

Integrated approaches for personalised cranio-maxillofacial implant design and manufacturing

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Abstract - Personalised implant design based on CT/MRI data has been developed since 1990s and commercially available in recent years. Although the technology brings in the well-recognised benefits, the number of clinical cases is still limited and the technology has not been widely applied for the treatment in hospitals due to the complexity of the technology, the high cost of implants and the lack of human resources in the area of biomodelling in hospitals. Especially, the closely multidisciplinary collaboration among radiologists, surgeons, and biomedical engineers is always needed during the design and manufacturing steps of the implant. In addition, the optimal solutions for investment of hardware and software are not easily obtained. In this paper, the integrated approaches for personalised cranio-maxillofacial implant design & manufacturing are presented. It covers the wide range of technical solutions based on the available design & manufacturing technologies. Different implant design methods based on different input data, medical image processing and geometrical modeling tools will be emphasized. Finally, the aspects related to the design for manufacturability of the implants are also discussed to utilize effectively limited hardware & software tools.

Keywords: Implant design and manufacturing, biomodelling, cranio-maxillofacial surgery

1. INTRODUCTION

Medical image based modeling technology or Bio-modelling has been familiar with surgeons and biomedical engineers since the ends of 1990s, especially in the area of design and manufacturing of biomodels, personalized implants, surgical tools as well as medical devices [1-4]. Although the benefits are well recognised, the number of clinical cases is still limited and the technology has not been widely applied for diagnosis and treatment due to difficulties of technology transfer to hospitals. The main reasons that lead to these difficulties are as follows.

▪ R1: *The complexity of the implant design:* Modelling of the personalized implants is heavily dependent on the patient data as well as specific clinical constraints. In order to complete the design process, high skills about 3D modelling and medical image processing are needed. In addition, the

designers need to be equipped with relevant medical and engineering know-how so that the designed implant could meet well both technical and clinical requirements. These highly skilled human resources are not always available in the hospitals.

▪ R2: *Challenges about multi-disciplinary collaboration & communication:* Traditionally, most of the clinical cases come from surgeons who directly treat the patients from which the clinical requirements are established for implant design. The designers, working closely with both surgeons and radiologists, transform the medical images into 3D data which is then used as the database for designing the implant and surgical tools that are needed for diagnosis, surgical planning and operation. Depending on which biomaterials used for fabricating the implants and surgical tools, prototyping and manufacturing processes are determined. The implant model is then designed and finally checked by the surgeons before it is transferred to the manufacturing stage. The implant design and manufacturing processes involve the multi-disciplinary collaboration among different experts which are normally not in the same office and organisation. Therefore, it may lead to time-consuming or miscommunication.

▪ R3: *High cost of technology:* The high cost is still a big challenge for the biomodelling technology [2, 4], especially for patients in the developing countries. Currently, investment for hardware and software for biomodelling is quite expensive. The state of the art medical image processing software and modeling tools cost from 20,000 to 50,000 USD. The Rapid Prototyping (RP) machines that can be used for biomodelling applications are from 50,000 to 200,000 USD. In addition, the reasons R1 & R2 also strongly increase the cost of biomodelling technology.

The integrated approaches presented in this paper are aimed to solve the above emerging challenges for developing personalised implants, surgical tools and biomodels in which both technological and economic aspects of the design and manufacturing technology are taken into account.

II. METHOD

Figure 1 presents the integrated approaches for design and manufacturing of personalised implants and surgical tools in which the data flow as well as associated tools and methods from medical image processing to the final implant are described.

