Journal of Cranio-Maxillo-Facial Surgery 45 (2017) 295–303

Contents lists available at ScienceDirect

Journal of Cranio-Maxillo-Facial Surgery

journal homepage: www.jcmfs.com

Patient-specific polymethylmethacrylate prostheses for secondary reconstruction of large calvarial defects: A retrospective feasibility study of a new intraoperative moulding device for cranioplasty

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ARTICLE INFO

Article history:
Paper received 16 August 2016
Accepted 22 November 2016
Available online 30 November 2016

Keywords:
Cranioplasty
PMMA
Patient-specific
CAD/CAM
CranioTool™

ABSTRACT

Purpose: The aim of this study was to review a new template-based technique for intraoperative patient-specific cranioplasty manufacturing (PSCM) with polymethylmethacrylate (PMMA) to cover large calvarial defects.

Material and methods: A polypropylene foil thermoformed on a three-dimensional reprint of the calvarial defect was used as an intraoperative moulding device for PMMA between August 2012 and December 2015. Surgical and radiological data were retrospectively reviewed, and a patient questionnaire was used to assess functional and cosmetic outcome (numeric rating scale, Odom's criteria).

Results: Seventeen patients (mean age 42.2 ± 14.5 years) received PSCM. Operating time averaged 130 ± 34 min, and the approximate blood loss was 293 ± 185 ml. Volumetric analysis revealed a lower implant volume compared to index bone (mean 66.5 vs. 72 cm^3, $p = 0.513$), the mean difference in thickness being the lowest in the posterior parietal and pterional (0.4–0.7 mm) and the highest in the anterior–superior frontal area (1.8 mm). Cosmetic satisfaction averaged 9 ± 1.5, with 70.6% of patients judging the overall result as excellent or good and 29.4% as satisfactory. Mean follow-up was 19.5 ± 13.3 months, with an overall complication rate of 17.6%, including 11.8% surgical site infections (SSIs) and one implant removal.

Conclusions: Intraoperative PSCM using PMMA moulded on a thermoformed polypropylene foil leads to satisfactory outcomes. It is a safe technique with complication rates comparable but not superior to those of other alloplastic techniques, but the device has considerable production costs.

1. Introduction

Interval cranioplasty following decompressive cranial surgery is a standard surgical procedure with the aim of restoring adequate protection of the central nervous system (CNS), improving aesthetic appearance (Goldstein et al., 2013; Dujovny et al., 1997; Fischer et al., 2012) and even facilitating neurological recovery and rehabilitation by improving cerebral haemodynamics and metabolism (Kuo et al., 2004; Song et al., 2014; Winkler et al., 2000). While re-implantation of the cryoconserved autologous bone flap is an inexpensive and easy method of cranial reconstruction, it needs storing infrastructure and might be associated with aseptic necrosis and delayed resorption of the flap (Sundseth et al., 2014; Lethaus et al., 2014; Stieglitz et al., 2015; Mracek et al., 2015; Kriegel et al., 2007; Lee et al., 2009), which is especially the case in paediatric patients (Martin et al., 2014; Kriegel et al., 2007). Therefore, and because the autologous bone flap cannot be used in all instances (e.g. bone-infiltrating tumours, infection, severe traumatic destruction) or is simply unavailable, numerous allograft techniques with varying materials have been used (Chim and Schantz, 2005; Shah et al., 2014; Harris et al., 2014; Feroze et al., 2015), but empirically there is no clear superiority of a certain material and a high cost variability. Advances in computer-aided design/computer-aided manufacturing (CAD/CAM) have led to a growing number of patient-specific implants (PSIs) in reconstructive cranial surgery during the last two decades (Chiarini et al., 2004; Joffe et al., 1999; Winder et al., 1999; Saringer et al., 2002; D'Urso et al., 2000; Wulf et al., 2005; Wiggins et al., 2013; Kasprzak

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http://dx.doi.org/10.1016/j.jcms.2016.11.016
1010-5182/

et al., 2012; Eufinger et al., 2005; Rotaru et al., 2012; Dean et al., 2003; Chim and Schantz, 2005; Bonda et al., 2015; Kim et al., 2012; Fiaschi et al., 2016).

In conjunction with a Swiss engineering institute for rapid prototyping and additive manufacturing (Irpd AG, St. Gallen, Switzerland), a new technique for patient-specific cranioplasty manufacturing (PSCM) consisting of a thermoformed polypropylene foil used as a sterile template for intraoperative application and moulding of polymethylmethacrylate (PMMA) was developed and introduced into clinical practice. This technique was intended to surgically facilitate cranioplasty, improve cosmetic outcome, and overcome possible disadvantages related to hand-kneaded PMMA. The aim of this study was to critically review this surgical technique with regard to perioperative complications, revision surgeries including implant failure, costs, and radiological, functional, and cosmetic outcomes.

2. Materials and methods

2.1. Ethical approval

Institutional review board approval was obtained from the Ethical Committee of the Canton St. Gallen (ID number EKSG 15/120). All individual participants included in this study gave written informed consent (WIC) for the collection of health-related data according to the Swiss Federal Act 810.30 (Humanforschungsgesetz [HFG]).

