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Direct fabrication through electron beam melting technology of custom cranial implants designed in a PHANToM-based haptic environment

Alida Mazzoli [a,*], Michele Germani [b], Roberto Raffaeli [b]

[a] Department of Materials and Environment Engineering and Physics (FIMET), Università Politecnica delle Marche, Faculty of Engineering, Via Brecce Bianche, 60131 Ancona, Italy
[b] DT&M Group – Mechanical Department, Università Politecnica delle Marche, Ancona, Italy

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ABSTRACT

Repairing critical human skull injuries requires the production and use of customized cranial implants and involves the integration of computer aided design and manufacturing (CAD and CAM). The main causes for large cranial defects are trauma, cranial tumors, infected craniotomy bone flaps and external neurosurgical decompression. The success of reconstructive cranial surgery depends upon: the preoperative evaluation of the defect, the design and manufacturing of the implant, and the skill of the operating surgeon. Cranial implant design is usually carried out manually using CAD although this process is very time-consuming and the quality of the end product depends wholly upon the skill of the operator.

This paper presents an alternative automated method for the design of custom-made cranial plates in a PHANToM®-based haptic environment, and their direct fabrication in biocompatible metal using electron beam melting (EBM) technology.

1. Introduction

The repair of severe human skull injuries, the main causes of which are trauma, cranial tumors, infected craniotomy bone flaps and external neurosurgical decompression, necessitates the use of customized cranial implants. The success of reconstructive cranial surgery depends on diverse aspects of the preoperative evaluation of the defect, the design and manufacturing of the implant, and the execution of surgery. Traditionally, medical sculptors employed their anatomical modelling expertise to manufacture implants using clay and wax [1]. Currently, however, shape reconstruction techniques for the skull surface involve both clay and spatulas and the use of computer aided design (CAD) tools [2].

Previous studies have explored computer-aided cranial implant design [3,4], whose procedures are highly effective but still time-consuming as they require a great deal of manual input. Therefore, even with the support of automated manufacturing techniques, the design process remains costly in terms of labour, materials and monetary expense. In fact, any modification to the sculpted implant necessitates an entirely new model to be fabricated. Moreover, CAD has limitations as far as the design of organic shapes are concerned.

At present, virtual reality (VR) environments which have been developed to simulate medical surgical procedures are being evaluated with a view to improving and optimizing the manufacture of customized implants [5–7]. In fact, translation of real-world tools to their VR equivalents could improve current pre-surgical evaluation and also the design of the implants themselves.

Among these virtual tools, the haptic interface is at the cutting edge of technology. The word "haptic" is from the Greek *haptesthai* and means pertaining to, or proceeding from, the sense of touch, and a haptic interface is a device which allows a user to interact with a computer by means of tactile feedback. This feedback is derived using a manipulator to apply a degree of opposing force to the user along the *x*-, *y*- and *z*-axes. Haptic interfaces can be used to simulate operations and actions like deformation and cutting, and three-dimensional (3D) haptic devices can be employed in applications such as the simulation of complex surgical procedures and the training of unskilled surgeons [8,9]. Moreover, when employing a haptic approach, designers can model freehand, using the interface as a virtual cutting tool and carving away simulated clay on screen, exploiting both visual and tactile feedback.

It is easy to imagine that these virtual tools could be used to replace many physical steps of the process of designing customized implants. As for manufacture, these implants can be directly fabricated in a biocompatible metal alloy using electron beam melting (EBM) technology. The Arcam EBM process, for example, is a direct-layered metal fabrication technique which has been used to make complex 3D parts such as tools with conformal cooling channels and medical implants [10,11]. This EBM technology features a thermionic emission gun which uses a tungsten filament to produce an electron beam with a maximum power of 4.8 kW. This process selectively melts metal powder in 0.07–0.25 mm thick layers after preheating each layer by scanning the beam at low power and high velocity to lightly sinter the particles. The lightly sintered

* Corresponding author. Tel.: +39 071 2204290; fax: +39 071 2204729.
E-mail address: a.mazzoli@univpm.it (A. Mazzoli).

