Computer Aided Design of Customized Implants Based on CT-Scan Data and Virtual Prototypes

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Abstract. Personal implants for reconstruction of craniofacial harms become more and more important due to their better performance than modelling titanium mesh or alloplastic material during surgical operation. This is due to the good fit in the implant area, reduced surgical time and better cosmetic results. The creating of such implants is a challenging task. In this article structured process workflow with clearly defined steps was introduced. All of the steps were evaluated with solving of clinical case. In this first article the reconstruction from CT-data and 3D modelling of custom implants for the purpose of cranioplasty were reviewed in details.

Keywords: Virtual engineering · CT-scan · 3D modelling · Custom implants · CAD/CAM surgery · Reconstructive surgical procedure

1 Introduction

The reconstruction of craniofacial skeleton is extremely challenging task even for the most experienced surgeon. Some of the critical factors that contribute to the complexity include anatomy, presence of vital structures adjacent to the affected part, uniqueness of each case and risks of infection. In any craniofacial reconstruction whether secondary to trauma, ablative tumour resection, infection and congenital/developmental deformities, restoration of aesthetics and function [1–3] is the primary goal and calls for precise pre-surgical planning and execution of the plan [4–7].

Craniofacial defects have complex anatomical shapes that are hard to achieve intraoperatively by carving harvested bone from same or other donor sites. Therefore, it would be very useful for the surgeon to be assisted by proven methods in mechanical engineering by virtue of which the design and production of cranioplasty implants can be planned prior to surgery with accuracy and precision.

V. Poulkov (Ed.): FABULOUS 2019, LNICST 283, pp. 339–346, 2019.
https://doi.org/10.1007/978-3-030-23976-3_30

2 State of the Art

Cranioplasty is a procedure for treatment of cranial defects, usually caused by trauma, tumour removal or decompressive craniotomy. The main goal of cranioplasty is to protect the brain and improve the quality of life and especially the social functioning of patients. Therefore, the ideal skull implant would adapt to the cranial defect and would achieve complete closure, being radiolucent – for post-operative imaging, resistant to infections, biomechanical-resistant, easy to fit on place, inexpensive, and easy to use.

Surgeons have adapted to enhanced visualization and even today this is an advancing field. Advantages of virtual reality can be totally beneficial only when transferred to the clinical practice and help the surgeons to achieve better results. Development of computer aided design (CAD) and computer aided manufacturing (CAM) systems that adapt to the surgeons needs has resulted in a gamut of the armamentarium for computer assisted processes in surgery. Such systems specifically focus on enhanced visualization tools – 3D modelling or better termed as virtual reality and gives the surgeon the ability for precise preoperative planning and perform virtual osteotomies resections and design patient specific implants preoperatively. These virtual models can be imported into an intraoperative navigation system for precise placement of different implants and medical devices.

Advances in image processing and manufacturing technologies have made it possible for the surgeons to have hand held models for a tactile perception of the defect. The next level of automation has brought in fabrication of custom designed implants as the best option for reconstruction of craniofacial defects. Custom implants for the reconstruction of craniofacial defects have recently gained importance due to their better performance over their generic, standardized counterparts. This is attributed to, the precise adaptation to the region of implantation, that reduces surgical times, in turn leading to fewer chances for infection, faster recovery and better cosmetic results [8–10].

Advances in manufacturing technology and material science has led to the possibility of turning such virtual model or design into reality as physical replica models, surgical guides or cutting jigs or splints for intraoperative use and patient specific implants.

This paper explores the process chain to derive individual design variants and to create patient-specific custom skull implants for the facial bones, frontal and temporal regions by using innovative reverse engineering and manufacturing methods based on CT-data, CAD and CAM. For this interdisciplinary project, technical scientists, medical scientists and engineers at the university work together.

The presented study is focused on the implementation of innovative technologies of Digital and Virtual engineering in the field of Medicine. It reviews the steps in 3D modelling of custom implants for the purpose of craniofacial reconstruction from CT scan data to 3D models. Steps and technics for physical prototyping will be presented in next article.

