Original article

From CT scan to the operating theatre: designing and producing a custom-made cranioplasty in porous hydroxyapatite

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SUMMARY: *None of the materials currently used to reconstruct skull defects is fully satisfactory. Their biological and physical properties are very different to those of natural bone. Solid state, high porosity hydroxyapatite seems to be the ideal support for bone regeneration within the prosthesis, enabling perfect integration of the heterologous material with low post-implant phlogistic and infective risk.*
In this article, the different production phases will be analysed, starting from the CT scan data acquisition to the manufacturing of a custom-made cranioplasty in porous hydroxyapatite, paying special attention to the validation of the model as it is the most important phase of the whole process.

KEY WORDS: *Cranioplasty, Porous hydroxyapatite, Production phases.*

Dalla TC alla sala operatoria: il design e la produzione della cranioplastica cust-made in idrossiapatite porosa

RIASSUNTO: *Nessuno dei materiali per le ricostruzioni craniche attualmente in uso è pienamente soddisfacente. Le loro proprietà biologiche e fisiche sono molto diverse da quelle dell'osso naturale. L'idrossiapatite altamente porosa sembra essere il supporto ideale per la rigenerazione ossea all'interno della protesi, assicurando una perfetta integrazione del materiale eterologo e basso rischio infettivo e di infiammazione post-impianto. In questo articolo analizziamo le diverse fasi della produzione, incominciando dall'acquisizione delle immagini TC al manufatto della cranioplastica custom-made in idrossiapatite porosa, con speciale attenzione alla validazione del modello, che rappresenta la più importante fase dell'intero processo.*

PAROLE CHIAVE: *Cranioplastica, Idrossiapatite porosa, Fasi di produzione.*

INTRODUCTION

If a few years ago, the science of materials for clinical applications only took an interest in the study, development and physical-chemical-mechanical production and characterisation of new solutions, nowadays, this can no longer occur without combining the words biomaterial and biotechnology. In this specific case, one of the fundamental keys in successfully producing custom-made devices in porous hydroxya-

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Topics in Medicine 2010; Special Issue 1-4.
ISSN: 1127-6339. *Fascicolo monografico: ISBN: 978-88-8041-028-7.*
"Cranial demolition and reconstruction. Cranioplasty in one step", editors B. Zanotti, A. Verlicchi and P.C. Parodi
 www.topicsmedicine.com

patite for reconstructing large, complex cranial-lacunae is having skills and in-depth knowledge within the sphere of ceramic biomaterials, and the availability of high-technology equipment for designing and producing them. Development of digital, electronic and computer science technologies which have allowed for an evolution of diagnostics by means of images has provided those who produce medical devices with the necessary tools for further increasing quality. This is true in terms of projects and production, to the advantage of surgeons and, most importantly, end users, i.e. patients.

□ MATERIAL

The cranioplasties discussed in this article are produced in porous hydroxyapatite, a porous bioceramic. Their biomimetic characteristics, in terms of biocompatibility and attachment, have already been widely dealt with in a large number of scientific articles. Consequently, we will not discuss this issue in depth.

□ METHODS

❒ CT SCAN DATA ACQUISITION AND PROCESSING

The first key to the success of custom-made hydroxyapatite cranioplasty is in the hands of the radiologist, as Computerised Tomography (CT) scan acquisition must be carried out carefully and respect specific protocols. Only in this way it will be possible to produce an implant which is perfectly suited to a patient's needs. Hence, the first step consists in acquisition of images by means of CT, which enables users to obtain sectional images of the patient under examination. Being in digital format, this technique makes it possible to produce 3D images which are useful for data processing.
As stated in advance, acquisition must occur by means of a number of specific parameters:
- maximum 2 mm acquisition step;
- maximum 2 mm acquisition thickness;
- 0° gantry tilt;
- 512 x 512 pixel resolution matrix;
- files which are non fragmented and/or divided;
- non compressed files.

Data transfer must occur as follows:
- saved in DICOM 3 (Digital Imaging and COmmunications in Medicine) format;
- transfer by means of CD-Rom and, in the near future, through a web portal.

In order for custom-made device design to occur in the best way possible, a few other issues must also be taken into consideration:
- in the case of cranial-lacunae, CT scan must include both the defect, and at least 1 cm above and 1 cm below it;
- the CT must comprise the patient's entire cranium in the case of tumoral pathologies;
- the CT must, if possible, have an even more accurate definition level in the presence of other prosthesis and/or autologous bone to remove;
- the patient must not move during CT scan acquisition.

If transfer is not carried out with due precision, the custom-made device may not correctly fill the defect. The CT data acquired are displayed and processed with high-definition software. By using the different physical and chemical characteristics of the tissues e.g. bone density, the software is able to selectively display one particular tissue, assisting 3D production and making those tissues which have not been selected, transparent.
After checking the patient's CT parameters and clinical data, the feasibility of the lacuna is determined and the design phase commences.