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powder surrounds the fabricated part and helps support its downward facing surfaces during the construction process, and is then broken up during the post-construction sifting process, allowing most of the unmelted powder to be recovered and reused. The elevated temperature involved in this operation also helps lessen residual stresses between the cooling melt pool and previously solidified layers. The entire process takes place in a vacuum at 10^{-4} mbar in the chamber and 10^{-6} mbar in the gun.

The EBM process is currently in use for low-volume production of medical components in both Europe and the US, and this paper describes a methodology for the automated design of customized cranial plates in a PHANToM-based force-feedback haptic environment and the manufacture of these implants using EBM technology.

2. Materials and methods

The aim of this research was to design and directly fabricate customized cranial plates in titanium. The manufacture of custom-made implants necessitates the recording of the patient's anatomical data by scanning processes and the 3D reconstruction of the patient's anatomical data through medical image processing, implant geometry modelling and solid free-form manufacturing (SFM) of the implant.

In this study, two different defects were selected and modelled using this process. In the first of these cases a patient affected by an osteoma, a benign tumour composed of bone tissue or a hard tumour of bonelike structure which develops on a bone (homoplastic osteoma) or other structures (heteroplastic osteoma), was analysed. In the second case a trauma-induced skull defect was examined. In both cases the reconstructed 3D models were imported into the haptic environment in order to design the customized cranial implant, which was then manufactured by the SFF process.

2.1. Medical image processing

A commercial medical modelling software which allows interfacing between computed tomography (CT) data and a CAD or SFF system was used to reproduce the anatomy of the defect.

3D reconstruction of the skull required the initial segmentation of anatomical bone structures via CT scan. The resultant 2D image slices were stored in DICOM3 (digital imaging and communications in medicine) format, an international gold standard in the field of medical information technology as far as the interoperable exchange of digital information between medical imaging equipment, such as radiological imaging, and other systems is concerned.

The CT images were then used as the basic data for reconstructing the 3D model. First the bony areas were extracted from each slice using the commercial software MIMICS (materialise interactive medical image control system – materialise NV, Belgium), to obtain the 3D images of the skull as shown in Fig. 1.

The 3D visual models were then obtained by stacking the segmented slices; the transformation from the sliced images to the STL (standard triangulation language) format was carried out employing the marching cubes algorithm [12], a well-known algorithm in 3D reconstruction. When creating the sliced files, a cubic interpolation algorithm was also used to enhance the resolution of the SFF models. The 3D visual models of the skulls obtained were then converted, and surface models in STL format, the de facto standard interface from CAD to SFF, were created.

