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Clinical Study

Cranioplasty using polymethyl methacrylate prostheses

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Abstract

In this retrospective study we attempted to assess the clinical performance of prefabricated polymethyl methacrylate (PMMA) prostheses and to determine whether they outperform intra-operatively moulded PMMA prostheses in reducing operating time, blood loss and surgical complications in elective delayed cranioplasty operations, after decompressive craniectomy, to repair large (> 100 cm^2) cranial defects. Patients ($n = 131$) were divided into three groups according to the cranioplasty technique used. Group 1 patients received fresh frozen autograft bone that had been removed at the craniectomy and refrigerated at -80 °C. Group 2 included patients whose PMMA prosthesis was moulded intra-operatively. Group 3 patients received a custom-made prefabricated PMMA prosthesis manufactured using computer-aided design/computer-aided manufacturing (CAD/CAM). Group 2 patients required significantly more operating time than both group 1 ($p < 0.001$) and group 3 ($p < 0.001$) patients, but operating time did not differ significantly between groups 1 and 3 ($p > 0.05$). Mean intra-operative blood loss was significantly higher in group 2 than in group 1 ($p = 0.015$) but did not differ significantly between group 1 and group 3 ($p > 0.05$). The infection rate associated with prefabricated PMMA prostheses was lower than that for intra-operatively moulded PMMA prostheses and was comparable to that for autograft bone flaps. A CAD/CAM PMMA prosthesis is an excellent alternative when no autogenous bone graft harvested during craniectomy is available.

Keywords: Computer-aided design; Computer-aided manufacturing; Craniectomy; Cranioplasty; Polymethyl methacrylate; Prosthesis

1. Introduction

Decompressive craniectomy, to increase the volume of the intracranial cavity, is a treatment of last resort for intracranial hypertension refractory to medical therapy.[1–6] A successful procedure not only increases survival, but also improves patient functional outcome. However, replacement of the skull bone during surgery is not possible in this procedure, resulting in a large skull defect that may require subsequent cranioplasty. Cranioplasty is often performed for aesthetic purposes or to ensure protection of the underlying neural tissue.[7,8] Cranioplasty can be described as a procedure not only for anatomical reconstruction but also for neurological improvement of the underlying physiology, including cerebral hemodynamics and metabolism.[9–13] A range of materials can be used to repair cranial defects, including autograft bone, allograft bone, xenograft bone and bone substitues.[14–17] Fresh frozen autogenous bone grafts obtained during the initial operation are excellent for delayed cranioplasty. However, when the autogenous bone graft is unavailable, a prosthesis may be necessary. Polymethyl methacrylate (PMMA) has long been used as a substrate for cranioplasties, and intra-operatively moulded prostheses are still very widely used in cranioplasties.[8,13,18] Since 1998, rapid developments in medical imaging and computational modeling have enabled fabrication of custom-made implants using computer-aided

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design/computer-aided manufacturing (CAD/CAM).[19–25] Prefabricated prostheses can now be precisely tailored to the shape of complex craniofacial defects. Many practitioners believe that a prosthesis prefabricated by computer modeling not only improves aesthetic outcome, but also minimizes operating time, blood loss and risk of infection.[26] In this retrospective study we aimed to assess the clinical performance of prefabricated PMMA prostheses and to determine whether they outperform intra-operatively moulded PMMA prostheses in reducing operating time, blood loss and surgical complications.

2. Materials and methods

In this four-year study we reviewed 131 elective delayed cranioplasty operations, performed at this institution after decompressive craniectomy, to repair large ($>100\ cm^2$) cranial defects. Patients who underwent other surgical procedures such as cerebrospinal fluid diversion surgery, plastic/cosmetic surgery or surgery other than the cranioplasty during the same anesthetic session were excluded. Patients were evaluated pre-operatively and all were considered clinically and neurologically stable and free of organ system infection.

