Patient specific hydroxyapatite implant

Biomimetic cranial reconstruction
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 3-D data acquisition is provided through the CustomizedBone Service web portal.
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.

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\(^1,2\).

Specific bio-mimetic chemical composition combined with an elevated interconnected porosity play a role in the perimetral osteointegration process. In particular CustomizedBone’s interconnected macro-pores are suitable for housing cells responsible for bone regeneration\(^3,4\). Based on CT studies, the implants demonstrate perimetral osteointegration\(^3\).\(^5\).\(^6\)\(^7\).\(^8\)\(^9\).

Manufacturing process featured by a high temperature sintering process, enhances highly crystalline non absorbable ceramic hydroxyapatite (HA).

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\(^4\) Maddalena Mastrogiacomo, Silvia Scaglione, Roberta Martinetti, Laura Dolcini, Francesco Beltrame, Reniero Cancetti, Rodolfo Quarto. Role of scaffold internal structure on in vivo bone formation in macroporous calcium phosphate bioceramics. 2006. Biomaterials


The unique properties of bio-mimetic ceramic material

- biomimetic 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 (*)
- the porous structure and hydrophilic surface allow for loco-regional use of antibiotics, 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

Limitations of other cranioplasty materials a, b, c

**Autologous bone:**
- conservation procedures are complex
- limited material quantity which may not be sufficient for large and complex defects
- donor site morbidity
- potentially reabsorbed, especially in certain patient groups

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


(**) Nataloni A., Martinetti R., Staffa G., Servadei F. Rifamcine release from porous hydroxyapatite as anti-infection prophylactic for the cranial theca reconstruction.


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 above 13 years of age). 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.

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.
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.


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.
Science and research are an integral part of Finceramica’s DNA. Finceramica’s research activity is aligned with the biomedical advances of today and tomorrow. By pioneering advanced neuroscience therapies, Codman Neuro, a Johnson & Johnson company, has become the leader in the treatment of central nervous system disorders.

Codman Neuro and Finceramica have combined their strengths to provide innovative and effective therapeutic solutions designed to satisfy the needs of both the surgeon and patient. Finceramica has specialised in the development and technology of bio-ceramic materials, while paying particular attention to the development of patient-specific solutions. Codman Neuro maintains a constant information exchange with the leading neurosurgeons, which Finceramica has relied on during product development.

The Finceramica-Codman Neuro team works in complete synergy to provide the surgeon with state-of-the-art technical support during the entire CustomizedBone Service process.