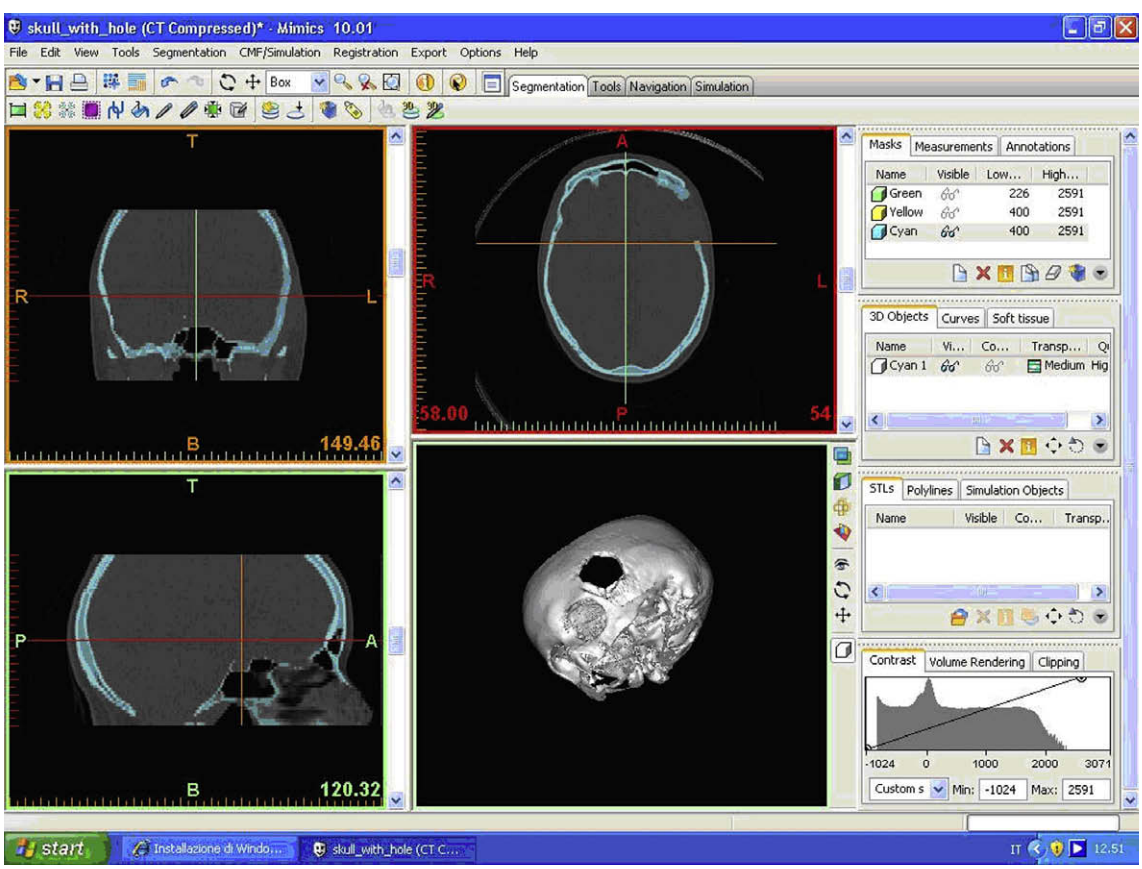

Fig. 1. MIMICS project and 3D model of the patient's skull.

2.2. Implant design

Both implants were virtually designed in a haptic environment; traditional surface-based CAD modelling would not have been easily applicable in this case due to the complexity and geometrical irregularities of the model. In cases where a CAD system is employed, this phase generally requires cooperation between the medical expert and the CAD operator as a traditional CAD system is characterised by a specific language and modelling strategy which does not easily lend itself to the medical way of thinking.

Haptic FreeForm modelling on the other hand is compatible with the skills of the medical practitioner as it involves the direct interaction between user and virtual model. Furthermore, the software system could one day be customized in order to accept any commands semantically similar to conventional medical terms in order for it to be used without the support of a CAD operator. A future study will be dedicated to defining these functionalities and to improving the system in this way.

Fig. 2. FreeForm modelling system by SensAble technologies.

The STL files of the segmented cranial defects resulting from the previous phase were imported into the FreeForm modelling system (SensAble Technologies) [13]. This software was used in conjunction with the PHANToM Omni, a haptic device which provides force feedback to the operator (Fig. 2).

The FreeForm modelling system is based on voxel, the 3D equivalent of a pixel, modelling. This representation of geometry can be seen as a 3D extrapolation of binary images in space.

Voxel-based modelling initiates with the construction of a voxmap, a 3D data array generated through voxelization. Voxelization of an object is its initial division into small cubes (voxels) of equal size and their subsequent description, via designation of an integer value, and storage in the corresponding volume buffer (voxmap). Since a voxel is the basic atomic unit of a volumetric object, the voxel-based model is useful when representing objects from scanned 3D data.

In such a design process, the operator creates a virtual implant which precisely fits the defect generated from the patient's CT data. Moreover, force feedback adds the sense of touch, allowing the sculptor to feel the surfaces of both the virtual defect and implant models, an essential feature in 3D modelling.

The FreeForm system imports the STL file and loads the model into the default position. Once imported, FreeForm uses voxel volumes to create the desired object; when importing a surface, FreeForm automatically modifies the dataset into a 3D object. At this point the operator is able to manipulate the anatomical data to obtain the best view of the defect and trace the defect edge interactively, so even irregularly-shaped defect geometry may be extracted.

