid PMMA-autologous cranial implant (Fig. 2E, F) after hardening (around 15 to 20 min). End product fixed to the skull defect using titanium plates and screws.

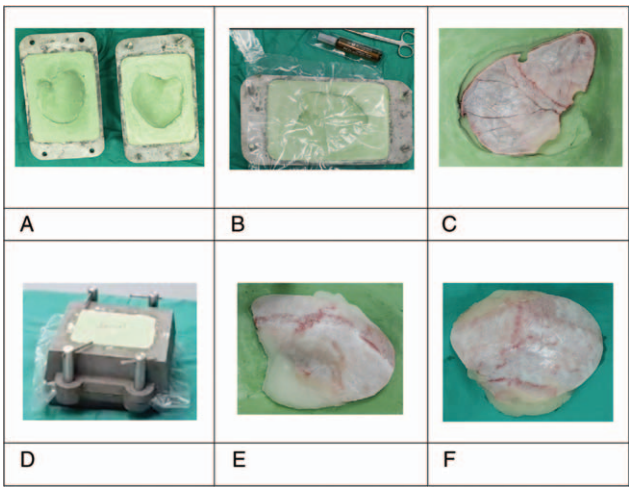

FIGURE 2. Hybrid polymethyl methacrylate (PMMA)—autologous cranial implant reconstruction (A) Gypsum molds (B) Gypsum mold covered with a layer of plastic (C) Patient's autologous bone flap retrieved from bone bank and place on the mold (D) Flask compressing molds that contained autologous bone and PMMA in liquid state (E, F) Hybrid PMMA-autologous bone flap implants.

Outcome Assessment and Evaluation

Clinical follow-up was conducted 6 weeks and 3 months after surgery. Patient's impression of their cosmetic outcome was evaluated using the visual analog scale for cosmesis (VASC).[3,6] Quality of life assessed using the validated Malay version of SF-36 score.[7] Radiological assessment was performed by computed tomography scans at 3 months after surgery. The studies were utilized to check for signs of infection, cerebrospinal fluid collections, hydrocephalus, and alignment of the implant. Alignment was considered excellent when the surface dislocation of implant compared to skull bone contour was <1 mm, and accurate if the implant dislocation was at least equal to the thickness of surrounding skull. Alignment considered inaccurate if the dislocation was beyond the thickness of surrounding skull.[6]

Statistical Method

Data were calculated and analyzed using the Statistical Packages for Social Sciences (SPSS) version 22.0. Descriptive data were reported as means $\pm$ standard deviation. Data that distributed normally was analyzed using the Independent t test. Data that distributed non-normally were analysed using the Mann–Whitney U test. Level of significance set at $\alpha = 0.05$. Results of statistical testing were reported as P value and confidence interval of 95%. A P value of less than 0.05 was considered significant. Relationships of outcome data between groups were determined using Pearson correlation coefficient and McNemar's test.

RESULTS

Twelve male and 1 female (mean age 27years $\pm$ 12, range 16–51 years) underwent partial bone flap reconstruction utilizing this technique. One patient involved in motor vehicle accident before outcome assessment; another patient experienced implant exposure and underwent implant removal. Both of them were excluded from result analysis. Table 1 (Supplemental Digital Content, http://links.lww.com/SCS/A581) presents a summary of patient characteristics, surgical data, and follow-up findings.

All cranial defects were located at the frontotemporoparietal region. Nine of them underwent craniectomy due to traumatic brain injury and the remaining 2 underwent craniectomy for hypertensive bleed. This was the first cranioplasty procedure for 8 patients and 3 of them underwent this procedure as their second cranioplasty due to bone resorption. The mean duration of intraoperative reconstruction of the partial bone flap defects was 30 minutes $\pm$ 7 7 (range 23–45 minutes). Implant sizes ranged from 24 to 132 cm^2 (mean size 50 $cm^2 \pm 34$). There was no correlation between implant size and the duration of intraoperative reconstruction ($r = 0.138$, $n = 11$, $P = 0.686$). One patient developed 1 episode of seizure following surgery. The postoperative clinical and laboratory course was uneventful for the rest of the patients.