2.2. Study patients and clinical and procedure-related data

Following institutional review board approval and after receiving WIC, surgical and radiological data were retrospectively collected and analysed from patients who had received PSCM using PMMA on a thermoformed polypropylene foil between August 2012 and December 2015 at our neurosurgical tertiary care centre. Data were extracted from the clinic's patient management and documentation software. Upon recruitment into the study patients were asked to fill out a paper questionnaire concerning clinical and cosmetic outcomes using Odom's criteria (excellent, good, satisfactory, poor) and a numeric rating scale (NRS) with ranges between 0 ('not at all' or 'none') and 10 ('very satisfied' or 'most severe'). Ten easy-to-understand questions in the German language were used concerning overall satisfaction (Odom's criteria), foreign body sensation, headache (NRS), improvements in quality of life, redo surgery knowing the result, cosmetic satisfaction (NRS), personal beliefs about the purpose of cranioplasty, and cranial surgery outside our institution after PSCM (yes/no). Cranioplasty failure was defined as definitive removal of a PSI.

2.3. Thermoforming and template production

Digital Imaging and Communications in Medicine (DICOM) data of 1-mm-sliced computed tomography (CT) scans of the trephined skull were converted into a three-dimensional computer model in stereolithography (STL) with Mimics® (Materialise, Leuven, Belgium). Using Geomagic® Studio (3D Systems, Rock Hill, South Carolina, USA), the inner border of the intact opposite hemicranium (index bone), corresponding to the dura in physiological circumstances, was mirrored and interpolated into the calvarial defect representing a digital negative form (Fig. 1), which was then repositioned and framed for the conservation of geometry. Within this step, the thickness of the latter polypropylene foil (0.9 mm) was already incorporated via circumferential subtraction adding another millimetre due to the scar tissue that overlies the bony edges of the defect. This was done to improve fitting accuracy without the necessity of meticulous resection of scar tissue during surgery. The digital planning report was reviewed by the surgeon in charge and validated. Finally, the reprint was produced with selective laser sintering (SLS) using the EOS P760 (EOS GmbH Electro Optical Systems, Krailing/Munich, Germany) and shipped for thermoforming a 0.9-mm transparent polypropylene foil (Ecoterm S 900 T1, Medipack AG, Schaffhausen, Switzerland). This foil was applicable for medical and pharmaceutical packaging, and all components of this product complied with the European Parliament and Council Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with food as well as the United States Food and Drug Administration (FDA) Code for regulations (CFR) for food packaging (FDA 21 CFR 177.1520), the foil being approved for a working temperature of 0–100 °C and a short-time maximum heat exposure of 130–140 °C [personal communication]. The formed and cured polypropylene foil was sterilized and packed (Fig. 2A) (Synergy Health AG, Däniken, Switzerland). Quality control included visual control after thermoforming and additional three-dimensional scanning to digitally verify the correct geometry with Geomagic® Studio (3D Systems, Rock Hill, United States). In total, five patient-specific foils were produced: two were sent to the surgeon (one for backup in case of contamination before or during surgery), one was used for quality control purposes, and two remained at the planning engineering institute (additional backup). Time expenditure was about 10–14 days from sending the CT data until receiving the final product. The fixed costs per order were CHF 5500, equalling USD 5675 according to current exchange rates.

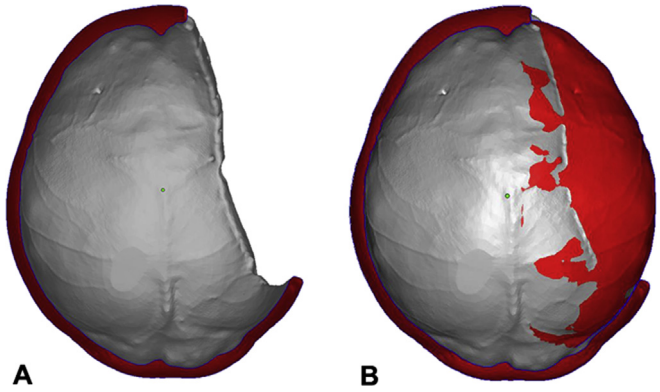

Fig. 1. Digital reconstruction of a calvarial defect using Geomagic® Studio. A) Axial illustration of a left-sided bony calvarial defect following decompressive skull surgery (red). B) The dura of the opposite hemicranium (index bone) was mirrored and interpolated into the defect representing a digital negative form, which was printed with SLS and later used for thermoforming a 0.9-mm polypropylene foil. See Fig. 4B for the radiological result of PSCM in this patient.

2.4. Introduction into clinical practice

An independent expert analysis found that the thermoformed polypropylene foil used as a template (CranioTool™) was not considered a medical device according to European Council Directive 93/42/EEC or Swiss Federal Act 812.21 (Heilmittelgesetz [HMG]) [personal communication]. Following rapid product development, it was introduced into clinical practice in August 2012. As the potential benefits of the technique were found to be fairly good after the first few cases, and the cosmetic and radiological results favourable, it was established as the first-choice method for interval cranioplasty of large calvarial defects at our institution.