2.3. Implant manufacture

After the design phase, the STL models of the skulls and implants were loaded into a quality inspection software system, in this case RapidForm by Inus Technology (Seoul, Korea). This software system allows the comparison of geometry and the analysis

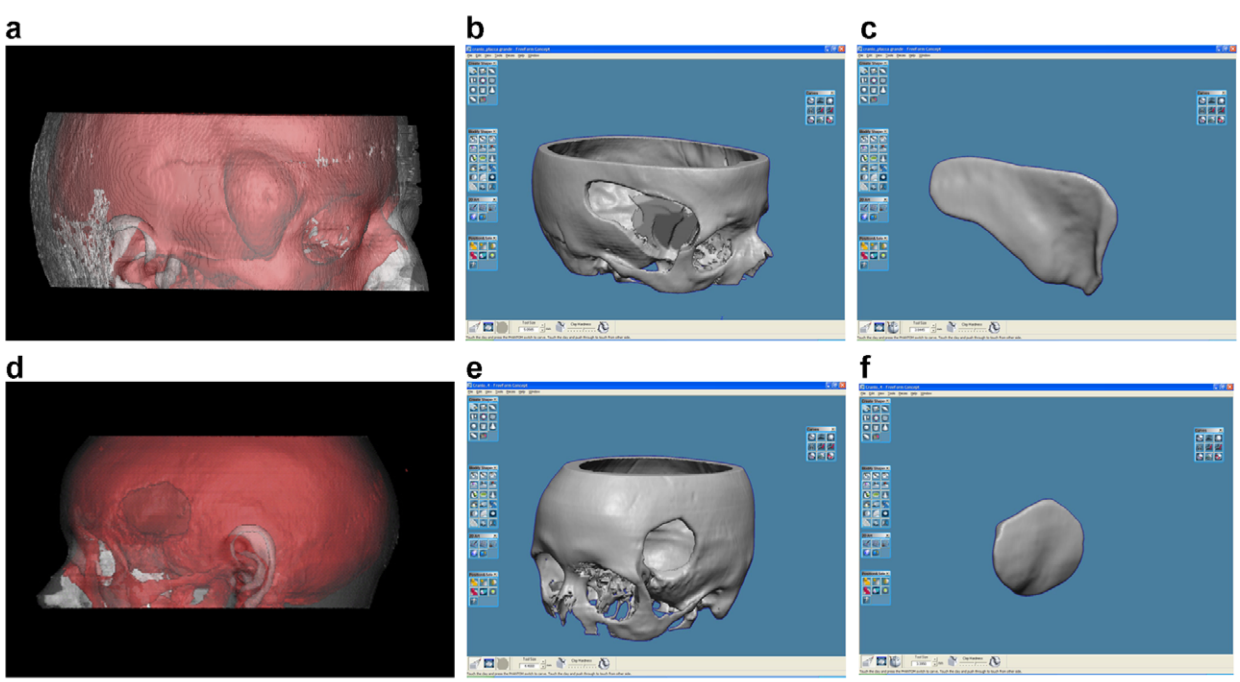

Fig. 3. Selected clinical cases (a, b, d, e) and their respective designed implants (c, f).

of any gaps or overlapping areas. Meaningful cross-sections along two perpendicular directions were analysed. From the morphological point of view, the continuity of the curvature between implant and cranium was also checked.

To validate the results of the virtual verification in this experimental phase, it was also decided to carry out a physical evaluation for quality of fit and shape using physical models manufactured via the selective laser sintering (SLS) process. Once the acceptability of the obtained results had been verified, both implants were directly manufactured in biocompatible titanium using EBM technology.

3. Results

Feeling the surface of a bone defect allows the operator to decide how to sculpt the patient's implant. In the case of the patient affected by an osteoma, using the haptic feedback as a guide, the operator was able to trace along the edge of bone and thus extract the defect geometry. The implant was then modelled using the symmetrically opposite part of the skull of the patient (Fig. 3 upper) as a reference.