3 Conventional Restoration

The most preferred way for surgeons is the removed during the surgical procedure bone to be returned back for the patient's cranioplasty. This bone has the advantage of fitting to the skull defect. In all other cases alloplastic materials, such as PMMA, hydroxyapatite, titanium mesh, etc, are used. All of them, however, are subject to some kind of processing during surgical intervention, such as preparation, adaptation, modelling and contouring, which prolongs the time of the intervention and sometimes does not achieve the desired result, especially for large and complex defects.

The use of pre-made alloplastic implants for the specific patient and cranial defect, based on 3D bio-modelling and printing, overcomes these inconveniences.

4 Process Workflow

The aim of this study combines engineering methods for rapid reconstruction of stranded geometric information with modern production methods to achieve efficient construction of personal implants. The developed complete process flow for CAD/CAM generated implants is shown in Fig. 1, tested in real case scenario and is described briefly below.

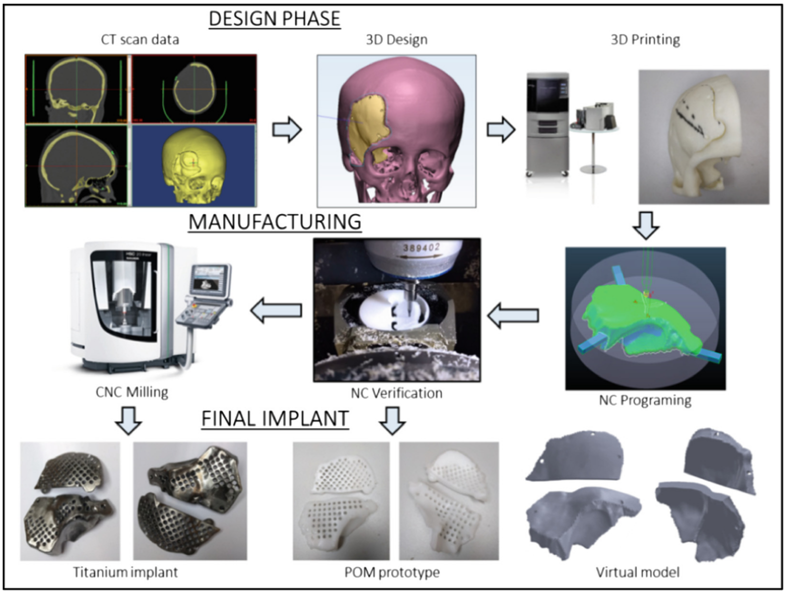

Fig. 1. Process flow for design and manufacture of CAD/CAM generated implants.

The process is known as “reverse engineering” in the engineering world and it starts with acquiring computerized tomography (CT) scan data or magnetic resonance imaging (MRI) 2D image data as DICOM (Digital Imaging and Communications in Medicine) files. The DICOM data is then processed using software as MIMICS, Bio-build or other to create a 3D model of the anatomy depicting the defected area. The 3D model file is then imported into 3D design software which could be either a haptic based environment as Freeform Geomagic or CAD based one as 3-matic to create the final implant design.

This article will review the process workflow and the latest achievements in custom implants in the cranial, skull base, maxillary and face-related treatments, and in particular the connection between applications for CAD/CAM technologies in the craniofacial reconstruction.

5 CT Scan Data

Special software (Mimics) for the image processing was used. A set of stacked 2D cross-sectional images is first imported. These 2D images shown on Fig. 2, in DICOM format, come from medical scanning equipment. Once the stacked images are imported, they can be viewed and edited using the tool box available in Mimics. The quality of 3D images that Mimics can create directly correlates to the slice thickness and pixel size of the 2D images.

