Cranioplasty Using Presurgically Fabricated Presterilised Polymethyl Methacrylate Plate by a Simple, Cost-Effective Technique on Patients With and Without Original Bone Flap: Study on 29 Patients

G. M. Sharavanan · Suresh Jayabalan ·
K. Rajasukumaran · Ganesh Veerasekar ·
G. Sathya

Received: 20 December 2013 / Accepted: 8 July 2014 / Published online: 28 August 2014
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Abstract

Objectives The purpose of the study was to assess the clinical effectiveness of presurgically fabricated pre-sterilized polymethyl methacrylate (PMMA) plate as a cranioplasty material.

Materials and Methods The study group consisted of 29 patients with skull defect following decompressive craniectomy. Some patients had their original bone flap preserved and some were without it. In either group pre-sterilized prefabricated PMMA plate was used. On each visit, patients were clinically assessed; CT scans were taken in immediate follow up period but if needed more films were taken in subsequent follow ups. Post-op complications that include infection, post-op hematoma, chronic pain, aesthetic, biocompatibility, post-op dimensional changes of prosthesis were evaluated.

Results Mean follow up was 7 1/2 months. Five patients developed swelling and pain in the subsequent follow ups. One patient was treated conservatively with antibiotics. Tapping was performed in couple of patients. Surgical evacuation of hematoma was performed in one patient. Of the five infected plates, one demanded removal from the patient. One complained of chronic pain. Post-op follow up

assessed clinically and by CT scan confirmed good aesthetic result, biocompatibility and dimensional stability of prosthesis.

Conclusion The result of this study support the view that the use of prefabricated pre-sterilized PMMA plate as cranioplasty material is a simple, reliable, convenient way that brings acceptable function and aesthetics to patients who underwent decompressive craniectomy, in an inexpensive way.

Keywords Decompressive craniectomy · Alginate impression material · Polymethyl methacrylate plate · Compression molding technique

Introduction

Decompressive craniectomy is the removal of part of skull bone to relieve intracranial pressure in various emergency situations like traumatic brain injury, ischemic and hemorrhagic strokes and in neoplastic conditions. One of the most challenging problems in the repair of cranial defect after decompressive craniectomy is the choice of material to be used. Autografts, non-metal and metal allografts are generally used. The goal of treatment is to return the patient to an acceptable state of function and aesthetics and to prevent surgical site infection. Poor economic status of Indian patients makes them seek an economical mode of treatment; the use of polymethyl methacrylate (PMMA) plate as the cranioplasty material serves the purpose. Pre-surgically fabricated pre-sterilized PMMA plate ensures shorter intra-operative time, proper fit and low infection rate.

Polymethyl methacrylate plate has many advantages compared to other cranioplasty material as it has eliminated the risk of second surgical site, risk of infection, difficulty

G. M. Sharavanan (✉) · K. Rajasukumaran · G. Sathya
Department of Oral and Maxillofacial Surgery, Kovai Medical
Center and Hospital Ltd, Coimbatore 641 014, Tamil Nadu,
India
e-mail: ritanya@yahoo.com

S. Jayabalan
Department of Neurosurgery, Kovai Medical Center and
Hospital Ltd, Coimbatore 641 014, Tamil Nadu, India

G. Veerasekar
Department of Epidemiology, Kovai Medical Center and
Hospital Ltd, Coimbatore 641 014, Tamil Nadu, India

in fabrication and expensive approach. The purpose of the study is to evaluate the clinical outcome of pre-surgically fabricated pre-sterilized PMMA plate as a cranioplasty material based on the clinical assessment and CT scan.

