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The therapeutic effect of patient-specific implants in cranioplasty

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ABSTRACT

Objective: Patient specific implants have been used for the reconstruction of large skull bone defects. Several therapeutic effects have been suggested in current literature but were never objectified. The aim of the current study was to evaluate the change in quality of life, pain, aesthetics, and the surgical and medical outcomes after reconstruction of large skull bone defects with titanium or polyetheretherketone (PEEK) implants.

Methods: We retrospectively evaluated 29 consecutive patients receiving a patient specific skull implant between November 2004 and December 2015. Twenty-one patients received PEEK implants and eight received titanium implants. Data was acquired regarding quality of life, aesthetics, pain, demographics and complications. Quality of life was measured using the Glasgow Benefit Inventory (GBI). Additional questions were asked concerning pain, satisfaction and aesthetics.

Results: The mean total GBI-score was +26.1 (95%CI 16.8–35.4, $p < 0.001$). Headache complaints or pain in the operation site improved in 75.0% and 77.8% of these patients, respectively. In 8.0% an increase was seen with regard to both variables.

Conclusion: Reconstruction of skull bone defects with PEEK and titanium patient specific implants gave a statistically significant improvement in quality of life. Furthermore, it decreased pain and headaches and gave aesthetically good results.

1. Introduction

Large skull bone defects of the cranial vault can result from decompressive surgery due to trauma, cerebral infections or the resection of intracranial processes or bone invading skin tumours. Defects in the cranial vault leave the brain exposed and unprotected against external forces and atmospheric pressure. A reconstruction of the cranial vault is not only desired for protective and aesthetic reasons, but is also required for maintenance and restoration of the physiological circulatory system of the cerebrum to regulate the intracranial pressure (Winkler et al., 2000; Alibhai et al., 2013). The reconstructive procedure, known as cranioplasty, can be carried out according to various techniques using different materials. Contemporarily, autologous bone still remains the material of first choice because of its lack of immune reactivity and its possible integration in the remaining bone due to its osteoconductivity. However, complications like resorption and infection of the bone specimen, or just the sheer size or complex morphology of the defect often create the need for alloplastic alternatives. In addition to the standard methods, such as the application of titanium meshes or polymethylmethacrylate (PMMA) cements, computer aided design and manufacturing techniques (CAD/CAM) have become an emerging field of interest in recent years. These have allowed for creating patient-specific implants (PSI) of any size with an accurate fit, reduced operation time resulting in excellent skull contours.

After craniectomy patients frequently suffer from pain or headaches (Rocha-Filho, 2015). Wehmöller et al. showed that the reconstruction of large skull bone defects with titanium PSI's contributes to pain reduction (Wehmöller et al., 2004). In the literature there are indications that reconstruction of large skull bone defects with PSI's could also increase postoperative quality of life (QoL) (Wehmöller et al., 2004; Eufinger et al., 2005; Cabraja et al., 2009). The shortcoming of these studies is that they did not objectify this

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hypothesis using validated measuring methods. Although improvement of QoL is one of the most important treatment goals, to date a change in QoL after cranioplasty with PSI's has never been properly measured with standardized validated instruments. Therefore, the aim of the present study was to evaluate the impact of the reconstruction of large skull bone defects using titanium or PEEK PSI's, on QoL.

2. Material and Methods

2.1. Patients

We retrospectively evaluated 29 consecutive patients, receiving PSI's between November 2004 and December 2015, in the Department of Cranio-Maxillofacial Surgery at Maastricht University Medical Centre (MUMC). Data were acquired regarding demographic, surgical and medical aspects and complications. An overview of patient demographic data is presented in Table 1. The anatomical locations of the defects are shown in Fig. 1.

2.2. Procedures

All patients were diagnosed, surgically planned and treated according to a standardized treatment protocol published earlier (Lethaus et al., 2011). All implants were manufactured by either IDEE (Instrument Development Engineering & Evaluation, Maastricht, The Netherlands) or Xilloc Medical (XILLOC Medical B.V., Geleen, The Netherlands). Titanium implants were made by milling or electron beam melting, all PEEK-implants were milled (Lethaus et al., 2011, 2014b).