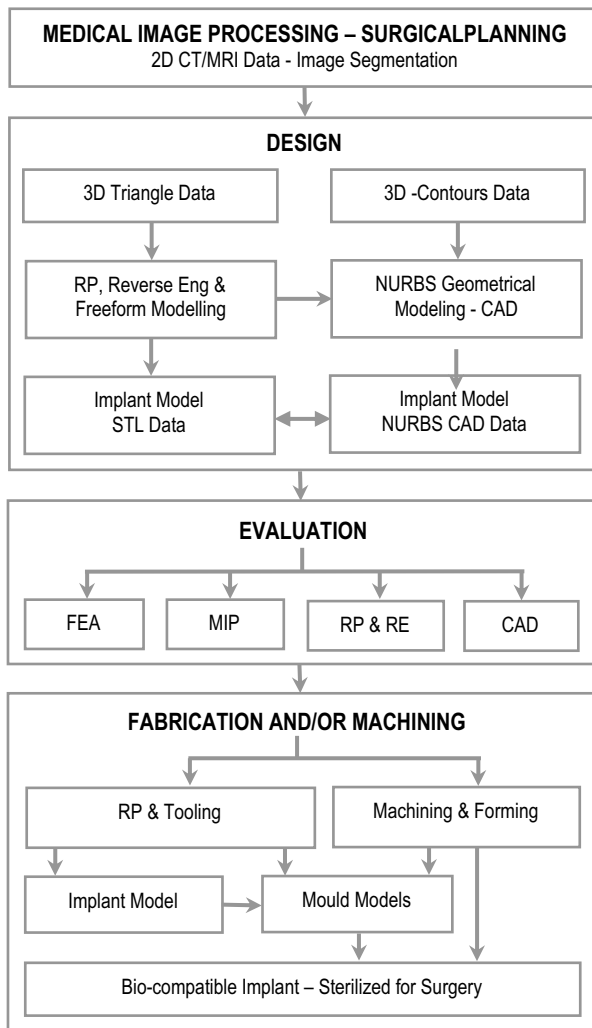


Fig.1 Integrated approaches for implant design and manufacturing

Each design and manufacturing method has its advantage and disadvantages, it depends on the skills of designers as well as available hardware and software. There are 4 main steps: (i) Medical image processing (MIP), (ii) Design, (iii) Evaluation, and (iv) Fabrication and/or machining.

A. Medical image processing and surgical planning

CT/MRI images of the patient in the form of DICOM format are used as the input for starting implant design and

manufacturing processes. Most of the MIP packages provide the necessary tools and functions for image segmentation which refers to the process of partitioning an image into multiple sets of pixels from which Regions of Interest (ROI) can be extracted. CT data gives better results for bone reconstruction compared to MRI images which are fundamentally good for soft tissue modelling.

The output of the MIP stage is the geometry of anatomical structures in form of 3D triangle mesh models or 2D slice contours which are commonly stored as STL and IGES files respectively. These data are used for surgical planning and implant design. The most typical commercial MIP packages are MIMICS (Materialise NV), Simpleware (impleware Ltd), 3D-Doctor (Able Software Corp), and Amira (Visage Imaging GmbH). However, if we only need to reconstruct 3D models of the anatomical structures from CT/MRI data for further development, the free and open source MIP packages can be used, including 3D Slicer (Slicer), Julius framework (CAESAR Research Center) and MedINRIA (INRIA Sophia Antipolis).

B. Implant design

Depending on the biomaterial used for an implant, manufacturing techniques which define implant design methods are determined. The methods for design and manufacturing of personalised implants based on Rapid Prototyping (RP) and CNC milling were well documented [1, 2, 3]. The most common biomaterials used for bone reconstruction in crano-maxillofacial surgery are bone cements, PMMA and titanium (Ti). When Ti is used, the implant is normally designed in two types: (i) On-lay implant which is made from Ti sheets by hydro-forming techniques and (ii) In-lay implant which is made by CNC machining from Ti block. When bone cements and PMMA are used, it is required to apply in-lay implant design methods [3].

The design methods for on-lay implants are simpler compared to the in-lay ones. Only external surfaces of the bone structures are taken into account. Mirrored data of the intact area of the skull is used as the reference for modeling the implant from which the hard-plaster mould is made for hydro-forming process, and finally the formed Ti sheet is cut to create final boundary of the implant to fit the defect window. Meanwhile, both internal and external surfaces as well as the contact between the bone and an implant have to be carefully taken into account when designing in-lay implants. The in-lay implants have the most complex geometry. The requirements about the weight and mechanical strength of the implant have also to be satisfied. Figure 2 presents the typical in-lay implant.