❒ DESIGNING CUSTOM-MADE DEVICES AND PRODUCING MODELS

Fin-Ceramica's 3D modelling system is based on CAD (Computer Aided Design) software which makes it possible to obtain geometric curves and precise sections in order to produce the project of the custom-made device. Design occurs by following the anatomical curves of the cranium examined, in order to achieve lacuna compensation (Figure 1).
The same software also allows for design demolitions and reconstructions in a single step. This process makes it possible to increase accuracy during surgery, shorten times and, most importantly, complete the work in one step rather than in two. This is to the advantage of both the patient and the hospital.
Once design has been completed, both the model of the patient's cranium and the prototype of the custom-made device are produced using a 3D printer (Figure 2).
The printer converts the 3D project into thousands of sections with a specific thickness by means of CAD

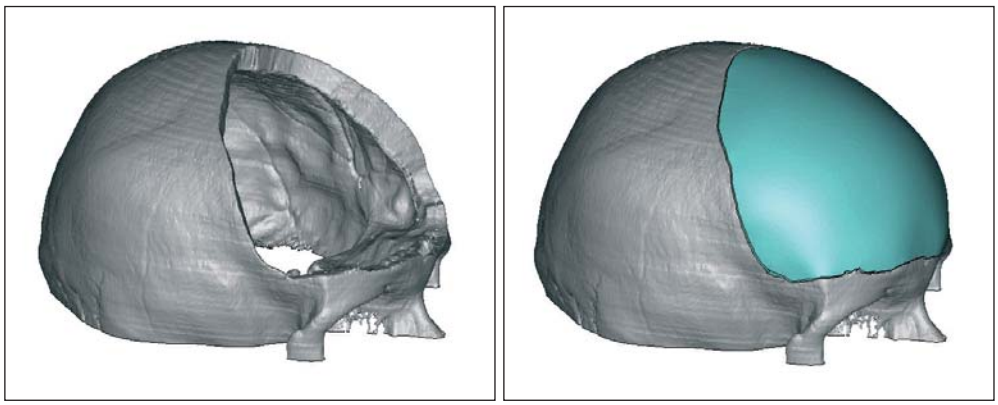

Figure 1. Design of the model of the device.

software. Said sections are printed one after the other, from the bottom to the top of the project. They are obviously identical in size and shape to both the patient's cranium and the bone defect to be reconstructed.

❒ Project validation

The validation stage is the most critical step in the entire process, perhaps even more than the surgery itself. Unlike reconstructions using materials modelled at the time of surgery (cements, retia, etc.), implants of custom-made devices combined with the specific characteristics of porous hydroxyapatite call for special attention. This is necessary, in order to carry into effect surgical precautions which are essential for achieving different biological and aesthetic results to those which have been required to date.
The following points must be assessed:

- the prototype is produced following the profiles of the defect and the characteristics of the material. Consequently, possible discontinuity can be determined either by the porosity of the material or the irregularity of the bone edge, impossible to produce. Taking into account the fact that attachment and colonisation occur through complete bone/device contact, it may be worth hypothesising the use of bone substitutes should discontinuity exist;
- the absence of atrophic muscle could determine an aesthetic result which is not entirely satisfactory. Compensation may be considered during the design stage, altering the curve of the prosthesis;
- in those cases in which the prosthesis is in the temporal fossa area, careful attention must be paid to the possibility of the muscle coming apart. Should this be the case, a reduction in the implant could be hypothesised;
- in the case of a large frontal defect, avoid direct contact between the prosthesis and paranasal sinuses (a primary reason for infection);
- the implant is developed and produced by making a symmetrical study of the patient's cranium. However, the surgeon's knowledge may indicate possible aesthetic alterations;
- should considerable time have passed between the craniotomy and the reconstruction work, introflection of the skin with relative atrophy may have developed. This may mean the prosthesis is not completely covered. Should this be the case, precautions must be taken using either a bone adjustor or by slightly bending the prosthesis;
- prosthetic thicknesses have a safety limit which often means they are larger than the tissue housing them, in a few points at least (Figure 2). Hence, it is necessary to pay careful attention to the fact that complete dural stripping must be carried out whenever the thickness of the bone differs from that of the prosthesis;
- the holes proposed for fastening and possible dural suspension must be correct, as it is better not to mill the prosthesis or make holes in it during surgery.

To date, this stage has only been accomplished using 3D models. However, with the operational advent of the web portal in September 2010, this process will occur directly on-line, thus accelerating processing times. Once validation has occurred, the project enters the final stage of production.