In the case of missing bone due to a trauma, the operator was able to feel the edge of the defect using force feedback and fill only the space where no bone was present. Once the defect was filled with clay, a carving tool was used to sculpt the implant and a smoothing tool to refine the surface (Fig. 3 lower).

The entire design process took between 30 and 40 min, a figure which depends on the complexity of the defect, and the FreeForm technology allowed holes to be filled, the inner structures to be connected and the model to be cut, mirrored, carved and smoothed into the right shape, as necessary. Both the skulls and the designed plates were subsequently converted to STL models prior to fabrication.

The STL model of the skulls and implants were preliminarily checked with a cutting plane in order to analyse the fit, and, if no modifications were required, were sent for SFF manufacturing.

As shown in Figs. 4 and 5, the resulting implant fit the skull satisfactorily, although in Fig. 5b a small gap (0.52 mm) due to the STL approximation can be seen. This type of flaw, however, can be eliminated using a refined triangulation tolerance.

The process was verified using another test case with a larger implant (Fig. 6) and this analysis yielded similar results, thereby confirming that this process generates good quality virtual implants in terms of 3D fit.

From the morphological point of view, the continuity of the curvature between the implants and cranium was also checked in this case (Fig. 7). Application of the algorithm to the larger surface of this second test case highlighted good homogeneity of cur-

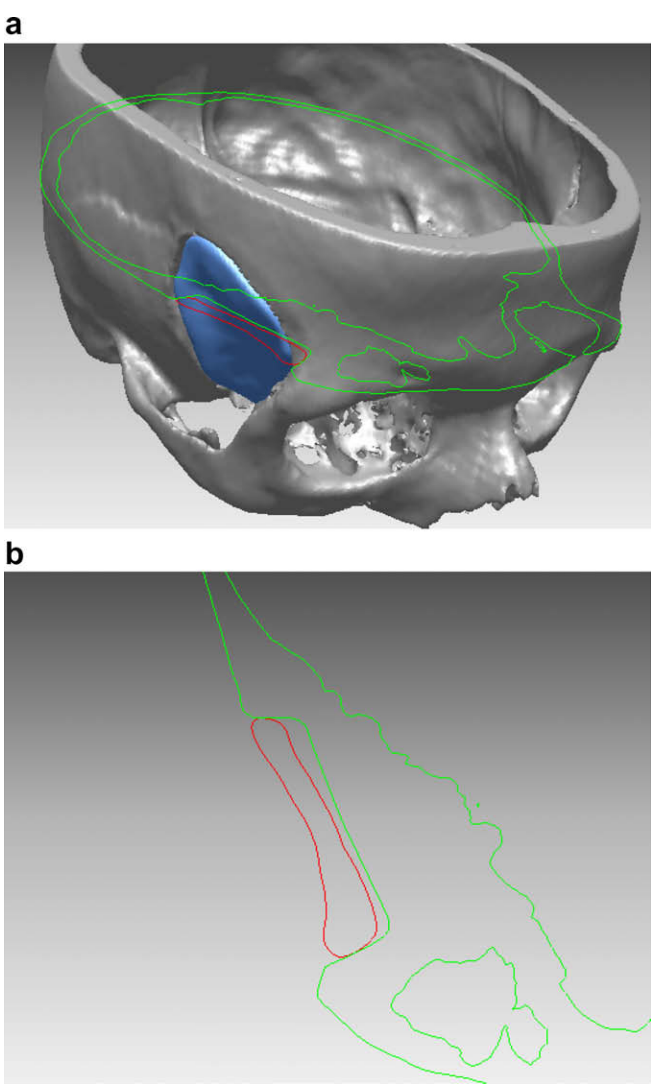

Fig. 4. (a) Cross-section analysis along the y-direction, and (b) magnification of the cross-section analysis.