There are 4 following methods for geometrical modelling of the implants, depending on the complexity of the im-

plants and the available modelling software and tools, including RP, Reverse Engineering (RE), freeform modelling and Computer Aided Design (CAD).

- **M1 - RP:** Most of the RP packages allow manipulating STL files as well as provide basic functions for editing 3D models. The implant is modeled based on mirrored intact area of the bone structure as well as Boolean operations. The disadvantage of this technique is the difficulty for controlling the implant thickness as well as to get the best fit implant for the defect window, because the skull is not completely symmetrical, and the tools for geometrical modelling of RP packages are quite limited. However, for the simple bone defects, this approach can provide the optimal solution in term of the cheap cost and simplicity; and when necessary, the fabricated implant can be manually corrected and refined based on the biomodel of the defect skulls. The typical RP packages include Magics (Materilise NV) and VisCAM RP (Marcam Engineering GmbH).

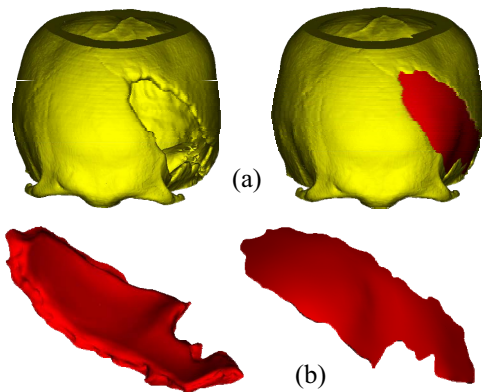


Fig.2 (a): Defect skull and in-lay implant fitted to the defect window.
(b): 3D model of the implant in different views

- **M2 - RE:** Most of the RE packages provide powerful freeform modelling tools, especially triangle mesh control and manipulations which are not commonly available in RP and CAD packages. Therefore, personalised implants can be modeled optimally. In order to model the implant based on RE tools, first of all, the defect window is filled to make it intact based on the mirrored intact area of the skull. Boolean operations are then used to create the basis shape of an implant. Finally the thickness of an implant and the contact between an implant and bone structure are controlled to get the optimal implant model. The typical RE packages are Rapidform (Rapidform, Inc.), CopyCAD (Delcam), Geomagic studio (Geomagic, Inc.), and Polyworks (InnovMetric Software Inc).

- **M3 - Freeform Modelling:** The freeform modeling techniques such as SensAble 3D modeling systems

(SensAble Technologies, Inc) and ZBrush (Pixologic, Inc) can be used for modelling the implant. However, high modeling skills and time-consuming are normally required to complete the implant design. The 3D model of the defect skull in the form of STL, VMRL, **OBJ** or 3DS format is used as the reference for modelling processes.

- **M4 - CAD:** CAD packages such as ProEngineer (PTC Inc), UG (Siemens), SolidWorks (Dassault Systèmes SolidWorks Corp) are based on Non-Uniform Rational B-spline (NURBS) modelling. Therefore, contour data of the bone structures are used as the reference for modelling the implant in CAD packages. Freeform modelling tools in CAD packages are quite limited; thus, it is difficult for modeling the complex implant, especially the ones in the zygomatic bone area (Fig. 3); and high skills are required.

When RP & Tooling techniques are used for prototyping implant models and moulds to fabricate PMMA and bone cement implants, all methods M1 to M4 can be applied. Methods M1 and M4 are normally used to design hydroforming moulds for making on-lay implants. Although the current CAD/CAM packages allow using STL data for process planning, in order to machine complex in-lay implants from Ti blocks, method M4 is generally used for developing implant models and preparing the optimal CNC tool-paths.

C. Implant evaluation

The designed implant needs to be carefully evaluated to assure that the technical and clinical requirements are met before it can be transferred to the prototyping and manufacturing phase. The optimal method for checking the implant geometry is to keep the coordinate system of the implant model identical with the one used for the defect skull. In this way, we could use MIP or RP & RE or CAD packages for implant evaluation by comparing the design in different cross-section views. The best option is to import the implant model into MIP packages to view the cross-sections directly on CT/MRI images. Finite Element Analysis (FEA) may need to be used for evaluating mechanical strength as well as simulating implant functions when necessary.