Materials and Methods

This study was conducted at Kovai Medical Center and Hospital (Coimbatore, India) between 2012 and 2013. More than 50 patients were treated during this time period using pre-surgically fabricated pre-sterilized PMMA plate for various reasons of cranial defect; Out of them, 29 patients were included in the study. Twenty-five patients had suffered traumatic brain injury (86.20 %), 2 patients had ischemic stroke (6.9 %) and 2 patients had hemorrhagic stroke (6.9 %). The criteria for inclusion in the study were, (1) ambulant patients following decompressive craniectomy/cranioplasty and (2) patients who got operated with pre-sterilized prefabricated PMMA plates. The exclusion criteria included those with debilitating diseases, death of patient after cranioplasty due to unrelated causes and cranioplasty done by other methods. Selected patients were in the age group of 22–67 years and were classified into two groups i.e. one having their original bone flap preserved and the other without it. For either groups, we used pre-surgically fabricated pre-sterilized PMMA plates as the material of choice. There were more males 24 (82.8 %) in the group than females 5 (17.2 %). The patients were followed up for a mean duration of 7 1/2 months (223 days) with a minimum follow up period of 1 3/4 weeks (12 days) to a maximum follow up period of 20 months (599 days). In every follow up, patients were assessed clinically. CT scan was taken in immediate follow up and if required in subsequent follow ups too. Patients were further assessed for any complaint. Patients were evaluated for post-op complications like infection, post-op hematoma, chronic pain, aesthetic, biocompatibility, post-op dimensional changes of prosthesis.

Impression Making of the Cranial Defect

For patients lacking their original bone the following impression technique was followed.

Objective was to obtain the impression of the skull that maintains the original contour. This was achieved by re-contouring the skull defect with plaster of Paris (POP) before making the impression. This technique helps in preparing prosthesis with shape and dimension very similar to the original skull bone.

This was a chair side procedure. Patient was asked to shave his head completely (Fig. 1). Anatomical landmarks were marked with indelible ink and the outline of bony

Fig. 1 Shaved head of the patient showing skull defect

Fig. 2 Anatomical landmarks and outline of defect marked with indelible ink

margins were palpated and demarcated with the same (Fig. 2). Operator stood on the side of the patient close to the defect. Separating media (vaseline) was applied over the defect area to avoid POP bind to the scalp. Required quantity of water and powder (POP) was mixed in rubber bowl and once it reached a sufficient consistency, POP was poured onto the defect. It was contoured to the shape of lost cranial fragment by comparing with normal opposing side (Fig. 3). Once the POP had reached its initial setting time, alginate impression material was manipulated and loaded onto the contoured POP with slight overextension along the border of skull defect (Fig. 4). Once the alginate was about to set, a stiff roughened wooden/plastic board that acts as an impression tray was seated over the material and stabilised with a finger at its center (Fig. 5). This helps to confine and control the impression material. Additional materials were added so that borders were refined to cover and reproduce all the areas of defect. Impression was removed carefully

Fig. 3 Contoured POP over patient's head to mimic normal shape of scalp

Fig. 6 Impression of the contoured skull defect

Fig. 4 Alginate impression material loaded onto contoured POP

Fig. 7 Master cast showing the outline of the defect

Fig. 5 Stiff roughened wooden board acting as impression tray

without distortion (Fig. 6). Positive replica of impression was made over the flat surface of slab with sufficient base using dental stone immediately after removal. The master cast was then removed after an hour of initial set. Outline of the marginal defect would then be evident on the cast (Fig. 7). As aesthetics was one of the primary concerns, the wax pattern was adapted with sufficient thickness for the proper fabrication of prosthesis (Fig. 8). Along with

Fig. 8 Wax pattern of adequate thickness adapted to master cast

Neurosurgeons, Maxillofacial surgeons evaluate the border and thickness of wax pattern by directly visualizing the cranial defect before sending it to the dental lab.

Fig. 9 Patient with skull defect on whom ‘try in’ was done with original bone flap

Fig. 10 Dental flask and clamp of larger size

Chair Side Procedures When Original Bone Flap is Available

In tertiary care hospital like ours, when a decompressive craniectomy was performed, the bone flaps were cleaned, autoclaved and stored in plastic bags with a unique identification tag. When patient was fit for undergoing cranioplasty procedure, the bone flaps of that patient were then identified. Bone flaps were sometimes available in multiple pieces. Bone flaps that were in pieces were aligned using sticky wax. ‘Try in’ was done over patient’s shaved head to evaluate any deficit (Fig. 9). If there was any deficit, wax pattern was obtained from the area of defect and then sent to dental lab.

