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Custom-made titanium cranioplasty: early and late complications of 151 cranioplasties and review of the literature

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Abstract. A diverse range of techniques is available for reconstruction of full-thickness calvarial defects and the optimum substrate for cranioplasty remains unproven. During a 9-year period, 149 patients underwent insertion of 151 custom-made titanium cranioplasties using the same technique. Data relating to patient demographics, indication for cranioplasty, and site and size of the defect were collected from the clinical records. Patients were followed up in all cases for a mean of 1 year 2 months (range 7 days to 8 years 8 months). Early complications requiring intervention were experienced in 7% and included seroma, haematoma, and continued bleeding necessitating implant removal in one patient. One death occurred at 3 days post-operation due to haemorrhagic stroke. Late self-limiting complications such as seroma were experienced in 19% of patients, however complete failure requiring implant removal was seen in only 4% of cases. Infection was the cause of failure in all cases. A comprehensive literature review was carried out and data abstracted to compare reported failure rates in other techniques of full-thickness cranial reconstruction. This review shows that custom-made patient-specific titanium cranioplasties compare very favourably to the other published techniques and remain a tried and tested option for reconstruction of all sizes of full-thickness calvarial defect.

Key words: calvarial reconstruction; cranioplasty; cranial implant.

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Full-thickness calvarial defects continue to challenge reconstructive surgeons. Defects of the cranium can arise from a wide range of pathological processes or from therapeutic interventions. Reconstruction of these defects is necessary to restore normal craniofacial cosmesis and to protect the otherwise exposed brain from trauma. The ideal cranioplasty technique should produce excellent aesthetics, the ability to withstand direct trauma without failure, have minimal effects on the

patient in terms of morbidity, and be stable in the long term. Although there are reports of cognitive improvement following cranioplasty and resolution of the so-called 'syndrome of the trephined',[1–3] currently it is the cosmetic and protective benefits of reconstructing the cranium that are the motivation for undertaking this type of surgery.[4]

Cranioplasty is one of the oldest known surgical procedures, with archaeological evidence of ancient Incans using gold to reconstruct trephination holes around 3000 BC.[5] The earliest written account of cranioplasty dates from 1505 when Ibrahim bin Abdullah, an Ottoman-era military surgeon, advocated the use of a cranial xenograft from a goat or dog.[6] In 1561, in *Observationes Anatomicae*, the Italian Fallopius described cranioplasty with a gold Plate.[5] As a result of this long history and as a testament to the complexity of cranial reconstruction, various techniques have been developed to repair these defects using autografts,[7–12] allografts,[13–15] and various biomaterials including gold, stainless steel, vitallium, tantalum, titanium, polythene, methylmethacrylate, polyether ether ketones (PEEK), acrylic, ceramics, and bioactive glass, used alone or in combination.[5,16–25] There is no ideal technique as each method has its limitations. When autografts are utilized, problems are encountered with satisfactory graft contour and long-term stability, particularly as regards resorption,[26–29] along with potential donor site morbidity.[10] High infection rates and material failure have been reported with biomaterials.[30–33]

This study is a retrospective review of early and late complications following cranioplasty in all patients who underwent custom-made titanium plate reconstruction of full-thickness calvarial defects carried out at a tertiary level hospital in London, UK.

Materials and method

In this retrospective study, operation records and the laboratory database were used to identify all patients who underwent titanium cranioplasty using a patient-specific custom-made implant at a tertiary level hospital in London between 2001 and 2010. Only patients with full-thickness calvarial defects were included in this study. Clinical records were analysed and data collected on patient demographics, age at operation, indication for cranioplasty, interval between acquisition of defect and reconstruction, length of inpatient stay, length of follow-up, defect site, defect surface area, complications arising early (defined as occurring during admission) and late complications (defined as arising after discharge). Postoperative follow-up was achieved in all cases; in six cases, the patient's general practitioner was contacted to identify complications as the hospital records were incomplete.