D. Implant fabrication and/or machining

There are two methods for making PMMA and bone cement implants. The first one is to use RP for making the implant prototype which is then used as the reference for making the silicon or dental plaster mould from which the implant is fabricated. The second one is to use RP for making the moulds which are directly used to fabricate PMMA or bone cement implants. With the recent progress of material development for RP applications, the current RP tech-

niques allow fabricate biocompatible parts and the ones with strong mechanical properties. In this way, soft-tooling techniques may not be necessary for preparation of the moulds based on implant prototypes as traditionally done.

CNC machining can be used for (i) direct milling of the implants from Ti blocks or (ii) milling the mould from which PMMA or bone cement implants are fabricated [4].

Finally, for the on-lay implants which are made by hydroforming, the moulds can be made by CNC machining, RP as well as rapid tooling techniques.

III. RESULTS, DISCUSSION AND CONCLUSIONS

More than 60 clinical cases have been conducted since 2001 based on the above presented design and manufacturing methods. Figs 2 and 3 present the typical implant design in which the geometry of the implants is complex. It took 3 to 5 working hours to complete the optimal design when all the necessary modelling tools are available.

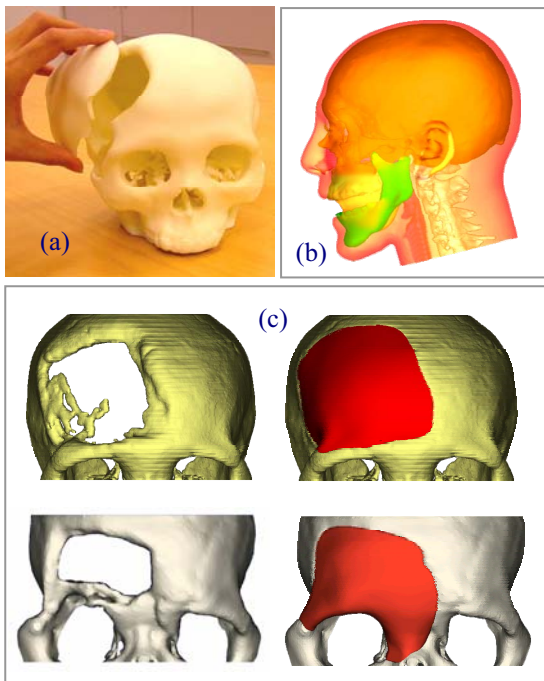


Fig.3 (a) Biomodels of the defect skull and implant. (b) 3D modelling of the hard and soft tissues. (c) Personalised implant design

Although the personalised implants have been clinically applied for treatment of the skull defects for more than 15 years and the benefits are well documented, the technology is still currently not widely used or available in most of the hospitals, even in the developed countries. The difficulties that limit the applications of the technology include (i) complexity of the implant design, (ii) challenges about multi-

disciplinary collaboration & communication; and (iii) High cost of personalised implants and surgical tools.

There have been efforts in developing specialised software and tools that simplify the implant design processes with more and more added modelling tools as well minimising the high skill requirements. However, there have been no-single package that can meet all the design requirements, and the commercial software is getting more and more expensive. In addition, each clinical case has its own clinical and technical requirements; and not all the hospital and companies can fully invest the necessary hardware and software as well as human resources. Therefore, optimal solutions need to be investigated to meet both technical and clinical requirements for personalised implants as well as to overcome obstacles about technology transfer into hospitals.

The paper presented different design and manufacturing methods with associated hardware and software options which were successfully implemented for clinical cases. Selection of the right work-flow will lead to the reasonable implant cost and effectively use the available resources. In this way, technology transfer to hospitals will be more and more convenient. Finally, the presented approaches will be useful for hospitals, universities and companies when considering investments about hardware and software which are necessary for developing BME applications for diagnosis and treatment of bone defects.

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