PATIENT - SPECIFIC RECONSTRUCTION UTILIZING COMPUTER
ASSISTED 3D MODELLING FOR PARTIAL BONE FLAP DEFECT IN
HYBRID CRANIOPLASTY

BY
DR LOW PEH HUEH

Dissertation Submitted In Partial Fulfillment Of The Requirement For
The Degree Of Master Of Surgery (Neurosurgery)

SCHOOL OF MEDICAL SCIENCES
UNIVERSITI SAINS MALAYSIA
2017
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Abstrak

Abstract

Background: 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 might not be affordable for all patients. Hence, some small to medium size defects were topped up with alloplastic material on a free hand basis intra-operatively that often resulted in inaccurate implant approximation with unsatisfactory cosmetic result. This rationale the need for an alternative technique for reconstruction of partial bone flap defect in cranioplasty. The objective of this study is to evaluate implant accuracy and cosmetic outcome of cranioplasty candidates with partial bone flap defect who underwent reconstruction utilising computer assisted 3D modelling.

Methods: This study consisted of thirteen patients. 3D images of their skull were obtained from post-cranieectomy axial 1-mm spiral computed tomography (CT) scans and virtual 3D models were generated using Materialise Mimics software. The Materialise 3-Matic was utilised to design patient-specific implant. Prefabrication of the implant performed by a 3D Objet printer, and negative gypsum molds were created with the prefabricated cranial implant. Intra-operatively, hybrid polymethyl methacrylate (PMMA)-autologous cranial implants were produced using the gypsum molds, and fit into the cranial defect.

Results: Thirteen patients underwent partial bone flap reconstruction utilising this technique. One patient involved in motor vehicle accident prior to outcome
assessment; another patient experienced implant exposure and underwent implant removal. The rest of the patients revealed satisfactory implant alignment with favourable cosmesis. The mean visual analogue scale for cosmesis (VASC) was 91, mean implant size was 50cm², and the mean duration of intra-operative reconstruction for the partial bone flap defect was 30 minutes. All of them revealed excellent implant alignment and 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 prostheses. The cost of a customized cranial prosthesis range from RM10,000 to RM15,000 depending on the size of cranial defect. Whereas the production cost for an individualized hybrid PMMA-autologous bone implant using this technique range from RM 3,000 to RM 4,000.

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

**Keywords:** Cranioplasty, hybrid, partial bone flap defect, computer-aided design, polymethyl-methacrylate
Introduction - literature review and rationale for the study

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 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, 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.\(^3\) 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 cometic 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.4

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.5 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 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.

Our study aim to evaluate the implant accuracy and cosmetic outcome of a new cranioplasty method in cranioplasty candidates with partial bone flap defect who underwent reconstruction utilising computer assisted 3D modelling. Intra-operative reconstruction time, cost of implant, and complications were documented. The impact of this procedure on quality of life were measured by SF-36 score.7
The Human Research Ethics Committee, Universiti Sains Malaysia (FWA Reg. No: 00007718; IRB Reg. No: 00004494) has approved in principle the study mentioned below:

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</tr>
<tr>
<td>Reviewed by Committee</td>
<td>Protocol received  Reviewed Amended Protocol</td>
</tr>
<tr>
<td>Co-investigator(s)</td>
<td>Dr. Marzuki Omar  Assoc. Prof. Dr. Zamzuri Idris  Assoc. Prof. Dr. Bahari Belaton  Dr. Dasmawati Mohamad  Prof. Ismail Ab. Rahman  Prof. Hajiwan Md Akil  Datu/ Dr. Abdul Rahman Izaini Ghani  Dr. Abdullah Pohchi  Dr. Nurul Asma Abdullah  Dr. Norhayati Luddin  Assoc. Prof. Dr. Adam Husain  Prof. Dr. Abd Rahim Mt Pinah  Assoc. Prof. Ahmad Majid  Dr. Norkhasha Abd Sadiq  Mr. Abdul Hakim Abdul Basir  Mr. Johari Yap Abdullah  Mr. Abdullah Hamat</td>
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<tr>
<td>Research Center</td>
<td>School of Dental Sciences, Universiti Sains Malaysia</td>
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<td>January 2013 – December 2016</td>
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<tr>
<td>Financial Support</td>
<td>Research University (Team) Grant, USM</td>
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<tr>
<td>Number of Samples</td>
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The following item (√) have been received and reviewed:

- Ethical Approval Application Form
- Study Protocol
- Patient Information Sheet and Consent Form
- Data Collection Form
- Questionnaires
Investigator(s) are required to:

a) follow instructions, guidelines and requirements of the Human Research Ethics Committee, Universiti Sains Malaysia (JEPeM)
b) report any protocol deviations/violations to Human Research Ethics Committee (JEPeM)
c) comply with International Conference on Harmonization – Guidelines for Good Clinical Practice (ICH-GCP)
d) note that Human Research Ethics Committee (JEPeM) may audit the approved study.

PROFESSOR DR. MOHD SHUKRI OTHMAN
Chairman
Human Research Ethics Committee
TARIKH: 14 Disember 2012

Prof. Madya Dr. Zainul Ahmad Rajion
Pusat Pengajian Sains Pergigian
Universiti Sains Malaysia
16150 Kubang Kerian
KELANTAN DARUL NA'IM

Tuan,

KEPUTUSAN PERMOHONAN GERAN UNIVERSITI PENYELIDIKAN (RU) TAHUN 2012
- EKSESAS SEPTEMBER 2012

Dengan hormatnya perkara di atas dirujuk

2. Adalah dimaklumkan bahawa Mesyuarat JKPPU Bil. 4/2012 yang telah bersidang pada 22 November 2012 telah memperakukan permohonan tuan seperti berikut:

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Sekian, terima kasih.

“BERKHIDMAT UNTUK NEGARA”
‘Memastikan Kelestarian Hari Esok’

Yang menjalankan tugas,

(HAZLAN ABDUL HAMID)
Ketua Pencipta Pendaftar
Pejabat Pengurusan & Kreativiti Penyelidikan
Bahagian Penyelidikan & Inovasi

s.k. Dekan Penyelidikan
Pelantar Sains Klinikal
Pejabat Pelantar Penyelidikan
USM Kampus Kesihatan

Dekan
Pusat Pengajian Sains Pergigian
USM Kampus Kesihatan
15th March 2016

Assoc. Prof. Dr. Zainul Ahmad Kajion
School of Dental Sciences
Universiti Sains Malaysia
16150 Kubang Kerian, Kelantan

JPEm USM Code: USMXX//PPP/JPEm/[1259.3(2)]


Dear Dr,

We wish to inform you that the Jawatankuasa Etika Penyelidikan Manusia, Universiti Sains Malaysia (JPEm USM) approved the proposed amendments in your study entitled, "Biomodelling for Cranio-Maxillofacial Reconstruction: Patient Specific Aesthetic Functional and Affordable Biomaterial Implants and Prostheses" [USMXX//PPP/JPEm/[1259.3(2)] during its meeting on 24th February 2016.

Upon review of JPEm USM FORM 3(A) 2014: Study Protocol Amendment Submission Form, the following amendments have been approved:

1. To add Dr. Low Feh Hui as co-investigator of this study, as she will be contributing by doing research on "Patient Specific Reconstruction Utilizing Computer Assisted 3D Modelling for Partial Bone Flap Defect in Cranioplasty".

Thank you.

"ENSURING A SUSTAINABLE TOMORROW"

Very truly yours,

(PROF. DR. MOHD SHUKRI OTHMAN)
Deputy Chairperson
Jawatankuasa Etika Penyelidikan (Manusia), JPEm
Universiti Sains Malaysia

(X) Secretary
Jawatankuasa Etika Penyelidikan (Manusia), JPEm
Universiti Sains Malaysia
Patient - Specific Reconstruction Utilizing Computer Assisted 3D Modelling for Partial Bone Flap Defect in Hybrid Cranioplasty

