Is There An Optimal Time for Performing Cranioplasties? Results from a Prospective Multinational Study

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■ BACKGROUND: **The optimal timing of cranioplasty remains uncertain.**

■ OBJECTIVE: **We hypothesized that the risk of infections after primary cranioplasty in adult patients who underwent craniectomies for non–infection-related indications are no different when performed early or delayed. We tested this hypothesis in a prospective, multicenter, cohort study.**

■ METHODS: **Data were collected prospectively from 5 neurosurgical centers in the United Kingdom, Malaysia, Singapore, and Bangladesh. Only patients older than 16 years from the time of the non–infection-related craniectomy were included. The recruitment period was over 17 months, and postoperative follow-up was at least 6 months. Patient baseline characteristics, rate of infections, and incidence of hydrocephalus were collected.**

■ RESULTS: **Seventy patients were included in this study. There were 25 patients in the early cranioplasty cohort (cranioplasty performed before 12 weeks) and 45 patients in the late cranioplasty cohort (cranioplasty performed after 12 weeks). The follow-up period ranged between 16 and 34 months (mean, 23 months). Baseline characteristics were largely similar but differed only in prophylactic antibiotics received ($P = 0.28$), and primary surgeon performing cranioplasty ($P = 0.15$). There were no infections in the early cranioplasty cohort, whereas 3 infections were recorded in the late cohort. This did not reach statistical significance ($P = 0.55$).**

■ CONCLUSIONS: **Early cranioplasty in non-infection–related craniectomy is relatively safe. There does not appear to be an added advantage to delaying cranioplasties more than 12 weeks after the initial craniectomy in terms of infection reduction. There was no significant difference in infection rates or risk of hydrocephalus between the early and late cohorts.**

INTRODUCTION

The optimal timing of cranioplasty has been an area of debate within the neurosurgical faculty. Anecdotal and limited evidence from proponents of late cranioplasty suggests that such a strategy favors a lower risk of infection.[1] Others disagree and believe that an early cranioplasty is just as safe and justifiable. The reality is that the optimal timing of cranioplasty remains uncertain. There are conflicting data regarding the complication rates with either early or late cranioplasty. Moreover, all studies published are retrospective and reflect either a single institution's experience or a case series of a single surgeon.[2-12]

Our study aimed to prospectively study the rate of infections in cranioplasty performed before and after 12 weeks. To our knowledge, this is the first prospective, multicenter observational study comparing the infection rates between early and late cranioplasty.

Key words
- Cranioplasty
- Early versus late
- Infection
- Timing

Abbreviations and Acronyms
PEEK: Polyether ether ketone

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METHODS

Data were collected prospectively from 5 participating neurosurgical centers, which included Queen's Hospital (Romford, United Kingdom), St Mary's Hospital (London, United Kingdom), National University Hospital (Singapore), United Hospital Limited (Dhaka, Bangladesh), and Hospital Pulau Pinang (Penang, Malaysia). There was no randomization process and the patients were not divided equally among the participating centers. Patients were recruited on admission for the cranioplasty procedure and were divided into 2 cohorts depending on the length of time between craniectomy and cranioplasty. The early cranioplasty cohort had the cranioplasty performed within 12 weeks of the craniectomy, whereas the late cranioplasty cohort had the procedure after 12 weeks. The primary outcome studied was the rate of infection after primary cranioplasty in adult patients. The U.S. Centers for Disease Control and Prevention criteria and definition for surgical site infection were adopted.[13] We included only adult patients aged 16 years and older at the time of the craniectomy. Any form of cranioplasty material was allowed and the choice was not influenced in any way by this study. Implant material selection was left to the preference of the individual recruitment center. Patients were excluded if they had undergone a previous cranioplasty at the same site or if the indication for craniectomy was an infective process. The recruitment period was 17 months, from January 2013 to June 2014. Patients were followed up in the postoperative period for a minimum of 6 months after the cranioplasty.

