Abstract

Repair of a skull defect using a custom-made PEEK Implant

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Short Abstract: This paper describes the design of a custom skull implant from medical images, with the purpose of repair a cranial injury, for 32 years-old woman, who suffered a lesion in the left fronto-parietal region of the skull. The implant was designed and fabricated in polyetheretherketone (PEEK). The implant was successfully assembled; the functional and aesthetic condition of the patient was improved significantly. The PEEK proved to be an effective alternative for repair skull defects due to its biocompatibility and mechanical properties.

Key words: Cranioplasty, custom-made, reverse engineering, biomaterials, rapid prototyping.

1- Introduction
Cranioplasty is defined as a neurosurgical procedure for covering an injured bone in the skull. Such injuries can be caused by congenital defects, diseases, accidents, infections or tumors[LA1]. This procedure is performed to protect and restore intracranial structures and to restore the appearance and psychological stability of the patient. The success of reconstructive skull surgery depends on the preoperative evaluation of the defect, the design and manufacturing of the implant and the execution of the surgical procedure [JL1]. This paper describes the design, based on medical images, of a custom skull implant used to repair a craniectomy (89.5 cm²) performed by the rupture of a cerebral aneurysm and a posterior cranial osteomyelitis in a 32-year-old woman. The prosthesis was made in PEEK and was successfully implanted. The aesthetic appearance of the patient was considerably improved and her quality of life was increased.

2- Materials and methods

2.1 – Clinical description of the patient

The patient was 32 year-old woman, who suffered an acute subdural hematoma by the rupture of a cerebral aneurysm. For this reason, it was necessary to perform a craniectomy in the left fronto-parietal region of the skull. The portion of skull removed was approximately 89.5 cm². Subsequently, the patient developed a cranial osteomyelitis. For this reason, it was necessary to perform an additional surgery. After a reasonable time, when the risk was over, a cranioplasty was performed based on a CT scan of the patient. In the Figure 1, the patient is observed before the craniectomy procedure.

Figure 1: Patient after craniotomy.

2.2 – Implant design and manufacturing
The implant was designed and fabricated using medical grade polyetheretherketone (PEEK) by Smartbone® (EAFIT and CES Universities, Medellín, Colombia). A CT scan of the patient was performed. The 3D reconstruction was completed in Simpleware Scan IP 6.0 (Simpleware Ltd, Brandninch Hall, UK) using a dataset of 234 images with a distance of 0.75 mm between cuts, Figure 2.

Figure 2: 3D reconstruction of skull.

The design of the implant was completed in Rapidform XOR4 (Inus Technology, Seoul, South Korea). A symmetry plane of the patient was created. Using this plane, a mirror operation was performed on the right half of the skull and was used as the basis for the geometric modelling of the implant, Figure 3.

Figure 3: design of custom-made implant

The dimensional and functional verification of the implant was performed by a superimposition analysis between the surface of the skull and the implant that are in contact. A value of ±0.2 mm was defined as acceptable tolerance, Figure 4. Additionally, the biomodels of the skull and implant were fabricated using a rapid prototyping system.

Figure 4: superimposition analysis between the surface of the skull and the implant

As material of the implant, medical grade PEEK was selected because of its high biocompatibility, mechanical properties (similar to the cranial bone), lightness, radiolucency and ability to be easily modified in the operating room.

3- Results

A custom-made PEEK implant for the repair of a cranial defect was designed and manufactured. Before the surgery, the implant was sterilized with ethylene oxide. After sterilization, the implant was successfully placed on the skull and assembled using titanium commercial miniscrews and miniplates. Modifications to the implant, such as folds or removal of material, were not necessary, Figure 5. Upon the completion of the cranial defect repair, the skin of the patient was closed using suture. The entire implantation process lasted approximately 2 hours and the aesthetic appearance of the patient was considerably improved and her quality of life was increased.
Development of a custom skull implant to repair a cranial defect resulted in good aesthetic and clinical outcomes. A craniotomy in which a large portion of the skull is removed is commonly associated with neurological deficits; cranioplasty has proven to be the best choice to restore cerebral function [CD1]. The design and manufacturing process was successful, an excellent fit of the implant was obtained, avoiding modifications to the implant or skull region around the injury during surgery. Additionally, the aesthetic appearance of the patient was improved, achieving adequate symmetry of the skull. The dimensional and functional verification of the implant using superimposition analysis and 3D biomodels designed in rapid prototyping systems, proved to be an effective practice in the implant development process [DB1]. The models were also an effective communication tool for the neurosurgeon, the patient and the patient’s family when discussing the surgical procedure [SH1]. According to others authors, medical grade PEEK used to manufacture the implant proved to be a suitable material for this type of application due to its low complications rates [LP1][JB1][SM1]. In this study, the good performance of PEEK is demonstrated by the absence of postoperative infections and its use resulted in proper healing and restoration of normal patient activities without any medical complications after four months.

7 - References


Figure 5: Cranioplasty