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² School of Dental Sciences, Universiti Sains Malaysia, Kubang Kerian, 16150 Kelantan, Malaysia.
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 might not be affordable for all patients. Hence, some small to medium size defects were topped up with alloplastic material on a free hand basis intra-operatively that often resulted in inaccurate implant approximation with unsatisfactory cosmetic result. This rationale the need for an alternative technique for reconstruction of partial bone flap defect in cranioplasty. The objective of this study was to evaluate implant accuracy and cosmetic outcome of cranioplasty candidates with partial bone flap defect who underwent reconstruction utilising computer assisted 3D modelling. This study consisted of thirteen patients. 3D images of their skull were obtained from post-craniecotomy axial 1-mm spiral computed tomography (CT) scans and virtual 3D models were generated using Materialise Mimics software. The Materialise 3-Matic was utilised to design patient-specific implant. Prefabrication of the implant performed by a 3D Objet printer, and negative gypsum molds were created with the prefabricated cranial implant. Intraoperatively, hybrid polymethyl methacrylate (PMMA)-autologous cranial implants were produced using the gypsum molds, and fit into the cranial defect. Thirteen patients underwent partial bone flap reconstruction utilising this technique. One patient involved in motor vehicle accident prior to outcome assessment; another patient experienced implant exposure and underwent implant removal. The rest of the patients
revealed satisfactory implant alignment with favourable cosmesis. The mean VASC was 91, mean implant size was 50cm$^2$, and the mean duration of intra-operative reconstruction for the partial bone flap defect was 30 minutes. All of them revealed excellent implant alignment and 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 prostheses. The cost of a customized cranial prosthesis is RM10,000-RM15,000 depending on the size of cranial defect. Whereas the cost for production of an individualized hybrid PMMA-autologous bone implant using pre-fabricated cranial implant and gypsum mold is RM 3,000-RM 4,000. This new technique and approach produces hybrid autologous-alloplastic bone flap that resulted in satisfactory implant alignment and favourable cosmetic outcome with relatively low costs.

**Keywords:** Cranioplasty, partial bone flap defect, computer-aided design, polymethyl-methacrylate
1 Introduction

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 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 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 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 cometic 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.\textsuperscript{1,4}

Intra-operative moulding 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.\textsuperscript{5} Outcome varies depending on the skills and experiences of a surgeon. It often produces an ill-fitting implant with poor aesthetic outcome. In addition to that, an inaccurate prothesis also increases the chance of implant movement and displacement.\textsuperscript{6} This rationale the need for a safe and alternative technique for reconstruction of partial bone flap defect in cranioplasty.

2 \hspace{1cm} \textbf{Materials and Methods}

2.1 Patient population

Thirteen cranioplasty candidates were recruited for this study and all of them have undergone cranioplasty using individualised gypsum molds produced at our institution. Subjects included 12 males and one female, aged 16 to 51 years
(mean = 26.7 years). Initial diagnoses consisted of 11 head injuries and two 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/JEPM/[259.3(2)]).

2.2 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 (Figure 1A), which was printed out by a 3D Objet printer (Figure 1B). Following that, a negative gypsum mold (Figure 1C) was created using the prefabricated cranial implant. The mold was then sterilized together with a flask by autoclave.

2.3 Surgical technique

All patients underwent cranioplasty under general anaesthesia. 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 (Figure 2). Gypsum molds (Figure 2A) were wrapped with one layer of sterilised plastic (Figure 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 (Figure 2C). PMMA resin was prepared using Synicem Cranioplastie [each box contained two packages of material. Each package composed by: one packet of
sterile polymer powder consisting of 29.49g Polymethyl Methacrylate (98.30% w/w) and 0.51g of benzoyl Peroxide (1.7% w/w); one ampoule of 17mls liquid monomer sterilised by ultrafiltration consisting of 16.80ml Methyl Methacrylate (98.8% w/w), 0.20ml of N,N dimethyl p-toluidine (1.2% w/w) and 18-20 ppm of Hydroquinone]. For each patient, one packet of polymer powder was mixed with one 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 (Figure 2D). The mold and plastic were separated from the hybrid PMMA-autologous cranial implant (Figure 2E, F) after hardening (around 15-20 minutes). End product fixed to the skull defect using titanium plates and screws.