A key point to this study was the fact that we chose not to disclose the definition of early and late cranioplasty to the participating centers to avoid any influence on the timing of the procedure. Also, the indications, timing, and type of implants used in the cranioplasty procedures were at the discretion of the consultant neurosurgeons in charge and were not influenced by this study. Patient baseline characteristics were also collected, which included age, gender, antibiotic prophylaxis regime, primary surgeon, type of implant, the indication for craniectomy, and duration of surgery. Data were collected and tabulated in a proforma. Data were analyzed using IBM SPSS Statistics version 21 (IBM Corp., Armonk, New York, USA). The *P* values were calculated with the $\chi 2$ test except when the expected value was less than 5, in which case the Fisher exact test was used. Univariate analysis was used to test for covariates predictive of cranioplasty infection. Only factors that were found to be predictive in univariate analysis ($P < 0.2$) were entered into a multivariate logistic regression analysis. Significance was established at the 95% level. All data handling was in accordance with the United Kingdom Data Protection Act 1998.

RESULTS

A total of 73 patients were recruited into the study: 31 patients recruited from the United Kingdom between January 2013 and February 2014, 30 patients recruited from Malaysia between May 2013 and June 2014, 9 patients from Singapore between July 2013 and December 2013, and 3 patients recruited from Bangladesh in April 2014. Three patients from the Malaysian cohort did not meet the inclusion criteria because they were younger than 16 years at the time of craniectomy and were therefore excluded. This gave a total of 70 patients, with 25 patients in the early cranioplasty cohort (range, 3–12 weeks; mean, 8 weeks), and 45 in the late cranioplasty cohort (range, 13–1080 weeks; mean, 71 weeks). One patient who made excellent recovery after an aneurysmal subarachnoid hemorrhage at 22 years of age returned to the clinic only after 20 years for a cranioplasty. This patient was initially adverse to the procedure, resulting in delayed cranioplasty. Patient ages ranged between 16 and 74 years (mean age, 40 years; standard deviation, 15.8). There were 20 women and 50 men. Despite the initially planned requirement for a follow-up period of at least 6 months, we managed to follow up patients postoperatively from the time of cranioplasty to 1 November 2015 (range, 16–33 months; mean, 23 months). Four types of implant material were used in this study: autologous bone, titanium, acrylic, and polyether etherketone (PEEK). Our study did not influence the choice of implants. Thirty-one patients underwent cranioplasty using autologous bone, titanium was used in 28 patients, acrylic in 6, and PEEK in 5. Two different regimens of antibiotic prophylaxis existed in all centers with 51 patients (12 patients in the early cranioplasty cohort and 39 patients in the late cohort) receiving single-dose prophylactic antibiotics at induction of anesthesia and 19 patients (13 patients in the early cranioplasty cohort and 6 patients in the late cohort) receiving a regime of 3 doses of antibiotics; the first dose of prophylactic antibiotics was administered at induction of anesthesia and a further 2 doses after 8-hour intervals. Antibiotics used were either first-generation or second-generation cephalosporin. The consultant was the primary surgeon in 28 cases and the registrar in 42 cases. Sixty-eight percent of the early cranioplasty procedures were performed by the consultant compared with 24% of cases in the late cranioplasty cohort. The indication for craniectomy for each patient was collected and divided into 4 broad categories, which included trauma, intracerebral hemorrhage, malignant middle cerebral artery (ischemic) infarct, and "others." Forty-seven patients (68%) underwent craniectomy because of trauma, 9 patients (13%) because of intracerebral hemorrhage, 8 patients (10%) because of infarcts, 2 patients because of aneurysmal subarachnoid hemorrhage, 2 patients because of cerebral edema after removal of tumors (meningioma and craniopharyngioma), 1 patient because of an atraumatic subdural hematoma, and 1 patient because of hemorrhage from an arteriovenous malformation. The last 6 patients (9%) constituted the group of patients labeled as "Others." The 2 patients with aneurysmal subarachnoid hemorrhage had craniotomies performed for aneurysm clipping that were converted to craniectomies because of concurrent intracerebral hematomas and brain swelling. Because of the various procedure lengths, the analyzed durations of cranioplasty surgery were divided into 3 groups. Two patients were in the first group with a surgical duration of less than 1 hour, 43 patients in the second group with surgical duration between 1 and 2 hours, and 25 patients in the third group with surgery lasting more than 2 hours.

There was no statistically significant difference in age, sex, implant type, duration of surgery, or indication for craniectomy between the early and late cohorts (**Table 1**). However, there was a significantly higher proportion of patients who received 3 doses of prophylactic antibiotics (early, 52%; late, 13%; $P < 0.001$) and significantly more patients with

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