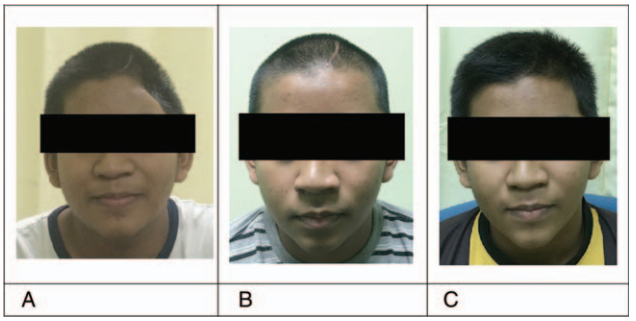

FIGURE 3. Cosmetic result evaluated (A) Pre-operatively (B) Six weeks after surgery (C) Three months following surgery.

No adverse events were reported during the follow-up at 6 weeks and 3 months post-operatively. All the study subjects were satisfied with their cosmetic result (Fig. 3) (mean VASC 91 ± 5, range 83–95), and experienced improvement in their quality of life as measured by the SF 36 score (mean improvement in score following surgery 38 ± 18, range 5–70). There was a positive correlation between the cosmetic result (VASC) and improvement in role limitations due to emotional problems ($r = 0.622$, $n = 11$, $P = 0.041$). A positive correlation was demonstrated between the cosmetic result (VASC) and emotional well being ($r = 0.632$, $n = 11$, $P = 0.037$) as well.

Radiological follow up at 3 months after surgery revealed excellent implant alignment in all patients (Fig. 4). McNemar's test showed that there was statistically significant improvement in the overall patient's satisfaction before and after surgery, $P = 0.004$.

DISCUSSION

The commonest practice for cranioplasty in the current setting involves re-implantation of a patient's original bone flap to the skull defect. However, partial bone flap defect is frequently encountered. A skull defect size of >6 to $10\,cm^2$ is recommended for reconstructive cranioplasty in order to protect the brain beneath against trauma.[8,9] Any bone defect as small as the size of a burr hole may lead to depression of the skin and result in poor cosmetic outlook especially in the frontal region.[6]

Replacing the original bone flap with pre-molded synthetic bone flap is costly and might not be affordable for all patients. Hence some of the small to medium size defects were topped up with alloplastic materials on a free hand basis intra-operatively, which may lead to 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 used intra-operatively to produce a hybrid PMMA-autologous cranial implant that fits well into the anatomical defect. A well-fitted implant improves cosmetic outcome and reduces the risk of implant movement or extrusion.

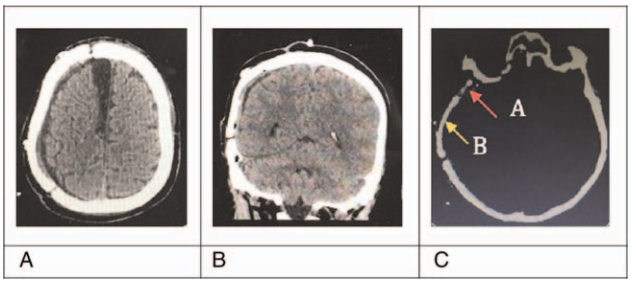

FIGURE 4. Computed tomography scan showing that the hybrid implant (A, PMMA; B, autologous bone flap) was well aligned to adjacent skull edges.

Most often, the degree of discrepancy between the original bone flap and skull defect can only be observed 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 assessed during surgery and the outcome of intra-operative molding relies heavily on the creativity and experience of the operator. This problem became negligible with our technique, as the gypsum mold that we have produced allow real-time re-construction and production of hybrid PMMA-autologous bone flap implant regardless of the size, shape, and sites of the bone flap defect.

The PMMA is the most frequently used alloplastic material for craniofacial reconstruction as it is very light, has good biocompatibility, and can be molded easily into the shape of the cranial defect.[10–12] However, PMMA has some unfavorable effect during polymerization, and 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 before re-implantation of bone flap. Hence, the exothermic and toxic effect of polymerization on the brain and surrounding structures can be avoided.[5,13–15]

This study shows that excellent cosmetic results can be achieved using a simple and inexpensive cranioplasty technique in patients with partial bone flap defect. Customized hybrid implants were produced real time during surgery using a negative mold that was created via computer-assisted 3D modeling technology pre-operatively. Follow-up evaluation using the VASC showed that all patients were satisfied with the cosmetic result of this procedure (mean VASC 91 ± 5, range 83–95). This was associated with improvement in quality of life as measured by the SF-36 score, especially the psychosocial aspect which demonstrated statistically significant improvement following surgery.