In each patient, the bone graft or cranioplastic prosthesis was surgically fixed to the skull using titanium plates and screws after dural tenting. Patients were divided into three groups according to the cranioplasty technique that was used. Group 1 patients received fresh frozen autograft bone removed via craniectomy surgery and refrigerated at −80°C. The banked bone was warmed to room temperature before use in repairing the cranial defect. If a fresh frozen autograft was unavailable, a PMMA prosthesis was used. Group 2 included patients whose PMMA prosthesis was moulded intra-operatively. Their implants were fashioned by mixing a poly [(methyl methacrylate) – co-Styrene] copolymer powder and a methyl methacrylate liquid at a ratio of about 2:1 (Osteobond, Zimmer, Warsaw, IN, USA). After several minutes of thorough mixing, the mixture reached mouldable viscosity and was poured into the cranial defect. The dura and brain were protected from the heat produced from the PMMA polymerization process by placement of moist Gelfoam between the dura and the hardening prosthesis. The PMMA prosthesis was shaped to achieve a smooth surface conforming to the normal contours of the skull. The prosthesis was constantly irrigated with cold saline until completion of the exothermic hardening process. Using a high-speed burr or other hand-held instrument, the prosthesis was then polished to achieve a good fit to the skull defect, to imitate the normal contour of the skull. Group 3 patients received a custom-made prefabricated PMMA prosthesis manufactured using CAD/CAM. All patients were informed pre-operatively that the described method was likely to achieve a cosmetic outcome superior to that of the conventional pour-in method. A pre-operative transversal 1-mm spiral CT scan with three-dimensional (3D) reconstruction of the cranium was performed before surgery. The Digital Imaging and Communications in Medicine (DICOM) data were then downloaded to medical imaging visualization software for editing (CranMed version 1.0.0, Medical Augmented Reality Research Center, Chang Gung University and Chang Gung Memorial Hospital, Taoyuan, Taiwan) (Fig. 1a). An image of the implant was generated by a digital subtraction mirror-imaging process whereby the normal side of the cranium is used as a model (Fig. 1b–i). The data for the border of the skull defect represented the framework from which the implant could be constructed, so about 1 cm around the skull defect was cut out. The 3D-CAD data were sent to a 3D printer (Dimension SST 768, Stratasys, Eden Prairie, MN, USA) and then 3D printed using acrylonitrile-butadiene-styrene copolymer (Fig. 2a,b). The master implant was finished for a precise fit to the skull biomodel then used to create an impression cavity mould (Fig 2c,d). Heat-curing methyl methacrylate (MMA) was mixed and the PMMA prosthesis was formed by compression into the mould. Each PMMA implant was sterilized by gas or autoclaving.

Patient data recorded included clinical history, diagnosis, type of cranioplastic graft material used, estimated operative blood loss, operative time, and surgical morbidity, including bone graft infection (if any). Clinical follow-up occurred for a minimum of 6 months. ‘‘Bone graft infection” in this study was defined as infection requiring removal of a bone graft. Local wound erythematous change or infection treated successfully with antibiotics and not necessitating bone flap removal were not considered bone graft infection.[27] Data were analyzed using descriptive statistics: The chi-square test and one-way analysis of variance (ANOVA) or *post hoc* comparison as appropriate. A p value of < 0.05 was considered statistically significant.

3. Results

The time between the craniectomy and the cranioplasty operation ranged from 3 to 28 months. Table 1 shows basic clinical data, operative time and operative blood loss. In group 1 there were 91 cranioplasty operations in 62 male and 29 female patients, aged 16 to 83 years (mean 43.84 ± 17.91 years). Group 2 and 3 patients underwent 23 and 17 operations, respectively. Group 2 included 14 males and nine females aged 17 to 72 years (mean, 40.96 ± 15.48 years). Group 3 included 12 males and five females aged 19 to 57 years (mean 40.24 ± 11.97 years). The three groups of patients did not significantly differ in age or gender ($p > 0.05$). Three patients in group 2 and two patients in group 3 had bone resorption after previous autograft cranioplasty and therefore PMMA cranioplasty was performed.

Mean operating time in group 1 was 138.05 ± 3.74 min. Mean operating times in groups 2 and 3 were