Preliminary Results of a Prospective Study on Methods of Cranial Reconstruction

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Purpose: Given its biological and anatomic features, autologous bone is the first choice for cranioplasty after bone decompression. When autologous bone is not available or must be replaced, surgeons can choose among various materials to create an alloplastic cranioplasty. The Italian Society for Neurosurgery promoted a prospective study conducted at 4 Italian neurosurgical units to compare different methods of cranioplasty and to assess the clinical results and incidence of complications.

Materials and Methods: Patients older than 14 years who underwent repositioning of autologous bone or 3-dimensional image-guided reconstruction with prostheses made of an alloplastic material (polyetheretherketone, polymethylmethacrylate, or hydroxyapatite) after cranial decompression were enrolled prospectively from January 2008 through December 2013. The collected data included the material used to produce the prosthesis, the type of cranioplasty (primary or secondary), and complications that required surgical removal of the prosthesis (eg, infection, bone resorption, and fracture of the cranioplasty).

Results: Ninety-six patients met the study criteria. Fifty cases were reconstructed with hydroxyapatite, 31 with bone, 13 with polymethylmethacrylate, and 2 with polyetheretherketone. Seven patients (7.3%) developed complications related to the cranioplastic implant that required reoperation. These complications included infection (4 cases), bone resorption (2 cases), and fracture of the cranioplastic prosthesis (1 case). Statistical analysis showed a higher rate of complications with the use of autologous bone versus alloplastic materials ($P = .03$). Owing to the limited number of cases, no statistically meaningful complication was seen among the different alloplastic materials or when the cranioplastic implant was placed as secondary treatment.

Conclusions: These data and those of other reports suggest that cranioplasty conducted using alloplastic 3-dimensional reconstruction materials have a lower rate of complications than those conducted using autologous bone.

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There is an increasing need for reconstruction after cranial decompression from various pathologies. Cranial reconstructive surgery often involves maxillofacial surgeons, neurosurgeons, and plastic surgeons. The gold standard for cranial reconstruction remains to be determined, and, overall, cranioplasties produce a high rate of complications. To date, many retrospective studies have compared different

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materials used for cranioplasty to determine the main factors involved in the development of postoperative complications.[1-3] To the authors' knowledge, this study is the first prospective work with the same objective.

Materials and Methods

DATA COLLECTION

Data from neurosurgical registries at 4 different hospitals in Italy (University Hospital of Parma, ASMN Reggio Emilia, Bellaria Hospital of Bologna, and Cannizzaro Hospital of Catania) were collected prospectively from 2008 through 2013. The study was approved by the local institutional review board and ethical committee of the principal investigator's center at the start of the study. Patients eligible for the study underwent cranioplasties performed with 4 different materials: autologous bone that the patient donated from the previous surgery for decompressive craniectomy or bone removal that had been stored in an institutional bone bank (Istituti Ortopedici Rizzoli, Bologna, Italy), custom-made hydroxyapatite (HA), custom-made polymethylmethacrylate (PMMA), or custom-made polyetheretherketone (PEEK). The data collected included patient age, reason for bone removal (trauma, subarachnoid hemorrhage owing to rupture of an aneurysm, stroke, tumor, infection), material used to create the cranioplastic prosthesis, type of cranioplasty (primary or secondary), complications that required surgical reoperation, clinical follow-up data (evaluated with the extended Glasgow Outcome Scale), and radiologic follow-up data (≥6 months; 11 ± 7 months; Table 1). Patients younger than 14 years were excluded. The 4 centers involved prospectively shared the same database and the same clinical and radiologic follow-up data, but did not specifically randomize patients to a specific treatment.

STATISTICAL ANALYSIS

The patient population was divided into 2 groups, autologous bone or alloplastic prosthesis, which were compared using an odds ratio based on the need for a second operation. The same analysis was performed by comparing porous HA devices with synthetic material (PEEK and PMMA) used for cranioplasty and by comparing primary with secondary cranioplasty (performed after a complication).

Results

Ninety-six patients met the study criteria: 31 underwent a cranioplasty with autologous bone, 50 with HA, and 15 with synthetic materials (13 with PMMA and 2 with PEEK). All alloplastic cranioplasties were custom made using 3-dimensional computed tomographic reconstruction techniques. Clinical and radiological data are presented in Table 1. Among patients in the alloplastic cranioplasty group, 39 underwent placement of a primary cranioplasty (27 with HA and 12 with PMMA or PEEK) and 26 (23 with HA and 3 with PMMA or PEEK) underwent a secondary cranioplasty because of bone resorption (21 cases) or infection of a previous cranioplasty (5 cases). Seven patients developed complications related to the cranioplasty and required a second operation: 4 developed infections (3 in the autologous bone group and 1 in the HA group), 1 had a postoperative fracture of an HA prosthesis, and 2 had bone resorption. Custom-made PEEK and PMMA devices were not associated with any complications.

The odds ratio showed a relation between the use of autologous bone and the development of major complications (P = .03710) compared with alloplastic materials. No meaningful difference was found for the comparison between different alloplastic materials or between primary and secondary cranioplasty. Furthermore, no meaningful difference was seen in the rate of hematomas after cranioplasty requiring surgical treatment (Table 1). The rate of infection for primary versus secondary cranioplasty showed no statistical significance (P = 1.06).

Discussion

Patients older than 14 years were chosen deliberately because the number of complications in pediatric cranioplasty cases, especially those requiring bone reconstruction, is larger than in adult cases.[4] In general, in Italy, the first choice for cranioplasty is the repositioning of patient's bone when available. This prospective study showed a higher rate of complications in patients with autologous cranioplasties. It has to be noted that all bone flaps were sent to a regional bone bank (Istituti Ortopedici Rizzoli) highly qualified for handling and preparing bone. The present findings are consistent with those of other retrospective studies. For example, Matsuno et al[2] compared 54 autologous cranioplasties, 58 PMMA cranioplastic prostheses, 7 HA prostheses, 77 titanium cranioplastic prostheses, and 10 cranioplasties accomplished with other materials and found a higher rate of complications (infections) in cranioplasties performed using autologous bone (25.9%). In their comparison of 52 autologous cranioplasties and 32 cranioplasties with PMMA prostheses, Cheng et al[3] also showed a higher rate of infection with autologous bone (10.7 vs 6.25% in synthetic cranioplasty). In contrast, De Bonis et al[4] conducted a retrospective study that compared 135 autologous cranioplasties with 31 hand-made PMMA, 15 custom-made PMMA, and 20