IOP Conf. Series: Materials Science and Engineering **448** (2018) 012060 doi:10.1088/1757-899X/448/1/012060

Tailor-made 3D model design of human implants for additive technologies

Laura Georgina Varga[1], János Dr. Takács[1], Ferenc Dr. Dömötör[1]

[1] BME KJK Department of Automotive Technologies

Abstract. This paper deals with the development of a model of individualized implants. It is presented how to produce an implant (bone model) based on digital medical information (CT, MRI). The biocompatibility criteria and human bone properties were taken into consideration during the studies. When creating models, the geometric design possibilities are focused, from the solid 3D body to the creation of hollow, bone-forming structures. The steps for creating models as well as the transitions between each work phase that are needed as input for additive production are presented.

1. Introduction

The new procedures of automated technology using new materials shall be capable to produce implants in high quality even among tailor made conditions. Tailor made manufacturing procedures of the so-called “health industry” reached the level of application of spatial additive manufacturing in a large number of cases. Tailor made implants can be manufactured from properly selected materials (e.g. metal powders), using laser beam methods. Designed implants shall be built from layer to layer by these methods. There are two methods, belonging to this procedure: the selective laser sintering (SLS), and the selective laser melting (SLM). Another important requirement is that tailor made implants shall be made of biocompatible materials in order for them to be capable to be built in the living human body and to cooperate with it. These materials are typically 316L and Ti-6Al-4V, respectively. Before the production a lot of tests shall be carried out. A doctor-engineer consultation and several steps of design procedure are necessary. [1]

2. Pre-modelling steps

The first step is the investigation of the bone to be implanted by using MRI or CT. MRI is an abbreviation for magnetic resonance investigation, while CT stands for computer tomography enabling X-ray tests. Both methods can be used successfully. However, CT has a wide range priority when modelling. The prepared photos then shall be digitalized. The most important task is the analysis of the gray values. This can efficiently characterize the density of the bones, which depends on the age, the sex and the various diseases. Density is an important piece of information, which has to be taken into account, because the goal of modelling is to manufacture implants, having nearly the same features as the original bones to be replaced. Only after this can the computer modelling be started. First, a simple 3D model shall be manufactured. All the necessary changes have to be made on this. [2]

Content from this work may be used under the terms of the Creative Commons Attribution 3.0 licence. Any further distribution of this work must maintain attribution to the author(s) and the title of the work, journal citation and DOI.
Published under licence by IOP Publishing Ltd

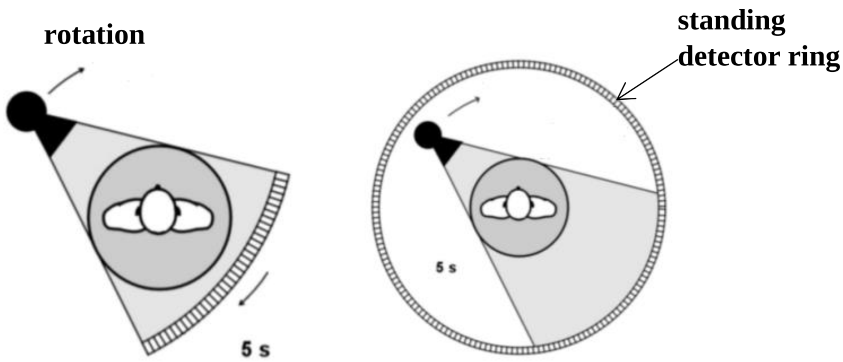

Figure 1: Operation of CT [2]

3. Changing the CT-pictures

CT-pictures are available in DICOM format. This type of file enables the storage of all photo-slices in one file only, making the processing and the transfer easier. These files contain text information about the patient. However, it has to be mentioned that only special types of software can open, process and transform them. The final purpose is that files of STL type shall be available for the manufacturing unit. An important aspect was that commercially available software has to be selected for processing. And this is what happened, so the CT-photos were transformed by InVesalius. Processing of the photos consists of several steps. After importing the data, surfaces to be tested shall be selected. Then, after generating 3D model surface, data shall be exported in a special file format. Shaping the bone models can be done only after this. This process shall be demonstrated via two examples. One of them shall be the middle bone of a big toe, while the other one shall be the middle bone of the hand. [3]

4. Modelling of the middle bone of a big-toe

As the first step CT photos were taken of the foot. Then a starting model was shaped about the complete foot using InVesalius.