Fig. 11 Cast with wax pattern immersed into plaster filled base

Lab Procedures

We use compression molding technique in the fabrication of the prosthesis. Base of the cast was trimmed so that it will fit into the processing flask. Flask contains 2 parts, a base of about 8 cm and a lid of about 6 cm height, both having diameter of 25 cm (approximately). Accordingly, clamp of larger size was used. This large size dental flask and clamp helps in fabrication of prosthesis of larger defect (Fig. 10).

De-waxing

The wax pattern was sealed to the cast using additional wax and then invested in two halves of dental flask with dental plaster using 2 pour technique. First the base of flask was filled with dental plaster, and then the cast with wax pattern was immersed into the plaster filled base (Fig. 11). After allowing it to set, separating media (cold mold seal) was applied. Lid portion was then filled with second pour of dental plaster and bottom portion (base) was fitted over the

Fig. 12 Bottom portion fitted over the plaster filled lid portion

Fig. 13 Separated flask after dewaxing showing mold space

Fig. 14 Bone flap immersed into plaster filled base

top portion (lid) (Fig. 12). After allowing the plaster to set, flask was placed in the clamp and was tightened. De-waxing was done by placing the flask in boiling water for 10 min. Flask was separated carefully and flushed with hot water to remove softened wax. A mold space was created for filling the acrylic material (Fig. 13).

Fig. 15 Bone flap separated showing mold space

Fig. 16 Separating media applied to mold space

When a bone flap is available, vaselined bone flap is invested directly into dental flask using 2 pour technique with application of separating media between the two halves of plaster as mentioned earlier (Fig. 14). After the plaster sets, flask is separated and the bone flap is removed (Fig. 15). By this method, negative impression of bone flap with exact width, size and shape is obtained in the plaster.

Packing

In the mold space created by either of the methods, separating media was applied (Fig. 16). Clear acrylic was then mixed in the ratio 3:1 (P:L) by volume. Clear acrylic was preferable as it shows blanching of tissues when placed intraoperatively that helps in relieving the pressure points for the neurosurgeon. When the mixture reaches the dough stage, sufficient dough was placed in the mold space and trial closure done (Fig. 17). Excess material was taken off and closed. Flask was tightened in the clamp and placed in boiling water for one and half hours at 65 °C. After curing cycle completes, it was allowed to bench cool for an hour. De-flasking was then done carefully (Figs. 18, 19).

Fig. 17 Clear acrylic packed into mold space

Fig. 18 Curing cycle at 65° for 1½ hours

Fig. 19 Cured acrylic plate

Fig. 20 Holes placed around the periphery and in center

Cranioplasty plate was then trimmed, sand papered and pumice washed.

To aid neurosurgeon, burr holes were placed at 1 cm intervals along the borders of the plate about 1 cm from periphery. This helps the neurosurgeon to secure the plate with sutures or with mini plates. Three to four holes were made in the center of the plate to prevent infection due to accumulation of fluid under the plate after the surgery (Fig. 20). Acrylic plate was then sterilized with ETO for 24 h. At this stage the acrylic plate was ready for implantation.

Results

Twenty-nine patients with pre-surgically fabricated pre-sterilized PMMA plate were evaluated post-surgically for post-op complication such as infection, post-op hematoma, chronic pain and biocompatibility (any adverse bony changes in the surrounding bone) and post-op dimensional changes of prosthesis.

In the first post operative week, none of the patients had any type of complications related to the procedure. During

Fig. 21 CT 3D image A–P view showing PMMA plate

Fig. 22 CT 3D image lateral view showing PMMA plate

the follow up visits, 5 (17.2 %) patients developed complications. They reported with swelling and pain in the cranioplasty site. One patient was treated conservatively with antibiotics. Tapping was performed in couple of patients. Surgical evacuation of hematoma was performed in one patient. After intervention, infection subsided thus we were able to secure the plates in all these patients. This shows infection may be related to hematoma that followed surgery rather than to the material used.

