Patient Specific Hydroxyapatite Implant

Biomimetic Cranial Reconstruction
Today, the reconstruction of large and complex cranial defects is no longer considered simply a matter of the aesthetics. Neurological and psychological side effects must also be taken into account.

Through use of an advanced and bio-mimetic ceramic material, CustomizedBone Service provides a proven solution for bone replacement.
From the CT scan to the customized implant

Acquisition and elaboration of the CT scan

CustomizedBone Service starts from the raw digital data obtained during the CT scan, and through extensive computer elaboration, allows the creation of an individualized 3D computer reproduction of the patient’s skull.

A detailed protocol providing all the necessary parameters for correct 3D data acquisition is provided through the CustomizedBone Service web portal.

3D model direct discussion with the surgeon

Together with “Finceramica’s team”, the surgeon has the opportunity to discuss and review the patient specific device design through CustomizedBone Services’s web portal ordering platform. This is a crucial phase in order to provide an individually tailored designed implant for patient.

From design to realization

Once the design has been approved by the surgeon, the high tech manufacturing process starts, leading to a highly crystalline hydroxyapatite prosthesis. Implants are supplied sterile, ready for surgery.
The importance of bio-mimetic materials

In modern medical science, the concept and application of bio-mimetic materials has been consolidated and incorporated into everyday clinical practice. These bio-mimetic materials are defined as synthetic materials with a chemical composition and structure that resembles the mineral component of human bones. For CustomizedBone Service, the research team at Finceramica has transferred this concept into reality through the development of a bio-mimetic ceramic biomaterial based on macro and micro porous hydroxyapatite, a major (70%) component of human bone. Specific bio-mimetic chemical composition combined with an elevated interconnected porosity play a role in the perimetral osteointegration process. In particular CustomizedBone's inter-connected macro-pores are suitable for housing cells responsible for bone regeneration. Based on CT studies, the implants demonstrate perimetral osteointegration. Manufacturing process featured by a high temperature sintering process, enhances highly crystalline non absorbable ceramic hydroxyapatite (HA).

Limitations of other cranioplasty materials

- **Titanium and acrylic resins:**
  - not biometric materials
  - not osteoconductive
  - artifacts during diagnostic MRI

- **Autologous bone:**
  - conservation procedures are complex
  - limited material quantity which may not be sufficient for large and complex defects
  - donor site morbidity

- **Bio-mimetic macro- and micro- porosity**

- **Interconnected macro-pores are suitable for housing cells responsible for bone regeneration**

- **Highly bio-compatible material, showing a reduced post-op infection incidence compared to titanium-based implants**, when deemed clinically useful by the surgeon

- **Natural aesthetic result leading to high level of patient satisfaction**

- **Completely radiolucent allowing for MRI diagnostics without artifacts**

**Indications**

CustomizedBone Service is indicated to replace bony voids in the cranial and/or craniofacial skeleton (frontal bone including the brow ridge). This device is indicated for both adult and pediatric use (for children 7 years of age and above). CustomizedBone implants are suitable for reconstructing cranial and/or craniofacial defects resulting from:

- trauma and vascular pathologies, either associated or non-associated to cranial decompression;
- removal of tumors;
- reabsorption of autologous bone;
- rejection of other prosthetic materials;
- congenital malformations.

**Trauma**

Patient presented a serious cranial trauma due to a car accident. A bilateral frontal decompression was performed and then, in a second operation, the cranioplasty was performed with CustomizedBone.

![Example of bifrontal cranial reconstruction following trauma. Top: pre-op image of the cranial (left) and pre-op CT scan (right). Bottom: aesthetic result after cranioplasty (left) and post-op CT scan (right).](image1)

**Absorption of autologous bone graft**

Seventeen-year-old patient presented absorption of the autologous bone graft after a craniotomy. The defect area was removed and the CustomizedBone prostheses implanted in a single operation.

![Reconstruction of parieto-temporal cranial defect due to autologous bone reabsorption. Top: lateral (left) and frontal (right) view of CT scan. Bottom: two-months followup CT scan, lateral (left) and frontal (right) view.](image2)

**Tumor resection**

Demolition and resection of an atypical meningioma relapse at the forehead was performed on a 45-year-old female patient. Cranial reconstruction with CustomizedBone implant was performed with one step procedure in combination with neuronavigational system.

![Example of bifrontal post-traumatic reconstruction followup removal of previously applied resin cranioplasty. Top: pre-op image of the cranial defect (left) and pre-op CT scan (right). Bottom: post-op CT scan (left) after 8 months from surgery and final aesthetic result (right).](image3)

**Second line treatment following other material rejection**

Patient underwent cranial decompression after trauma, reconstruction of the area was performed with a resin implant. An infection occurred and material was rejected. Final reconstruction was successfully performed using a CustomizedBone Service implant.

![Example of bifrontal reconstruction following trauma. Top: pre-op image of the cranial (left) and pre-op CT scan (right). Bottom: aestetic result after cranioplasty (left) and post-op CT scan (right).](image4)

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Science and research are an integral part of Finceramica’s DNA. Finceramica’s research activity is aligned with the innovation in biomimetic cranial reconstruction of today and tomorrow. Finceramica has collaborated to provide proven therapeutical solutions through the development and technology of bio-ceramic materials, while paying particular attention to the development of patient specific solutions designed to satisfy the needs of both surgeon and patient.

Finceramica maintains a constant exchange of information with the main neurosurgeons, with whom has collaborated and relied during the product development.

The Finceramica team works to provide the surgeon with cutting-edge technical support during the entire CustomizedBone Service process.