The effect of the procedure on quality of life was measured using the Glasgow Benefit Inventory (GBI), a validated Patient Reported Outcome Measures (PROMs) (Robinson et al., 1996; Hendry et al., 2016). The questionnaires were completed by interview or filled in by the patient, if interviews were not possible. The responses were averaged and scaled giving a score ranging from −100 to +100. A score of −100 represents a maximum decrease in QoL, a score of 0 represents no changes and a score of +100 represents a maximum increase in QoL compared to the preoperative situation. The scores were divided into three subscales: a general subscale (12 questions), a social support subscale (3 questions), and a physical health subscale (3 questions). Additional questions were asked concerning pain, aesthetics and overall satisfaction.

Table 1
Patient demographics.

Patient demographic data n = 29	
Gender, n (%)	
Male	20 (69%)
Female	9 (31%)
Age at operation, mean (range)	43.2 (15–69)
Diagnosis leading to craniectomy, n (%)	
Stroke	8 (28%)
Trauma	7 (24%)
Tumour	7 (24%)
Intracranial infection	4 (14%)
Epilepsy	3 (10%)
Previous reconstruction, n (%)	
Autologous bone	17 (59%)
PMMA	2 (7%)
Titanium mesh	1 (3%)
No previous reconstruction	9 (31%)
Indication for secondary reconstruction with PSI, n (%)	
Infection original reconstruction material	13 (45%)
Resorption bone flap	4 (14%)
Persistent defect	11 (38%)
Fracture of PMMA implant	1 (3%)
Defect classification according to (Poukens et al., 2008), n (%)	
Class II	12 (41%)
Class III	15 (52%)
Class IV	2 (7%)
PSI material, n (%)	
Titanium	8 (28%)
PEEK	21 (72%)
Follow-up in months, mean (range)	56.6 (5.3–139.0)

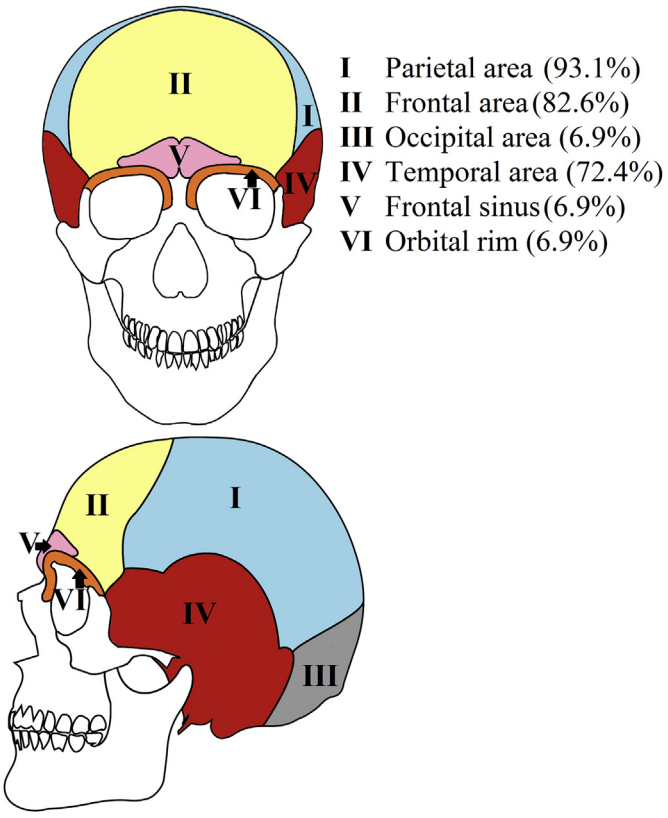

Fig. 1. Anatomical locations of the skull bone defects. Defects overlapping multiple regions account for percentages in each concerning independent region.

2.3. Statistical analysis

For statistical analysis, quantitative data was processed in SPSS (v. 23.0.0.2, IBM Corporation, Armonk, USA). Data was presented as mean, range and confidence interval (CI) if continuous, and counts (n) and percentage (%) if categorical. Missing values were replaced with series mean. Statistical analysis was done with one sample t-tests. In order to assess correlation, a Pearson product–moment correlation coefficient (2-sided) was computed. A p-value of 0.05 represents an acceptable level of statistical significance.

3. Results

Two patients (6.9%) suffered from postoperative complications. Of these patients, one underwent removal of an epidural haematoma on the third postoperative day. The PEEK implant was successfully reset. In the other patient a PEEK implant was removed due to a low grade infection with exposition of the implant. Two patients died during follow-up due to other medical reasons. One patient was excluded from the PROMs due to severe cognitive impairment making it impossible to complete the questionnaire. One patient could not be reached. After all, a total of 25 patients filled in the questionnaires. The response rate was 86%.