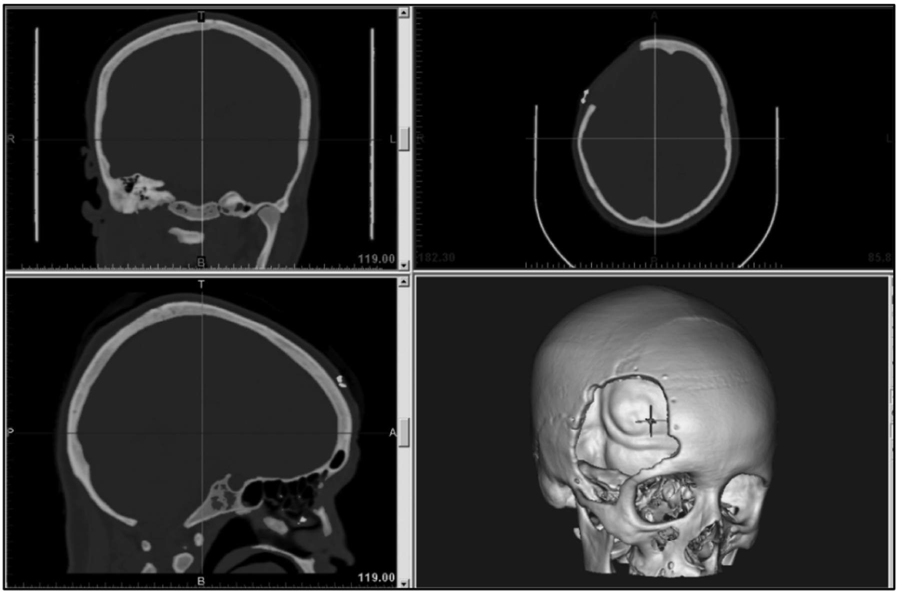

Fig. 2. CT scans data inside the Mimics software.

The medical images coming from CT or MRI scanners consist of grayscale information. By grouping together similar grey values, the image data can be segmented, and models created. The first step in creating a 3D image from 2D data is segmentation. Mimics have several tools to segment, or section, regions of interest.

After thresholding, a mask may need to be separated into numerous objects. Mimics create a mask based off of how surrounding pixels compare to a selected data point's grey value, automatically determining threshold values. This tool proves very useful for segmenting structures such as bone structures [11]. As final result from Mimics there is a 3D model of segmented bone structures.

The 3D models created in Mimics are in STL file format. STL became as standard for rapid prototyping systems, commonly known as 3D printers, and can describe very complex geometries (such as medical geometries) as triangle mesh. Because the STL models match the patient data, the models are useful in communication and clinical work planning. The RP models allow surgeons and engineers to test the shape, fit, function, and validation of projects before implement them on actual patient.

The next step is to use the software “3-matic”.

6 3D Design

Typically the design of an individual cranioplasty implant is a very complex and time consuming task, since it requires the integration of anatomical structures into the design. The flanges need to fit perfectly on the patient’s head. In this case challenge was the designing of proper eye orbit restoration. This entails incorporating scanned anatomical data into the design. The first phase of preparing the model, after importing, is creating the outline for the cranial plate with the defected area (Fig. 3), however the skull needs to be smooth enough. It is important to reduce the number of triangles, which makes the model easier to work with. It is important to define the curve close to the defect, but in a low curvature area, so that tangency is maintained between the skull and the implant. 3-matic has a tool that helps with identifying areas of high tangency. This will project a colour map of the surface curvature on the skull model.

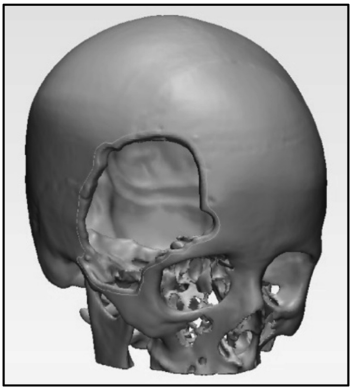

Fig. 3. Creating the outline.

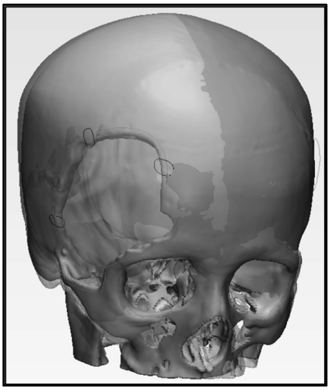

Fig. 4. Matching the mirrored skull.

The next step in the creation of the cranioplasty implant is to mirror the healthy geometry (Fig. 4) and create a guiding line. These lines can be used for surface construction operation to ‘guide’ the new surface. This makes the implant to fit perfectly in the skull and results in a smooth skull-implant transition.

The intersection of the defect curve will serve as the starting/ending point for the guiding curve. The goal is to match the mirrored skull as closely as possible, and use the imported points as beginning and ending points.

The next step is creating the cranioplasty implant using the curve as “Defect outline”, and the mirrored side of the skull as a reference (Fig. 5). After creating the Implant, additional software procedures can be done to further improve the design of the implant.