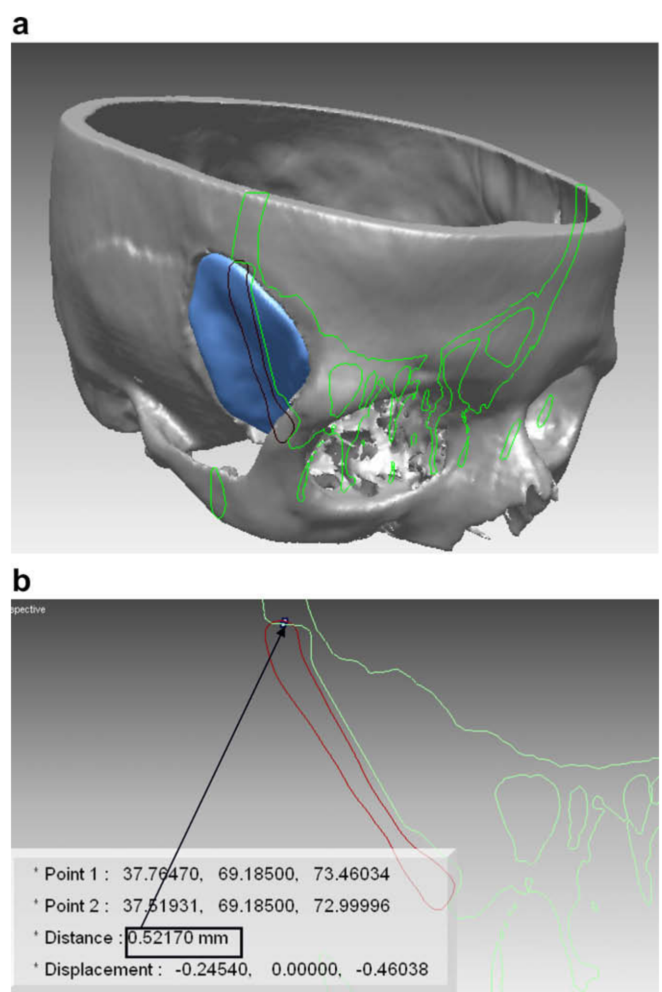

Fig. 5. (a) Cross-section analysis along the z-direction, and (b) magnification of the cross-section analysis.