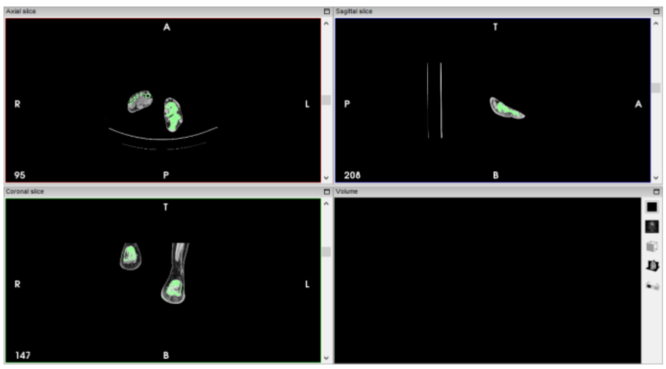

Figure 2: CT-photos by InVesaliusban

Further transforms were carried out by using the freely available Autodesk Meshmixer. First, the middle bone of the big toe had to be “cut out” from the foot. This means a cutting by planes (encountered). After this step the tight bone, as a starting model, was created. This has to be transformed in order to get the features of the natural bone. The goal is to create a model lighter, with holes, but having proper load carrying capacity. Apart from the tight version, several other versions were constructed. There are holes both on the outer surface and the internal parts of this first model. This kind of structure enables the adaptation of the bone, so the implant can be adopted into the human body. The rest of the powder unused during the manufacturing can be removed via these holes. Due to the connection of planes created during the process a repair afterwards might be necessary. E.g. to connect the open edges.

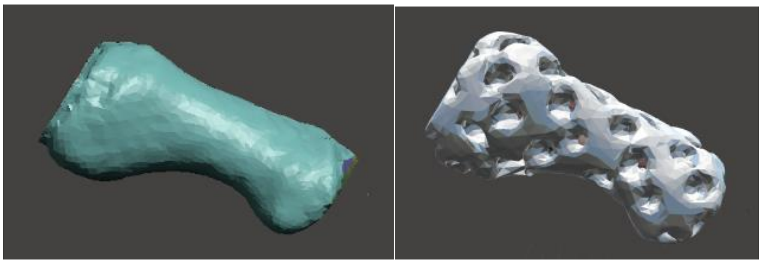

Figure 3: Models, tight and with holes

The second type is a model with tight outer surface, but inside having a grid structure. This means a thin (having determined thickness) outer surface, and an internal structure with perfect grid structure. There is a problem to be solved yet, namely that due to the closed outer surfaces the unused (not melted) powder cannot be removed from the internal parts of the model. This is a problem because the powder cannot be left in the human body.
As another version a model with grid structure was manufactured. The thin outer surface has a grid structure, as well. The wall thickness can be changed within a certain range. The load carrying capacity of the model can be increased in order to be applicable for building into the human body.

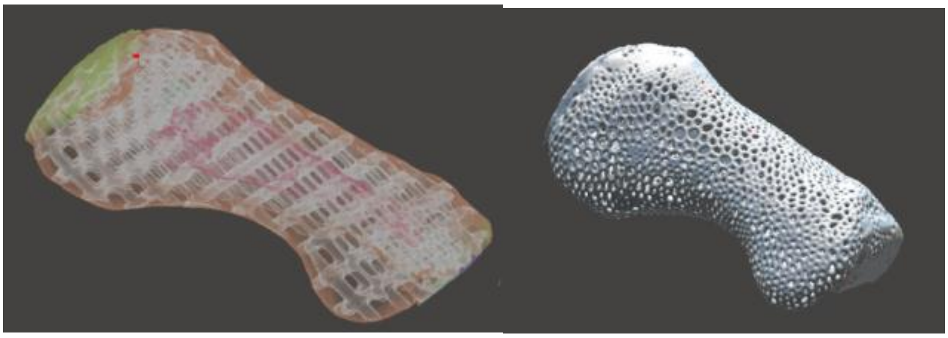

Figure 4: Model with tight outer surface and grid structure inside, and another model with grid structure outside

The next two models have similar structures. Both of them have full grid structure, but one of them with while the other one without internal stiffening. Both of the mentioned bone models are compatible with the human body, because the natural bones can emulate the implants. It is also important for the implants to be capable of bearing the forces acting on the bones. In order to prove this a simulation by finite element method shall be carried out. The question, whether an internal strengthening is necessary or not, can be answered by a finite element simulation only. In both cases it has to be taken into account that due to the non-contacting surfaces a repair afterwards might be necessary.