In our study, only one out of 29 patients underwent removal. So the removal rate of the plate is 3.45 %. One patient complained of chronic pain (3.45 %). The overall complication rate is 24.13 %. Post-op dimension of the plate assessed in the follow up CT showed no dimensional changes and showed no resorption of the surrounding bones (Figs. 21, 22). Post-op follow up assessed clinically confirmed skull continuity, thereby restoring the contour defect that arose as a result of decompressive craniectomy. Aesthetics was successfully achieved in all cases (Fig. 23).

Fig. 23 Post-op photograph of the patient restoring the contour defect

Discussion

For a long period of time, autografts and synthetic materials are used in the reconstruction of cranial defect. In synthetic materials, non-metal allografts (such as celluloid, hydroxyapatite, polymethyl methacrylate), and metal allografts (such as titanium, tantalum) are used. Each of the materials offer unique advantages/disadvantages. The most concerning factor in the selection of material in reconstructing the cranial defect is aesthetics and its cost factor.

In case of autografts, dry freezing the bone flap or saving the graft in abdominal fat are documented. It is observed that surgeons found difficulty in harvesting due to post-op complications [1]. Resorption and transmission of infections are also common.

Metal allografts gain popularity because of their strength and availability. Titanium plates are sensitive to the technique used and are difficult to fabricate because of its inability to mold easily [1]. Its radio opacity limits any roentgenographic examination which is necessary in post-op tumor resected patient. This is the main reason that non-metallic substitutes become popular. With scientific advances, computer based implant fabrication methods (CAD/CAM associated titanium prosthesis) serve as almost perfect means to reconstruct facial deficiencies in complex situations. They offer perfect design and fit [2] but are too costly for rehabilitation.

In non-metal allografts PMMA gained importance than others. PMMA, a well known material in dentistry, has proved to be a reliable material in the long run because of its physical strength and biocompatibility. There are many studies that demonstrate the usefulness of PMMA as cranioplasty material. However, methyl methacrylate molded intra-operatively with cold-cure acrylic materials provide complexity in shaping three dimensionally and is time consuming during trimming and finishing. As the material sets by chemical reaction, the heat liberated may damage surrounding tissues that leads to collection of exudates and infection [3].

Present study shows pre-surgically fabricated pre-sterilized methyl methacrylate plate has many properties that are ideal for a cranioplasty material. It allows the physician to perform a trial check on patient's head before fabrication which ensures proper dimension and thereby near adaptation of plate to cranium. As excess material is trimmed off preoperatively, it reduces intra-operative time considerably [4]. It has low infection rate due to pre-sterilization. Its biocompatibility is due to low intrinsic toxicity and low inflammatory activation. Based on projection to cranial bone, with low infection rate, it appears to offer protection similar to that of native osseous tissue [5]. It is dimensionally stable with improved physical properties, has low heat conduction rate compared to titanium plates and is radiolucent. It eliminates thermal injuries to tissues that could occur in intra-operatively cured PMMA plates.

Technique described in our study is simple and cost effective. Yamamoto et al. [6] has described a simple technique using alginate impression material. Different techniques have been documented. Advantage of the technique showed in our study is the ability to modify the skull contour before taking the impression. This helps in obtaining prosthesis with proper shape and dimension. Routine compression molding technique in fabrication of denture made the technique simple. This technique produces satisfactory result at significantly lower cost than techniques that seek help from sophisticated computer based softwares.

Prefabricated plates constructed using patient's own bone flap provide exact duplication and excellent results in terms of anatomical reconstruction [7]. Its perfect fit provides satisfactory esthetic results. Except for a rare complication of delayed hypersensitivity reaction, it appears as a proven method of rehabilitation [8]. In the present study, good results were achieved with prefabricated acrylic plates. Thus it can be considered as one of the preferred material of choice to repair cranial defect.

Conclusion

In conclusion though sample size is too small, the result of the study suggests that the use of heat cure PMMA plate is simple, convenient, cost effective, very much appreciated by surgeon and the patient as well. It has the ability to satisfy the functional and aesthetic demands of the patients by allowing them to regain their social life.

Acknowledgments Dr. Senthil Kumar, MDS, Sri Ramakrishna Dental College and Hospital, Coimbatore. This study did not draw support from any individual or institution.

Conflict of interest None.

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