A literature search was undertaken of PubMed and Science Direct using the search terms 'cranioplasty', 'calvarial reconstruction', 'cranial reconstruction', 'cranial defect' and 'calvarial defect'. Returned search articles and their references were used to identify articles reporting complications of cranioplasty. Data were then abstracted from these studies to identify the reported failure rates for the commonly used cranioplasty materials to be used as comparison for the outcome of cranioplasties in the series from the study hospital. Criteria applied to studies for data abstraction were the following: (1) case series reporting the outcome in at least seven patients; (2) publication date during or after 1995; (3) the reported reconstruction method was for full-thickness cranial defects in humans; (4) the failure rate pertaining to each reported method was clearly stated or calculable from the published data. Series of composite reconstruction, i.e. cranioplasty and simultaneous microvascular scalp reconstruction, and case series of allograft cranioplasty were not included in the literature review. The follow-up period and defect size were also recorded if stated or calculable from the data presented in the papers.

Manufacture of implant and surgical technique

DICOM data from a fine cut craniofacial computed tomography (CT) scan (1 mm slice, 0° gantry angle) is converted to STL file format to generate a stereolithographic model using rapid prototyping. This model of the defect and surrounding calvarium is invested in plaster and used in a hydraulic press to cold form 0.8-mm thick titanium sheet. The moulded sheet is trimmed to leave a 1 cm margin of titanium to contact the bony edges of the defect. Several holes are drilled at the periphery of the plate to allow screw insertion for fixation, and multiple holes drilled in the central part of the plate to allow extradural fluid collections to drain via vacuum drains. The holes drilled centrally also allow placement of looped PDS sutures hitching the dura to the plate to reduce the extradural space and prevent fluid collections from exerting a space-occupying lesion effect on the brain parenchyma. After polishing, the cranioplasty plate is anodized and treated with nitric acid. Sterilization is by autoclave prior to insertion into the patient.

Surgical access predominantly utilizes existing scars; however if previous incisions have been made in an unfavourable fashion, a bicoronal approach is used to maximize the vascularity of the scalp. The titanium cranioplasty implant is secured with 2-mm titanium screws and the scalp closed in layers with vacuum drains inserted between the scalp and cranioplasty plate. Drains are usually removed at 48 h. A tight head bandage is applied and left *in situ* until review at 10 days post operation (Fig. 1).

Results

For a period of 9 years between August 2001 and August 2010, 149 patients underwent insertion of 151 custom-made titanium cranioplasties for reconstruction of full-thickness calvarial defects. Two patients had bilateral defects reconstructed with individual plates.

Seventy-two percent of the patients in this series were male. The average age at operation was 36 years (median 37, mode 56, range 6–78 years). Four of the cranioplasties were carried out as immediate reconstructions following tumour resection; the remainder involved either congenital deformity or delayed reconstruction carried out at an interval following initial craniectomy. The injury date for 13 patients was unknown. For the remaining 133 patients, the average interval between cranial defect and insertion of the cranioplasty was 2 years 1 month (median 1 year, mode 10 months, range 2.5 months to 28 years 9 months). The mean follow-up to discharge was 1 year 2 months (median 5 months, range 7 days to 8 years 8 months). The average length of the inpatient episode was 6.4 days (median 4, mode 4, range 2–121 days).

Data on the defect size was accurately calculated using the volume rendering function of the CT scan software (Centricity PACS/AW Suite; GE Healthcare). Due to a change in software used in the hospital we were unable to calculate the accurate surface area for 28 patients. Of the remaining 123 patients, the average defect surface area was 67.5 cm^2 (median 65, mode 78.4, range 5.3–173.7 cm^2). Very large defects were reconstructed in this group of patients, with 45 implants (36%) being inserted for defects with a surface area greater than 80 cm^2 (Table 1). The sites of the defects are illustrated in Fig. 2.