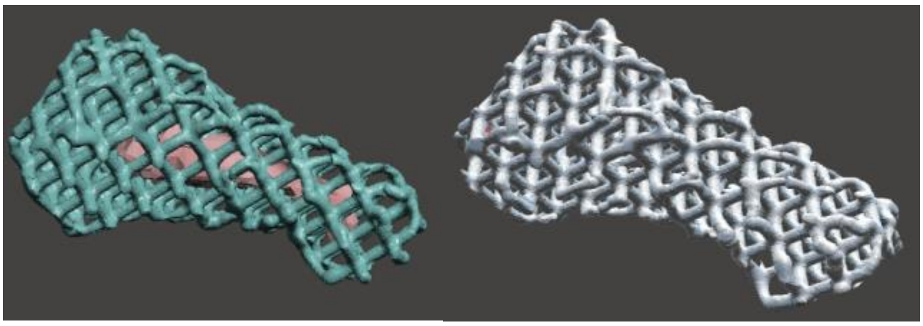

Figure 5: Models with fully grid structure, with and without internal stiffening

5. Modelling middle bone of hand

Apart from modelling bones of the foot, a model for the middle bone of the hand was created. The mechanical load on this bone is quite complicated. The middle bone of the hand plays an important role in the movement of the hand and the fingers. If this bone is damaged, and it cannot be regenerated, or replaced, some functions of the hand are lost. Based on this, it seems to be obvious that implants shall be modelled and manufactured individually.

That is why an X-ray picture of the hand is necessary. The first step in this case was again the creation of the starting model using InVesalius. After this, three further models have been created.

The fully tight model in this case served as the starting point. For the final construction a transformation into hollow structure was necessary. This model provides better mechanical features, similar to the natural bones.

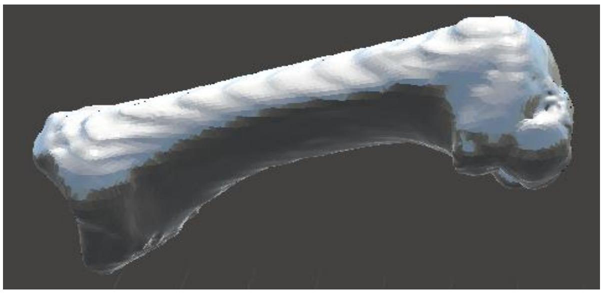

Figure 6: Model of a tight middle bone of a hand

The second version was again a model with internal holes. On the surface again hollows and indentations were created. They promote the adaptation of the bone structure. Moreover, the powder created during manufacturing can be removed through the hollows. If the edges of the hollows cannot be closed, damages shall be repaired afterwards. Apart from this there might be surface damages as well.

Figure 7: Model with inside holes and surface indentations

The following two models have a complete grid structure, which enables the implants to be compatible when being built into the human body. The bone structure has the capability of adopting the built-in implant. It can happen that only a part of the bone has to be replaced, not the full bone. Due to this, a connection surface to the bones and to the joints has to be provided. According to the medical needs either tight or hollow type structures can be created.

