

The application of Rapid Prototyping Technologies for manufacturing the custom implants

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ABSTRACT: Medical applications are some of the most interesting applications of the rapid prototyping technologies. These technologies are able to produce a physical model of the anatomic structures, which is very useful for diagnosis, surgery planning, training, and for design and manufacture of the custom implants. The paper presents the manufacturing process of the custom implants, used for skull reconstruction.

Key words: rapid prototyping applications, custom implants

1 INTRODUCTION

Analysis, imaging and visualization technologies are being applied increasingly in medical applications, particularly in evaluating different approaches to surgery and in determining the best ways to proceed to the surgical operations.

Medical imaging technologies such as the Computer Aided Tomographs with X rays (CT) and with magnetic resonance imaging (MRI), deliver slices or projection images of the internal areas of the human body. These tools are generally used to visualize the configurations of bones, organs and tissues, but they also have the ability to export image data and additional information in commonly known medical file format, such as DICOM.

These files can be processed by third-party computer programs for assessing and diagnosing the condition of the patient and for planning a surgical intervention. That is how the surgical procedure could be performed. Other very promising application fields include telesurgery, virtual environments in medical school education and prototype modelling of the artificial joints.

On the other side, using these files, the rapid prototyping technologies allow to manufacture physical models of the internal structure of the human body. The most important advantages of the

physical models, comparing with the virtual models, are:

a) A 3D physical model could be used like a hard copy of a data set, very useful for diagnosis, therapy choices and for teaching purposes. These models simplify so much the communication between the members of the surgery teams, between the radiologist and surgeon and generally, between the physician and the patient. Even if the radiologist could give a good interpretation of the 2D sections or of the 3D virtual reconstruction, in many cases these interpretations are not sufficient for the surgeon. Most of the surgeons prefer a physical model, which replaces the virtual model. Also, the physical models could be easily measured.

b) The 3D physical model could be very useful for planning and training the very complex surgeries. For example, the maxilo-facial surgeons use the 3D model of the patient skull for planning the osteothomies because the surgeries could be simulated very well using these models. The greatest advantage of this simulation is not the possibility of choosing the sections position. This simulation is very useful in choosing the right decision about the fixing solutions and to measure the bones displacements.

c) When there is an accurate 3D physical model of an existent structure, it is very easy to manufacture a custom implant. This model could be used like a

negative or a master model of the custom implant. In the close future, the custom implants will be manufactured directly onto the rapid prototyping systems, using biocompatible materials.

The goal of the research is to establish an appropriate technology for manufacturing the custom implants starting from the CT data and using a health region of the patient body.

2 BUILDING MEDICAL MODELS

2.1 CT data files

The first step in building a medical model is to extract an image file from medical data exchange formats. As the CT images represent the X-ray absorption of a given cross-section, the intensity values of their pixels represent this 12-bit absorption rate, rather than common colour ranges. Since the slice density is usually reduced for in-vivo scanning, considerable information often is lost, especially in complex regions of the human body. For visualisation purposes, this deficiency can be compensated with interpolation techniques, but no lost anatomical data can be recovered in this way.

For manufacturing and for obtaining a good accuracy of the physical models, any lost information is not accepted. In order to decrease the quantity of the lost information, a spiral technique was adopted for scanning. This technique allows to do the scanning a full volume and after that it is easy to generate a high number of slices and in each slice, the pixel dimension could be reduced as much as is necessary. All these information are exported from the CT into the DICOM format.

2.2 Image enhancement and segmentation

The interpretation and the processing of the images provided by a CT represent the major stage for obtaining the correct medical models. As the given tissue structures have their own absorption rate, a windowing technique might be sufficient for a simple visualisation. To manufacture the physical models, it is necessary to obtain a 3D virtual model of the internal structure by a good segmentation and by excluding other structures from the scanned volume.

For this reason, the Materialise Company (Belgium) developed a software package (called MIMICS), which can manipulate the medical images. This

software allows the user to import the sections from the CT and to generate the 3D model, into the right format, for rapid prototyping systems.

The technique used for segmentation is region growing, based on the threshold values. This technique makes the segmentation, considering the density of the tissues and using threshold limits (lowest and highest values) provided by the user. The tissues which have a lower density as compare to the smallest value, are shown in black and the tissues which have higher density as compare to the biggest value, are shown in white. While using this technique, it is quite difficult to establish the threshold values. For this reason, an object is placed into the scanning area of the CT, which has a similar density, or approximately equal with the studied tissue. The thresholds limits are modifying until the right dimensions of the test object are obtained in the image.

Using the technique shown above, a good segmentation could be obtained, with a good resolution of the studied structure, if the dimensions of the pixels are small enough. If the dimensions of the pixels are large, then the regions could be found, where a pixel covers structures with different densities and in these situations, it is not possible to do a good segmentation.

Figure 1 shows two cases of segmentation. The models are the same and they have been provided by the same CT. The only difference was the pixels dimension.