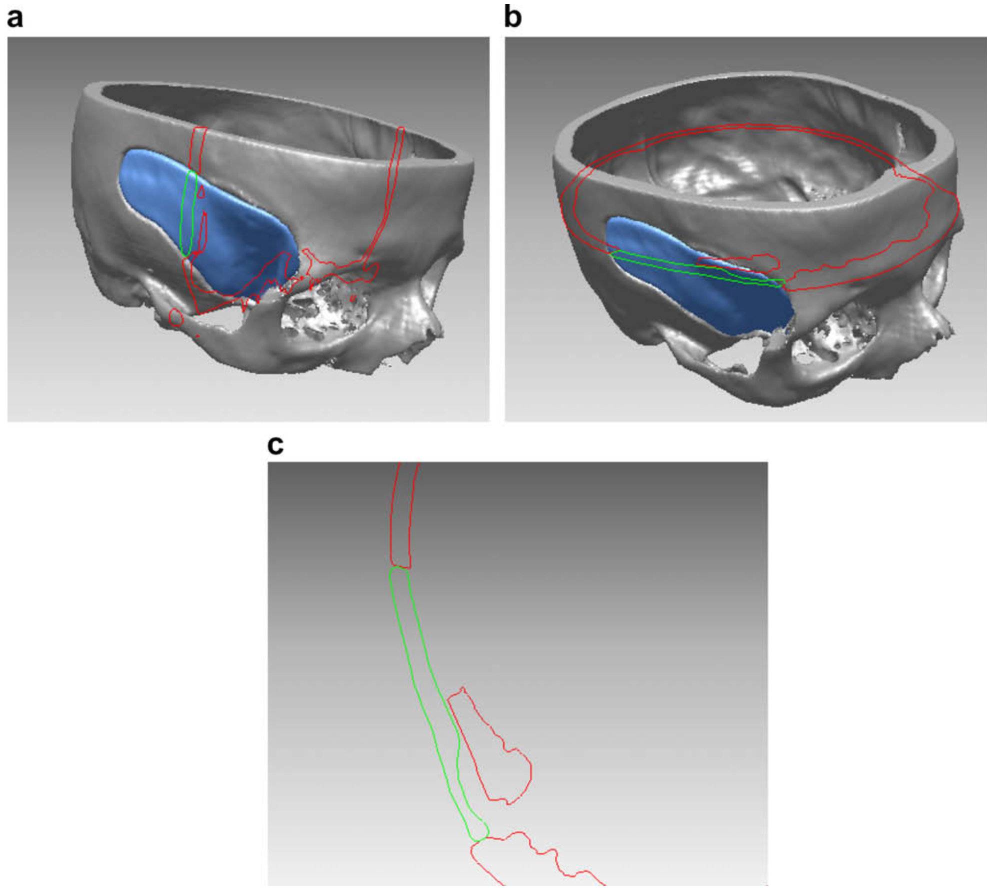

Fig. 6. Cross-section analysis along the y (a) and z-directions (b) for a larger implant. (c) Magnification along the z-direction.

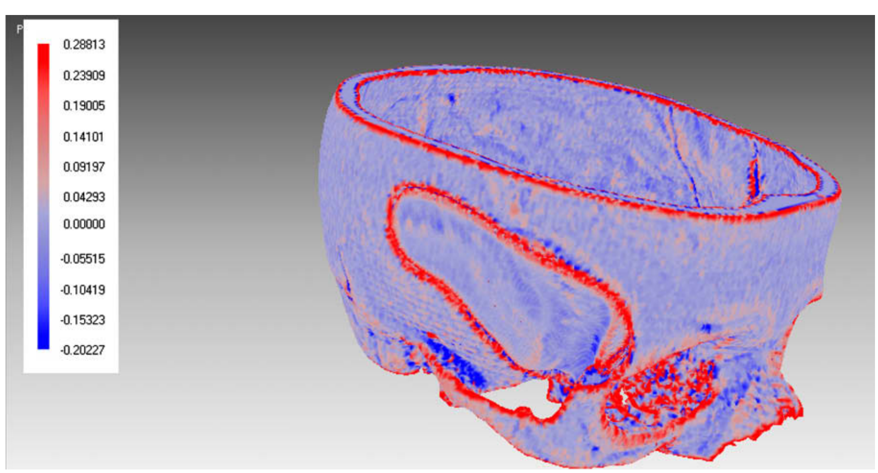

Fig. 7. Evaluation of curvature continuity of implant and skull.

vatures values between implant and skull. In fact the colours used in the representation reveal discontinuity only in the perimeter area. In this way it is possible to virtually validate the application of the implant in terms of orientation. This could be useful, for example, for driving a robotics system able to perform surgical operations.

In order to validate the results of the virtual verification in this experimental phase, a physical evaluation for quality of fit and shape was carried out using SFF models manufactured by selective laser sintering (SLS). The STL files were transferred to a SLS machine in order to fabricate skull models and customized implants. The skull replicas were then used to evaluate the accuracy of fit, shape and symmetry of the implants (Fig. 8).

The preliminary experimental tests, performed using data obtained via a coordinate measuring machine (CMM), demonstrated a good correspondence between the virtual verification and the measurement on physical models. As the obtained results were deemed acceptable, both implants were directly manufactured in