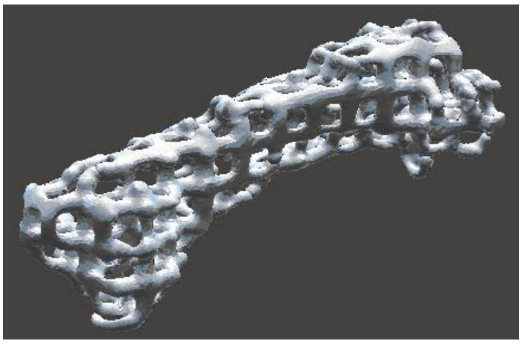

Figure 8: Model of the middle bone of the hand, having fully grid structure

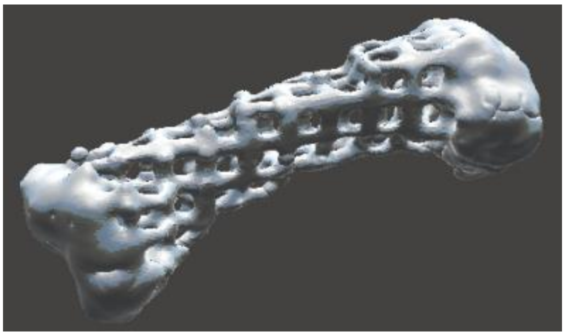

Figure 9: A fully grid structured model, at both ends with tight material

If all the versions are available, the analysis by Finite Element Method shall be used. [4]

The individual constructions can be compared from the load carrying capacity point of view by using these results. The final decision can be made upon the results of these tests. The decision criteria are based on the comparison of the features to the natural bones. The best one shall be declared to be the version to be manufactured.

6. System plan

In order for the modelling and manufacturing process to be easily controlled, the creation of a system plans is necessary. This plan shall have the following steps. (Fig. 10.)

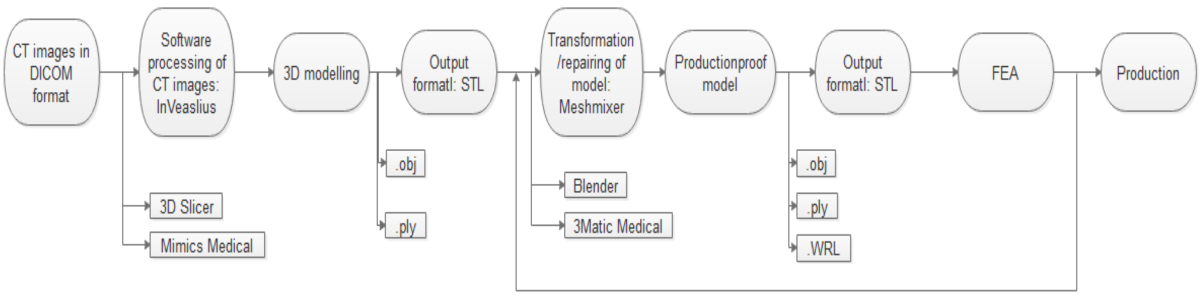

Figure 10: The final plan of the system, with consultations and feedback

Figure 11: Photos of the firstly manufactured models

Steps of the system plan:
1. Creating CT-pictures in DICOM formats;
2. Processing the photos by InVesalius software;
3. Creation of the starting 3D model in STL file formats;
4. Creation and repair of the model in various forms of construction;
5. Creation of the final version suitable for manufacturing in STL format;
6. Analysis using Finite Element Methods;
7. Manufacturing of implants; design of implants to be placed in powder-beds;
8. Testing of trial versions;
9. Fine tuning according to feedback.

In case the created model does not meet the requirements (features of the natural bones) according to the Finite Element Method testing, a step back is necessary. A new model shall be created. This procedure has to be repeated as long as the proper model of implant meeting all the requirements shall be available.
The first trial pieces after the models shall be manufactured using the material Ti-6Al-4V. (See the attached *Fig. 11.).*

7. Acknowledgements
This project was supported by the National Institute for Research and Innovation. Title of the project: „Manufacturing new generations of individual medical-biological implants and auxiliary tools using additive technologies"; identification number of the support project: NVKP_16-1- 2016-0022.
Authors are grateful for the support.

References
[1] Bose, S., Ke, D., Sahasrabudhe, H., Bandyopadhyay, A., Additive Manufacturing of Biomaterials, *Progress in Materials Science* (2017), doi: http://dx.doi.org/10.1016/j.pmatsci.2017.08.003
[2] Bogner P.: Physics of creating pictures for the medical students Laboratory and Diagnostics courses (2014, In Hungarian) ISBN 978 963 226 450 9
[3] Features of DICOM formats: https://www.lifewire.com/dicom-file-2620657
[4] Dr. Molnár László: Practice of Finite Element Method, Ministry of Employment and Labour (In Hungarian): Program for Operation for Development of Human Resources *„Development of higher education both in structure and contents (in Hungarian) "*HEFOP-3.3.1-P.-2004-06-0039/1.0