❒ Production of custom-made devices

Production commences with the manufacture of a semi-processed piece obtained by means of manipulating hydroxy-apatite with a porous matrix of a prede-

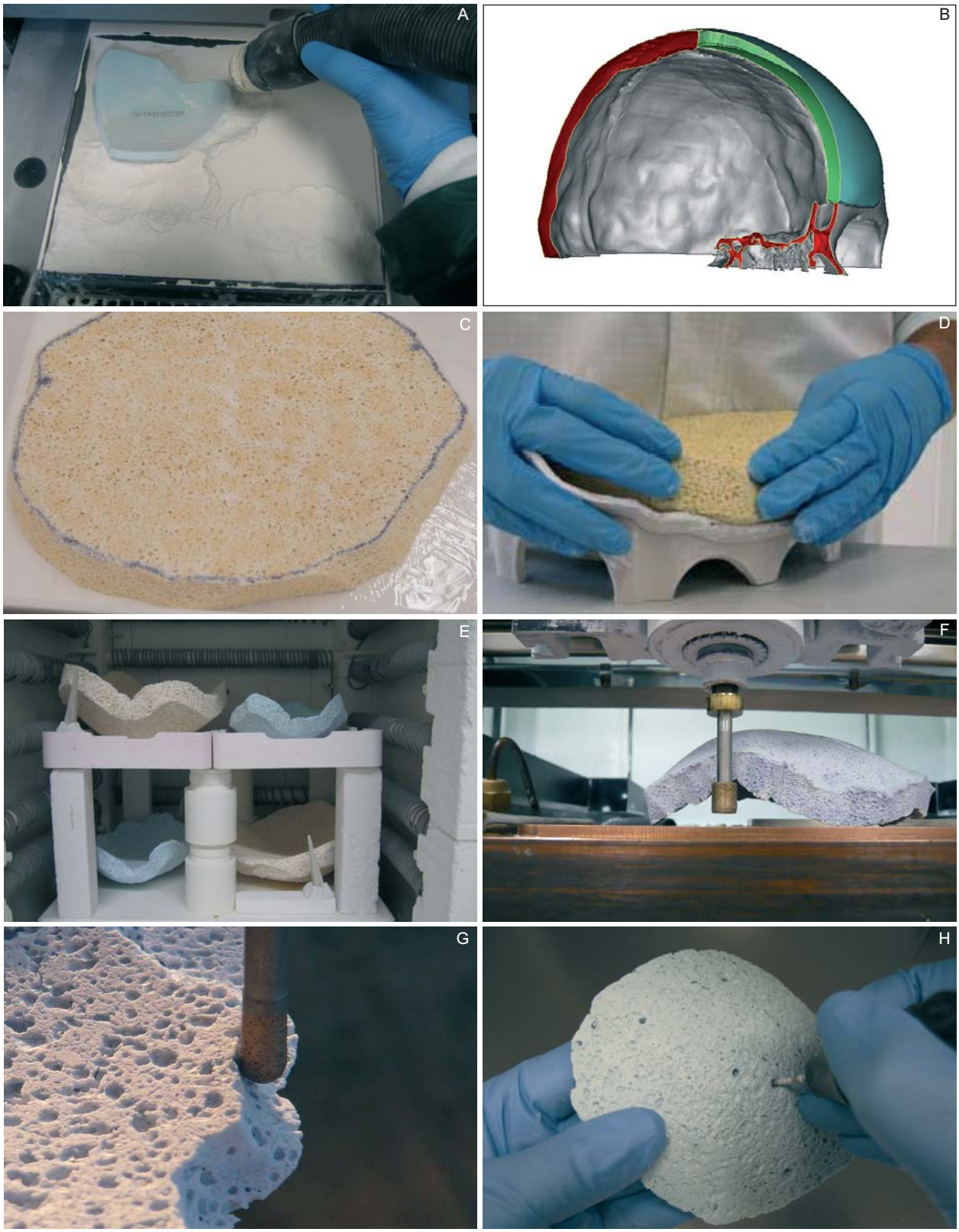

Figure 2. A. Production of a prototype of a custom-made device. B. Section of the cranium and the prototype during model validation. C. Impregnation of the porous matrix with hydroxy-apatite. D. Moulding the semi-processed piece. E. The semi-processed pieces before (in yellow) and after firing (in light blue). F. G. Processing of the porous block using CNC machinery.

fined size to which the device curve is set (patented technology).
The semi-processed piece subsequently undergoes a long drying out and sintering process. The result is a porous block in hydroxyapatite.
The porous block of hydroxy-apatite is then processed using CNC (Computerized Numerical Control) machinery in order to obtain a device which is identical to the approved model.
Small finishes are carried out using diamond tips, and the fastening holes indicated by the doctor are made.
Lastly, after having passed all the necessary quality controls, the device is packaged up in a controlled environment and sent for sterilization by means of gamma rays.
The prosthesis is then ready for surgical implant.

□ CONCLUSIONS

As stated in the introduction, the development of biotechnologies, be they applied to production or the transfer of data, have enabled a quantum leap in prosthetic design. The design and validation stages, even if highly critical, can be carried out in just a few days. However, real production of the device goes through a series of steps which can be neither accelerated nor optimised. This explains why production of a device in porous hydroxy-apatite for cranioplasty requires several weeks of intense work.
Moreover, the new computerised technologies offer surgeons a further advantage, as they can interact directly with 3D modelling technology, and observe the project in great detail from different angles, take measurements and provide more accurate feedback on the design of the device in real time. All this means a change in the frame of mind, but it is the price of scientific innovation, also in medicine.

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