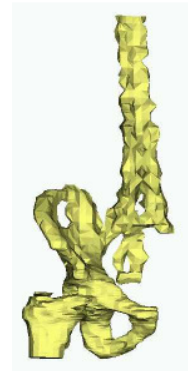
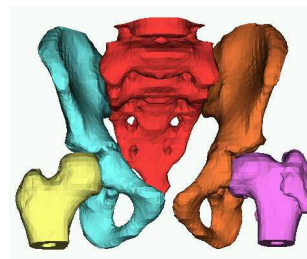


Fig. 1. Good and bad segmentation

2.3 The manufacturing of the physical model

Using the rapid prototyping technologies, the objects are manufactured by adding the material in successive layers. Generally, it could be said that all the rapid prototyping technologies are based on the same "philosophy":

- start with a 3D virtual model build into a CAD system
- import the model into dedicated software, specific to each RP system. This software intersects the virtual model with parallel planes and determines the shape of the section in each plane
- produce the part by RP. The RP system manufactures each section and the part is build by bounding these sections one over other.

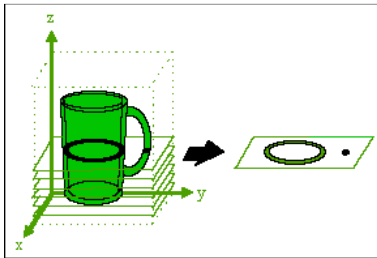


Fig. 2. The “philosophy” of the rapid prototyping technologies

The main difference between the rapid prototyping technologies is the material used to manufacture the models. With regards to the available technologies, the models could be manufactured using paper (on the LOM systems), ABS plastic wire (on the FDM systems), photopolymer (on the SLA systems), plastic powder or another kind of powders (on the SLS and 3D Printing systems) and wax (on the 3D Printing systems).

The main reason which justifies the utility of the physical medical models is the “model of the broken area”. The model of the broken area is a part of a medical model, manufactured in real dimensions (1:1 scale), where the natural structure is broken. For medical reasons, it is necessary a reconstruction of this structure and in this region the surgeries will be made. Figure 3 shows the model of the broken area used into the case study.



Fig. 3. The model of the broken area

The subject from this case study has an internal haemorrhage and after the trepanation the bone tissue has dead. For this reason, the bone was removed.

3 MANUFACURING THE CUSTOM IMPLANT

Using these models, the implant is quite simple to be manufactured. It is not very important what technology is used for manufacturing, because for one part, any kind of technology could be used. The only important thing is that the implant should be fitted into the broken area and for this objective the implant could suffer any number of adjustments before being fixed. Once the right shape of the implant was obtained, the surgeon team must focus onto the fixing of the implant into the patient body. Usually, the model of the implant is manufactured into a dentist laboratory, using manual methods. After the model of the implant is fitted into the broken area, the real implant is cast from biocompatible material using lost model casting technologies. This solution is useful for such situation, where the final shape of the implant is not very important except the region where the implant must be assembled within the existing structure. Considering the aesthetic reasons for facial or skull reconstruction, generally, the shape of the implant is very important.

This was the reason why we tried to manufacture an implant using the symmetrical side of the healthy region. In this way, the first step was to generate the models (virtual and physical) of the entire skull. Using the mirroring technique, a symmetric virtual skull was generated, as compare to the real one. These two virtual models were precisely positioned one over the other and using Boolean operation, the real skull was subtracted from the symmetric one. The result was the preliminary shape of the implant in virtual space. All files operations needed to obtain the virtual implant were made using the MAGICS software package from Materialise Company (Belgium). This software package allows the manipulation of the *.STL files and to prepare them to be used onto the rapid prototyping systems.



Fig. 4. The model of the implant and its fit into the broken area

All the physical models were manufactured using the Sinterstation 2000 Selective Laser Sintering system, within the Rapid Prototyping Laboratory,

from the Technical University of Cluj-Napoca.

Once the implant was manufactured, it was manually fitted into the broken area, using a portable high-speed milling machine. Figure 4 shows the model of the implant and its fitting into the broken area.

The material used to manufacture the model of the implant was the polyamide plastic, but this material is not biocompatible. The manufactured model was used as "master model" to obtain a mould, where different kind of biocompatible materials were moulded, before finally the results were tested. The mould was built using silicone rubber. Polyethylmethacrilate (PEMA), polymethylmethacrilate (PMMA) and some kind of medical cement were used to make the actual implant. After testing, the conclusion of the medical staff was that, considering the material properties, the most suitable material for this implant is PEMA. Figure 5 shows the mould and the PEMA implant moulded in it.



Fig. 5. The mould and the implant

The implant was fixed into the patient body at the Maxilo-facial Surgery Clinic in Cluj-Napoca. The medical team had chosen preliminarily a solution using the Y elements and titanium screws. During the surgery, the implant was properly fitted into its place, without being necessary other special elements.

4 CONCLUSIONS

The case study presented above is not singular. By analysing more than other 7 case studies, the following conclusions were pointed out, in collaboration with the medical staff:

- A right shape of the implant could be obtained only if a correct segmentation is made.
- This technology of manufacturing the custom implants is suitable for present conditions. Other solution, such as casting the biomaterials, especially metals, using lost model casting technologies, could be considered too, but the casting process of titanium or other biocompatible metal is quite difficult to be done.
- The material used for implants depends on the shape of the implants and on its destination. For the implants which have thin walls and where there is not necessary a relatively high strength, the material could be a medical cement. For the implants where there are necessary good mechanical properties, the material must be PEMA or PMMA, depending on the requested elasticity.
- Future research will include the manufacturing of the implant directly on the Selective Laser Sintering system using biocompatible powder. Experimental research is being undertaken in our laboratory, using titanium powder.

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