2.4 Outcome assessment and evaluation

Clinical follow-up were conducted six weeks and three months after surgery. Patient’s impression of their cosmetic outcome was evaluated using the visual analogue scale for cosmesis (VASC).\textsuperscript{3,6} Quality of life assessed using the validated Malay version of SF-36 score.\textsuperscript{7} Radiological assessment was performed by computed tomography (CT) scans at three months after surgery. The studies were utilised 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 <1mm, 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.\textsuperscript{6}
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.

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.
2.5 Statistical method

Data were calculated and analysed using the Statistical Packages for Social Sciences (SPSS) version 22.0. Descriptive data were reported as means ± standard deviation (SD). Data that distributed normally was analysed using the Independent t test. Data that distributed non-normally was 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. Relationship of outcome data between groups were determined using Pearson correlation coefficient and McNemar’s test.

Results

Twelve male and one female (mean age 27years ± 12, range 16-51years) underwent partial bone flap reconstruction utilising this technique. One patient involved in motor vehicle accident prior to outcome assessment; another patient experienced implant exposure and underwent implant removal. Both of them were excluded from result analysis. Table 1 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 two underwent craniectomy for hypertensive bleed. This was the first cranioplasty procedure for eight patients and three 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 ± 7 (range 23-45 minutes). Implant sizes ranged from 24-132cm² (mean size 50cm² ± 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 one episode of seizure following surgery. The postoperative clinical and laboratory course was uneventful for the rest of the patients.

No adverse events were reported during the follow-up at six weeks and three months post-operatively. All the study subjects were satisfied with their cosmetic result (Figure 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 three months after surgery revealed excellent implant alignment in all patients (Figure 4). McNemar’s test showed that there was statistically significant improvement in the overall patient’s satisfaction before and after surgery, P = 0.004.
Table 1: Patient Characteristics, Surgery-Related Data, Clinical and Radiological Outcome After Surgery.

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VASC: Visual analogue scale for cosmesis; SF 36: 36-item short form health survey; FTP: frontotemporoparietal; M: Male; F: Female.

Figure 3: Cosmetic result evaluated (A) pre-operatively (B) Six weeks after surgery (C) Three months following surgery
A representative case of partial bone flap reconstruction following bone resorption using the above mentioned technique is described.

**Case Illustration**

A 37 year-old policeman underwent autologous cranioplasty four years ago for a large left frontotemporoparietal cranial defect. He had undergone a left decompressive craniectomy for severe brain swelling caused by traumatic acute subdural hematoma six months prior to that. Following cranioplasty, he noticed that his operative site became sunken over a course of three to four months. Initially he experienced implant movement upon changes in posture, about four months following the onset of symptoms, the cranioplasty site became more depressed and he started to develop headache and giddiness associated with changes in position.

**Figure 4**: Computed tomography (CT) scan showing that the hybrid implant (Red arrow - PMMA, yellow arrow - autologous bone flap) was well aligned to adjacent skull edges.
Fine cut CT brain with 3D reconstruction was performed (Figure 5A), a virtual 3D patient-specific implant was designed for him. Prefabrication of the implant was performed using 3D printer, and a negative gypsum mold was created using that prefabricated cranial implant. This negative mold which contained the intended size and shape of his skull defect was sent for autoclave. Intra-operatively, his original bone flap appeared smaller than his skull defect (Figure 5B,C). His bone flap was removed and reconstructed intra-operatively to a hybrid PMMA-autologous implant (Figure 5D) using the negative mold. The hybrid implant was fixed to the skull defect using titanium plates and screws (Figure 5E). Following surgery, he was satisfied with his cosmetic appearance (Figure 6) and there was marked improvement in his quality of life as measured by the SF-36 score (Table 2).

Figure 5: (A) CT brain with 3D reconstruction image (B) Intra-operatively, bone flap was shrunken and detached from skull edges (C) Bone flap removed from operative site (D) Hybrid PMMA-autologous bone flap implant (E) Hybrid implant fixed to skull defect