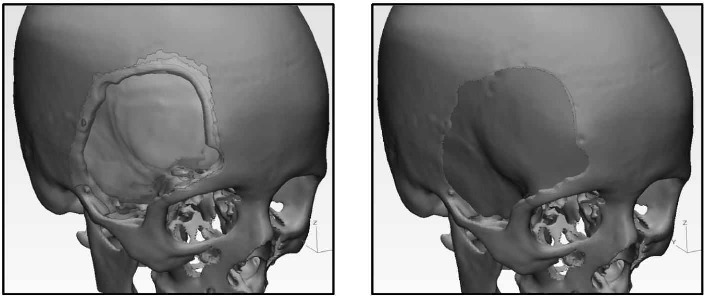

Fig. 5. Creating the implant.

The fitting direction of the prosthesis is defined as the direction in which the prosthesis should be taken in or out. Depending on this direction the exact area of blocking material (undercuts) is determined. This direction can be any direction, depending on the preferences of the user. In this case we will use a direction that corresponds with the average normal direction of the prosthesis (Fig. 6). To obtain this average normal direction, the surface normal of the upper surface will be selected. Smoothing of the edges is also applied, that would allow a better fitting of the prosthesis.

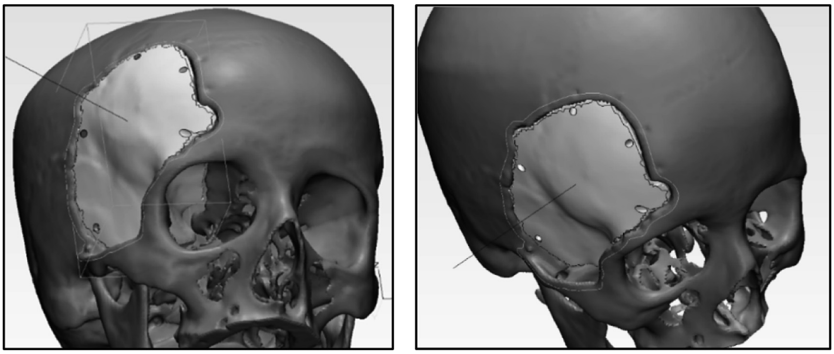

Fig. 6. Creating the fitting direction and offset.

Finally the implant goes to several operations to ensure a better fit, which include an offset in the inner direction. It leaves a clearance around the implant which would give the structure enough room to adjust and heal correctly. The final shape of the implant is shown on Fig. 7. It follows head's natural shape and has very good eye orbit restoration with relatively simple design and enough thickness to fulfil production constraints. With the implant fully prepared in the 3-matic software, the next stage of model preparation can begin.

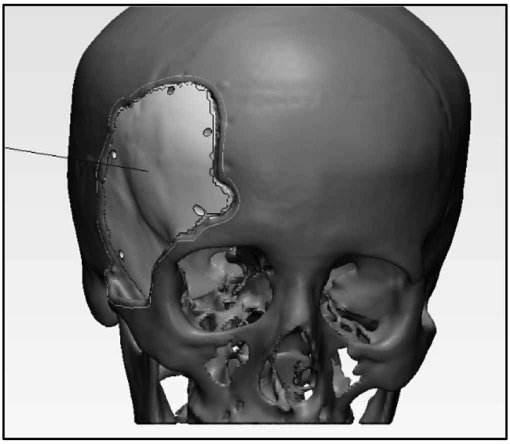

Fig. 7. The final shape of the implant in 3-matic.

At the end of this stage the goal is to ensure that the implant is suited for 3D printing. Because of the many transition stages performed, the STL file fixing of flipped triangles, bad edges, holes and other defects is required.

7 Conclusion

In the current study a structured process workflow chain which requires good knowledge of medical imaging and of various specialized software products for CT reconstruction and 3D modelling was presented. Creation of this model is a milestone for next stages of manufacturing customized implant which will be presented in details in next article.

Designing of a custom cranioplasty implant is a difficult procedure which requires the collaborative work of experienced team composed of surgeons and engineers who should discover a common solution from different perspectives.

Acknowledgements. This work has been supported by the National Science Fund of Bulgaria under the Project DH-17-23 "Developing an approach for bone reconstruction and implant manufacturing through virtual engineering tools".

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