Excellent implant alignment was achieved in all cases. A well-fitted implant minimizes the chances of bone flap subsidence and wound dehiscence by reducing the tension on wound, also shortened the time needed for adjustment during implant insertion. No statistically significant correlation was found between the implant size and duration of intra-operative reconstruction indicating that the duration of intra-operative reconstruction remains the same regardless of the size of bony defect when this technique is used.

This method is more cost-effective compared to customized cranial prostheses. The cost of a customized cranial prosthesis range from Euro 2000 to Euro 3500 (RM 10,000– RM 15,000) depending on the size of cranial defect. Whereas the cost for production of an individualized hybrid PMMA-autologous bone implant using this new technique range from Euro 650 to Euro 900 (RM 3000 to RM 4000).

CONCLUSION

In conclusion, patient-specific reconstruction of partial bone flap defect by the production of hybrid PMMA-autologous implant using this new technique results in satisfactory implant alignment with favourable cosmetic outcome. This method reduced operative time for adjustment and insertion of implant and has a relatively lower cost.

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Application of a Layered Muscle Flap Technique for the Reconstruction of the Cupid's Bow and Vermilion in the Repair of Secondary Cleft Lip Deformities

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Abstract: In the repair of unilateral cleft lip, the Cupid's bow, and vermilion on the affected side are sometimes lowered excessively. Methods involving skin and mucosa flaps have been used to correct this issue, but they pose some risk of scarring. The authors here describe a layered muscle flap technique that was based on the anatomical research of nasal-labial muscles, especially the levator labii superioris alaeque nasi muscle. This technique can be used to suspend the Cupid's bow and vermilion in secondary unilateral cleft lip repair. Forty-five patients with secondary unilateral cleft lip with excessively lowered Cupid's bows and vermilion on the affected side were included in this study, which lasted 3 years. These patients were treated using the layered muscle flap surgical technique. The heights of specific bilateral landmarks were measured on patient photos and used to define the symmetry of bilateral Cupid's bow and vermilion. The comparison between post-operative and pre-operative symmetries was used to evaluate the post-operative results, and most of them were satisfactory. The results were also mostly well retained in follow-up investigations. This layered muscle flap technique could be effective in selected cases.

Key Words: Cupid's bow, layered muscle flap, muscle reconstruction, secondary unilateral cleft lip

Reconstruction of the Cupid's bow and vermilion is a major issue in the repair of secondary unilateral cleft lip deformities.[1–4] There are many methods of shaping the Cupid's bow and the vermilion into a symmetric and bow-like appearance. Common methods of primary repair include Millard's rotation flap technique[5] and Tennison's triangular flap technique,[6] which primarily focus on lowering the peak of the Cupid's bow on the affected side. Improper flap design can result in an over-lowered lateral Cupid's bow and excess on the lateral vermilion following surgery. An over-lowered lateral Cupid's bow is typically corrected with a small Z-plasty.[7] Furthermore, W-plasty[8] has been used to correct the double curve of the entire Cupid's bow. However, the complicated incision and possible scarring might limit the effects of skin flap techniques. Excess on the vermilion is commonly corrected with local excision,[9] Z-plasty,[7] or Y-V advancement[10] on the protruding mucosa. However, a new incision to the mucosa raises the potential risk of scarring. In reality, these 2 deformities are situation dependent and should be corrected with appropriate methods, as necessary.

An anatomical study[11] on nasal-labial muscles demonstrated that some fibers of the levator labii superioris alaeque nasi muscle run in a superficial layer of the orbicularis oris muscle, interweave with the latter, and attach subcutaneously on the philtrum and vermilion border. Philtrum reconstruction using the levator labii superioris alaeque nasi muscle flap has been previously described.[12] The research proposed that these muscle fibers might contribute to the shape of the Cupid's bow and the vermilion.[13] The lower position of the lateral Cupid's bow and an excess on the vermilion might contribute to inadequate reconstruction at the initial surgery. In this paper, the authors describe their experience in re-shaping the

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Received August 17, 2018.
Accepted for publication May 8, 2019.

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The authors report no conflicts of interest.
Supplemental digital contents are available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Web site (www.jcraniofacialsurgery.com).

ISSN: 1049-2275
DOI: 10.1097/SCS.0000000000005714