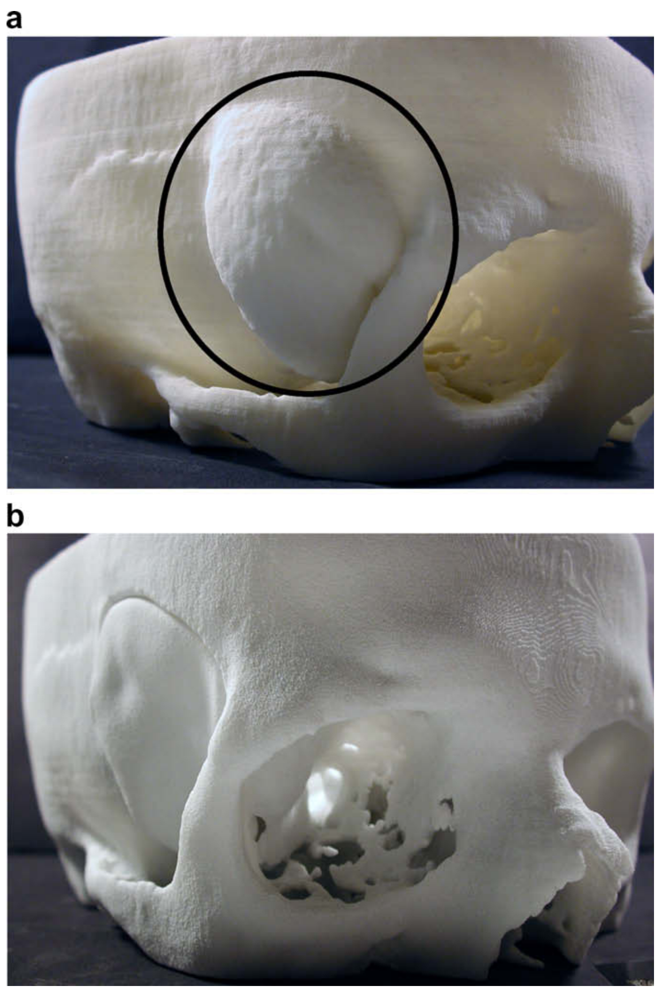

Fig. 8. SLS manufactured skulls. (a) Affected by an osteoma (black circle), and (b) after the placement of the customized implant after removal of the defect.

biocompatible titanium using EBM technology. In Fig. 9, the titanium implant fabricated for treatment of the osteoma is depicted.

The surface of the EBM manufactured implants was subsequently smoothed, shaped and cleaned by a steel shot sandblasting process.

Fig. 9. Skull plate manufactured using CAD to metal technology (EBM).

4. Discussion

In this study, volumetric tools and direct metal fabrication techniques were analysed and applied in the design and fabrication of high-quality cranial implants from patient CT data.

The virtual tools employed replaced time-consuming physical sculpting, mold-making and casting steps, and the selected PHANToM haptic device allowed the medical sculptor to feel the surfaces of the virtual defect and implant models, creating a rich sensory environment for development of the cranial implants. In addition to these advantages, integration of the FreeForm modelling system in the implant design workflow reduced the time it took to develop the prostheses: an estimated reduction of over 50%. In fact, each plate was manufactured in about 30–40 min, as compared to an average of about 4 h when using conventional methods.

As for the SFF manufacturing process, it allows rapid production of physical models and prototypal parts from 3D CAD models, 3D digitizing system-acquired data or CT and magnetic resonance imaging (MRI) scan data. The physical object is manufactured layer-by-layer, transforming the 3D information into 2D layers of fused liquids, powders or sheet materials. Layer-by-layer, SFF machines fabricate plastic, wood, ceramic, metal and composite parts using thin, horizontal cross-sections of the computer-designed model.

In contrast to traditional machining methods (i.e. computer numerical control machines – CNC), the majority of SFF systems fabricate parts using an additive procedure, rather than a subtractive one (removing material). Therefore, this type of fabrication is unconstrained by limitations attributed to conventional machining techniques, such as tool clash, and any geometrical shape can be replicated to a high degree of accuracy. Moreover, the direct SFF manufacture of implants via CAD to metal technology drastically reduces the time-to-implant with respect to casting [4,14,15] or CNC machining [16], and is considerably advantageous in the fabrication of custom orthopaedic implants.

5. Conclusions

In conclusion, CT imaging, computer modelling and EBM technologies markedly improve both surgical planning and the manufacture of customized implants, and also achieve efficient and immediate reconstruction. The use of these techniques leads to accurate fit, reduces the operating time required and cuts down on surgical errors. Other advantages of this methodology include the simplification of surgical procedure, the possibility of testing the implant fit before commencing surgery, and improvement of the accuracy of implant positioning, therefore, the surgical procedure is limited to removal of the defect and placement and fixation of the customized implant.

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